

109TH CONGRESS
2^D SESSION

S. 3582

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

JUNE 27, 2006

Mr. KOHL (for himself, Mr. LEAHY, Mr. GRASSLEY, and Mr. SCHUMER) introduced the following bill; which was read twice and referred to the Committee on Commerce, Science, and Transportation

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. UNFAIR COMPETITION.**

7 Section 5 of the Federal Trade Commission Act (15
8 U.S.C. 45) is amended by adding at the end the following:

1 “(o)(1) It shall be considered an unfair method of
2 competition affecting commerce under subsection (a)(1)
3 for a person, in connection with the sale of a drug product,
4 to directly or indirectly be a party to any agreement re-
5 solving or settling a patent infringement claim in which—

6 “(A) an ANDA filer receives anything of value;

7 and

8 “(B) the ANDA filer agrees not to research, de-
9 velop, manufacture, market, or sell the ANDA prod-
10 uct for any period of time.

11 “(2) CONSTRUCTION.—Nothing in this subsection
12 shall prohibit a resolution or settlement of patent infringe-
13 ment claim in which the value paid by the NDA holder
14 to the ANDA filer as a part of the resolution or settlement
15 of the patent infringement claim includes no more than
16 the right to market the ANDA product prior to the expira-
17 tion of the patent that is the basis for the patent infringe-
18 ment claim.

19 “(3) In this subsection:

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

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

4 “(C) 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 “(D) 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 “(E) 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 “(F) The term ‘NDA holder’ means—

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

20 “(ii) 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 “(iii) 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 “(G) 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 “(H) 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.”.

○