

109TH CONGRESS
2^D 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

A BILL

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

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 “Public Research in
5 the Public Interest Act of 2006”.

6 **SEC. 2. PURPOSE AND FINDINGS.**

7 (a) PURPOSE.—The purpose of this Act is to promote
8 global public health and America’s national security by en-
9 suring that innovations developed at federally-funded in-

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

3 (b) FINDINGS.—Congress finds the following:

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

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

10 (3) Congress funds universities and Federal re-
11 search laboratories as institutions dedicated to the
12 creation and dissemination of knowledge in the pub-
13 lic interest.

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

22 (5) Millions of people with HIV/AIDS in devel-
23 oping countries need antiretroviral drugs. More than
24 40,000,000 people worldwide have HIV and 95 per-
25 cent of them live in developing countries. Malaria,

1 tuberculosis, and other infectious diseases kill mil-
2 lions of people a year in developing nations.

3 (6) The World Health Organization (“WHO”)
4 has estimated that $\frac{1}{3}$ of the world’s population lacks
5 regular access to essential medicines, including
6 antiretroviral drugs. The WHO reported that just by
7 improving access to existing medicines roughly
8 10,000,000 lives could be saved around the world
9 every year.

10 (7) To help address the access to medicines cri-
11 sis, the World Health Organization’s 2006 Commis-
12 sion on Intellectual Property Rights, Innovation, and
13 Public Health recommended that universities adopt
14 licensing practices designed to increase access to
15 medicines in developing countries.

16 (8) The Department of State has reported to
17 Congress under the President’s Emergency Plan for
18 AIDS Relief that, “[I]n every case generics prices
19 present an opportunity for cost savings; in some
20 cases, the branded price per pack of a drug is up to
21 11 times the cost of the approved generic version.”.

22 (9) Since sales of the patented, brand-name
23 versions of such medicines are minimal or non-exist-
24 ent in many impoverished regions of the world, al-
25 lowing generic versions of those medicines will have

1 minimal impact on the sales of brand-name, pat-
2 ented versions in such regions, or the licensing reve-
3 nues of publicly funded research institutions, while
4 saving an untold number of lives.

5 **SEC. 3. DEFINITIONS.**

6 In this Act:

7 (1) ASSOCIATED MEDICAL PRODUCT.—The
8 term “associated medical product”, when used in re-
9 lation to a subject invention, means any medical
10 product of which the manufacture, use, sale, offering
11 for sale, import, or export relies upon or is covered
12 by the rights guaranteed by title in that invention.

13 (2) ASSOCIATED RIGHTS.—The term “associ-
14 ated rights,” when used in relation to a subject in-
15 vention, means—

16 (A) all patent and marketing rights, pos-
17 sessed by a current or former holder of title in
18 that invention, or licensee of rights guaranteed
19 by such title, that are reasonably necessary to
20 make, use, sell, offer to sell, import, export, or
21 test any associated medical product ever made,
22 used, sold, offered for sale, imported, or ex-
23 ported by that party; and

24 (B) the right to rely on biological, chem-
25 ical, biochemical, toxicological, pharmacological,

1 metabolic, formulation, clinical, analytical, sta-
2 bility, and other information and data for pur-
3 poses of regulatory approval of any associated
4 medical product.

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

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

12 (5) FAIR ROYALTY.—The term “fair royalty”,
13 when used in relation to a subject invention,
14 means—

15 (A) for a country classified by the World
16 Bank as “low-income” at the time of the sales
17 on which royalties are due, 2 percent of a li-
18 censee’s net sales of associated medical prod-
19 ucts in such country; and

20 (B) for a country classified by the World
21 Bank as “lower-middle-income” at the time of
22 sales on which royalties are due, 5 percent of
23 a licensee’s net sales of associated medical prod-
24 ucts in such country.

1 (6) INVENTION.—The term “invention” means
2 any invention or discovery which is or may be pat-
3 entable or otherwise protectable under title 35,
4 United States Code, or any novel variety of plant
5 which is or may be protectable under the Plant Vari-
6 ety Protection Act (7 U.S.C. 2321 et seq.).

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

13 (8) MEDICAL PRODUCT.—The term “medical
14 product” means any drug, treatment, prophylaxis,
15 vaccine, or medical device.

16 (9) NEGLECTED RESEARCH.—The term “ne-
17 glected research” means any use of a subjected in-
18 vention or the associated rights in an effort to de-
19 velop medical products for a rare disease or condi-
20 tion, as defined in section 526(a)(2) of the Federal
21 Food, Drug, and Cosmetic Act (21 U.S.C.
22 360bb(a)(2)).

23 (10) SUBJECT INSTITUTION.—The term “sub-
24 ject institution” means any institution of higher edu-
25 cation (as such term is defined in section 101(a) of

1 the Higher Education Act of 1965 (20 U.S.C.
2 1001(a)) or research that receives federal financial
3 assistance, including Federal laboratories as defined
4 in section 12(d) of the Stevenson-Wydler Technology
5 Innovation Act of 1980 (15 U.S.C. 3710a(d)).

