

# Calendar No. 183

111<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# S. 369

To prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market.

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## IN THE SENATE OF THE UNITED STATES

FEBRUARY 3, 2009

Mr. KOHL (for himself, Mr. GRASSLEY, Mr. FEINGOLD, Mr. DURBIN, Mr. BROWN, Ms. COLLINS, Ms. KLOBUCHAR, Mr. NELSON of Florida, and Mr. FRANKEN) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

OCTOBER 15, 2009

Reported by Mr. LEAHY, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

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## A BILL

To prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market.

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 “~~Preserve Access to Af-~~  
5 ~~ordable Generics Act~~”.

1 **SEC. 2. CONGRESSIONAL FINDINGS AND DECLARATION OF**  
2 **PURPOSES.**

3 (a) FINDINGS.—The Congress finds that—

4 (1) prescription drugs make up 10 percent of  
5 the national health care spending but for the past  
6 decade have been one of the fastest growing seg-  
7 ments of health care expenditures;

8 (2) 67 percent of all prescriptions dispensed in  
9 the United States are generic drugs, yet they ac-  
10 count for only 20 percent of all expenditures;

11 (3) generic drugs, on average, cost 30 to 80  
12 percent less than their brand-name counterparts;

13 (4) consumers and the health care system  
14 would benefit from free and open competition in the  
15 pharmaceutical market and the removal of obstacles  
16 to the introduction of generic drugs;

17 (5) full and free competition in the pharma-  
18 ceutical industry, and the full enforcement of anti-  
19 trust law to prevent anticompetitive practices in this  
20 industry, will lead to lower prices, greater innova-  
21 tion, and inure to the general benefit of consumers;

22 (6) the Federal Trade Commission has deter-  
23 mined that some brand name pharmaceutical manu-  
24 facturers collude with generic drug manufacturers to  
25 delay the marketing of competing, low-cost, generic  
26 drugs;

1           (7) collusion by pharmaceutical manufacturers  
2 is contrary to free competition, to the interests of  
3 consumers, and to the principles underlying anti-  
4 trust law;

5           (8) in 2005, two appellate court decisions re-  
6 versed the Federal Trade Commission's long-stand-  
7 ing position, and upheld settlements that include  
8 pay-offs by brand name pharmaceutical manufactur-  
9 ers to generic manufacturers designed to keep ge-  
10 neric competition off the market;

11           (9) in the 6 months following the March 2005  
12 court decisions, the Federal Trade Commission  
13 found there were three settlement agreements in  
14 which the generic received compensation and agreed  
15 to a restriction on its ability to market the product;

16           (10) the FTC found that  $\frac{1}{2}$  of the settlements  
17 made in 2006 and 2007 between brand name and  
18 generic companies, and over  $\frac{2}{3}$  of the settlements  
19 with generic companies with exclusivity rights that  
20 blocked other generic drug applicants, included a  
21 pay-off from the brand name manufacturer in ex-  
22 change for a promise from the generic company to  
23 delay entry into the market; and

24           (11) settlements which include a payment from  
25 a brand name manufacturer to a generic manufac-

1 turer to delay entry by generic drugs are anti-com-  
 2 petitive and contrary to the interests of consumers.

3 (b) PURPOSES.—The purposes of this Act are—

4 (1) to enhance competition in the pharma-  
 5 ceutical market by prohibiting anticompetitive agree-  
 6 ments and collusion between brand name and ge-  
 7 neric drug manufacturers intended to keep generic  
 8 drugs off the market;

9 (2) to support the purpose and intent of anti-  
 10 trust law by prohibiting anticompetitive agreements  
 11 and collusion in the pharmaceutical industry; and

12 (3) to clarify the law to prohibit payments from  
 13 brand name to generic drug manufacturers with the  
 14 purpose to prevent or delay the entry of competition  
 15 from generic drugs.

