

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, and Mr. BROWN) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

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”.

6 **SEC. 2. CONGRESSIONAL FINDINGS AND DECLARATION OF**
7 **PURPOSES.**

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

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

5 (2) 67 percent of all prescriptions dispensed in
6 the United States are generic drugs, yet they ac-
7 count for only 20 percent of all expenditures;

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

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

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

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

24 (7) collusion by pharmaceutical manufacturers
25 is contrary to free competition, to the interests of

1 consumers, and to the principles underlying anti-
2 trust law;

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

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

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

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

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

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

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

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

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

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

18 **“SEC. 29. UNLAWFUL INTERFERENCE WITH GENERIC MAR-**
19 **KETING.**

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

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

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 Food and Drug Admin-
3 istration.

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 one or more other ingre-
11 dients, as defined in section 314.3(b) of title 21,
12 Code 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 (b) REGULATIONS.—The Federal Trade Commission
22 may, by rule promulgated under section 553 of title 5,
23 United States Code, exempt certain agreements described
24 in section 29 of the Clayton Act, as added by subsection
25 (a), if the Commission finds such agreements to be in fur-

1 therance of market competition and for the benefit of con-
 2 sumers. Consistent with the authority of the Commission,
 3 such rules may include interpretive rules and general
 4 statements of policy with respect to the practices prohib-
 5 ited under section 29 of the Clayton Act.

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

7 (a) NOTICE OF ALL AGREEMENTS.—Section
 8 1112(c)(2) of the Medicare Prescription Drug, Improve-
 9 ment, and Modernization Act of 2003 (21 U.S.C. 3155
 10 note) is amended by—

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

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

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

20 “(d) CERTIFICATION.—The Chief Executive Officer
 21 or the company official responsible for negotiating any
 22 agreement required to be filed under subsection (a), (b),
 23 or (c) shall execute and file with the Assistant Attorney
 24 General and the Commission a certification as follows: ‘I
 25 declare under penalty of perjury that the following is true

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

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

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

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