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113TH CONGRESS
1ST SESSION

H. R. 3709

To prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 11, 2013

Mr. RUSH (for himself, Mr. VAN HOLLEN, and Mr. WAXMAN) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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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, and for other purposes.

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 ''Protecting Consumer Access to Generic Drugs Act of 2013''.

SEC. 2. UNFAIR AND DECEPTIVE ACTS AND PRACTICES RELATED TO NEW DRUG APPLICATIONS.

(a) CONDUCT PROHIBITED.—It shall be unlawful for any person to directly or indirectly be a party to any agreement resolving or settling a patent infringement claim in which—

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

(2) the ANDA filer agrees not to research, develop, manufacture, market, or sell, for any period of time, the drug that is to be manufactured under the ANDA involved and is the subject of the patent infringement claim.

(b) EXCEPTIONS.—Notwithstanding subsection (a)(1), subsection (a) does not prohibit a resolution or settlement of a patent infringement claim in which the value received by the ANDA filer includes no more than—

(1) the right to market the drug that is to be manufactured under the ANDA involved and is the subject of the patent infringement claim, before the expiration of—

(A) the patent that is the basis for the patent infringement claim; or

(B) any other statutory exclusivity that would prevent the marketing of such drug; and

(2) the waiver of a patent infringement claim for damages based on prior marketing of such drug.

(c) ENFORCEMENT.—A violation of subsection (a) shall be treated as an unfair and deceptive act or practice and an unfair method of competition in or affecting interstate commerce prohibited under section 5 of the Federal Trade Commission Act (15 U.S.C. 45). The Federal Trade Commission shall enforce this Act in the same manner, by the same means, and with the same jurisdiction as though all applicable terms and provisions of the Federal Trade Commission Act were incorporated into and made a part of this Act.

(d) DEFINITIONS.—In this section:

(1) AGREEMENT.—The term ''agreement'' means anything that would constitute an agreement for purposes of section 5 of the Federal Trade Commission Act (15 U.S.C. 45).

(2) AGREEMENT RESOLVING OR SETTLING.—The term ''agreement resolving or settling'', in reference to 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) ANDA.—The term ''ANDA'' means an abbreviated new drug application for the approval of a

new drug under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

(4) ANDA FILER.—The term ''ANDA filer'' means a party that has filed an ANDA with the Food and Drug Administration.

(5) PATENT INFRINGEMENT.—The term ''patent infringement'' means infringement of any patent or of any filed patent application, extension, reissuance, renewal, division, continuation, continuation in part, reexamination, patent term restoration, patent of addition, or extension thereof.

(6) PATENT INFRINGEMENT CLAIM.—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 drug to be manufactured under such ANDA may infringe any patent.

SEC. 3. FTC RULEMAKING.

The Federal Trade Commission may, by rule promulgated under section 553 of title 5, United States Code, exempt certain agreements described in section 2 if the Commission finds such agreements to be in furtherance of market competition and for the benefit of consumers. Consistent with the authority of the Commission, such rules may include interpretive rules and general state-

ments of policy with respect to the practices prohibited under section 2.

SEC. 4. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD UNDER THE FFDCA.

Section 505(j)(5)(D)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)) is amended in subclause (V) by inserting ''section 2 of the Protecting Consumer Access to Generic Drugs Act of 2013 or'' after ''that the agreement has violated''.

SEC. 5. 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 agreements, 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.'.''.

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