Calendar No. 183

111TH CONGRESS
1ST 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.

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]

A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

~~**SECTION 1. SHORT TITLE.**~~

~~This Act may be cited as the "Preserve Access to Affordable Generics Act".~~

SEC. 2. CONGRESSIONAL FINDINGS AND DECLARATION OF PURPOSES.

(a) FINDINGS.—The Congress finds that—

(1) prescription drugs make up 10 percent of the national health care spending but for the past decade have been one of the fastest growing segments of health care expenditures;

(2) 67 percent of all prescriptions dispensed in the United States are generic drugs, yet they account for only 20 percent of all expenditures;

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

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

(5) full and free competition in the pharmaceutical industry, and the full enforcement of antitrust law to prevent anticompetitive practices in this industry, will lead to lower prices, greater innovation, and inure to the general benefit of consumers;

(6) the Federal Trade Commission has determined that some brand name pharmaceutical manufacturers collude with generic drug manufacturers to delay the marketing of competing, low-cost, generic drugs;

(7) collusion by pharmaceutical manufacturers is contrary to free competition, to the interests of consumers, and to the principles underlying antitrust law;

(8) in 2005, two appellate court decisions reversed the Federal Trade Commission's long-standing position, and upheld settlements that include pay-offs by brand name pharmaceutical manufacturers to generic manufacturers designed to keep generic competition off the market;

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

(10) the FTC found that ½ of the settlements made in 2006 and 2007 between brand name and generic companies, and over ⅔ of the settlements with generic companies with exclusivity rights that blocked other generic drug applicants, included a pay-off from the brand name manufacturer in exchange for a promise from the generic company to delay entry into the market; and

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

turer to delay entry by generic drugs are anti-competitive and contrary to the interests of consumers.

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

(1) to enhance competition in the pharmaceutical market by prohibiting anticompetitive agreements and collusion between brand name and generic drug manufacturers intended to keep generic drugs off the market;

(2) to support the purpose and intent of antitrust law by prohibiting anticompetitive agreements and collusion in the pharmaceutical industry; and

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

SEC. 3. UNLAWFUL COMPENSATION FOR DELAY.

(a) IN GENERAL.—The Clayton Act (15 U.S.C. 12 et seq.) is amended by inserting after section 28 the following:

"SEC. 29. UNLAWFUL INTERFERENCE WITH GENERIC MARKETING.

"(a) It shall be unlawful under this Act for any person, in connection with the sale of a drug product, to directly or indirectly be a party to any agreement resolving or settling a patent infringement claim in which—

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

''(2) the ANDA filer agrees not to research, develop, manufacture, market, or sell the ANDA product for any period of time.

''(b) Nothing in this section shall prohibit a resolution or settlement of patent infringement claim in which the value paid by the NDA holder to the ANDA filer as a part of the resolution or settlement of the patent infringement claim includes no more than the right to market the ANDA product prior to the expiration of the patent that is the basis for the patent infringement claim.

''(c) In this section:

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

''(2) The term 'agreement resolving or settling a patent infringement claim' includes, any agreement that is contingent upon, provides a contingent condition for, or is otherwise related to the resolution or settlement of the claim.

''(3) The term 'ANDA' means an abbreviated new drug application, as defined under section

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

''(4) The term 'ANDA filer' means a party who has filed an ANDA with the Food and Drug Administration.

''(5) The term 'ANDA product' means the product to be manufactured under the ANDA that is the subject of the patent infringement claim.

''(6) The term 'drug product' means a finished dosage form (e.g., tablet, capsule, or solution) that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients, as defined in section 314.3(b) of title 21, Code of Federal Regulations.

''(7) The term 'NDA' means a new drug application, as defined under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)).

''(8) The term 'NDA holder' means—

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

''(B) a party owning or controlling enforcement of the patent listed in the Approved Drug Products With Therapeutic Equivalence Eval-

uations (commonly known as the 'FDA Orange Book') in connection with the NDA; or

''(C) the predecessors, subsidiaries, divisions, groups, and affiliates controlled by, controlling, or under common control with any of the entities described in subclauses (i) and (ii) (such control to be presumed by direct or indirect share ownership of 50 percent or greater), as well as the licensees, licensors, successors, and assigns of each of the entities.

''(9) The term 'patent infringement' means infringement of any patent or of any filed patent application, extension, reissue, renewal, division, continuation, continuation in part, reexamination, patent term restoration, patents of addition and extensions thereof.

''(10) The term 'patent infringement claim' means any allegation made to an ANDA filer, whether or not included in a complaint filed with a court of law, that its ANDA or ANDA product may infringe any patent held by, or exclusively licensed to, the NDA holder of the drug product.''.