16 **SEC. 3. UNLAWFUL COMPENSATION FOR DELAY.**

17 (a) IN GENERAL.—The Clayton Act (15 U.S.C. 12  
 18 et seq.) is amended by inserting after section 28 the fol-  
 19 lowing:

20 **“SEC. 29. UNLAWFUL INTERFERENCE WITH GENERIC MAR-**  
 21 **KETING.**

22 “(a) It shall be unlawful under this Act for any per-  
 23 son, in connection with the sale of a drug product, to di-  
 24 rectly or indirectly be a party to any agreement resolving  
 25 or settling a patent infringement claim in which—

1           “(1) an ANDA filer receives anything of value;  
2           and

3           “(2) the ANDA filer agrees not to research, de-  
4           velop, manufacture, market, or sell the ANDA prod-  
5           uct for any period of time.

6           “(b) Nothing in this section shall prohibit a resolu-  
7           tion or settlement of patent infringement claim in which  
8           the value paid by the NDA holder to the ANDA filer as  
9           a part of the resolution or settlement of the patent in-  
10          fringement claim includes no more than the right to mar-  
11          ket the ANDA product prior to the expiration of the pat-  
12          ent that is the basis for the patent infringement claim.

13          “(c) In this section:

14                 “(1) The term ‘agreement’ means anything that  
15                 would constitute an agreement under section 1 of  
16                 the Sherman Act (15 U.S.C. 1) or section 5 of the  
17                 Federal Trade Commission Act (15 U.S.C. 45).

18                 “(2) The term ‘agreement resolving or settling  
19                 a patent infringement claim’ includes, any agree-  
20                 ment that is contingent upon, provides a contingent  
21                 condition for, or is otherwise related to the resolu-  
22                 tion or settlement of the claim.

23                 “(3) The term ‘ANDA’ means an abbreviated  
24                 new drug application, as defined under section

1 505(j) of the Federal Food, Drug, and Cosmetic Act  
2 (21 U.S.C. 355(j)).

3 “(4) The term ‘ANDA filer’ means a party who  
4 has filed an ANDA with the Food and Drug Admin-  
5 istration.

6 “(5) The term ‘ANDA product’ means the  
7 product to be manufactured under the ANDA that  
8 is the subject of the patent infringement claim.

9 “(6) The term ‘drug product’ means a finished  
10 dosage form (e.g., tablet, capsule, or solution) that  
11 contains a drug substance, generally, but not nec-  
12 essarily, in association with one or more other ingre-  
13 dients, as defined in section 314.3(b) of title 21,  
14 Code of Federal Regulations.

15 “(7) The term ‘NDA’ means a new drug appli-  
16 cation, as defined under section 505(b) of the Fed-  
17 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
18 355(b)).

19 “(8) The term ‘NDA holder’ means—

20 “(A) the party that received FDA approval  
21 to market a drug product pursuant to an NDA;

22 “(B) a party owning or controlling enforce-  
23 ment of the patent listed in the Approved Drug  
24 Products With Therapeutic Equivalence Eval-

1           uations (commonly known as the ‘FDA Orange  
2           Book’) in connection with the NDA; or

3           “(C) the predecessors, subsidiaries, divi-  
4           sions, groups, and affiliates controlled by, con-  
5           trolling, or under common control with any of  
6           the entities described in subclauses (i) and (ii)  
7           (such control to be presumed by direct or indi-  
8           rect share ownership of 50 percent or greater),  
9           as well as the licensees, licensors, successors,  
10          and assigns of each of the entities.

11          “(9) The term ‘patent infringement’ means in-  
12          fringement of any patent or of any filed patent ap-  
13          plication, extension, reissue, renewal, division, con-  
14          tinuation, continuation in part, reexamination, pat-  
15          ent term restoration, patents of addition and exten-  
16          sions thereof.

17          “(10) The term ‘patent infringement claim’  
18          means any allegation made to an ANDA filer,  
19          whether or not included in a complaint filed with a  
20          court of law, that its ANDA or ANDA product may  
21          infringe any patent held by, or exclusively licensed  
22          to, the NDA holder of the drug product.”.

