

119TH CONGRESS
1ST SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

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 _____

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”.

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 or modification to, or reformulation of,
4 the same manufacturer's previously approved
5 drug or biological product that has an indica-
6 tion that is identical or substantively similar to
7 an indication of the same manufacturer's pre-
8 viously approved drug or biological product; 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 the generic drug
10 or biosimilar biological product that is the subject of
11 the abbreviated new drug application or biosimilar
12 biological product license application or another ge-
13 neric drug or biosimilar biological product ref-
14 erencing the listed drug or reference product is first
15 marketed or 3 years after the date on which the fol-
16 low-on product is first marketed, the manufacturer
17 engaged in either of the following actions:

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

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

1 for the listed drug or reference product or
2 placed the listed drug or reference product
3 on the discontinued products list and the
4 manufacturer marketed or sold a follow-on
5 product.

6 “(ii) The manufacturer of the listed
7 drug or reference product—

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

21 “(bb) destroyed the inventory of
22 the listed drug or reference product in
23 a manner that impedes competition
24 from a generic drug or a biosimilar bi-

1 ological product, which may be estab-
2 lished by objective circumstances; and

3 “**(II)** marketed or sold a follow-
4 on product.

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

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

19 “(ii) The manufacturer marketed or
20 sold a follow-on product.

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

23 “(A) truthful, non-misleading promotional
24 marketing; or

1 “(B) ceasing promotional marketing for
2 the listed drug or reference product.

3 “(3) JUSTIFICATION.—

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

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

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

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

4 “(aa) is outside of the control of
5 the manufacturer;

6 “(bb) prevents the production or
7 distribution of the applicable listed
8 drug or reference product; and

9 “(cc) cannot be remedied by rea-
10 sonable efforts; or

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

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

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

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

1 “(B) establish by a preponderance of the
2 evidence that—

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

10 “(ii)(I) the conduct described in para-
11 graph (1) is not reasonably necessary to
12 address or achieve the justifications de-
13 scribed in clause (ii) of paragraph (3)(A);
14 or

15 “(II) the justifications described in
16 clause (ii) of paragraph (3)(A) could be
17 reasonably addressed or achieved through
18 less anticompetitive means.

19 “(c) ENFORCEMENT.—

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

1 “(A) Institute a proceeding under section
2 5(b).

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

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

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

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

14 “(iii) any other equitable remedy, in-
15 cluding ancillary equitable relief.

16 “(2) JUDICIAL REVIEW.—

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

1 “(i) the United States Court of Ap-
2 peals for the District of Columbia Circuit;
3 or

4 “(ii) the court of appeals of the
5 United States for the circuit in which the
6 ultimate parent entity of the manufacturer
7 is incorporated.

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

14 “(3) EQUITABLE REMEDIES.—

15 “(A) DISGORGEMENT.—

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

22 “(ii) CALCULATION.—Any
23 disgorgement that is ordered with respect
24 to a person under clause (i) shall be offset

1 by any amount of restitution ordered
2 under subparagraph (B).

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

12 “(B) RESTITUTION.—

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

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

1 suit in which the Commission seeks the
2 restitution.

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

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

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

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

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

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

20 (c) ANTITRUST LAWS.—Except to the extent sub-
21 section (a) establishes an additional basis for liability
22 under the Federal Trade Commission Act (15 U.S.C. 41
23 et seq.), nothing in this section, or the amendments made
24 by this section, shall modify, impair, limit, or supersede
25 the applicability of the antitrust laws, as defined in sub-

1 section (a) of the first section of the Clayton Act (15
2 U.S.C. 12), or of section 5 of the Federal Trade Commis-
3 sion Act (15 U.S.C. 45) to the extent that it applies to
4 unfair methods of competition.

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