

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.

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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

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## 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-

1 logical product first enters, or could enter,  
2 the market, or is denied—

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

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

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

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

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

23 “(B) REBUTTAL.—

24 “(i) IN GENERAL.—Subject to sub-  
25 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—

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

4 “(ii) in which the Commission may  
 5 impose on the manufacturer any penalty  
 6 that the Commission may impose for a vio-  
 7 lation of section 5.

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 drug manufac-  
 12 turer.

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

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

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

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

22 “(2) JUDICIAL REVIEW.—

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

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