23          (b) REGULATIONS.—The Federal Trade Commission  
24          may, by rule promulgated under section 553 of title 5,  
25          United States Code, exempt certain agreements described

1 in section 29 of the Clayton Act, as added by subsection  
 2 (a), if the Commission finds such agreements to be in fur-  
 3 therance of market competition and for the benefit of con-  
 4 sumers. Consistent with the authority of the Commission,  
 5 such rules may include interpretive rules and general  
 6 statements of policy with respect to the practices prohib-  
 7 ited under section 29 of the Clayton Act.

8 **SEC. 4. NOTICE AND CERTIFICATION OF AGREEMENTS.**

9 (a) NOTICE OF ALL AGREEMENTS.—Section  
 10 1112(e)(2) of the Medicare Prescription Drug, Improve-  
 11 ment, and Modernization Act of 2003 (21 U.S.C. 3155  
 12 note) is amended by—

13 (1) striking “the Commission the” and insert-  
 14 ing “the Commission (1) the”; and

15 (2) inserting before the period at the end the  
 16 following: “; and (2) a description of the subject  
 17 matter of any other agreement the parties enter into  
 18 within 30 days of an entering into an agreement  
 19 covered by subsection (a) or (b)”.

20 (b) CERTIFICATION OF AGREEMENTS.—Section 1112  
 21 of such Act is amended by adding at the end the following:

22 “(d) CERTIFICATION.—The Chief Executive Officer  
 23 or the company official responsible for negotiating any  
 24 agreement required to be filed under subsection (a), (b),  
 25 or (c) shall execute and file with the Assistant Attorney



1 General and the Commission a certification as follows: “I  
 2 declare under penalty of perjury that the following is true  
 3 and correct: The materials filed with the Federal Trade  
 4 Commission and the Department of Justice under section  
 5 1112 of subtitle B of title XI of the Medicare Prescription  
 6 Drug, Improvement, and Modernization Act of 2003, with  
 7 respect to the agreement referenced in this certification:  
 8 (1) represent the complete, final, and exclusive agreement  
 9 between the parties; (2) include any ancillary agreements  
 10 that are contingent upon, provide a contingent condition  
 11 for, or are otherwise related to, the referenced agreement;  
 12 and (3) include written descriptions of any oral agree-  
 13 ments, representations, commitments, or promises be-  
 14 tween the parties that are responsive to subsection (a) or  
 15 (b) of such section 1112 and have not been reduced to  
 16 writing.”.

17 **SEC. 5. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.**

18 Section 505 of the Federal Food, Drug and Cosmetic  
 19 Act (~~21 U.S.C. 355(j)(5)(D)(i)(V)~~) is amended by insert-  
 20 ing “section 29 of the Clayton Act or” after “that the  
 21 agreement has violated”.

22 **SECTION 1. SHORT TITLE.**

23 *This Act may be cited as the “Preserve Access to Af-*  
 24 *fordable Generics Act”.*

1 **SEC. 2. CONGRESSIONAL FINDINGS AND DECLARATION OF**  
2 **PURPOSES.**

3 (a) *FINDINGS.*—Congress finds the following:

4 (1) *In 1984, the Drug Price Competition and*  
5 *Patent Term Restoration Act (Public Law 98–417)*  
6 *(referred to in this Act as the “1984 Act”), was en-*  
7 *acted with the intent of facilitating the early entry of*  
8 *generic drugs while preserving incentives for innova-*  
9 *tion.*

10 (2) *Prescription drugs make up 10 percent of the*  
11 *national health care spending but for the past decade*  
12 *have been one of the fastest growing segments of health*  
13 *care expenditures.*

14 (3) *Until recently, the 1984 Act was successful in*  
15 *facilitating generic competition to the benefit of con-*  
16 *sumers and health care payers – although 67 percent*  
17 *of all prescriptions dispensed in the United States are*  
18 *generic drugs, they account for only 20 percent of all*  
19 *expenditures.*

20 (4) *Generic drugs cost substantially less than*  
21 *brand name drugs, with discounts off the brand price*  
22 *sometimes exceeding 90 percent.*

