

109<sup>TH</sup> CONGRESS  
2<sup>D</sup> 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.

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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.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Life-Saving Medicines  
3 Export Act of 2006”.

4 **SEC. 2. PURPOSES AND FINDINGS.**

5 (a) **PURPOSE.**—The purpose of this Act is to promote  
6 public health by permitting the export of life-saving phar-  
7 maceutical products and other medicines manufactured in  
8 the United States by compulsory license to residents of  
9 participating countries with insufficient or no manufac-  
10 turing capability in the pharmaceutical sector for the  
11 product in question consistent with the General Council  
12 Decision of the World Trade Organization.

13 (b) **FINDINGS.**—Congress finds the following:

14 (1) The United States Trade Representative re-  
15 cently announced that it “welcomes” the World  
16 Trade Organization amendment to “allow countries  
17 to override patent rights when necessary to export  
18 life-saving drugs to developing countries that face  
19 public health crises but cannot produce drugs for  
20 themselves.”. United States Ambassador Portman  
21 called this “a landmark achievement that we hope  
22 will help developing countries.”.

23 (2) Compulsory licensing of patents is a “fix-  
24 ture in almost all patent systems” in the world as  
25 noted in the Berkeley Technology Law Journal in  
26 2003. By the end of the 1950s, for example, an esti-

1 mated 40,000 to 50,000 compulsory licenses were  
2 issued regarding patents in the United States. (Ac-  
3 cess to Patented Medicine in Developing Countries,  
4 F.M. Scherer, [www.cmhealth.org/docswg4](http://www.cmhealth.org/docswg4); World  
5 Health Organization). Indeed, the WHO paper notes  
6 that the “United States has led the world in issuing  
7 compulsory licenses to restore competition when vio-  
8 lations of the antitrust laws have been found, or in  
9 the negotiated settlement of antitrust cases before  
10 full adjudication has occurred.”

11 (3) The vast majority of people living in devel-  
12 oping countries or least developed nations have lim-  
13 ited or no access to many medicines that are saving  
14 and extending lives of those in other, more developed  
15 nations. Since sales of the patented, brand-name  
16 versions of such medicines are minimal or non-exist-  
17 ent in many impoverished regions of the world pro-  
18 viding generic versions of those medicines under the  
19 WTO General Council Decision will have minimal  
20 impact on the sales of brand-name, patented  
21 versions in such regions.

22 (4) The World Health Organization has esti-  
23 mated that  $\frac{1}{3}$  of the world’s population lacks reg-  
24 ular access to essential medicines, including

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

3 (5) Medicines and vaccines are needed through-  
4 out the world to combat newly arising public health  
5 threats such as the avian flu. A United States Na-  
6 tional Intelligence Estimate in January 2000 notes  
7 that “New and emerging infectious diseases will pose  
8 a rising global health threat...”.

9 (6) Millions of people with HIV/AIDS in devel-  
10 oping countries need antiretroviral drugs. More than  
11 40,000,000 people worldwide have HIV and 95 per-  
12 cent of them live in developing countries. Malaria,  
13 tuberculosis, and other infectious diseases kill mil-  
14 lions of people a year in developing nations.

15 (7) Comprehensive reports of the World Health  
16 Organization of the United Nations, in 2004 and  
17 2005 detail the urgent need for pharmaceutical  
18 products in developing countries and in least devel-  
19 oped nations.

20 (8) The World Trade Organization decisions of  
21 August 30, 2003, on access to generic medicines is  
22 now being considered by member nations of the  
23 World Trade Organization for ratification as a per-  
24 manent amendment to the WTO Agreement on

1 Trade Related Aspects of Intellectual Property  
2 Rights.

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

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

8 **“§ 298. Exportation of pharmaceutical products for**  
9 **public health purposes**

10 “(a) DEFINITIONS.—In this section:

11 “(1) ELIGIBLE COUNTRY.—The term ‘eligible  
12 country’ means a country that—

13 “(A)(i) is designated by the United Na-  
14 tions as a least developed country; or

15 “(ii) if not so designated—

16 “(I) has certified to the General  
17 Council that the country seeks to partici-  
18 pate in the compulsory licensing system  
19 under this section as authorized by the  
20 General Council Decision; or

21 “(II) has certified through an official  
22 government finding if not a member of the  
23 World Trade Organization, that the coun-  
24 try does not possess sufficient manufac-  
25 turing capacities to produce the pharma-

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

3            “(B) has provided notice to the Director  
4            describing such lack of sufficient manufacturing  
5            capacities; and

6            “(C) has not terminated that country’s  
7            participation in such compulsory licensing sys-  
8            tem by certifying to the General Council or to  
9            the Director that it no longer desires to partici-  
10          pate in such a system.

