

Calendar No. 43

119TH CONGRESS
1ST SESSION**S. 1040**

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

IN THE SENATE OF THE UNITED STATES

MARCH 13, 2025

Mr. CORNYN (for himself, Mr. BLUMENTHAL, Mr. GRASSLEY, and Mr. DURBIN) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

APRIL 10, 2025

Reported by Mr. GRASSLEY, with an amendment

[Omit the part struck through and insert the part printed in *italic*]

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 “Drug Competition En-
5 hancement Act”.

1 **SEC. 2. PRODUCT HOPPING.**

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. 57c–2) the following:

5 **“SEC. 27. PRODUCT HOPPING.**

6 “(a) DEFINITIONS.—In this section:

7 “(1) ABBREVIATED NEW DRUG APPLICATION.—

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

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

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

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

25 “(A) means a drug approved through an
26 application or supplement to an application sub-

mitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) or a biological product licensed through an application or supplement to an application submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) for a change or modification to, or reformulation of, the same manufacturer's previously approved drug or biological product that has an indication that is identical or substantively similar to an indication of the same manufacturer's previously approved drug or biological product; and

“(B) excludes such an application or supplement to an application for a change, modification, or reformulation of a drug or biological product that is requested by the Secretary or necessary to comply with law, including sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c).

“(5) GENERIC DRUG.—The term ‘generic drug’ means any drug approved under an ~~application submitted under subsection (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or an application under subsection (b)(2) of such section 505 that seeks a therapeutic equiva-~~

1 ~~license rating to the reference product~~ *abbreviated new*
 2 *drug application.*

3 “(6) 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 “(7) 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 “(8) 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 “(9) 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.—A manufacturer of a ref-
 25 erence product or listed drug shall be considered to

1 have engaged in an unfair method of competition in
2 or affecting commerce in violation of section 5(a) if
3 complaint counsel or the Commission demonstrates
4 in an action or proceeding initiated by the Commis-
5 sion under subsection (c) that, during the period be-
6 ginning on the date on which the manufacturer of
7 the reference product or listed drug first receives no-
8 tice that an applicant has submitted to the Commis-
9 sioner of Food and Drugs an abbreviated new drug
10 application or biosimilar biological product license
11 application referencing the reference product or list-
12 ed drug and ending on the date that is the earlier
13 of 180 days after the date on which the generic drug
14 or biosimilar biological product that is the subject of
15 the abbreviated new drug application or biosimilar
16 biological product license application or another ge-
17 neric drug or biosimilar biological product ref-
18 erencing the listed drug or reference product is first
19 marketed or 3 years after the date on which the fol-
20 low-on product is first marketed, the manufacturer
21 engaged in either of the following actions:

22 “(A) The manufacturer engaged in a hard
23 switch, which shall be established by dem-
24 onstrating that the manufacturer engaged in ei-
25 ther of the following actions:

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

10 “(ii) The manufacturer of the listed
11 drug or reference product—

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

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

7 “(II) marketed or sold a follow-
8 on product.

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

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

23 “(ii) The manufacturer marketed or
24 sold a follow-on product.

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

3 “(A) truthful, non-misleading promotional
4 marketing; or

5 “(B) ceasing promotional marketing for
6 the listed drug or reference product.

7 “(3) JUSTIFICATION.—

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

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

24 “(ii)(I) with respect to a hard switch
25 under paragraph (1)(A), the manufacturer

1 took the action for reasons relating to the
2 safety risk to patients of the listed drug or
3 reference product;

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

7 “(aa) is outside of the control of
8 the manufacturer;

9 “(bb) prevents the production or
10 distribution of the applicable listed
11 drug or reference product; and

12 “(cc) cannot be remedied by rea-
13 sonable efforts; or

14 “(III) with respect to a soft switch
15 under paragraph (1)(B), the manufacturer
16 had legitimate pro-competitive reasons,
17 apart from the financial effects of reduced
18 competition, to take the action.

19 “(B) RULE OF CONSTRUCTION.—Nothing
20 in subparagraph (A) may be construed to limit
21 the information that the Commission may oth-
22 erwise obtain in any proceeding or action insti-
23 tuted with respect to a violation of this section.

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

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

6 “(B) establish by a preponderance of the
7 evidence that—

8 “(i) on balance, the pro-competitive
9 benefits from the conduct described in sub-
10 paragraph (A) or (B) of paragraph (1), as
11 applicable, do not outweigh any anti-
12 competitive effects of the conduct, even in
13 consideration of the justification so offered;
14 or

15 “(ii)(I) the conduct described in para-
16 graph (1) is not reasonably necessary to
17 address or achieve the justifications de-
18 scribed in clause (ii) of paragraph (3)(A);
19 or

20 “(II) the justifications described in
21 clause (ii) of paragraph (3)(A) could be
22 reasonably addressed or achieved through
23 less anticompetitive means.

24 “(c) ENFORCEMENT.—

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

6 “(A) Institute a proceeding under section
7 5(b).

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

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

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

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

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

21 “(2) JUDICIAL REVIEW.—

22 “(A) IN GENERAL.—Notwithstanding any
23 provision of section 5, any manufacturer that is
24 subject to a final cease and desist order issued
25 in a proceeding to enforce this section, or a rule

1 promulgated under this section, may, not later
 2 than 30 days after the date on which the Com-
 3 mission issues the order, petition for review of
 4 the order in—

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

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

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

18 “(3) EQUITABLE REMEDIES.—

19 “(A) DISGORGEMENT.—

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

1 “(ii) CALCULATION.—Any
 2 disgorgement that is ordered with respect
 3 to a person under clause (i) shall be offset
 4 by any amount of restitution ordered
 5 under subparagraph (B).

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

15 “(B) RESTITUTION.—

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

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

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

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

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

12 “(B) affecting the authority of the Federal
13 Trade Commission under any other provision of
14 law.”.

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

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

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

22 (c) ANTITRUST LAWS.—Except to the extent sub-
23 section (a) establishes an additional basis for liability
24 under the Federal Trade Commission Act (15 U.S.C. 41
25 et seq.), nothing in this section, or the amendments made

1 by this section, shall modify, impair, limit, or supersede
2 the applicability of the antitrust laws, as defined in sub-
3 section (a) of the first section of the Clayton Act (15
4 U.S.C. 12), or of section 5 of the Federal Trade Commis-
5 sion Act (15 U.S.C. 45) to the extent that it applies to
6 unfair methods of competition.

7 (d) RULEMAKING.—The Federal Trade Commission
8 may issue rules under section 553 of title 5, United States
9 Code, to define any terms used in section 27 of the Fed-
10 eral Trade Commission Act, as added by subsection (a)
11 (other than terms that are defined in subsection (a) of
12 such section 27).

Calendar No. 43

119TH CONGRESS
1ST Session

S. 1040

A BILL

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

APRIL 10, 2025

Reported with an amendment