II

109TH CONGRESS
2D SESSION

S. 2699

To promote the research and development of drugs related to neglected and tropical diseases, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 2, 2006

Mr. BROWNBACK (for himself and Mr. LIEBERMAN) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

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A BILL

To promote the research and development of drugs related to neglected and tropical diseases, 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 ''Elimination of Neglected Diseases Act of 2006''.

SEC. 2. PATENT EXTENSION AND RESTORATION.

(a) IN GENERAL.—Chapter 14 of title 35, United States Code, is amended by inserting after section 156 the following:

"§ 156a. Extension and restoration of patent terms relating to neglected and tropical diseases

''(a) DEFINITIONS.—In this section, the term—

''(1) 'AIDS' means the acquired immune deficiency syndrome;

''(2) 'AIDS drug' means a drug indicated for treating HIV;

''(3) 'eligible patent' means a patent that—

''(A) claims—

''(i) an approved new molecular entity standard review drug;

''(ii) an active ingredient of such new molecular entity standard review drug;

''(iii) a process of making or using the new molecular entity standard review drug; or

''(iv) a process of making an active ingredient of such new molecular entity standard review drug; and

''(B) is owned by or licensed to a person that has filed and received approval of an application described in section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)), for a tropical disease product;

''(4) 'HIV' means the human immunodeficiency virus, the pathogen that causes AIDS;

''(5) 'neglected or tropical disease' means—

''(A) HIV, malaria, tuberculosis, and related diseases; or

''(B) any other infectious disease that disproportionately affects poor and marginalized populations, including those diseases targeted by the Special Programme for Research and Training in Tropical Diseases cosponsored by the United Nations Development Program, UNICEF, the World Bank, and the World Health Organization;

''(6) 'new molecular entity standard review drug'—

''(A) means a drug that—

''(i) has never been marketed in the United States;

''(ii) appears to have therapeutic qualities superior to the therapeutic qualities of another drug that is marketed in the United States; and

''(iii) is designated by the Secretary of Health and Human Services under section 524 of the Federal Food, Drug, and Cos-

metic Act as having a new molecular entity chemical type classification and standard review drug treatment potential classification, other than drugs developed to treat serious or life-threatening diseases; and

''(B) shall not include a subpart E drug or an AIDS drug;

''(7) 'regulatory review period' means the period described under section 506(g)(1)(B);

''(8) 'subpart E drug' means a drug developed or evaluated under special procedures for drugs to treat life-threatening or severely debilitating illnesses under subpart E of part 312 of title 21 of the Code of Federal Regulations; and

''(9) 'tropical disease product' means a product that—

''(A) is approved for use in the treatment of a neglected or tropical disease;

''(B) is a new drug, antibiotic drug, biological product, device, diagnostic, or other tool for treatment, as those terms are used in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and the Public Health Service Act (42 U.S.C. 201 et seq.); and

''(C) is certified by the Secretary of Health and Human Services under section 524 of the Federal Food, Drug, and Cosmetic Act .

''(b) PATENT TERM EXTENSION.—The term of an eligible patent shall be extended by a period not to exceed 2 years and not less than 6 months in duration if—

''(1) an application in conformance with the requirements of subsection (d) is submitted to the Director by either the owner of record of the patent or its agent on the later of—

''(A) on or before the date specified under subsection (d)(3); or

''(B) within 45 days after the date of issuance of the patent;

''(2) the term of the eligible patent that is the basis of the application has not expired prior to the date that the application is submitted under subsection (d);

''(3) the regulatory review period for the tropical disease product has not been relied upon to support an application to extend the term of another patent under this section or under any other provision of law; and

''(4) the Food and Drug Administration has certified the eligibility of that tropical disease product for patent extension.

''(c) PATENT TERM RESTORATION.—The term of a patent for a tropical disease product shall be restored by a period equal to the number of days in the regulatory review period, if, with respect to the patent that is the basis for application—

''(1) the owner of record of the patent or its agent submits an application to the Director on the later of—

''(A) on or before the date specified under subsection (d)(3); or

''(B) on or before 45 days after the date of issuance of the patent;

''(2) the patent has not been previously restored or extended under this section;

''(3) the term of the patent has not expired prior to the date that the owner of the record of the patent or its agent submits an application to the Director;

''(4) the regulatory review period for the product has not been relied upon to support an application to extend the term of another patent under any section of this title; and

''(5) the Food and Drug Administration has certified the eligibility of that tropical disease product for patent restoration.

