109TH CONGRESS
2D SESSION

S. 4040

To ensure that innovations developed at federally-funded institutions are available in certain developing countries at the lowest possible cost.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 29, 2006

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

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A BILL

To ensure that innovations developed at federally-funded institutions are available in certain developing countries at the lowest possible cost.

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 ''Public Research in the Public Interest Act of 2006''.

SEC. 2. PURPOSE AND FINDINGS.

(a) PURPOSE.—The purpose of this Act is to promote global public health and America's national security by ensuring that innovations developed at federally-funded in-

stitutions are available in eligible developing countries at the lowest possible cost.

(b) FINDINGS.—Congress finds the following:

(1) It is in the national interest of the United States that people around the world live healthier lives, and that they perceive the United States in a more favorable light.

(2) The United States Government funds a major portion of all academic research.

(3) Congress funds universities and Federal research laboratories as institutions dedicated to the creation and dissemination of knowledge in the public interest.

(4) The Federal Government's investment in science and technology fuels a thriving pharmaceutical industry and rising longevity and quality of life in the United States. In 2000, a Senate Joint Economic Committee Report found that public research was instrumental in developing 15 of the 21 drugs considered by experts to have had the highest therapeutic impact on society.

(5) Millions of people with HIV/AIDS in developing countries need antiretroviral drugs. More than 40,000,000 people worldwide have HIV and 95 percent of them live in developing countries. Malaria,

tuberculosis, and other infectious diseases kill millions of people a year in developing nations.

(6) The World Health Organization (''WHO'') has estimated that ⅓ of the world's population lacks regular access to essential medicines, including antiretroviral drugs. The WHO reported that just by improving access to existing medicines roughly 10,000,000 lives could be saved around the world every year.

(7) To help address the access to medicines crisis, the World Health Organization's 2006 Commission on Intellectual Property Rights, Innovation, and Public Health recommended that universities adopt licensing practices designed to increase access to medicines in developing countries.

(8) The Department of State has reported to Congress under the President's Emergency Plan for AIDS Relief that, ''[I]n every case generics prices present an opportunity for cost savings; in some cases, the branded price per pack of a drug is up to 11 times the cost of the approved generic version.''.

(9) Since sales of the patented, brand-name versions of such medicines are minimal or non-existent in many impoverished regions of the world, allowing generic versions of those medicines will have

minimal impact on the sales of brand-name, patented versions in such regions, or the licensing revenues of publicly funded research institutions, while saving an untold number of lives.

SEC. 3. DEFINITIONS.

In this Act:

(1) ASSOCIATED MEDICAL PRODUCT.—The term ''associated medical product'', when used in relation to a subject invention, means any medical product of which the manufacture, use, sale, offering for sale, import, or export relies upon or is covered by the rights guaranteed by title in that invention.

(2) ASSOCIATED RIGHTS.—The term ''associated rights,'' when used in relation to a subject invention, means—

(A) all patent and marketing rights, possessed by a current or former holder of title in that invention, or licensee of rights guaranteed by such title, that are reasonably necessary to make, use, sell, offer to sell, import, export, or test any associated medical product ever made, used, sold, offered for sale, imported, or exported by that party; and

(B) the right to rely on biological, chemical, biochemical, toxicological, pharmacological,

metabolic, formulation, clinical, analytical, stability, and other information and data for purposes of regulatory approval of any associated medical product.

(3) DRUG.—The term ''drug'' has the meaning given such term in section 201 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321).

(4) ELIGIBLE COUNTRY.—The term ''eligible country'' means any country of which the economy is classified by the World Bank as ''low-income'', or ''lower-middle-income''.

(5) FAIR ROYALTY.—The term ''fair royalty'', when used in relation to a subject invention, means—

(A) for a country classified by the World Bank as ''low-income'' at the time of the sales on which royalties are due, 2 percent of a licensee's net sales of associated medical products in such country; and

(B) for a country classified by the World Bank as ''lower-middle-income'' at the time of sales on which royalties are due, 5 percent of a licensee's net sales of associated medical products in such country.

(6) INVENTION.—The term ''invention'' means any invention or discovery which is or may be patentable or otherwise protectable under title 35, United States Code, or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321 et seq.).

(7) MEDICAL DEVICE.—The term ''medical device'' means a device, as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)), and includes any device component of any combination product, as that term is used in section 503(g) of such Act (21 U.S.C. 353(g)).

(8) MEDICAL PRODUCT.—The term ''medical product'' means any drug, treatment, prophylaxis, vaccine, or medical device.

(9) NEGLECTED RESEARCH.—The term ''neglected research'' means any use of a subjected invention or the associated rights in an effort to develop medical products for a rare disease or condition, as defined in section 526(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb(a)(2)).

(10) SUBJECT INSTITUTION.—The term ''subject institution'' means any institution of higher education (as such term is defined in section 101(a) of

the Higher Education Act of 1965 (20 U.S.C. 1001(a)) or research that receives federal financial assistance, including Federal laboratories as defined in section 12(d) of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710a(d)).

(11) SUBJECT INVENTION.—The term ''subject invention'' means any invention—

(A) conceived or first actually reduced to practice by a subject institution, or its employees in the course of their employment, on or after the effective date of this Act; or

(B) in which a subject institution holds title, provided the invention was first conceived or reduced to practice on or after the effective date of this Act.

