

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.

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

7 (2) 56 percent of all prescriptions dispensed in
8 the United States are generic drugs, yet they ac-
9 count for only 13percent of all expenditures;

10 (3) generic drugs, on average, cost 63 percent
11 less than their brand-name counterparts;

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

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

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

1 (7) collusion by the brand name pharmaceutical
2 manufacturers is contrary to free competition, to the
3 interests of consumers, and to the principles under-
4 lying antitrust law;

5 (8) in 2005, 2 appellate court decisions reversed
6 the Federal Trade Commission's long-standing posi-
7 tion, and upheld settlements that include pay-offs by
8 brand name pharmaceutical manufacturers to ge-
9 neric manufacturers designed to keep generic com-
10 petition 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 more than $\frac{2}{3}$ of the
17 approximately ten settlement agreements made in
18 2006 include a pay-off from the brand in exchange
19 for a promise by the generic company to delay entry
20 into the market; and

21 (11) settlements which include a payment from
22 a brand name manufacturer to a generic manufac-
23 turer to delay entry by generic drugs are anti-com-
24 petitive and contrary to the interests of consumers.

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

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

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

11 “(c) In this section:

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

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

21 “(3) The term ‘ANDA’ means an abbreviated
22 new drug application, as defined under section
23 505(j) of the Federal Food, Drug, and Cosmetic Act
24 (21 U.S.C. 355(j)).

1 “(4) The term ‘ANDA filer’ means a party who
2 has filed an ANDA with the Federal Drug Adminis-
3 tration.

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

7 “(6) The term ‘drug product’ means a finished
8 dosage form (e.g., tablet, capsule, or solution) that
9 contains a drug substance, generally, but not nec-
10 essarily, in association with 1 or more other ingredi-
11 ents, as defined in section 314.3(b) of title 21, Code
12 of Federal Regulations.

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

17 “(8) The term ‘NDA holder’ means—

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

20 “(B) a party owning or controlling enforce-
21 ment of the patent listed in the Approved Drug
22 Products With Therapeutic Equivalence Eval-
23 uations (commonly known as the ‘FDA Orange
24 Book’) in connection with the NDA; or

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

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

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

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

22 (a) NOTICE OF ALL AGREEMENTS.—Section
23 1112(c)(2) of the Medicare Prescription Drug, Improve-
24 ment, and Modernization Act of 2003 (21 U.S.C. 3155
25 note) is amended by—

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

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

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

10 “(d) CERTIFICATION.—The Chief Executive Officer
11 or the company official responsible for negotiating any
12 agreement required to be filed under subsection (a), (b),
13 or (c) shall execute and file with the Assistant Attorney
14 General and the Commission a certification as follows: ‘I
15 declare under penalty of perjury that the following is true
16 and correct: The materials filed with the Federal Trade
17 Commission and the Department of Justice under section
18 1112 of subtitle B of title XI of the Medicare Prescription
19 Drug, Improvement, and Modernization Act of 2003, with
20 respect to the agreement referenced in this certification:
21 (1) represent the complete, final, and exclusive agreement
22 between the parties; (2) include any ancillary agreements
23 that are contingent upon, provide a contingent condition
24 for, or are otherwise related to, the referenced agreement;
25 and (3) include written descriptions of any oral agree-

1 ments, representations, commitments, or promises be-
2 tween the parties that are responsive to subsection (a) or
3 (b) of such section 1112 and have not been reduced to
4 writing.’.”.

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

6 Section 505 of the Federal Food, Drug and Cosmetic
7 Act (21 U.S.C. 355(j)(5)(D)(i)(V)) is amended by insert-
8 ing “section 28 of the Clayton Act or” after “that the
9 agreement has violated”.

10 **SEC. 6. STUDY BY THE FEDERAL TRADE COMMISSION.**

11 (a) REQUIREMENT FOR A STUDY.—Not later than
12 180 days after the date of enactment of this Act and pur-
13 suant to its authority under section 6(a) of the Federal
14 Trade Commission Act (15 U.S.C. 46(a)) and its jurisdic-
15 tion to prevent unfair methods of competition, the Federal
16 Trade Commission shall conduct a study regarding—

17 (1) the prevalence of agreements in patent in-
18 fringement suits of the type described in section 28
19 of the Clayton Act, as added by this Act, during the
20 last 5 years;

21 (2) the impact of such agreements on competi-
22 tion in the pharmaceutical market; and

23 (3) the prevalence in the pharmaceutical indus-
24 try of other anticompetitive agreements among com-
25 petitors or other practices that are contrary to the

1 antitrust laws, and the impact of such agreements or
2 practices on competition in the pharmaceutical mar-
3 ket during the last 5 years.

4 (b) CONSULTATION.—In conducting the study re-
5 quired under this section, the Federal Trade Commission
6 shall consult with the Antitrust Division of the Depart-
7 ment of Justice regarding the Justice Department’s find-
8 ings and investigations regarding anticompetitive practices
9 in the pharmaceutical market, including criminal antitrust
10 investigations completed by the Justice Department with
11 respect to practices or conduct in the pharmaceutical mar-
12 ket.

13 (c) REQUIREMENT FOR A REPORT.—Not later than
14 1 year after the date of enactment of this Act, the Federal
15 Trade Commission shall submit a report to the Judiciary
16 Committees of Senate and House of Representatives, and
17 to the Department of Justice regarding the findings of the
18 study conducted under subsection (a). This report shall
19 contain the Federal Trade Commission’s recommendation
20 as to whether any amendment to the antitrust laws should
21 be enacted to correct any substantial lessening of competi-
22 tion found during the study.

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

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

6 **SEC. 7. AUTHORIZATION OF APPROPRIATIONS.**

7 There are authorized to be appropriated to the Fed-
8 eral Trade Commission such sums as may be necessary
9 to carry out the provisions of this Act.

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