11          “(2) GENERAL COUNCIL.—The term ‘General  
12          Council’ means the General Council of the WTO es-  
13          tablished by paragraph (2) of Article IV of the  
14          Agreement Establishing the World Trade Organiza-  
15          tion entered into on April 15, 1994.

16          “(3) GENERAL COUNCIL DECISION.—The term  
17          ‘General Council Decision’ means the decision of the  
18          General Council of 30 August 2003 on the Imple-  
19          mentation of Paragraph 6 of the Doha Declaration  
20          on the TRIPS Agreement and Public Health and the  
21          WTO General Council Chairman’s statement accom-  
22          panying the Decision (JOB(03)/177, WT/GC/M/82)  
23          (collectively known as the ‘TRIPS/health solution’).

24          “(4) GENERIC MANUFACTURER.—The term ‘ge-  
25          neric manufacturer’ means, with respect to a phar-

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

5               “(5) PHARMACEUTICAL PRODUCT.—The term  
6       ‘pharmaceutical product’ means any patented prod-  
7       uct, or pharmaceutical product, including compo-  
8       nents of that product, manufactured through a pat-  
9       ented process, of the pharmaceutical sector including  
10      any drug, active ingredient of a drug, diagnostic, or  
11      vaccine needed to prevent or treat potentially life  
12      threatening public health problems, including those  
13      listed in Paragraph 6 of the Doha Declaration on  
14      the TRIPS Agreement and Public Health.

15              “(6) TRIPS AGREEMENT.—The term ‘TRIPS  
16      Agreement’ means the Agreement on Trade-Related  
17      Aspects of Intellectual Property Rights (described in  
18      section 101(d)(15) of the Uruguay Round Agree-  
19      ments Act (19 U.S.C. 3501 note)).

20              “(7) WORLD TRADE ORGANIZATION.—The term  
21      ‘World Trade Organization’ means the organization  
22      established pursuant to the WTO Agreement.

23              “(8) WTO AGREEMENT.—The term ‘WTO  
24      Agreement’ means the Agreement Establishing The

1 World Trade Organization entered into on April 15,  
2 1994.

3 “(9) WTO.—The term ‘WTO’ has the meaning  
4 given that term in section 2 of the Uruguay Round  
5 Agreements Act (19 U.S.C. 3501).

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

10 “(b) ISSUANCE OF COMPULSORY LICENSE.—Not-  
11 withstanding any other provision of part II or this part,  
12 and subject to subsections (c) and (d), the Director shall  
13 issue a compulsory license to a generic manufacturer of  
14 a pharmaceutical product or a patented product under this  
15 section consistent with the Life-Saving Medicines Export  
16 Act of 2006 for the purposes of—

17 “(1) manufacturing and exporting to an eligible  
18 country, (including using nongovernmental agencies  
19 to assist in handling and distribution to eligible  
20 countries) such pharmaceutical products, including  
21 exporting for the purpose of foreign testing and cer-  
22 tification and other activities reasonable related to  
23 such manufacturing and exporting; and

24 “(2) such other purposes under that Act.

25 “(c) APPLICATION FOR COMPULSORY LICENSE.—

1 “(1) IN GENERAL.—

2 “(A) SUBMISSION.—Except as provided  
3 under subsection (g), a generic manufacturer  
4 that seeks to manufacture and export a phar-  
5 maceutical product to an eligible country (in-  
6 cluding through the use of a nongovernmental  
7 organization) shall submit to the Director an  
8 application as developed by the Director for a  
9 compulsory license as described in this section.

10 “(B) ASSISTANCE.—The Director shall es-  
11 tablish an office within the Patent and Trade-  
12 mark Office to assist—

13 “(i) applicants under this section, in-  
14 cluding aiding persons in identifying what  
15 patents cover which pharmaceutical prod-  
16 ucts and in providing other advice and  
17 guidance to facilitate the filing of complete  
18 applications; and

19 “(ii) eligible countries, nongovern-  
20 mental organizations, or nations likely to  
21 become eligible countries, identify compa-  
22 nies in the United States which could pro-  
23 vide pharmaceutical products under this  
24 section to such countries.

