109TH CONGRESS
2D SESSION

S. 3175

To amend title 35, United States Code, with respect to establishing procedures for granting authority to the Under Secretary for Commerce for Intellectual Property and Director of the Patent and Trademark Office to grant compulsory patent licenses for exporting patented pharmaceutical products to certain countries consistent with international commitments made by the United States, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 25, 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 amend title 35, United States Code, with respect to establishing procedures for granting authority to the Under Secretary for Commerce for Intellectual Property and Director of the Patent and Trademark Office to grant compulsory patent licenses for exporting patented pharmaceutical products to certain countries consistent with international commitments made by the United States, 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 ''Life-Saving Medicines Export Act of 2006''.

SEC. 2. PURPOSES AND FINDINGS.

(a) PURPOSE.—The purpose of this Act is to promote public health by permitting the export of life-saving pharmaceutical products and other medicines manufactured in the United States by compulsory license to residents of participating countries with insufficient or no manufacturing capability in the pharmaceutical sector for the product in question consistent with the General Council Decision of the World Trade Organization.

(b) FINDINGS.—Congress finds the following:

(1) The United States Trade Representative recently announced that it ''welcomes'' the World Trade Organization amendment to ''allow countries to override patent rights when necessary to export life-saving drugs to developing countries that face public health crises but cannot produce drugs for themselves.''. United States Ambassador Portman called this ''a landmark achievement that we hope will help developing countries.''.

(2) Compulsory licensing of patents is a ''fixture in almost all patent systems'' in the world as noted in the Berkeley Technology Law Journal in 2003. By the end of the 1950s, for example, an esti-

mated 40,000 to 50,000 compulsory licenses were issued regarding patents in the United States. (Access to Patented Medicine in Developing Countries, F.M. Scherer, www.cmhealth.org/docswg4; World Health Organization). Indeed, the WHO paper notes that the ''United States has led the world in issuing compulsory licenses to restore competition when violations of the antitrust laws have been found, or in the negotiated settlement of antitrust cases before full adjudication has occurred.''

(3) The vast majority of people living in developing countries or least developed nations have limited or no access to many medicines that are saving and extending lives of those in other, more developed nations. Since sales of the patented, brand-name versions of such medicines are minimal or non-existent in many impoverished regions of the world providing generic versions of those medicines under the WTO General Council Decision will have minimal impact on the sales of brand-name, patented versions in such regions.

(4) The World Health Organization has estimated that ⅓ of the world's population lacks regular access to essential medicines, including

antiretroviral drugs, and that a number of essential medicines are under patent.

(5) Medicines and vaccines are needed throughout the world to combat newly arising public health threats such as the avian flu. A United States National Intelligence Estimate in January 2000 notes that ''New and emerging infectious diseases will pose a rising global health threat. . .''.

(6) 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.

(7) Comprehensive reports of the World Health Organization of the United Nations, in 2004 and 2005 detail the urgent need for pharmaceutical products in developing countries and in least developed nations.

(8) The World Trade Organization decisions of August 30, 2003, on access to generic medicines is now being considered by member nations of the World Trade Organization for ratification as a permanent amendment to the WTO Agreement on

Trade Related Aspects of Intellectual Property Rights.

SEC. 3. EXPORTATION OF PHARMACEUTICAL PRODUCTS FOR PUBLIC HEALTH PURPOSES.

(a) IN GENERAL.—Chapter 29 of title 35, United States Code, is amended by inserting after section 297 the following:

"§ 298. Exportation of pharmaceutical products for public health purposes

''(a) DEFINITIONS.—In this section:

''(1) ELIGIBLE COUNTRY.—The term 'eligible country' means a country that—

''(A)(i) is designated by the United Nations as a least developed country; or

''(ii) if not so designated—

''(I) has certified to the General Council that the country seeks to participate in the compulsory licensing system under this section as authorized by the General Council Decision; or

''(II) has certified through an official government finding if not a member of the World Trade Organization, that the country does not possess sufficient manufacturing capacities to produce the pharma-

ceutical product that such country seeks to import under this section;

"(B) has provided notice to the Director describing such lack of sufficient manufacturing capacities; and

"(C) has not terminated that country's participation in such compulsory licensing system by certifying to the General Council or to the Director that it no longer desires to participate in such a system.