23 (5) *Federal dollars currently account for an esti-*  
24 *mated 30 percent of the \$235,000,000,000 spent on*  
25 *prescription drugs in 2008, and this share is expected*  
26 *to rise to 40 percent by 2018.*

1           (6)(A) *In recent years, the intent of the 1984 Act*  
2 *has been subverted by certain settlement agreements*  
3 *between brand companies and their potential generic*  
4 *competitors that make “reverse payments” which are*  
5 *payments by the brand company to the generic com-*  
6 *pany.*

7           (B) *These settlement agreements have unduly de-*  
8 *layed the marketing of low-cost generic drugs con-*  
9 *trary to free competition, the interests of consumers,*  
10 *and the principles underlying antitrust law.*

11           (C) *Because of the price disparity between brand*  
12 *name and generic drugs, such agreements are more*  
13 *profitable for both the brand and generic manufactur-*  
14 *ers than competition, and will become increasingly*  
15 *common unless prohibited.*

16           (D) *These agreements result in consumers losing*  
17 *the benefits that the 1984 Act was intended to pro-*  
18 *vide.*

19           (b) *PURPOSES.—The purposes of this Act are—*

20           (1) *to enhance competition in the pharma-*  
21 *ceutical market by stopping anticompetitive agree-*  
22 *ments between brand name and generic drug manu-*  
23 *facturers that limit, delay, or otherwise prevent com-*  
24 *petition from generic drugs; and*

1           (2) to support the purpose and intent of anti-  
2           trust law by prohibiting anticompetitive practices in  
3           the pharmaceutical industry that harm consumers.

4 **SEC. 3. UNLAWFUL COMPENSATION FOR DELAY.**

5           (a) *IN GENERAL.*—*The Federal Trade Commission Act*  
6 *(15 U.S.C. 44 et seq.) is amended by—*

7           (1) redesignating section 28 as section 29; and  
8           (2) inserting before section 29, as redesignated,  
9           the following:

10 **“SEC. 28. PRESERVING ACCESS TO AFFORDABLE GENERICS.**

11           “(a) *IN GENERAL.*—

12           “(1) *ENFORCEMENT PROCEEDING.*—*The Federal*  
13 *Trade Commission may initiate a proceeding to en-*  
14 *force the provisions of this section against the parties*  
15 *to any agreement resolving or settling, on a final or*  
16 *interim basis, a patent infringement claim, in con-*  
17 *nection with the sale of a drug product.*

18           “(2) *PRESUMPTION.*—

19           “(A) *IN GENERAL.*—*Subject to subpara-*  
20 *graph (B), in such a proceeding, an agreement*  
21 *shall be presumed to have anticompetitive effects*  
22 *and be unlawful if—*

23           “(i) *an ANDA filer receives anything*  
24           *of value; and*

1                   “(ii) the ANDA filer agrees to limit or  
2                   forego research, development, manufac-  
3                   turing, marketing, or sales of the ANDA  
4                   product for any period of time.

5                   “(B) EXCEPTION.—The presumption in  
6                   subparagraph (A) shall not apply if the parties  
7                   to such agreement demonstrate by clear and con-  
8                   vincing evidence that the procompetitive benefits  
9                   of the agreement outweigh the anticompetitive ef-  
10                  fects of the agreement.

11                  “(b) COMPETITIVE FACTORS.—In determining whether  
12                  the settling parties have met their burden under subsection  
13                  (a)(2)(B), the fact finder shall consider—

14                   “(1) the length of time remaining until the end  
15                   of the life of the relevant patent, compared with the  
16                   agreed upon entry date for the ANDA product;

17                   “(2) the value to consumers of the competition  
18                   from the ANDA product allowed under the agreement;

19                   “(3) the form and amount of consideration re-  
20                   ceived by the ANDA filer in the agreement resolving  
21                   or settling the patent infringement claim;

22                   “(4) the revenue the ANDA filer would have re-  
23                   ceived by winning the patent litigation;

24                   “(5) the reduction in the NDA holder’s revenues  
25                   if it had lost the patent litigation;