1           “(2) CONTENT OF APPLICATION.—The Director  
2 shall approve an application submitted under para-  
3 graph (1) if such application contains—

4           “(A) the name of the pharmaceutical prod-  
5 uct to be manufactured and exported under the  
6 license;

7           “(B) an estimate of the quantities of the  
8 pharmaceutical product to be manufactured and  
9 exported under the license and a stipulation  
10 that the amount manufactured and exported  
11 shall not exceed the amount necessary to meet  
12 the needs of the eligible country;

13           “(C) for each patented invention to which  
14 the application relates—

15           “(i) the name of the patent holder  
16 and the applicable patent number; or

17           “(ii) a statement by the applicant on  
18 information and belief of the name of the  
19 patent holder and applicable patent num-  
20 ber;

21           “(D) the name of the eligible country to  
22 which the pharmaceutical product will be ex-  
23 ported and the name of any nongovernmental  
24 organization which will assist in the effort;

1           “(E)(i) copies of the notifications of the el-  
2           igible countries that are member countries of  
3           the WTO, as defined in the General Council  
4           Decision, made to the Council for TRIPS re-  
5           garding notifications set forth under 2(a) of  
6           such Decision; and

7           “(ii) for eligible countries that are not  
8           member countries of the WTO, a copy of the in-  
9           formation required by the notification as set  
10          forth under 2(a) of such Decision published on  
11          a public website and the address of such  
12          website;

13          “(F) a copy of a written request for a vol-  
14          untary license sent by registered mail to each  
15          patent holder, which shall have occurred during  
16          a period of at least 60 days before the submis-  
17          sion of the application to the Director, and a  
18          brief description of any subsequent negotia-  
19          tions;

20          “(G) copies of—

21                  “(i) notifications required under the  
22                  General Counsel Decision;

23                  “(ii) the name of the authorized des-  
24                  ignated official of the eligible country, or a  
25                  nongovernmental organization duly author-

1            ized to assist in the distribution of phar-  
2            maceutical products—

3                    “(I) from whom the generic man-  
4                    ufacturer has received a specific re-  
5                    quest for a pharmaceutical product  
6                    and is taking steps to prepare such  
7                    product or related products; or

8                    “(II) with whom the generic  
9                    manufacturer has reached an agree-  
10                    ment to manufacture and export the  
11                    pharmaceutical product; or

12                    “(iii) a copy of a valid license, other  
13                    authorization, or communication issued by  
14                    a potential eligible country permitting im-  
15                    port of the pharmaceutical product from  
16                    the United States; and

17                    “(H) an agreement or understanding en-  
18                    tered into by the applicant to comply with the  
19                    conditions described under subsection (d) and  
20                    with the provisions of the General Council Deci-  
21                    sions; and

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

1           “(3) COMBINED LICENSE APPLICATIONS.—The  
2 Director may—

3                   “(A) establish procedures to permit a com-  
4 bined license application from more than 1 eli-  
5 gible country;

6                   “(B) issue a multi-country license if appro-  
7 priate;

8                   “(C) issue rules based on the requirements  
9 of this section relating to separate country ap-  
10 plicants, in consultation with the National Advi-  
11 sory Board on Implementation of the General  
12 Council Decision established under section 5 of  
13 the Life-Saving Medicines Export Act of 2006,  
14 except for modifications made to accommodate  
15 applying the rules for 1 country to applications  
16 filed by more than 1 eligible country in the  
17 same filing; and

18                   “(D) waive any record keeping, applica-  
19 tion, or related provision of this subsection to  
20 the extent necessary to implement this para-  
21 graph for any combined application from mul-  
22 tiple countries.

23           “(4) ACTION BY DIRECTOR.—

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

4           “(B) CONDITIONAL DENIAL.—The Direc-  
5           tor may deny an application and request addi-  
6           tional information or evidence to be submitted  
7           within 30 days after making the request. If ad-  
8           ditional information or evidence is submitted  
9           within the 30-day period, the Director shall  
10          make a final approval or denial of the applica-  
11          tion within 60 days after the date of submission  
12          of the additional information or evidence.

13          “(5) APPEAL OF DENIAL.—An applicant may  
14          seek review of a final adverse decision of the Direc-  
15          tor, including any adverse decision based on failure  
16          to comply with any provision of paragraph (2) in the  
17          United States Court of Appeals for the Federal Cir-  
18          cuit. The judgement of such court shall be subject  
19          to final review by the Supreme Court upon certiorari  
20          in the manner prescribed in section 1254 of title 28.  
21          The United States Court of Appeals for the Federal  
22          Circuit shall decide all relevant questions of law,  
23          provide appropriate orders, relief, or judgments, and  
24          shall hold unlawful and set aside any determination  
25          of the Director that the court finds to be—

1           “(A) arbitrary, capricious, an abuse of dis-  
2 cretion, inconsistent with this section, or other-  
3 wise not in accordance with law;

4           “(B) contrary to constitutional right,  
5 power, privilege, or immunity;

6           “(C) in excess of statutory jurisdiction, au-  
7 thority, or limitations, or in violation of a statu-  
8 tory right; or

9           “(D) without observance of procedure re-  
10 quired by law.