"(2) GENERAL COUNCIL.—The term 'General Council' means the General Council of the WTO established by paragraph (2) of Article IV of the Agreement Establishing the World Trade Organization entered into on April 15, 1994.

"(3) GENERAL COUNCIL DECISION.—The term 'General Council Decision' means the decision of the General Council of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health and the WTO General Council Chairman's statement accompanying the Decision (JOB(03)/177, WT/GC/M/82) (collectively known as the 'TRIPS/health solution').

"(4) GENERIC MANUFACTURER.—The term 'generic manufacturer' means, with respect to a phar-

maceutical product, a manufacturer that does not hold the patent to such pharmaceutical product or is not otherwise authorized by the patent holder to make use of the invention.

''(5) PHARMACEUTICAL PRODUCT.—The term 'pharmaceutical product' means any patented product, or pharmaceutical product, including components of that product, manufactured through a patented process, of the pharmaceutical sector including any drug, active ingredient of a drug, diagnostic, or vaccine needed to prevent or treat potentially life threatening public health problems, including those listed in Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.

''(6) TRIPS AGREEMENT.—The term 'TRIPS Agreement' means the Agreement on Trade-Related Aspects of Intellectual Property Rights (described in section 101(d)(15) of the Uruguay Round Agreements Act (19 U.S.C. 3501 note)).

''(7) WORLD TRADE ORGANIZATION.—The term 'World Trade Organization' means the organization established pursuant to the WTO Agreement.

''(8) WTO AGREEMENT.—The term 'WTO Agreement' means the Agreement Establishing The

World Trade Organization entered into on April 15, 1994.

''(9) WTO.—The term 'WTO' has the meaning given that term in section 2 of the Uruguay Round Agreements Act (19 U.S.C. 3501).

''(10) URUGUAY ROUND AGREEMENTS.—The term 'Uruguay Round Agreements' has the meaning given such term in section 2(7) of the Uruguay Round Agreements Act (19 U.S.C. 3501(7)).

''(b) ISSUANCE OF COMPULSORY LICENSE.—Notwithstanding any other provision of part II or this part, and subject to subsections (c) and (d), the Director shall issue a compulsory license to a generic manufacturer of a pharmaceutical product or a patented product under this section consistent with the Life-Saving Medicines Export Act of 2006 for the purposes of—

''(1) manufacturing and exporting to an eligible country, (including using nongovernmental agencies to assist in handling and distribution to eligible countries) such pharmaceutical products, including exporting for the purpose of foreign testing and certification and other activities reasonable related to such manufacturing and exporting; and

''(2) such other purposes under that Act.

''(c) APPLICATION FOR COMPULSORY LICENSE.—

''(1) IN GENERAL.—

''(A) SUBMISSION.—Except as provided under subsection (g), a generic manufacturer that seeks to manufacture and export a pharmaceutical product to an eligible country (including through the use of a nongovernmental organization) shall submit to the Director an application as developed by the Director for a compulsory license as described in this section.

''(B) ASSISTANCE.—The Director shall establish an office within the Patent and Trademark Office to assist—

''(i) applicants under this section, including aiding persons in identifying what patents cover which pharmaceutical products and in providing other advice and guidance to facilitate the filing of complete applications; and

''(ii) eligible countries, nongovernmental organizations, or nations likely to become eligible countries, identify companies in the United States which could provide pharmaceutical products under this section to such countries.

''(2) CONTENT OF APPLICATION.—The Director shall approve an application submitted under paragraph (1) if such application contains—

''(A) the name of the pharmaceutical product to be manufactured and exported under the license;

''(B) an estimate of the quantities of the pharmaceutical product to be manufactured and exported under the license and a stipulation that the amount manufactured and exported shall not exceed the amount necessary to meet the needs of the eligible country;

''(C) for each patented invention to which the application relates—

''(i) the name of the patent holder and the applicable patent number; or

''(ii) a statement by the applicant on information and belief of the name of the patent holder and applicable patent number;

''(D) the name of the eligible country to which the pharmaceutical product will be exported and the name of any nongovernmental organization which will assist in the effort;