1           “(6) *the time period between the date of the*  
2 *agreement conveying value to the ANDA filer and the*  
3 *date of the settlement of the patent infringement*  
4 *claim; and*

5           “(7) *any other factor that the fact finder, in its*  
6 *discretion, deems relevant to its determination of*  
7 *competitive effects under this subsection.*

8           “(c) *LIMITATIONS.—In determining whether the set-*  
9 *tling parties have met their burden under subsection*  
10 *(a)(2)(B), the fact finder shall not presume—*

11           “(1) *that entry would not have occurred until the*  
12 *expiration of the relevant patent or statutory exclu-*  
13 *sivity; or*

14           “(2) *that the agreement’s provision for entry of*  
15 *the ANDA product prior to the expiration of the rel-*  
16 *evant patent or statutory exclusivity means that the*  
17 *agreement is pro-competitive, although such evidence*  
18 *may be relevant to the fact finder’s determination*  
19 *under this section.*

20           “(d) *EXCLUSIONS.—Nothing in this section shall pro-*  
21 *hibit a resolution or settlement of a patent infringement*  
22 *claim in which the consideration granted by the NDA hold-*  
23 *er to the ANDA filer as part of the resolution or settlement*  
24 *includes only one or more of the following:*

1           “(1) *The right to market the ANDA product in*  
2 *the United States prior to the expiration of—*

3                   “(A) *any patent that is the basis for the*  
4 *patent infringement claim; or*

5                   “(B) *any patent right or other statutory ex-*  
6 *clusivity that would prevent the marketing of*  
7 *such drug.*

8           “(2) *A payment for reasonable litigation ex-*  
9 *penses not to exceed \$7,500,000.*

10           “(3) *A covenant not to sue on any claim that the*  
11 *ANDA product infringes a United States patent.*

12           “(e) *REGULATIONS AND ENFORCEMENT.—*

13                   “(1) *REGULATIONS.—The Federal Trade Com-*  
14 *mission may issue, in accordance with section 553 of*  
15 *title 5, United States Code, regulations implementing*  
16 *and interpreting this section. These regulations may*  
17 *exempt certain types of agreements described in sub-*  
18 *section (a) if the Commission determines such agree-*  
19 *ments will further market competition and benefit*  
20 *consumers. Judicial review of any such regulation*  
21 *shall be in the United States District Court for the*  
22 *District of Columbia pursuant to section 706 of title*  
23 *5, United States Code.*

24                   “(2) *ENFORCEMENT.—A violation of this section*  
25 *shall be treated as a violation of section 5.*

1           “(3) *JUDICIAL REVIEW.*—Any person, partner-  
2           ship or corporation that is subject to a final order of  
3           the Commission, issued in an administrative adju-  
4           dicative proceeding under the authority of subsection  
5           (a)(1), may, within 30 days of the issuance of such  
6           order, petition for review of such order in the United  
7           States Court of Appeals for the District of Columbia  
8           Circuit or the United States Court of Appeals for the  
9           circuit in which the ultimate parent entity, as defined  
10          at 16 C.F.R. 801.1(a)(3), of the NDA holder is incor-  
11          porated as of the date that the NDA is filed with the  
12          Secretary of the Food and Drug Administration, or  
13          the United States Court of Appeals for the circuit in  
14          which the ultimate parent entity of the ANDA filer is  
15          incorporated as of the date that the ANDA is filed  
16          with the Secretary of the Food and Drug Administra-  
17          tion. In such a review proceeding, the findings of the  
18          Commission as to the facts, if supported by evidence,  
19          shall be conclusive.

