Calendar No. 59

110TH CONGRESS
1ST SESSION

S. 316

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

JANUARY 17, 2007

Mr. KOHL (for himself, Mr. GRASSLEY, Mr. LEAHY, Mr. SCHUMER, Mr. FEINGOLD, Mr. KENNEDY, and Mr. DURBIN) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

FEBRUARY 27, 2007

Reported by Mr. LEAHY, without amendment

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 11 percent of the national health care spending but are 1 of the largest and fastest growing health care expenditures;

(2) 56 percent of all prescriptions dispensed in the United States are generic drugs, yet they account for only 13percent of all expenditures;

(3) generic drugs, on average, cost 63 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 the brand name pharmaceutical manufacturers is contrary to free competition, to the interests of consumers, and to the principles underlying antitrust law;

(8) in 2005, 2 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 more than ⅔ of the approximately ten settlement agreements made in 2006 include a pay-off from the brand in exchange for a promise by the generic company to delay entry into the market; and

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

The Clayton Act (15 U.S.C. 12 et seq.) is amended—

(1) by redesignating section 25 as section 29; and

(2) by inserting after section 27 the following:

"SEC. 28. 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 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 Federal 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 1 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 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 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.''.

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 agree-

ments, 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 28 of the Clayton Act or'' after ''that the agreement has violated''.

SEC. 6. STUDY BY THE FEDERAL TRADE COMMISSION.

(a) REQUIREMENT FOR A STUDY.—Not later than 180 days after the date of enactment of this Act and pursuant to its authority under section 6(a) of the Federal Trade Commission Act (15 U.S.C. 46(a)) and its jurisdiction to prevent unfair methods of competition, the Federal Trade Commission shall conduct a study regarding—

(1) the prevalence of agreements in patent infringement suits of the type described in section 28 of the Clayton Act, as added by this Act, during the last 5 years;

(2) the impact of such agreements on competition in the pharmaceutical market; and

(3) the prevalence in the pharmaceutical industry of other anticompetitive agreements among competitors or other practices that are contrary to the

antitrust laws, and the impact of such agreements or practices on competition in the pharmaceutical market during the last 5 years.

(b) CONSULTATION.—In conducting the study required under this section, the Federal Trade Commission shall consult with the Antitrust Division of the Department of Justice regarding the Justice Department's findings and investigations regarding anticompetitive practices in the pharmaceutical market, including criminal antitrust investigations completed by the Justice Department with respect to practices or conduct in the pharmaceutical market.

(c) REQUIREMENT FOR A REPORT.—Not later than 1 year after the date of enactment of this Act, the Federal Trade Commission shall submit a report to the Judiciary Committees of Senate and House of Representatives, and to the Department of Justice regarding the findings of the study conducted under subsection (a). This report shall contain the Federal Trade Commission's recommendation as to whether any amendment to the antitrust laws should be enacted to correct any substantial lessening of competition found during the study.

(d) FEDERAL AGENCY CONSIDERATION.—Upon receipt of the report required by subsection (c), the Attorney General or the Chairman of the Federal Trade Commis-

sion, as appropriate, shall consider whether any additional enforcement action is required to restore competition or prevent a substantial lessening of competition occurring as a result of the conduct or practices that were the subject of the study conducted under subsection (b).

SEC. 7. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated to the Federal Trade Commission such sums as may be necessary to carry out the provisions of this Act.

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