''(E)(i) copies of the notifications of the eligible countries that are member countries of the WTO, as defined in the General Council Decision, made to the Council for TRIPS regarding notifications set forth under 2(a) of such Decision; and

''(ii) for eligible countries that are not member countries of the WTO, a copy of the information required by the notification as set forth under 2(a) of such Decision published on a public website and the address of such website;

''(F) a copy of a written request for a voluntary license sent by registered mail to each patent holder, which shall have occurred during a period of at least 60 days before the submission of the application to the Director, and a brief description of any subsequent negotiations;

''(G) copies of—

''(i) notifications required under the General Counsel Decision;

''(ii) the name of the authorized designated official of the eligible country, or a nongovernmental organization duly author-

ized to assist in the distribution of pharmaceutical products—

"(I) from whom the generic manufacturer has received a specific request for a pharmaceutical product and is taking steps to prepare such product or related products; or

"(II) with whom the generic manufacturer has reached an agreement to manufacture and export the pharmaceutical product; or

"(iii) a copy of a valid license, other authorization, or communication issued by a potential eligible country permitting import of the pharmaceutical product from the United States; and

"(H) an agreement or understanding entered into by the applicant to comply with the conditions described under subsection (d) and with the provisions of the General Council Decisions; and

"(I) any additional information reasonably required by the Director, including information necessary to ensure the identification of the product that is the subject of the application.

''(3) COMBINED LICENSE APPLICATIONS.—The Director may—

''(A) establish procedures to permit a combined license application from more than 1 eligible country;

''(B) issue a multi-country license if appropriate;

''(C) issue rules based on the requirements of this section relating to separate country applicants, in consultation with the National Advisory Board on Implementation of the General Council Decision established under section 5 of the Life-Saving Medicines Export Act of 2006, except for modifications made to accommodate applying the rules for 1 country to applications filed by more than 1 eligible country in the same filing; and

''(D) waive any record keeping, application, or related provision of this subsection to the extent necessary to implement this paragraph for any combined application from multiple countries.

''(4) ACTION BY DIRECTOR.—

"(A) IN GENERAL.—Not later than 60 days after the submission of an application, the Director shall approve or deny that application.

"(B) CONDITIONAL DENIAL.—The Director may deny an application and request additional information or evidence to be submitted within 30 days after making the request. If additional information or evidence is submitted within the 30-day period, the Director shall make a final approval or denial of the application within 60 days after the date of submission of the additional information or evidence.

"(5) APPEAL OF DENIAL.—An applicant may seek review of a final adverse decision of the Director, including any adverse decision based on failure to comply with any provision of paragraph (2) in the United States Court of Appeals for the Federal Circuit. The judgement of such court shall be subject to final review by the Supreme Court upon certiorari in the manner prescribed in section 1254 of title 28. The United States Court of Appeals for the Federal Circuit shall decide all relevant questions of law, provide appropriate orders, relief, or judgments, and shall hold unlawful and set aside any determination of the Director that the court finds to be—

''(A) arbitrary, capricious, an abuse of discretion, inconsistent with this section, or otherwise not in accordance with law;

''(B) contrary to constitutional right, power, privilege, or immunity;

''(C) in excess of statutory jurisdiction, authority, or limitations, or in violation of a statutory right; or

''(D) without observance of procedure required by law.

''(d) CONDITIONS OF LICENSE.—Under rules issued by the Director, the following conditions shall apply to a compulsory license issued under this section:

''(1) The pharmaceutical product—

''(A) shall be a generic version of a patented product approved as safe and efficacious by the World Health Organization of the United Nations or the United States Food and Drug Administration; and

''(B) shall be manufactured solely for export to the eligible country listed in the application under subsection (c); and

''(C) shall not be exported to any other country except for nation parties to a regional

trade agreement as set forth in paragraph 6(i) of the General Council Decision.