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

14           “(1) The pharmaceutical product—

15           “(A) shall be a generic version of a pat-  
16 ented product approved as safe and efficacious  
17 by the World Health Organization of the  
18 United Nations or the United States Food and  
19 Drug Administration; and

20           “(B) shall be manufactured solely for ex-  
21 port to the eligible country listed in the applica-  
22 tion under subsection (c); and

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

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

3 “(2) The pharmaceutical product, or the label  
4 or packaging of the pharmaceutical product, for ex-  
5 port shall be—

6 “(A) clearly identified as being produced  
7 under the system set out in the General Council  
8 Decision; and

9 “(B) distinguished from the pharma-  
10 ceutical product or its label or packaging manu-  
11 factured by the patent holder through labeling,  
12 shaping, sizing, marking, special packaging, or  
13 other means or combinations of means, which  
14 shall be consistent with paragraph 2(b)(ii) of  
15 the General Council Decision and include—

16 “(i) a statement that such pharma-  
17 ceutical product has been manufactured  
18 solely for export to the specific eligible  
19 country or to nation parties to a regional  
20 trade agreement as provided for in para-  
21 graphs 6(i) and 6(ii) of the General Coun-  
22 cil Decision and is not approved for mar-  
23 keting in the United States;

24 “(ii) a statement indicating that the  
25 pharmaceutical product is subject to a

1 compulsory license issued to the generic  
2 manufacturer; and

3 “(iii) any other markings determined  
4 appropriate by the Director to distinguish  
5 such pharmaceutical product from the pat-  
6 ented pharmaceutical product, which may  
7 include a different trademark name or dis-  
8 tinctive color or shaping, so long as—

9 “(I) such distinction is feasible  
10 and does not have a significant impact  
11 on price and will not undermine the  
12 humanitarian purposes of the Life-  
13 Saving Medicines Export Act of 2006;  
14 and

15 “(II) the Director may tempo-  
16 rarily waive the requirements of the  
17 distinguishing marks under urgent  
18 circumstances for limited quantities of  
19 such pharmaceutical products.

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

22 “(A) 7 years after the date of issuance of  
23 the license;

24 “(B) the date the importing country is no  
25 longer an eligible country; or

1           “(C) on a petition from the original patent  
2 holder, on the date that the Director, in con-  
3 sultation with the National Advisory Board on  
4 Implementation of the General Council Decision  
5 established under section 5 of the Life-Saving  
6 Medicines Export Act of 2006, determines that  
7 the circumstances that have led to the granting  
8 of the license cease to exist and it appears prob-  
9 able that such circumstances will not reoccur.

10           “(4) The licensee shall keep accurate records of  
11 all quantities of products manufactured and distrib-  
12 uted under its license and shall make such records  
13 available upon request to an independent person  
14 agreed to by the parties, or otherwise approved by  
15 the Director, for the sole purpose of ensuring wheth-  
16 er the terms of the license have been met.

17           “(5) A generic manufacturer issued a license  
18 under this section may notify the Director if the es-  
19 timated quantity of the pharmaceutical product set  
20 forth in the application and subsection (c)(2)(B) will  
21 be insufficient to meet the projected need during the  
22 remainder of the license period. The Director shall  
23 adjust the estimated quantity to the quantity pro-  
24 posed by the licensee unless compelling evidence

1 demonstrates that the proposed quantity is exces-  
2 sive.

3 “(e) COMPENSATION TO PATENT HOLDER.—

4 “(1) IN GENERAL.—The holder of a compulsory  
5 license under this section shall pay to the patent  
6 holder a royalty in an amount and by a date deter-  
7 mined by the Director that shall not be—

8 “(A) earlier than the date of each ship-  
9 ment for export of the pharmaceutical product  
10 under the compulsory license; or

11 “(B) later than 45 days after the date of  
12 each shipment.

13 “(2) AMOUNT OF ROYALTY.—In consultation  
14 with the Secretary of Health and Human Services,  
15 the Director of the National Institutes of Health,  
16 the Director of the United States Agency for Inter-  
17 national Development, and the Director of the Cen-  
18 ters of Disease Control, the Director, when deter-  
19 mining a royalty amount under paragraph (1), shall  
20 consider the following:

21 “(A) The provisions of paragraph 3 of the  
22 General Council Decision and the need for the  
23 licensee under this section to make a reasonable  
24 return sufficient to sustain a continued partici-  
25 pation in humanitarian objectives.

1           “(B) The humanitarian and noncommer-  
2           cial reasons for issuing a compulsory license  
3           under this section.