''(d) ADMINISTRATIVE PROVISIONS.—

''(1) IN GENERAL.—To obtain an extension or restoration of the term of an eligible patent or patent of a tropical disease product under this section, the assigner of record and licensee of record of the eligible patent or tropical disease product or the agent of the assigner of record and licensee shall submit an application to the Director.

''(2) CONTENT.—The application shall contain—

''(A) a description of the approved tropical disease product and the Federal statute under which regulatory review relating to such product occurred;

''(B) the identity of—

''(i) the eligible patent for which an extension is sought under this section; or

''(ii) the patent for a tropical disease product for which a restoration is sought under this section;

''(C) an undertaking by the applicant to make publicly available independently audited

financial statements to verify commercialization of the approved tropical disease product; and

''(D) such other information as the Director may require including additional information to establish that the eligible patent or tropical disease product meets the requirements of this section.

''(3) SUBMISSION OF APPLICATION.—Upon submission of the application for approval of the tropical disease product to the Food and Drug Administration, the sponsor shall give notice of which patent it would extend if the patent becomes eligible for the extension or restoration upon successfully completing the research. The Secretary of Health and Human Services shall publish the notice.

''(4) IRREVOCABLE ELECTION.—The submission of an application under this section is an irrevocable election of the application of this section to the eligible patent or patent for a tropical disease product that is the basis of the application. An eligible patent or patent for a tropical disease product that is the basis of an application submitted under this section may not be the subject of an application made under section 156 or any other provision of law.

''(5) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit an extension, under an application made under any other section of this title, of the term of a patent relating to a tropical disease product that, prior to the effective date of this section, was approved for commercial marketing for a nontropical disease use.

''(e) LIMITATION.—An eligible patent may not be extended under this section if—

''(1) the tropical disease product was approved for commercial marketing prior to the date of enactment of this section; or

''(2) the eligible patent that is the basis of the application under this section expired prior to the date of enactment of this section.''.

(b) DESIGNATION FOR PATENT EXTENSION AND RESTORATION.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 523 the following:

''SEC. 524. DESIGNATION FOR PATENT EXTENSION AND RESTORATION.

''(a) DEFINITIONS.—In this section:

''(1) NEW MOLECULAR ENTITY STANDARD REVIEW DRUG.—The term 'new molecular entity stand-

ard review drug' has the meaning given that term in section 156a of title 35, United States Code.

''(2) TROPICAL DISEASE PRODUCT.—The term 'tropical disease product' has the meaning given that term in section 156a of title 35, United States Code.

''(b) NEW MOLECULAR ENTITY STANDARD REVIEW DRUG.—The Secretary, acting through the Commissioner of Food and Drugs—

''(1) shall designate a drug as a new molecular entity standard review drug for purposes of section 156a of title 35, United States Code, if that drug—

''(A) has a new molecular entity chemical type classification and standard review drug treatment potential classification; and

''(B) is not a drug developed to treat serious or life-threatening diseases;

''(2) shall apply the guidance issued in calendar year 2002 on serious or life-threatening diseases for purposes of paragraph (1)(B);

''(3) shall maintain and annually update a classification list of serious and life-threatening diseases; and

''(4) may remove the designation of a drug as a new molecular entity standard review drug as designated under paragraph (1).

''(c) TROPICAL DISEASE PRODUCTS.—The Secretary shall certify tropical disease products for purposes of section 156a of title 35, United States Code.''.

(c) TECHNICAL AND CONFORMING AMENDMENT.—The table of sections for chapter 14 of title 35, United States Code, is amended by inserting after the item relating to section 156 the following:

''156a. Extension and restoration of patent terms relating to neglected and tropical diseases.''.

(d) STUDY AND REPORT.—

(1) STUDY.—The Director of the United States Patent and Trademark Office, in conjunction with the Food and Drug Administration, the Department of Health and Human Services, and the United States Agency for International Development, shall conduct a study on the effect of patent extension and restoration on the ability of pharmaceutical companies to develop and distribute tropical disease products for poor and marginalized populations.

(2) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Director of the United States Patent and Trademark Office shall submit a report on the results of the study under paragraph (1) to—

(A) the Committee on Foreign Relations of the Senate and the Committee on Health, Education, Labor, and Pensions of the Senate; and

(B) the appropriate committees of the House of Representatives.

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