''(2) The pharmaceutical product, or the label or packaging of the pharmaceutical product, for export shall be—

''(A) clearly identified as being produced under the system set out in the General Council Decision; and

''(B) distinguished from the pharmaceutical product or its label or packaging manufactured by the patent holder through labeling, shaping, sizing, marking, special packaging, or other means or combinations of means, which shall be consistent with paragraph 2(b)(ii) of the General Council Decision and include—

''(i) a statement that such pharmaceutical product has been manufactured solely for export to the specific eligible country or to nation parties to a regional trade agreement as provided for in paragraphs 6(i) and 6(ii) of the General Council Decision and is not approved for marketing in the United States;

''(ii) a statement indicating that the pharmaceutical product is subject to a

compulsory license issued to the generic manufacturer; and

''(iii) any other markings determined appropriate by the Director to distinguish such pharmaceutical product from the patented pharmaceutical product, which may include a different trademark name or distinctive color or shaping, so long as—

''(I) such distinction is feasible and does not have a significant impact on price and will not undermine the humanitarian purposes of the Life-Saving Medicines Export Act of 2006; and

''(II) the Director may temporarily waive the requirements of the distinguishing marks under urgent circumstances for limited quantities of such pharmaceutical products.

''(3) The term of such compulsory license shall expire on the date that is the earliest of—

''(A) 7 years after the date of issuance of the license;

''(B) the date the importing country is no longer an eligible country; or

''(C) on a petition from the original patent holder, on the date that the Director, in consultation with the National Advisory Board on Implementation of the General Council Decision established under section 5 of the Life-Saving Medicines Export Act of 2006, determines that the circumstances that have led to the granting of the license cease to exist and it appears probable that such circumstances will not reoccur.

''(4) The licensee shall keep accurate records of all quantities of products manufactured and distributed under its license and shall make such records available upon request to an independent person agreed to by the parties, or otherwise approved by the Director, for the sole purpose of ensuring whether the terms of the license have been met.

''(5) A generic manufacturer issued a license under this section may notify the Director if the estimated quantity of the pharmaceutical product set forth in the application and subsection (c)(2)(B) will be insufficient to meet the projected need during the remainder of the license period. The Director shall adjust the estimated quantity to the quantity proposed by the licensee unless compelling evidence

demonstrates that the proposed quantity is excessive.

''(e) COMPENSATION TO PATENT HOLDER.—

''(1) IN GENERAL.—The holder of a compulsory license under this section shall pay to the patent holder a royalty in an amount and by a date determined by the Director that shall not be—

''(A) earlier than the date of each shipment for export of the pharmaceutical product under the compulsory license; or

''(B) later than 45 days after the date of each shipment.

''(2) AMOUNT OF ROYALTY.—In consultation with the Secretary of Health and Human Services, the Director of the National Institutes of Health, the Director of the United States Agency for International Development, and the Director of the Centers of Disease Control, the Director, when determining a royalty amount under paragraph (1), shall consider the following:

''(A) The provisions of paragraph 3 of the General Council Decision and the need for the licensee under this section to make a reasonable return sufficient to sustain a continued participation in humanitarian objectives.

''(B) The humanitarian and noncommercial reasons for issuing a compulsory license under this section.

''(C) The economic value to the importing country of the use that has been authorized by the Director.

''(D) The need for low-cost pharmaceutical products by persons in eligible countries.

''(E) Whether the importing country has a patent applicable to the pharmaceutical product sought to be imported under this section.

''(F) The ordinary levels of profitability in the United States, of commercial agreements involving pharmaceutical products, and any relevant international trends in relevant prices as reported by the United Nations or other appropriate humanitarian organizations or agencies for the supply of such products for humanitarian purposes.

''(3) ROYALTY RATE FORMULAS.—

''(A) IN GENERAL.—

''(i) FACTORS.—Except as provided in subparagraph (B), the amount of the royalty payable to any patentee under this subsection—

''(I) shall be based on considerations under paragraph (2); and

''(II) shall not exceed the amount determined by multiplying the commercial value of the pharmaceutical product to be exported under the supply agreement by 4 percent.

''(ii) MULTIPLE PATENTEES.—If more than 1 patentee is due a royalty for a pharmaceutical product under this section, the amount of the royalty payable for the pharmaceutical product shall be divided by the number of patentees.

''(B) ALTERNATIVE ROYALTY RATE FORMULA.—

''(i) IN GENERAL.—

''(I) ESTABLISHMENT AND USE.—Subject to subclause (II), the Director may establish and use an alternative royalty rate formula under this subparagraph instead of the royalty rate formula under subparagraph (A), if—

''(aa) the Director makes a determination that the alter-

native royalty rate formula is more appropriate or efficient to employ; and

"(bb) the alternative royalty rate formula is based on the methodology described under clauses (ii) through (v).