20          “(f) *ANTITRUST LAWS.*—Nothing in this section shall  
21          be construed to modify, impair or supersede the applica-  
22          bility of the antitrust laws as defined in subsection (a) of  
23          the 1st section of the Clayton Act (15 U.S.C. 12(a)) and  
24          of section 5 of this Act to the extent that section 5 applies  
25          to unfair methods of competition. Nothing in this section



1 *shall modify, impair, limit or supersede the right of an*  
2 *ANDA filer to assert claims or counterclaims against any*  
3 *person, under the antitrust laws or other laws relating to*  
4 *unfair competition.*

5 “(g) *PENALTIES.—*

6 “(1) *FORFEITURE.—Each person, partnership or*  
7 *corporation that violates or assists in the violation of*  
8 *this section shall forfeit and pay to the United States*  
9 *a civil penalty sufficient to deter violations of this*  
10 *section, but in no event greater than 3 times the value*  
11 *received by the party that is reasonably attributable*  
12 *to a violation of this section. If no such value has*  
13 *been received by the NDA holder, the penalty to the*  
14 *NDA holder shall be shall be sufficient to deter viola-*  
15 *tions, but in no event greater than 3 times the value*  
16 *given to the ANDA filer reasonably attributable to the*  
17 *violation of this section. Such penalty shall accrue to*  
18 *the United States and may be recovered in a civil ac-*  
19 *tion brought by the Federal Trade Commission, in its*  
20 *own name by any of its attorneys designated by it for*  
21 *such purpose, in a district court of the United States*  
22 *against any person, partnership or corporation that*  
23 *violates this section. In such actions, the United*  
24 *States district courts are empowered to grant manda-*

1 *tory injunctions and such other and further equitable*  
2 *relief as they deem appropriate.*

3 “(2) *CEASE AND DESIST.*—

4 “(A) *IN GENERAL.*—*If the Commission has*  
5 *issued a cease and desist order with respect to a*  
6 *person, partnership or corporation in an admin-*  
7 *istrative adjudicative proceeding under the au-*  
8 *thority of subsection (a)(1), an action brought*  
9 *pursuant to paragraph (1) may be commenced*  
10 *against such person, partnership or corporation*  
11 *at any time before the expiration of one year*  
12 *after such order becomes final pursuant to sec-*  
13 *tion 5(g).*

14 “(B) *EXCEPTION.*—*In an action under sub-*  
15 *paragraph (A), the findings of the Commission*  
16 *as to the material facts in the administrative ad-*  
17 *judicative proceeding with respect to such per-*  
18 *son’s, partnership’s or corporation’s violation of*  
19 *this section shall be conclusive unless—*

20 “(i) *the terms of such cease and desist*  
21 *order expressly provide that the Commis-*  
22 *sion’s findings shall not be conclusive; or*

23 “(ii) *the order became final by reason*  
24 *of section 5(g)(1), in which case such find-*

1            *ing shall be conclusive if supported by evi-*  
2            *dence.*

3            “(3) *CIVIL PENALTY.—In determining the*  
4            *amount of the civil penalty described in this section,*  
5            *the court shall take into account—*

6            “(A) *the nature, circumstances, extent, and*  
7            *gravity of the violation;*

8            “(B) *with respect to the violator, the degree*  
9            *of culpability, any history of violations, the abil-*  
10           *ity to pay, any effect on the ability to continue*  
11           *doing business, profits earned by the NDA hold-*  
12           *er, compensation received by the ANDA filer,*  
13           *and the amount of commerce affected; and*

14           “(C) *other matters that justice requires.*

15           “(4) *REMEDIES IN ADDITION.—Remedies pro-*  
16           *vided in this subsection are in addition to, and not*  
17           *in lieu of, any other remedy provided by Federal law.*  
18           *Nothing in this paragraph shall be construed to affect*  
19           *any authority of the Commission under any other*  
20           *provision of law.*

21           “(h) *DEFINITIONS.—In this section:*

22           “(1) *AGREEMENT.—The term ‘agreement’ means*  
23           *anything that would constitute an agreement under*  
24           *section 1 of the Sherman Act (15 U.S.C. 1) or section*  
25           *5 of this Act.*

1           “(2) *AGREEMENT RESOLVING OR SETTLING A*  
2           *PATENT INFRINGEMENT CLAIM.*—*The term ‘agreement*  
3           *resolving or settling a patent infringement claim’ in-*  
4           *cludes any agreement that is entered into within 30*  
5           *days of the resolution or the settlement of the claim,*  
6           *or any other agreement that is contingent upon, pro-*  
7           *vides a contingent condition for, or is otherwise re-*  
8           *lated to the resolution or settlement of the claim.*