4           “(C) The economic value to the importing  
5           country of the use that has been authorized by  
6           the Director.

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

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

12          “(F) The ordinary levels of profitability in  
13          the United States, of commercial agreements  
14          involving pharmaceutical products, and any rel-  
15          evant international trends in relevant prices as  
16          reported by the United Nations or other appro-  
17          priate humanitarian organizations or agencies  
18          for the supply of such products for humani-  
19          tarian purposes.

20          “(3) ROYALTY RATE FORMULAS.—

21                  “(A) IN GENERAL.—

22                          “(i) FACTORS.—Except as provided in  
23                          subparagraph (B), the amount of the roy-  
24                          alty payable to any patentee under this  
25                          subsection—

1           “(I) shall be based on consider-  
2           ations under paragraph (2); and

3           “(II) shall not exceed the amount  
4           determined by multiplying the com-  
5           mercial value of the pharmaceutical  
6           product to be exported under the sup-  
7           ply agreement by 4 percent.

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

14          “(B) ALTERNATIVE ROYALTY RATE FOR-  
15          MULA.—

16                 “(i) IN GENERAL.—

17                         “(I) ESTABLISHMENT AND  
18                         USE.—Subject to subclause (II), the  
19                         Director may establish and use an al-  
20                         ternative royalty rate formula under  
21                         this subparagraph instead of the roy-  
22                         alty rate formula under subparagraph  
23                         (A), if—

24                                 “(aa) the Director makes a  
25                                 determination that the alter-

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

4 “(bb) the alternative royalty  
5 rate formula is based on the  
6 methodology described under  
7 clauses (ii) through (v).

8 “(II) LIMITATION.—If the roy-  
9 alty amount determined under the al-  
10 ternative royalty rate formula under  
11 subclause (I) exceeds the dollar  
12 amount determined by multiplying the  
13 commercial value of the pharma-  
14 ceutical product to be exported under  
15 the supply agreement by 4 percent the  
16 royalty amount shall be set at such  
17 dollar amount.

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

1           paid to any patentee shall be determined  
2           by—

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

5                   “(II) subtracting from the sum  
6                   determined under subclause (I) the  
7                   numerical rank on the Index of the  
8                   country to which the pharmaceutical  
9                   product is to be exported;

10                  “(III) dividing the difference de-  
11                  termined under subclause (II) by the  
12                  total number of countries listed on the  
13                  Index; and

14                  “(IV) multiplying the quotient  
15                  determined under subclause (III) by  
16                  0.04.

17                  “(iii) SINGLE AND MULTIPLE PAT-  
18                  ENTEES.—For a country described under  
19                  clause (ii), the amount of the royalty pay-  
20                  able to any patentee shall be determined—

21                   “(I) if there is only 1 patentee,  
22                   by multiplying the total monetary  
23                   value of the agreement pertaining to  
24                   the pharmaceutical product to be ex-  
25                   ported under this section by the roy-

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

3 “(II) if there is more than 1 pat-  
4 entee, by dividing the amount deter-  
5 mined under subclause (I) by the  
6 number of patentees.

7 “(iv) COUNTRIES NOT ON HUMAN DE-  
8 VELOPMENT INDEX.—If the name of the  
9 country to which a pharmaceutical product  
10 is to be delivered under this section is not  
11 on the Human Development Index main-  
12 tained by the United Nations Development  
13 Program, the Director shall—

14 “(I) determine if relevant cir-  
15 cumstances in that country are rea-  
16 sonably similar to another country on  
17 that Human Development Index;

18 “(II) if determining a similar  
19 country under subclause (I), use the  
20 procedures under clause (ii) to deter-  
21 mine a royalty payment using the nu-  
22 merical rank of that other country;  
23 and

24 “(III) if determining a royalty  
25 rate under subclause (II), state the

1 reasons for making the determination  
2 that the country to which the product  
3 is to be exported was reasonably simi-  
4 lar to the country on such Index used  
5 in the calculation.

6 “(v) REGIONAL TRADE AGREE-  
7 MENTS.—If the Director knows during re-  
8 view of an application that the pharma-  
9 ceutical products are to be delivered under  
10 this section to parties to a regional trade  
11 agreement where re-exportation is allowed  
12 under paragraph 6(i) and (ii) of the Gen-  
13 eral Council Decision, the Director shall—

14 “(I) determine if relevant cir-  
15 cumstances in those countries are rea-  
16 sonably similar to a country on the  
17 Human Development Index;

18 “(II) if determining a similar  
19 country under subclause (I), use the  
20 procedures under clause (ii) to deter-  
21 mine a royalty payment based on the  
22 numerical rank of that other country;  
23 and

24 “(III) if determining a royalty  
25 rate under subclause (III), shall state

1 the reasons for making the determina-  
2 tion that the countries to which the  
3 products are to be re-exported under  
4 paragraph 6(i) and (ii) of such Deci-  
5 sion were reasonably similar to the  
6 country selected on such Index.