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

in section 29 of the Clayton Act, as added by subsection (a), if the Commission finds such agreements to be in furtherance of market competition and for the benefit of consumers. Consistent with the authority of the Commission, such rules may include interpretive rules and general statements of policy with respect to the practices prohibited under section 29 of the Clayton Act.

SEC. 4. NOTICE AND CERTIFICATION OF AGREEMENTS.

(a) NOTICE OF ALL AGREEMENTS.—Section 1112(c)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (21 U.S.C. 3155 note) is amended by—

(1) striking ''the Commission the'' and inserting ''the Commission (1) the''; and

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

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

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

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

~~SEC. 5. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.~~

~~Section 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V)) is amended by inserting ''section 29 of the Clayton Act or'' after ''that the agreement has violated''.~~

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Preserve Access to Affordable Generics Act''.

SEC. 2. CONGRESSIONAL FINDINGS AND DECLARATION OF PURPOSES.

(a) FINDINGS.—Congress finds the following:

(1) In 1984, the Drug Price Competition and Patent Term Restoration Act (Public Law 98–417) (referred to in this Act as the "1984 Act"), was enacted with the intent of facilitating the early entry of generic drugs while preserving incentives for innovation.

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

(3) Until recently, the 1984 Act was successful in facilitating generic competition to the benefit of consumers and health care payers – although 67 percent of all prescriptions dispensed in the United States are generic drugs, they account for only 20 percent of all expenditures.

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

(5) Federal dollars currently account for an estimated 30 percent of the $235,000,000,000 spent on prescription drugs in 2008, and this share is expected to rise to 40 percent by 2018.

(6)(A) In recent years, the intent of the 1984 Act has been subverted by certain settlement agreements between brand companies and their potential generic competitors that make "reverse payments" which are payments by the brand company to the generic company.

(B) These settlement agreements have unduly delayed the marketing of low-cost generic drugs contrary to free competition, the interests of consumers, and the principles underlying antitrust law.

(C) Because of the price disparity between brand name and generic drugs, such agreements are more profitable for both the brand and generic manufacturers than competition, and will become increasingly common unless prohibited.

(D) These agreements result in consumers losing the benefits that the 1984 Act was intended to provide.

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

(1) to enhance competition in the pharmaceutical market by stopping anticompetitive agreements between brand name and generic drug manufacturers that limit, delay, or otherwise prevent competition from generic drugs; and

(2) to support the purpose and intent of antitrust law by prohibiting anticompetitive practices in the pharmaceutical industry that harm consumers.

SEC. 3. UNLAWFUL COMPENSATION FOR DELAY.

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

(1) redesignating section 28 as section 29; and

(2) inserting before section 29, as redesignated, the following:

"SEC. 28. PRESERVING ACCESS TO AFFORDABLE GENERICS.

"(a) IN GENERAL.—

"(1) ENFORCEMENT PROCEEDING.—The Federal Trade Commission may initiate a proceeding to enforce the provisions of this section against the parties to any agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a drug product.

"(2) PRESUMPTION.—

"(A) IN GENERAL.—Subject to subparagraph (B), in such a proceeding, an agreement shall be presumed to have anticompetitive effects and be unlawful if—

"(i) an ANDA filer receives anything of value; and

"(ii) the ANDA filer agrees to limit or forego research, development, manufacturing, marketing, or sales of the ANDA product for any period of time.

"(B) EXCEPTION.—The presumption in subparagraph (A) shall not apply if the parties to such agreement demonstrate by clear and convincing evidence that the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement.

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

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

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

"(3) the form and amount of consideration received by the ANDA filer in the agreement resolving or settling the patent infringement claim;

"(4) the revenue the ANDA filer would have received by winning the patent litigation;

"(5) the reduction in the NDA holder's revenues if it had lost the patent litigation;

"(6) the time period between the date of the agreement conveying value to the ANDA filer and the date of the settlement of the patent infringement claim; and

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

"(c) LIMITATIONS.—In determining whether the settling parties have met their burden under subsection (a)(2)(B), the fact finder shall not presume—

"(1) that entry would not have occurred until the expiration of the relevant patent or statutory exclusivity; or

"(2) that the agreement's provision for entry of the ANDA product prior to the expiration of the relevant patent or statutory exclusivity means that the agreement is pro-competitive, although such evidence may be relevant to the fact finder's determination under this section.