9           “(3) *ANDA.*—*The term ‘ANDA’ means an abbrev-*  
10           *viated new drug application, as defined under section*  
11           *505(j) of the Federal Food, Drug, and Cosmetic Act*  
12           *(21 U.S.C. 355(j)).*

13           “(4) *ANDA FILER.*—*The term ‘ANDA filer’*  
14           *means a party who has filed an ANDA with the Food*  
15           *and Drug Administration.*

16           “(5) *ANDA PRODUCT.*—*The term ‘ANDA prod-*  
17           *uct’ means the product to be manufactured under the*  
18           *ANDA that is the subject of the patent infringement*  
19           *claim.*

20           “(6) *DRUG PRODUCT.*—*The term ‘drug product’*  
21           *means a finished dosage form (e.g., tablet, capsule, or*  
22           *solution) that contains a drug substance, generally,*  
23           *but not necessarily, in association with 1 or more*  
24           *other ingredients, as defined in section 314.3(b) of*  
25           *title 21, Code of Federal Regulations.*

1           “(7) *NDA*.—*The term ‘NDA’ means a new drug*  
2 *application, as defined under section 505(b) of the*  
3 *Federal Food, Drug, and Cosmetic Act (21 U.S.C.*  
4 *355(b)).*

5           “(8) *NDA HOLDER*.—*The term ‘NDA holder’*  
6 *means—*

7                   “(A) *the party that received FDA approval*  
8 *to market a drug product pursuant to an NDA;*

9                   “(B) *a party owning or controlling enforce-*  
10 *ment of the patent listed in the Approved Drug*  
11 *Products With Therapeutic Equivalence Evalua-*  
12 *tions (commonly known as the ‘FDA Orange*  
13 *Book’) in connection with the NDA; or*

14                   “(C) *the predecessors, subsidiaries, divi-*  
15 *sions, groups, and affiliates controlled by, con-*  
16 *trolling, or under common control with any of*  
17 *the entities described in subparagraphs (A) and*  
18 *(B) (such control to be presumed by direct or in-*  
19 *direct share ownership of 50 percent or greater),*  
20 *as well as the licensees, licensors, successors, and*  
21 *assigns of each of the entities.*

22           “(9) *PATENT INFRINGEMENT*.—*The term ‘patent*  
23 *infringement’ means infringement of any patent or of*  
24 *any filed patent application, extension, reissue, re-*  
25 *newal, division, continuation, continuation in part,*

1        *reexamination, patent term restoration, patents of ad-*  
2        *dition and extensions thereof.*

3                “(10) *PATENT INFRINGEMENT CLAIM.*—*The term*  
4        *‘patent infringement claim’ means any allegation*  
5        *made to an ANDA filer, whether or not included in*  
6        *a complaint filed with a court of law, that its ANDA*  
7        *or ANDA product may infringe any patent held by,*  
8        *or exclusively licensed to, the NDA holder of the drug*  
9        *product.*

10               “(11) *STATUTORY EXCLUSIVITY.*—*The term ‘stat-*  
11        *utory exclusivity’ means those prohibitions on the ap-*  
12        *proval of drug applications under clauses (ii) through*  
13        *(iv) of section 505(c)(3)(E) (5- and 3-year data exclu-*  
14        *sivity), section 527 (orphan drug exclusivity), or sec-*  
15        *tion 505A (pediatric exclusivity) of the Federal Food,*  
16        *Drug, and Cosmetic Act .”.*

17               (b) *EFFECTIVE DATE.*—*Section 28 of the Federal*  
18        *Trade Commission Act, as added by this section, shall*  
19        *apply to all agreements described in section 28(a)(1) of that*  
20        *Act entered into after November 15, 2009. Section 28(g) of*  
21        *the Federal Trade Commission Act, as added by this sec-*  
22        *tion, shall not apply to agreements entered into before the*  
23        *date of enactment of this Act.*