7 “(4) NOTICE OF SHIPMENTS.—Before each  
8 shipment of any product manufactured under this  
9 section, the manufacturer shall, within 15 days be-  
10 fore such product is exported, provide notice through  
11 registered mail specifying the approximate quantity  
12 to be exported to—

13 “(A) the patentee;

14 “(B) the purchaser of the product; and

15 “(C) the Director.

16 “(f) RENEWAL OF COMPULSORY LICENSE.—

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

21 “(2) CONTENT OF RENEWAL APPLICATION.—

22 An application under paragraph (1) shall contain—

23 “(A) an assurance that the quantities of  
24 the pharmaceutical product authorized to be ex-  
25 ported under the renewal compulsory license

1 will not be exported before such original com-  
2 pulsory license ceases to be valid;

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

6 “(C) any other information that the Direc-  
7 tor may reasonably require.

8 “(3) TIMING OF RENEWAL.—An application for  
9 renewal shall be submitted to the Director not later  
10 than 45 days before the expiration date of the com-  
11 pulsory license.

12 “(4) TERM OF RENEWAL.—The term of a re-  
13 newed compulsory license shall not exceed the term  
14 of the original compulsory license.

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

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

21 “(1) a national emergency or other cir-  
22 cumstances of extreme urgency in the eligible coun-  
23 try; or

24 “(2) a public noncommercial governmental use.

1       “(h) EMERGENCIES AND CIRCUMSTANCES OF EX-  
2 TREME URGENCY.—

3               “(1) EXPEDITED APPROVAL.—

4                       “(A) IN GENERAL.—The Director may  
5 provide approval on an expedited basis for a  
6 limited period of time to grant a compulsory li-  
7 cense regarding a pharmaceutical product to a  
8 generic manufacturer to address a national  
9 emergency or other circumstances of extreme  
10 urgency under such expedited procedures as the  
11 Director determines appropriate.

12                      “(B) PROCEDURES.—Procedures under  
13 this paragraph may include—

14                               “(i) waiving any requirement to seek  
15 a voluntary license from the patent holder;  
16 and

17                               “(ii) delaying the determination of  
18 compensation until after an approval is  
19 made.

20                      “(2) WAIVER.—In carrying out expedited ap-  
21 provals under this subsection, the Director may tem-  
22 porarily waive any provision of this section.

23                      “(i) NOTIFICATION TO WTO.—The Director shall no-  
24 tify the WTO of the issuance, termination, or renewal of  
25 a compulsory license under this section and of the name

1 and address of the licensee, the product for which the li-  
2 cense has been granted, the quantities for which it has  
3 been granted, and the countries to which the product is  
4 to be supplied.”.

5 (b) ESTABLISHMENT OF PROCEDURES.—

6 (1) IN GENERAL.—The Under Secretary of  
7 Commerce for Intellectual Property and Director of  
8 the United States Patent and Trademark Office (re-  
9 ferred to in this section as the “Director”) shall es-  
10 tablish procedures for implementing this Act and the  
11 amendments made by this Act.

12 (2) REPORT.—The Director shall annually sub-  
13 mit to the Committee on the Judiciary of the Senate  
14 and the Committee on the Judiciary of the House of  
15 Representatives a report that describes the activities  
16 related to the implementation of this Act and the  
17 amendments made by this Act.

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

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

“298. Exportation of pharmaceutical products for public health purposes.”.

1 **SEC. 4. NONINFRINGEMENT OF PATENT.**

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

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

6 (2) by inserting after subsection (g) the fol-  
7 lowing:

8 “(h)(1) It shall not be an act of infringement to man-  
9 ufacture within the United States or for export outside  
10 the United States any patented invention relating to a  
11 pharmaceutical product (as defined under section 298) by  
12 any person that—

13 “(A) is issued a compulsory license to manufac-  
14 ture and sell that drug under section 298; and

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

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

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

22 (a) DEFINITIONS.—In this section:

23 (1) BOARD.—The term “Board” means the Na-  
24 tional Advisory Board on Implementation of the  
25 General Council Decision established under this sec-  
26 tion.

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

5           (3) ELIGIBLE COUNTRY.—The term “eligible  
6 country” means a country that—

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

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

14                 (B) has provided notice to the Director de-  
15 scribing such lack of sufficient manufacturing  
16 capacities.

