

109TH CONGRESS  
1ST SESSION

# H. R. 4102

To amend title 35, United States Code, to provide for compulsory licensing of certain patented inventions relating to health care emergencies.

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## IN THE HOUSE OF REPRESENTATIVES

OCTOBER 20, 2005

Mr. BROWN of Ohio introduced the following bill; which was referred to the Committee on the Judiciary

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## A BILL

To amend title 35, United States Code, to provide for compulsory licensing of certain patented inventions relating to health care emergencies.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Public Health Emer-  
5 gency Medicines Act”.

6 **SEC. 2. COMPULSORY LICENSING OF PATENTED INVEN-**  
7 **TIONS.**

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

1 **“§ 158. Compulsory licensing**

2       “(a) COMPULSORY LICENSING OF PATENTED INVEN-  
3 TIONS IN PUBLIC HEALTH EMERGENCY.—In the case of  
4 any invention relating to health care the Secretary of  
5 Health and Human Services shall have the right to au-  
6 thorize use of the subject matter of the patent without  
7 authorization of the patent holder or any licensees of the  
8 patent holder if the Secretary makes the determination  
9 that the invention is needed to address a public health  
10 emergency.

11       “(b) COMPENSATION FOR USE OF A PATENT.—In ex-  
12 ercising the right under subsection (a) to authorize other  
13 use of the subject matter of a patent, the right holder shall  
14 be paid reasonable remuneration for the use of the patent.  
15 In determining the reasonableness of remuneration for the  
16 use of a patent, the Secretary of Health and Human Serv-  
17 ices may consider—

18               “(1) evidence of the risks and costs associated  
19 with the invention claimed in the patent and the  
20 commercial development of products that use the in-  
21 vention;

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

25               “(3) the degree to which the invention benefited  
26 from publicly funded research;

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

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

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

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

9           “(8) the need to correct anti-competitive prac-  
10          tices; or

11          “(9) other public interest considerations.

12          “(c) EXPORT OF HEALTH CARE PRODUCTS IN PUB-  
13          LIC HEALTH EMERGENCIES.—The Secretary may author-  
14          ize the use of a patent, without authorization of the patent  
15          holder or any licensees of the patent holder, to export  
16          medicines or other health care products that are needed  
17          to address global public health emergencies, when the le-  
18          gitimate rights of the patent holder are protected in the  
19          export market.

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

1       “(e) DEFINITION.—In this section, the term ‘health  
2 care product’ means any drug or device (as those terms  
3 are defined in section 201 of the Federal Food, Drug, and  
4 Cosmetic Act), any biological product (as defined in sec-  
5 tion 351 of the Public Health Service Act), or any tech-  
6 nology or process to the extent the technology or process  
7 is applied to health or health care.”.

8       (b) CONFORMING AMENDMENT.—The table of sec-  
9 tions for chapter 14 of title 35, United States Code, is  
10 amended by adding at the end the following new item:

“158. Compulsory licensing.”.

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