109TH CONGRESS
2D 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

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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. UNFAIR COMPETITION.

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

''(o)(1) It shall be considered an unfair method of competition affecting commerce under subsection (a)(1) for a 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—

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

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

''(2) CONSTRUCTION.—Nothing in this subsection 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.

''(3) In this subsection:

''(A) 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)).

''(B) The term 'ANDA filer' means a party who has filed an ANDA with the Federal Drug Administration.

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

''(D) 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.

''(E) 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)).

''(F) The term 'NDA holder' means—

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

''(ii) 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

"(iii) 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.

"(G) 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.

"(H) 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.".

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