17           (4) GENERAL COUNCIL.—The term “General  
18 Council” means the General Council of the WTO es-  
19 tablished by paragraph (2) of Article IV of the  
20 Agreement Establishing the World Trade Organiza-  
21 tion entered into on April 15, 1994.

22           (5) GENERAL COUNCIL DECISION.—The term  
23 “General Council Decision” means the decision of  
24 the General Council of 30 August 2003 on the Im-  
25 plementation of Paragraph 6 of the Doha Declara-

1       tion on the TRIPS Agreement and Public Health  
2       and the WTO General Council Chairman’s state-  
3       ment accompanying the Decision (JOB(03)/177,  
4       WT/GC/M/82) (collectively known as the “TRIPS/  
5       health solution”).

6               (6) **GENERIC MANUFACTURER.**—The term “ge-  
7       neric manufacturer” means, with respect to a phar-  
8       maceutical product, a manufacturer that does not  
9       hold the patent to such pharmaceutical product or is  
10      not otherwise authorized by the patent holder to  
11      make use of the invention.

12              (7) **PHARMACEUTICAL PRODUCT.**—The term  
13      “pharmaceutical product” means any patented phar-  
14      maceutical product, or pharmaceutical product man-  
15      ufactured through a patented process, including any  
16      drug, active ingredient of a drug, diagnostic, or vac-  
17      cine needed to prevent or treat public health prob-  
18      lems.

19              (8) **TRIPS AGREEMENT.**—The term “TRIPS  
20      Agreement” means the Agreement on Trade-Related  
21      Aspects of Intellectual Property Rights (described in  
22      section 101(d)(15) of the Uruguay Round Agree-  
23      ments Act (19 U.S.C. 3501 note)).

1           (9) WORLD TRADE ORGANIZATION.—The term  
2           “World Trade Organization” means the organization  
3           established pursuant to the WTO Agreement.

4           (10) WTO AGREEMENT.—The term “WTO  
5           Agreement” means the Agreement Establishing The  
6           World Trade Organization entered into on April 15,  
7           1994.

8           (11) WTO.—The term “WTO” has the mean-  
9           ing given that term in section 2 of the Uruguay  
10          Round Agreements Act (19 U.S.C. 3501).

11          (12) URUGUAY ROUND AGREEMENTS.—The  
12          term “Uruguay Round Agreements” has the mean-  
13          ing given such term in section 2(7) of the Uruguay  
14          Round Agreements Act (19 U.S.C. 3501(7)).

15          (b) ESTABLISHMENT.—The Director shall establish  
16          the National Advisory Board on Implementation of the  
17          General Council Decision in accordance with the Federal  
18          Advisory Committee Act (5 U.S.C. App.) to provide advice  
19          and guidance regarding the implementation and adminis-  
20          tration of the compulsory licensing program established  
21          under section 298 of title 35, United States Code (as  
22          added by this Act), including royalty amounts to be deter-  
23          mined under that section.

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

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

4           (2) 2 shall be an individual with expertise relat-  
5 ing to the WTO, the TRIPS/health solution, and the  
6 General Council Decision;

7           (3) 2 shall be an individual with expertise relat-  
8 ing to the needs of persons living in least-developed  
9 and developing nations with respect to access to low-  
10 cost patented pharmaceutical products;

11           (4) 2 shall be individuals who represent inter-  
12 national organizations, such as the United Nations,  
13 the World Bank, international nongovernmental or-  
14 ganizations, and religious faiths, and who have ex-  
15 pert knowledge regarding the General Council Deci-  
16 sion and the issues raised by that decision;

17           (5) 1 shall be a physician with experience in  
18 treating persons with HIV/AIDS, malaria, tuber-  
19 culosis, or other infectious diseases;

20           (6) 1 shall be an individual representing major  
21 pharmaceutical manufacturers in the United States;  
22 and

23           (7) 1 shall be an individual representing major  
24 generic manufacturers of pharmaceutical products in  
25 the United States.

1 (d) APPOINTMENTS.—Not later than 120 days after  
2 the date of enactment of this Act, the Director, in con-  
3 sultation with the Director of the National Institutes of  
4 Health (or a designee), the Director of the United States  
5 Agency for International Development (or a designee), and  
6 the Director of the Centers for Disease Control (or a des-  
7 ignee) shall appoint—

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

10 (A) from nominations received from a re-  
11 quest for applications published in the Federal  
12 Register; and

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

18 (2) 1 member of the Board described under  
19 subsection (c)(2), from recommendations of the Ma-  
20 jority Leader of the Senate;

21 (3) 1 member of the Board described under  
22 subsection (c)(2), from recommendations of the Mi-  
23 nority Leader of the Senate;

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

4           (5) 1 member of the Board described under  
5 subsection (c)(3) from recommendations of the Mi-  
6 nority Leader of the House of Representatives; and

7           (6) 2 members of the Board described under  
8 subsection (c)(4) from recommendations of the Sec-  
9 retary of State in consultation with the United  
10 States Ambassador to the United Nations.