"(d) EXCLUSIONS.—Nothing in this section shall prohibit a resolution or settlement of a patent infringement claim in which the consideration granted by the NDA holder to the ANDA filer as part of the resolution or settlement includes only one or more of the following:

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

"(A) any patent that is the basis for the patent infringement claim; or

"(B) any patent right or other statutory exclusivity that would prevent the marketing of such drug.

"(2) A payment for reasonable litigation expenses not to exceed $7,500,000.

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

"(e) REGULATIONS AND ENFORCEMENT.—

"(1) REGULATIONS.—The Federal Trade Commission may issue, in accordance with section 553 of title 5, United States Code, regulations implementing and interpreting this section. These regulations may exempt certain types of agreements described in subsection (a) if the Commission determines such agreements will further market competition and benefit consumers. Judicial review of any such regulation shall be in the United States District Court for the District of Columbia pursuant to section 706 of title 5, United States Code.

"(2) ENFORCEMENT.—A violation of this section shall be treated as a violation of section 5.

"(3) JUDICIAL REVIEW.—Any person, partnership or corporation that is subject to a final order of the Commission, issued in an administrative adjudicative proceeding under the authority of subsection (a)(1), may, within 30 days of the issuance of such order, petition for review of such order in the United States Court of Appeals for the District of Columbia Circuit or the United States Court of Appeals for the circuit in which the ultimate parent entity, as defined at 16 C.F.R. 801.1(a)(3), of the NDA holder is incorporated as of the date that the NDA is filed with the Secretary of the Food and Drug Administration, or the United States Court of Appeals for the circuit in which the ultimate parent entity of the ANDA filer is incorporated as of the date that the ANDA is filed with the Secretary of the Food and Drug Administration. In such a review proceeding, the findings of the Commission as to the facts, if supported by evidence, shall be conclusive.

"(f) ANTITRUST LAWS.—Nothing in this section shall be construed to modify, impair or supersede the applicability of the antitrust laws as defined in subsection (a) of the 1st section of the Clayton Act (15 U.S.C. 12(a)) and of section 5 of this Act to the extent that section 5 applies to unfair methods of competition. Nothing in this section

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

"(g) PENALTIES.—

"(1) FORFEITURE.—Each person, partnership or corporation that violates or assists in the violation of this section shall forfeit and pay to the United States a civil penalty sufficient to deter violations of this section, but in no event greater than 3 times the value received by the party that is reasonably attributable to a violation of this section. If no such value has been received by the NDA holder, the penalty to the NDA holder shall be shall be sufficient to deter violations, but in no event greater than 3 times the value given to the ANDA filer reasonably attributable to the violation of this section. Such penalty shall accrue to the United States and may be recovered in a civil action brought by the Federal Trade Commission, in its own name by any of its attorneys designated by it for such purpose, in a district court of the United States against any person, partnership or corporation that violates this section. In such actions, the United States district courts are empowered to grant manda-

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

"(2) CEASE AND DESIST.—

"(A) IN GENERAL.—If the Commission has issued a cease and desist order with respect to a person, partnership or corporation in an administrative adjudicative proceeding under the authority of subsection (a)(1), an action brought pursuant to paragraph (1) may be commenced against such person, partnership or corporation at any time before the expiration of one year after such order becomes final pursuant to section 5(g).

"(B) EXCEPTION.—In an action under subparagraph (A), the findings of the Commission as to the material facts in the administrative adjudicative proceeding with respect to such person's, partnership's or corporation's violation of this section shall be conclusive unless—

"(i) the terms of such cease and desist order expressly provide that the Commission's findings shall not be conclusive; or

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

ing shall be conclusive if supported by evidence.

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

"(A) the nature, circumstances, extent, and gravity of the violation;

"(B) with respect to the violator, the degree of culpability, any history of violations, the ability to pay, any effect on the ability to continue doing business, profits earned by the NDA holder, compensation received by the ANDA filer, and the amount of commerce affected; and

"(C) other matters that justice requires.

"(4) REMEDIES IN ADDITION.—Remedies provided in this subsection are in addition to, and not in lieu of, any other remedy provided by Federal law. Nothing in this paragraph shall be construed to affect any authority of the Commission under any other provision of law.

"(h) DEFINITIONS.—In this section:

"(1) AGREEMENT.—The term 'agreement' means anything that would constitute an agreement under section 1 of the Sherman Act (15 U.S.C. 1) or section 5 of this Act.

"(2) AGREEMENT RESOLVING OR SETTLING A PATENT INFRINGEMENT CLAIM.—The term 'agreement resolving or settling a patent infringement claim' includes any agreement that is entered into within 30 days of the resolution or the settlement of the claim, or any other agreement that is contingent upon, provides a contingent condition for, or is otherwise related to the resolution or settlement of the claim.