"(II) LIMITATION.—If the royalty amount determined under the alternative royalty rate formula under subclause (I) exceeds the dollar amount determined by multiplying the commercial value of the pharmaceutical product to be exported under the supply agreement by 4 percent the royalty amount shall be set at such dollar amount.

"(ii) HUMAN DEVELOPMENT INDEX COUNTRIES.—If the name of the country to which a pharmaceutical product is to be delivered under this section is on the Human Development Index maintained by the United Nations Development Program, the rate for calculation of the royalty to be

paid to any patentee shall be determined by—

"(I) adding 1 to the total number of countries listed on such Index;

"(II) subtracting from the sum determined under subclause (I) the numerical rank on the Index of the country to which the pharmaceutical product is to be exported;

"(III) dividing the difference determined under subclause (II) by the total number of countries listed on the Index; and

"(IV) multiplying the quotient determined under subclause (III) by 0.04.

"(iii) SINGLE AND MULTIPLE PATENTEES.—For a country described under clause (ii), the amount of the royalty payable to any patentee shall be determined—

"(I) if there is only 1 patentee, by multiplying the total monetary value of the agreement pertaining to the pharmaceutical product to be exported under this section by the roy-

alty rate determined in accordance with clause (ii); and

''(II) if there is more than 1 patentee, by dividing the amount determined under subclause (I) by the number of patentees.

''(iv) COUNTRIES NOT ON HUMAN DEVELOPMENT INDEX.—If the name of the country to which a pharmaceutical product is to be delivered under this section is not on the Human Development Index maintained by the United Nations Development Program, the Director shall—

''(I) determine if relevant circumstances in that country are reasonably similar to another country on that Human Development Index;

''(II) if determining a similar country under subclause (I), use the procedures under clause (ii) to determine a royalty payment using the numerical rank of that other country; and

''(III) if determining a royalty rate under subclause (II), state the

reasons for making the determination that the country to which the product is to be exported was reasonably similar to the country on such Index used in the calculation.

''(v) REGIONAL TRADE AGREEMENTS.—If the Director knows during review of an application that the pharmaceutical products are to be delivered under this section to parties to a regional trade agreement where re-exportation is allowed under paragraph 6(i) and (ii) of the General Council Decision, the Director shall—

''(I) determine if relevant circumstances in those countries are reasonably similar to a country on the Human Development Index;

''(II) if determining a similar country under subclause (I), use the procedures under clause (ii) to determine a royalty payment based on the numerical rank of that other country; and

''(III) if determining a royalty rate under subclause (III), shall state

the reasons for making the determination that the countries to which the products are to be re-exported under paragraph 6(i) and (ii) of such Decision were reasonably similar to the country selected on such Index.

''(4) NOTICE OF SHIPMENTS.—Before each shipment of any product manufactured under this section, the manufacturer shall, within 15 days before such product is exported, provide notice through registered mail specifying the approximate quantity to be exported to—

''(A) the patentee;

''(B) the purchaser of the product; and

''(C) the Director.

''(f) RENEWAL OF COMPULSORY LICENSE.—

''(1) IN GENERAL.—A generic manufacturer that is the holder of a compulsory license under this section may submit to the Director an application to renew the compulsory license.

''(2) CONTENT OF RENEWAL APPLICATION.—An application under paragraph (1) shall contain—

''(A) an assurance that the quantities of the pharmaceutical product authorized to be exported under the renewal compulsory license

will not be exported before such original compulsory license ceases to be valid;

''(B) an assurance that the applicant has complied with the terms, conditions, and royalty payment required under this section; and

''(C) any other information that the Director may reasonably require.

''(3) TIMING OF RENEWAL.—An application for renewal shall be submitted to the Director not later than 45 days before the expiration date of the compulsory license.

''(4) TERM OF RENEWAL.—The term of a renewed compulsory license shall not exceed the term of the original compulsory license.

''(5) LIMITATION.—A compulsory license may not be renewed more than once.

''(g) EFFECT OF SECTION.—To the extent authorized in Article 31(b) of the TRIPS Agreement, nothing in this section shall be construed as requiring an effort to obtain a voluntary license in the event of—

''(1) a national emergency or other circumstances of extreme urgency in the eligible country; or

''(2) a public noncommercial governmental use.