11       (e) TERM.—A member of the Board shall serve for  
12 a term of 4 years, except that the Director shall appoint  
13 the original members of the Board for staggered terms  
14 of not more than 4 years. A member may not serve a con-  
15 secutive term unless such member served an original term  
16 that was less than 4 years.

17       (f) MEETINGS.—The Director shall convene—

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

20           (2) subsequent meetings on a periodic basis;  
21 and

22           (3) at least 2 meetings a year during the first  
23 4 years after the date of enactment of this Act.

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

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

7 (h) CHAIRPERSON.—The Board shall select a chair-  
8 person for the Board.

9 (i) QUORUM.—A majority of the members of the  
10 Board shall constitute a quorum for the purpose of con-  
11 ducting business.

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

15 (k) OTHER TERMS AND CONDITIONS.—The Director  
16 shall authorize the Board to hire a staff director and shall  
17 detail staff of the Patent and Trademark Office or allow  
18 for the hiring of other staff and may pay necessary ex-  
19 penses incurred by the Board in carrying out this section.  
20 The Director shall provide technical assistance, work  
21 space, facilities, and other amenities to facilitate the meet-  
22 ings and operations of the Board. The Director, or des-  
23 igned staff, may attend any such meetings and provide  
24 advice and guidance.

25 (l) RESPONSIBILITIES OF BOARD.—

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

7           (2) TECHNICAL ADVISORY PANELS.—The  
8           Board may convene technical advisory panels to pro-  
9           vide scientific, legal, international, economic, and  
10          other information to the Board.

11          (m) EVALUATION AND REPORTS.—

12           (1) IN GENERAL.—The Board shall evaluate the  
13           implementation and administration of section 298 of  
14           title 35, United States Code (as added by this Act),  
15           and shall provide periodic and special reports to the  
16           Director, the Secretary of Health and Human Serv-  
17           ices, the National Institutes of Health, the Director  
18           of the Centers for Disease Control, and to the Com-  
19           mittee on the Judiciary of the Senate and the Com-  
20           mittee on the Judiciary of the House of Representa-  
21           tives.

22           (2) DUTIES.—If the Director uses the com-  
23           pensation method under section 298(e)(3)(A) of title  
24           35, United States Code (as added by this Act), the  
25           Board shall—

1 (A) not later than 160 days after the date  
2 of enactment of this Act, begin to gather infor-  
3 mation regarding proposals for the compensa-  
4 tion of patent holders and shall carefully exam-  
5 ine various compensation options;

6 (B) not later than 240 days after the date  
7 of enactment of this Act, submit preliminary  
8 recommendations to the entities and officers de-  
9 scribed under paragraph (1);

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

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

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

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

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

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

3                   (i) the advantages and disadvantages  
4                   which might result from allowing non-  
5                   governmental organizations to be able to  
6                   apply to obtain a compulsory license under  
7                   procedures similar to those set forth in  
8                   that section for such countries where the  
9                   national government declines to apply for  
10                  such a license, including an analysis of  
11                  whether World Trade Organization under-  
12                  standings would permit such an approach  
13                  and how such an approach might be imple-  
14                  mented; and

15                   (ii) whether this Act provides suffi-  
16                   cient economic incentives to generic compa-  
17                   nies for the research and development of  
18                   new generic products.

19           (n) PETITIONS.—The Board shall establish proce-  
20           dures under which persons may petition the Board for the  
21           purpose of evaluating various issues related to the imple-  
22           mentation and administration of section 298 of title 35,  
23           United States Code (as added by this Act).

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

4 (p) APPROPRIATIONS.—

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

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

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

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

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

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

20 (2) USE OF APPROPRIATIONS.—Amounts ap-  
21 propriated under paragraph (1) shall be used for the  
22 expenses and activities of the Board under this sec-  
23 tion, except no more than \$200,000 of such amounts  
24 in each fiscal year may be used for the expenses and  
25 activities of the Office established under section

1       298(c)(B) of title 35, United States Code (as added  
2       by this Act). Such amounts not obligated in any fis-  
3       cal year may be carried over into subsequent fiscal  
4       years, except that any amounts not obligated by  
5       September 30, 2011, shall be provided to the Sec-  
6       retary of the Treasury to be returned to the United  
7       States Treasury.

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

○