1 **SEC. 4. NOTICE AND CERTIFICATION OF AGREEMENTS.**

2 (a) NOTICE OF ALL AGREEMENTS.—Section  
3 1112(c)(2) of the Medicare Prescription Drug, Improve-  
4 ment, and Modernization Act of 2003 (21 U.S.C. 355 note)  
5 is amended by—

6 (1) striking “the Commission the” and inserting  
7 the following: “the Commission—

8 “(1) the”;

9 (2) striking the period and inserting “; and”;  
10 and

11 (3) inserting at the end the following:

12 “(2) any other agreement the parties enter into  
13 within 30 days of entering into an agreement covered  
14 by subsection (a) or (b).”.

15 (b) CERTIFICATION OF AGREEMENTS.—Section 1112  
16 of such Act is amended by adding at the end the following:

17 “(d) CERTIFICATION.—The Chief Executive Officer or  
18 the company official responsible for negotiating any agree-  
19 ment required to be filed under subsection (a), (b), or (c)  
20 shall execute and file with the Assistant Attorney General  
21 and the Commission a certification as follows: ‘I declare  
22 that the following is true, correct, and complete to the best  
23 of my knowledge: The materials filed with the Federal  
24 Trade Commission and the Department of Justice under  
25 section 1112 of subtitle B of title XI of the Medicare Pre-  
26 scription Drug, Improvement, and Modernization Act of

1 2003, with respect to the agreement referenced in this cer-  
 2 tification: (1) represent the complete, final, and exclusive  
 3 agreement between the parties; (2) include any ancillary  
 4 agreements that are contingent upon, provide a contingent  
 5 condition for, or are otherwise related to, the referenced  
 6 agreement; and (3) include written descriptions of any oral  
 7 agreements, representations, commitments, or promises be-  
 8 tween the parties that are responsive to subsection (a) or  
 9 (b) of such section 1112 and have not been reduced to writ-  
 10 ing.’”.

11 **SEC. 5. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.**

12 Section 505(j)(5)(D)(i)(V) of the Federal Food, Drug  
 13 and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V)) is amend-  
 14 ed by inserting “section 28 of the Federal Trade Commis-  
 15 sion Act or” after “that the agreement has violated”.

16 **SEC. 6. COMMISSION LITIGATION AUTHORITY.**

17 Section 16(a)(2) of the Federal Trade Commission Act  
 18 (15 U.S.C. 56(a)(2)) is amended—

19 (1) in subparagraph (D), by striking “or” after  
 20 the semicolon;

21 (2) in subparagraph (E), by inserting “or” after  
 22 the semicolon; and

23 (3) inserting after subparagraph (E) the fol-  
 24 lowing:

25 “(F) under section 28;”.



1 **SEC. 7. STATUTE OF LIMITATIONS.**

2       *The Commission shall commence any enforcement pro-*  
3 *ceeding described in section 28 of the Federal Trade Com-*  
4 *mission Act, as added by section 3, except for an action*  
5 *described in section 28(g)(2) of the Federal Trade Commis-*  
6 *sion Act, not later than 3 years after the date on which*  
7 *the parties to the agreement file the Notice of Agreement*  
8 *as provided by sections 1112(c)(2) and (d) of the Medicare*  
9 *Prescription Drug Improvement and Modernization Act of*  
10 *2003 (21 U.S.C. 355 note).*

11 **SEC. 8. SEVERABILITY.**

12       *If any provision of this Act, an amendment made by*  
13 *this Act, or the application of such provision or amendment*  
14 *to any person or circumstance is held to be unconstitu-*  
15 *tional, the remainder of this Act, the amendments made by*  
16 *this Act, and the application of the provisions of such Act*  
17 *or amendments to any person or circumstance shall not be*  
18 *affected thereby.*

Calendar No. 183

111<sup>TH</sup> CONGRESS  
1<sup>ST</sup> Session

**S. 369**

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**A BILL**

To prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market.

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OCTOBER 15, 2009

Reported with an amendment