''(h) EMERGENCIES AND CIRCUMSTANCES OF EXTREME URGENCY.—

''(1) EXPEDITED APPROVAL.—

''(A) IN GENERAL.—The Director may provide approval on an expedited basis for a limited period of time to grant a compulsory license regarding a pharmaceutical product to a generic manufacturer to address a national emergency or other circumstances of extreme urgency under such expedited procedures as the Director determines appropriate.

''(B) PROCEDURES.—Procedures under this paragraph may include—

''(i) waiving any requirement to seek a voluntary license from the patent holder; and

''(ii) delaying the determination of compensation until after an approval is made.

''(2) WAIVER.—In carrying out expedited approvals under this subsection, the Director may temporarily waive any provision of this section.

''(i) NOTIFICATION TO WTO.—The Director shall notify the WTO of the issuance, termination, or renewal of a compulsory license under this section and of the name

and address of the licensee, the product for which the license has been granted, the quantities for which it has been granted, and the countries to which the product is to be supplied.''.

(b) ESTABLISHMENT OF PROCEDURES.—

(1) IN GENERAL.—The Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office (referred to in this section as the ''Director'') shall establish procedures for implementing this Act and the amendments made by this Act.

(2) REPORT.—The Director shall annually submit to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives a report that describes the activities related to the implementation of this Act and the amendments made by this Act.

(3) REGULATIONS.—The Director may issue such regulations as are necessary and appropriate to carry out this Act and the amendments made by this Act.

(c) TECHNICAL AND CONFORMING AMENDMENT.—The table of sections for chapter 29 of title 35, United States Code, is amended by adding after the item relating to section 297 the following:

''298. Exportation of pharmaceutical products for public health purposes.''.

SEC. 4. NONINFRINGEMENT OF PATENT.

Section 271 of title 35, United States Code, is amended—

(1) by redesignating subsections (h) and (i) as subsections (i) and (j), respectively; and

(2) by inserting after subsection (g) the following:

''(h)(1) It shall not be an act of infringement to manufacture within the United States or for export outside the United States any patented invention relating to a pharmaceutical product (as defined under section 298) by any person that—

''(A) is issued a compulsory license to manufacture and sell that drug under section 298; and

''(B) manufactures and exports that drug in compliance with all conditions of that license.

''(2) Subsection (d) (4) or (5) shall not apply to any patent affected by a license described under paragraph (1) of this subsection.''.

SEC. 5. NATIONAL ADVISORY BOARD ON IMPLEMENTATION OF THE GENERAL COUNCIL DECISION.

(a) DEFINITIONS.—In this section:

(1) BOARD.—The term ''Board'' means the National Advisory Board on Implementation of the General Council Decision established under this section.

(2) DIRECTOR.—The term ''Director'' means the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

(3) ELIGIBLE COUNTRY.—The term ''eligible country'' means a country that—

(A)(i) is designated by the United Nations as a least developed country; or

(ii) if not so designated, does not possess sufficient manufacturing capacities to produce the pharmaceutical product that such country seeks to import under section 298 of title 35, United States Code (as added by this Act); and

(B) has provided notice to the Director describing such lack of sufficient manufacturing capacities.

(4) GENERAL COUNCIL.—The term ''General Council'' means the General Council of the WTO established by paragraph (2) of Article IV of the Agreement Establishing the World Trade Organization entered into on April 15, 1994.

(5) GENERAL COUNCIL DECISION.—The term ''General Council Decision'' means the decision of the General Council of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declara-

tion on the TRIPS Agreement and Public Health and the WTO General Council Chairman's statement accompanying the Decision (JOB(03)/177, WT/GC/M/82) (collectively known as the ''TRIPS/health solution'').

(6) GENERIC MANUFACTURER.—The term ''generic manufacturer'' means, with respect to a pharmaceutical product, a manufacturer that does not hold the patent to such pharmaceutical product or is not otherwise authorized by the patent holder to make use of the invention.

(7) PHARMACEUTICAL PRODUCT.—The term ''pharmaceutical product'' means any patented pharmaceutical product, or pharmaceutical product manufactured through a patented process, including any drug, active ingredient of a drug, diagnostic, or vaccine needed to prevent or treat public health problems.