"(3) ANDA.—The term 'ANDA' means an abbreviated new drug application, as defined under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

"(4) ANDA FILER.—The term 'ANDA filer' means a party who has filed an ANDA with the Food and Drug Administration.

"(5) ANDA PRODUCT.—The term 'ANDA product' means the product to be manufactured under the ANDA that is the subject of the patent infringement claim.

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

"(7) NDA.—The term 'NDA' means a new drug application, as defined under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)).

"(8) NDA HOLDER.—The term 'NDA holder' means—

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

"(B) a party owning or controlling enforcement of the patent listed in the Approved Drug Products With Therapeutic Equivalence Evaluations (commonly known as the 'FDA Orange Book') in connection with the NDA; or

"(C) the predecessors, subsidiaries, divisions, groups, and affiliates controlled by, controlling, or under common control with any of the entities described in subparagraphs (A) and (B) (such control to be presumed by direct or indirect share ownership of 50 percent or greater), as well as the licensees, licensors, successors, and assigns of each of the entities.

"(9) PATENT INFRINGEMENT.—The term 'patent infringement' means infringement of any patent or of any filed patent application, extension, reissue, renewal, division, continuation, continuation in part,

reexamination, patent term restoration, patents of addition and extensions thereof.

"(10) PATENT INFRINGEMENT CLAIM.—The term 'patent infringement claim' means any allegation made to an ANDA filer, whether or not included in a complaint filed with a court of law, that its ANDA or ANDA product may infringe any patent held by, or exclusively licensed to, the NDA holder of the drug product.

"(11) STATUTORY EXCLUSIVITY.—The term 'statutory exclusivity' means those prohibitions on the approval of drug applications under clauses (ii) through (iv) of section 505(c)(3)(E) (5- and 3-year data exclusivity), section 527 (orphan drug exclusivity), or section 505A (pediatric exclusivity) of the Federal Food, Drug, and Cosmetic Act .".

(b) EFFECTIVE DATE.—Section 28 of the Federal Trade Commission Act, as added by this section, shall apply to all agreements described in section 28(a)(1) of that Act entered into after November 15, 2009. Section 28(g) of the Federal Trade Commission Act, as added by this section, shall not apply to agreements entered into before the date of enactment of this Act.

SEC. 4. NOTICE AND CERTIFICATION OF AGREEMENTS.

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

(1) striking "the Commission the" and inserting the following: "the Commission—

"(1) the";

(2) striking the period and inserting "; and"; and

(3) inserting at the end the following:

"(2) any other agreement the parties enter into within 30 days of entering into an agreement covered by subsection (a) or (b).".

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

"(d) CERTIFICATION.—The Chief Executive Officer or the company official responsible for negotiating any agreement required to be filed under subsection (a), (b), or (c) shall execute and file with the Assistant Attorney General and the Commission a certification as follows: 'I declare that the following is true, correct, and complete to the best of my knowledge: The materials filed with the Federal Trade Commission and the Department of Justice under section 1112 of subtitle B of title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of

2003, with respect to the agreement referenced in this certification: (1) represent the complete, final, and exclusive agreement between the parties; (2) include any ancillary agreements that are contingent upon, provide a contingent condition for, or are otherwise related to, the referenced agreement; and (3) include written descriptions of any oral agreements, representations, commitments, or promises between the parties that are responsive to subsection (a) or (b) of such section 1112 and have not been reduced to writing.'.".

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

Section 505(j)(5)(D)(i)(V) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V)) is amended by inserting "section 28 of the Federal Trade Commission Act or" after "that the agreement has violated".

SEC. 6. COMMISSION LITIGATION AUTHORITY.

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

(1) in subparagraph (D), by striking "or" after the semicolon;

(2) in subparagraph (E), by inserting "or" after the semicolon; and

(3) inserting after subparagraph (E) the following:

"(F) under section 28;".

SEC. 7. STATUTE OF LIMITATIONS.

The Commission shall commence any enforcement proceeding described in section 28 of the Federal Trade Commission Act, as added by section 3, except for an action described in section 28(g)(2) of the Federal Trade Commission Act, not later than 3 years after the date on which the parties to the agreement file the Notice of Agreement as provided by sections 1112(c)(2) and (d) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (21 U.S.C. 355 note).

SEC. 8. SEVERABILITY.

If any provision of this Act, an amendment made by this Act, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this Act, the amendments made by this Act, and the application of the provisions of such Act or amendments to any person or circumstance shall not be affected thereby.

Calendar No. 183

111TH CONGRESS
1ST SESSION

S. 369

A BILL

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

OCTOBER 15, 2009

Reported with an amendment