SEC. 4. ACCESS TO LIFESAVING MEDICINES DEVELOPED AT GOVERNMENT FUNDED INSTITUTIONS.

(a) GRANT OF LICENSE.—

(1) IN GENERAL.—As a condition of receiving Federal assistance, any subject institution that conceives, reduced to practice, or holds title in a subject invention shall be required to grant irrevocable, perpetual, nonexclusive licenses to the invention and any associated rights the institution may own or

ever acquire, to any party requesting such a license pursuant to subsection (g).

(2) PURPOSE OF LICENSE.—The licenses described under paragraph (1) shall be for the sole purpose of—

(A) supplying medical products in accordance with subsection (e); or

(B) conducting neglected research anywhere in the world, royalty-free.

(b) INCORPORATION INTO TITLE.—The open-licensing requirement created by subsection (a) and all licenses granted thereunder shall be part of the subject institution's title in a subject invention. No transfer or license may be interpreted in any manner inconsistent with making any grant under subsection (a) effective, or in any manner that prevents or frees the holder of title in the invention from granting licenses.

(c) SUBSEQUENT LICENSES.—

(1) IN GENERAL.—If a subject institution licenses or grants rights in a subject invention to any other party, as a condition of such grant the licensee or grantee, and any future sublicensees or subsequent grantees, ad infinitum, shall also be required in perpetuity, to grant irrevocable, perpetual, nonexclusive licenses on any associated rights which the

licensee or grantee may own or later acquire, to any party requesting such a license pursuant to subsection (g).

(2) PURPOSE OF LICENSE.—The licenses shall be for the sole purposes described in subsection (a)(2).

(3) APPLICATION OF THIS SUBSECTION.—This subsection applies to licenses for a subject invention acquired under subsection (a).

(d) CONSTRUCTION.—No grant or licensee of any subject invention may be interpreted in any manner that prevents or frees the grantee or licensee from granting licenses for associated rights under subsection (c).

(e) LICENSE FOR SUPPLY OF MEDICAL PRODUCTS.—

(1) IN GENERAL.—A license under subsection (a)(2)(A) shall be a license for the sole purpose of permitting the making, using, selling, offering to sell, importing, exporting, and testing of medical products in eligible countries and the making and exporting of medical products worldwide for the sole purpose of supplying medical products to eligible countries.

(2) LABELING.—If the recipient of a license under subsection (a) exercises its right to make and export a medical product in any country other than

an eligible country for the sole purpose of export to an eligible country, then the licensee shall use reasonable efforts to visibly distinguish the medical product it manufactures from any similar medical product sold by others in the country of manufacture, provided that such reasonable efforts do not require the licensee to expend significant expense.

(3) ROYALTIES.—

(A) LICENSE OF SUBJECT INVENTION.—A license of a subject invention under subsection (a)(2)(A) shall be irrevocable and perpetual so long as the licensee submits to the licensor payment of a fair royalty on sales of any associated medical product within 90 days of such sales. Failure or refusal of the licensor to accept the fair royalty shall not terminate or affect in any way the license.

(B) LICENSE OF ASSOCIATED RIGHTS.—A license of associated rights to a subject invention under subsection (a)(2)(A) shall be royalty free.

(f) TRANSFER.—In accordance with subsections (a) through (d), any license or other transfer of a subject invention by a subject institution or the licensee or grantee

of such institution for a subject invention, shall be invalid unless—

(1) the license or grant includes a clause, ''This grant or license is subject to the provisions of the Public Research in the Public Interest Act of 2006.'';

(2) the licensor or grantor complies with the notification requirements of subsection (h); and

(3) the license or grant does not include any terms that contradict any requirement of this Act.

(g) PROCEDURES FOR ACQUISITION OF LICENSES.—

(1) IN GENERAL.—Any party, upon providing to the Food and Drug Administration—

(A) notification of its intent to supply medical products or conduct neglected research as provided in subsection (a);

(B) a specific list of the rights it wishes to license for those purposes; and

(C) the names of the party or parties it believes are obligated to grant such licenses under subsections (a) through (d),

shall automatically be deemed to receive the license so requested without the need for any further action on the part of the licensing party if the party or parties specified in the request do not object and notify

the requesting party of such objection, within 30 days of the publication of such request by the Administration.

(2) ENFORCEMENT ACTION.—

(A) IN GENERAL.—If the party or parties specified under paragraph (1) object to the grant of a requested license, the requesting party may bring an action to enforce its right to a license of a subject invention or associated rights under subsections (a) through (d).

(B) PROCESS.—In any suit under this subsection, the requesting party shall be entitled to separate, expedited review of the legal issues required to adjudicate whether it is entitled to the requested license, without prejudice to any other issues in the lawsuit. If the party objecting to the license is found to have objected without reasonable cause or without a good faith belief that there was a justifiable controversy under the facts and the law, the party requesting the license shall be entitled to attorney's fees, other reasonably necessary costs of the lawsuit, and treble damages from the objecting party.

(3) PUBLICATION.—The Food and Drug Administration shall publish any request made under paragraph (1) within 15 days of receipt of such request. The Food and Drug Administration shall also make reasonable efforts to directly notify the parties named in any such request.

(h) NOTIFICATION OF TRANSFER OR LICENSE OF SUBJECT INVENTIONS.—The holder of title or any license in a subject invention shall notify the Food and Drug Administration of any grant or license of rights in that invention. The Food and Drug Administration shall publish all such notifications within 15 days of receipt.

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