(8) TRIPS AGREEMENT.—The term ''TRIPS Agreement'' means the Agreement on Trade-Related Aspects of Intellectual Property Rights (described in section 101(d)(15) of the Uruguay Round Agreements Act (19 U.S.C. 3501 note)).

(9) WORLD TRADE ORGANIZATION.—The term ''World Trade Organization'' means the organization established pursuant to the WTO Agreement.

(10) WTO AGREEMENT.—The term ''WTO Agreement'' means the Agreement Establishing The World Trade Organization entered into on April 15, 1994.

(11) WTO.—The term ''WTO'' has the meaning given that term in section 2 of the Uruguay Round Agreements Act (19 U.S.C. 3501).

(12) URUGUAY ROUND AGREEMENTS.—The term ''Uruguay Round Agreements'' has the meaning given such term in section 2(7) of the Uruguay Round Agreements Act (19 U.S.C. 3501(7)).

(b) ESTABLISHMENT.—The Director shall establish the National Advisory Board on Implementation of the General Council Decision in accordance with the Federal Advisory Committee Act (5 U.S.C. App.) to provide advice and guidance regarding the implementation and administration of the compulsory licensing program established under section 298 of title 35, United States Code (as added by this Act), including royalty amounts to be determined under that section.

(c) COMPOSITION OF THE BOARD.—The Board shall be composed of 10 members, of which—

(1) 1 shall be an individual who is an academic expert on the subject of pharmaceutical matters and patent law;

(2) 2 shall be an individual with expertise relating to the WTO, the TRIPS/health solution, and the General Council Decision;

(3) 2 shall be an individual with expertise relating to the needs of persons living in least-developed and developing nations with respect to access to low-cost patented pharmaceutical products;

(4) 2 shall be individuals who represent international organizations, such as the United Nations, the World Bank, international nongovernmental organizations, and religious faiths, and who have expert knowledge regarding the General Council Decision and the issues raised by that decision;

(5) 1 shall be a physician with experience in treating persons with HIV/AIDS, malaria, tuberculosis, or other infectious diseases;

(6) 1 shall be an individual representing major pharmaceutical manufacturers in the United States; and

(7) 1 shall be an individual representing major generic manufacturers of pharmaceutical products in the United States.

(d) APPOINTMENTS.—Not later than 120 days after the date of enactment of this Act, the Director, in consultation with the Director of the National Institutes of Health (or a designee), the Director of the United States Agency for International Development (or a designee), and the Director of the Centers for Disease Control (or a designee) shall appoint—

(1) the members of the Board described under subsection (c)(1), (5), (6), and (7)—

(A) from nominations received from a request for applications published in the Federal Register; and

(B) after engaging in other efforts to make institutions of higher education within the United States, international organizations, and groups representing the medical profession aware of the solicitation for nominations;

(2) 1 member of the Board described under subsection (c)(2), from recommendations of the Majority Leader of the Senate;

(3) 1 member of the Board described under subsection (c)(2), from recommendations of the Minority Leader of the Senate;

(4) 1 member of the Board described under subsection (c)(3) from recommendations of the Speaker of the House of Representatives;

(5) 1 member of the Board described under subsection (c)(3) from recommendations of the Minority Leader of the House of Representatives; and

(6) 2 members of the Board described under subsection (c)(4) from recommendations of the Secretary of State in consultation with the United States Ambassador to the United Nations.

(e) TERM.—A member of the Board shall serve for a term of 4 years, except that the Director shall appoint the original members of the Board for staggered terms of not more than 4 years. A member may not serve a consecutive term unless such member served an original term that was less than 4 years.

(f) MEETINGS.—The Director shall convene—

(1) a meeting of the Board not later than 60 days after the appointment of its members;

(2) subsequent meetings on a periodic basis; and

(3) at least 2 meetings a year during the first 4 years after the date of enactment of this Act.

(g) COMPENSATION AND EXPENSES.—A member of the Board shall serve without compensation. While away

from their homes or regular places of business on the business of the Board, members of the Board may be allowed travel expenses, including per diem in lieu of subsistence, as is authorized under section 5703 of title 5, United States Code, for persons employed intermittently in the Government service.

