

109TH CONGRESS
1ST SESSION

H. R. 4131

To amend title 35, United States Code, to provide for compulsory licensing of certain patented inventions relating to health care emergencies, and to provide that applications under section 505 of the Federal Food, Drug, and Cosmetic Act that are submitted pursuant to such licenses may be approved with immediate effective dates.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 25, 2005

Mr. BROWN of Ohio (for himself, Mr. NADLER, Mr. WAXMAN, Mr. BERRY, Mr. STARK, Mr. ALLEN, and Mr. KUCINICH) introduced the following bill; which was referred to the Committee on the Judiciary, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend title 35, United States Code, to provide for compulsory licensing of certain patented inventions relating to health care emergencies, and to provide that applications under section 505 of the Federal Food, Drug, and Cosmetic Act that are submitted pursuant to such licenses may be approved with immediate effective dates.

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 “Public Health Emer-
3 gency Medicines Act”.

4 **SEC. 2. COMPULSORY LICENSING OF PATENTED INVEN-**
5 **TIONS; APPROVAL BY FOOD AND DRUG AD-**
6 **MINISTRATION OF RELATED APPLICATIONS.**

7 (a) COMPULSORY LICENSING.—

8 (1) IN GENERAL.—Chapter 14 of title 35,
9 United States Code, is amended by adding at the
10 end the following:

11 **“§ 158. Compulsory licensing**

12 “(a) COMPULSORY LICENSING OF PATENTED INVEN-
13 TIONS IN PUBLIC HEALTH EMERGENCY.—In the case of
14 any invention relating to health care the Secretary of
15 Health and Human Services shall have the right to au-
16 thorize use of the subject matter of the patent without
17 authorization of the patent holder or any licensees of the
18 patent holder if the Secretary makes the determination
19 that the invention is needed to address a public health
20 emergency.

21 “(b) COMPENSATION FOR USE OF A PATENT.—In ex-
22 ercising the right under subsection (a) to authorize other
23 use of the subject matter of a patent, the right holder shall
24 be paid reasonable remuneration for the use of the patent.
25 In determining the reasonableness of remuneration for the

1 use of a patent, the Secretary of Health and Human Serv-
2 ices may consider—

3 “(1) evidence of the risks and costs associated
4 with the invention claimed in the patent and the
5 commercial development of products that use the in-
6 vention;

7 “(2) evidence of the efficacy and innovative na-
8 ture and importance to the public health of the in-
9 vention or products using the invention;

10 “(3) the degree to which the invention benefited
11 from publicly funded research;

12 “(4) the need for adequate incentives for the
13 creation and commercialization of new inventions;

14 “(5) the interests of the public as patients and
15 payers for health care services;

16 “(6) the public health benefits of expanded ac-
17 cess to the invention;

18 “(7) the benefits of making the invention avail-
19 able to working families and retired persons;

20 “(8) the need to correct anti-competitive prac-
21 tices; or

22 “(9) other public interest considerations.

23 “(c) EXPORT OF HEALTH CARE PRODUCTS IN PUB-
24 LIC HEALTH EMERGENCIES.—The Secretary may author-
25 ize the use of a patent, without authorization of the patent

1 holder or any licensees of the patent holder, to export
2 medicines or other health care products that are needed
3 to address global public health emergencies, when the le-
4 gitimate rights of the patent holder are protected in the
5 export market.

6 “(d) CONSISTENCY WITH TRIPS.—The Secretary of
7 Health and Human Services may adopt regulations to im-
8 plement the purposes of this section, consistent with the
9 Agreement on Trade-Related Aspects of Intellectual Prop-
10 erty Rights referred to in section 101(d)(15) of the Uru-
11 guay Round Agreements Act.

12 “(e) DEFINITION.—In this section, the term ‘health
13 care product’ means any drug or device (as those terms
14 are defined in section 201 of the Federal Food, Drug, and
15 Cosmetic Act), any biological product (as defined in sec-
16 tion 351 of the Public Health Service Act), or any tech-
17 nology or process to the extent the technology or process
18 is applied to health or health care.”.

19 (2) CONFORMING AMENDMENT.—The table of
20 sections for chapter 14 of title 35, United States
21 Code, is amended by adding at the end the following
22 new item:

“158. Compulsory licensing.”.

23 (b) RELATED APPLICATIONS UNDER FEDERAL
24 FOOD, DRUG, AND COSMETIC ACT.—If a person author-
25 ized to manufacture a drug under section 158 of title 35,

1 United States Code, seeks approval of the drug under sec-
2 tion 505 of the Federal Food, Drug, and Cosmetic Act,
3 the Secretary of Health and Human Services may approve
4 the drug with an immediate effective date notwithstanding
5 any limitation on approval pursuant to subsection (c)(3),
6 (j)(4)(D), or (j)(5)(B) of such section.

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