6 (11) SUBJECT INVENTION.—The term “subject
7 invention” means any invention—

8 (A) conceived or first actually reduced to
9 practice by a subject institution, or its employ-
10 ees in the course of their employment, on or
11 after the effective date of this Act; or

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

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

18 (a) GRANT OF LICENSE.—

19 (1) IN GENERAL.—As a condition of receiving
20 Federal assistance, any subject institution that con-
21 ceives, reduced to practice, or holds title in a subject
22 invention shall be required to grant irrevocable, per-
23 petual, nonexclusive licenses to the invention and
24 any associated rights the institution may own or

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

3 (2) PURPOSE OF LICENSE.—The licenses de-
4 scribed under paragraph (1) shall be for the sole
5 purpose of—

6 (A) supplying medical products in accord-
7 ance with subsection (e); or

8 (B) conducting neglected research any-
9 where in the world, royalty-free.

10 (b) INCORPORATION INTO TITLE.—The open-licens-
11 ing requirement created by subsection (a) and all licenses
12 granted thereunder shall be part of the subject institu-
13 tion's title in a subject invention. No transfer or license
14 may be interpreted in any manner inconsistent with mak-
15 ing any grant under subsection (a) effective, or in any
16 manner that prevents or frees the holder of title in the
17 invention from granting licenses.

18 (c) SUBSEQUENT LICENSES.—

19 (1) IN GENERAL.—If a subject institution li-
20 censes or grants rights in a subject invention to any
21 other party, as a condition of such grant the licensee
22 or grantee, and any future sublicensees or subse-
23 quent grantees, ad infinitum, shall also be required
24 in perpetuity, to grant irrevocable, perpetual, non-
25 exclusive licenses on any associated rights which the

1 licensee or grantee may own or later acquire, to any
2 party requesting such a license pursuant to sub-
3 section (g).

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

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

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

14 (e) LICENSE FOR SUPPLY OF MEDICAL PRODUCTS.—

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

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

1 an eligible country for the sole purpose of export to
2 an eligible country, then the licensee shall use rea-
3 sonable efforts to visibly distinguish the medical
4 product it manufactures from any similar medical
5 product sold by others in the country of manufac-
6 ture, provided that such reasonable efforts do not re-
7 quire the licensee to expend significant expense.

8 (3) ROYALTIES.—

9 (A) LICENSE OF SUBJECT INVENTION.—A

10 license of a subject invention under subsection
11 (a)(2)(A) shall be irrevocable and perpetual so
12 long as the licensee submits to the licensor pay-
13 ment of a fair royalty on sales of any associated
14 medical product within 90 days of such sales.
15 Failure or refusal of the licensor to accept the
16 fair royalty shall not terminate or affect in any
17 way the license.

18 (B) LICENSE OF ASSOCIATED RIGHTS.—A

19 license of associated rights to a subject inven-
20 tion under subsection (a)(2)(A) shall be royalty
21 free.

22 (f) TRANSFER.—In accordance with subsections (a)

23 through (d), any license or other transfer of a subject in-
24 vention by a subject institution or the licensee or grantee

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

3 (1) the license or grant includes a clause, “This
4 grant or license is subject to the provisions of the
5 Public Research in the Public Interest Act of
6 2006.”;

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

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

11 (g) PROCEDURES FOR ACQUISITION OF LICENSES.—

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

14 (A) notification of its intent to supply med-
15 ical products or conduct neglected research as
16 provided in subsection (a);

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

19 (C) the names of the party or parties it be-
20 lieves are obligated to grant such licenses under
21 subsections (a) through (d),

22 shall automatically be deemed to receive the license
23 so requested without the need for any further action
24 on the part of the licensing party if the party or par-
25 ties specified in the request do not object and notify

1 the requesting party of such objection, within 30
2 days of the publication of such request by the Ad-
3 ministration.

4 (2) ENFORCEMENT ACTION.—

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

11 (B) PROCESS.—In any suit under this sub-
12 section, the requesting party shall be entitled to
13 separate, expedited review of the legal issues re-
14 quired to adjudicate whether it is entitled to the
15 requested license, without prejudice to any
16 other issues in the lawsuit. If the party object-
17 ing to the license is found to have objected
18 without reasonable cause or without a good
19 faith belief that there was a justifiable con-
20 troversy under the facts and the law, the party
21 requesting the license shall be entitled to attor-
22 ney's fees, other reasonably necessary costs of
23 the lawsuit, and treble damages from the ob-
24 jecting party.

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

7 (h) NOTIFICATION OF TRANSFER OR LICENSE OF
8 SUBJECT INVENTIONS.—The holder of title or any license
9 in a subject invention shall notify the Food and Drug Ad-
10 ministration of any grant or license of rights in that inven-
11 tion. The Food and Drug Administration shall publish all
12 such notifications within 15 days of receipt.

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