(h) CHAIRPERSON.—The Board shall select a chairperson for the Board.

(i) QUORUM.—A majority of the members of the Board shall constitute a quorum for the purpose of conducting business.

(j) DECISIVE VOTES.—Two-thirds of the votes cast at a meeting of the Board at which a quorum is present shall be decisive of any motion.

(k) OTHER TERMS AND CONDITIONS.—The Director shall authorize the Board to hire a staff director and shall detail staff of the Patent and Trademark Office or allow for the hiring of other staff and may pay necessary expenses incurred by the Board in carrying out this section. The Director shall provide technical assistance, work space, facilities, and other amenities to facilitate the meetings and operations of the Board. The Director, or designated staff, may attend any such meetings and provide advice and guidance.

(l) RESPONSIBILITIES OF BOARD.—

(1) IN GENERAL.—The Board shall provide recommendations to the Director on the implementation of section 298 of title 35, United States Code (as added by this Act), including the appropriate royalty rates for compensating patent holders under that section.

(2) TECHNICAL ADVISORY PANELS.—The Board may convene technical advisory panels to provide scientific, legal, international, economic, and other information to the Board.

(m) EVALUATION AND REPORTS.—

(1) IN GENERAL.—The Board shall evaluate the implementation and administration of section 298 of title 35, United States Code (as added by this Act), and shall provide periodic and special reports to the Director, the Secretary of Health and Human Services, the National Institutes of Health, the Director of the Centers for Disease Control, and to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives.

(2) DUTIES.—If the Director uses the compensation method under section 298(e)(3)(A) of title 35, United States Code (as added by this Act), the Board shall—

(A) not later than 160 days after the date of enactment of this Act, begin to gather information regarding proposals for the compensation of patent holders and shall carefully examine various compensation options;

(B) not later than 240 days after the date of enactment of this Act, submit preliminary recommendations to the entities and officers described under paragraph (1);

(C) advise the Director on various matters raised by the Director;

(D) submit a report to the Director, the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives at least once each year on—

(i) recommendations for improving procedures or the administration of the program established under that section; and

(ii) other factual or policy matters which may provide guidance or assistance to those Committees; and

(E) submit a report to the Director and the Committee on the Judiciary of the Senate

and the Committee on the Judiciary of the House of Representatives on—

(i) the advantages and disadvantages which might result from allowing non-governmental organizations to be able to apply to obtain a compulsory license under procedures similar to those set forth in that section for such countries where the national government declines to apply for such a license, including an analysis of whether World Trade Organization understandings would permit such an approach and how such an approach might be implemented; and

(ii) whether this Act provides sufficient economic incentives to generic companies for the research and development of new generic products.

(n) PETITIONS.—The Board shall establish procedures under which persons may petition the Board for the purpose of evaluating various issues related to the implementation and administration of section 298 of title 35, United States Code (as added by this Act).

(o) CONFIDENTIALITY.—Any confidential business information obtained by the Board in carrying out this section shall not be released to the public.

(p) APPROPRIATIONS.—

(1) AMOUNTS OF APPROPRIATIONS.—There are appropriated out of any money in the Treasury not otherwise appropriated to the United States Patent and Trademark Office for purposes of carrying out paragraph (2)—

(A) $1,500,000 for the fiscal year ending September 30, 2007;

(B) $1,500,000 for the fiscal year ending September 30, 2008;

(C) $1,300,000 for the fiscal year ending September 30, 2009;

(D) $1,100,000 for the fiscal year ending September 30, 2010; and

(E) $900,000 for the fiscal year ending September 30, 2011.

(2) USE OF APPROPRIATIONS.—Amounts appropriated under paragraph (1) shall be used for the expenses and activities of the Board under this section, except no more than $200,000 of such amounts in each fiscal year may be used for the expenses and activities of the Office established under section

298(c)(B) of title 35, United States Code (as added by this Act). Such amounts not obligated in any fiscal year may be carried over into subsequent fiscal years, except that any amounts not obligated by September 30, 2011, shall be provided to the Secretary of the Treasury to be returned to the United States Treasury.

(q) TERMINATION.—The Board shall terminate on September 30, 2011.

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