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(Original Signature of Member)

107TH CONGRESS
1ST SESSION

H. R. _____

IN THE HOUSE OF REPRESENTATIVES

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

A BILL

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

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 “Affordable Prescription
5 Drugs and Medical Inventions Act”.



1 **SEC. 2. COMPULSORY LICENSING OF PATENTED INVEN-**
2 **TIONS.**

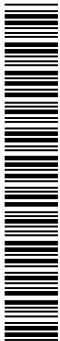
3 (a) IN GENERAL.—Chapter 14 of title 35, United
4 States Code, is amended by adding at the end the fol-
5 lowing:

6 **“§ 158. Compulsory licensing**

7 “(a) COMPULSORY LICENSING OF PATENTED INVEN-
8 TIONS.—In the case of any invention relating to health
9 care, in which a patent holder, contractor, exclusive li-
10 censee, or assignee has acquired title under this title, the
11 Secretary of Health and Human Services and the Federal
12 Trade Commission shall each have the right to establish
13 other use of the subject matter of the patent without au-
14 thorization of the right holder if the Secretary or the Com-
15 mission (as the case may be) makes the determination de-
16 scribed in subsection (b).

17 “(b) DETERMINATION.—The determination referred
18 to in subsection (a) with respect to an invention claimed
19 in a patent is a determination that one or more of the
20 following applies:

21 “(1) The patent holder, contractor, licensee, or
22 assignee referred to in subsection (a) has not taken,
23 or is not expected to take within a reasonable time,
24 effective steps to achieve practical application of the
25 subject invention in a field of use.



1 “(2) Establishing other use of the subject mat-
2 ter of the patent is necessary to alleviate health or
3 safety needs which are not adequately satisfied by
4 the patent holder, contractor, licensee, or assignee.

5 “(3) The patent holder has engaged in anti-
6 competitive behavior. Such determination may in-
7 clude, but is not limited to, a determination that—

8 “(A) the patented invention is priced ex-
9 cessively relative to the median price for devel-
10 oped countries or by other reasonable stand-
11 ards, and that such pricing contravenes the
12 public interest; or

13 “(B) the patented invention is an essential
14 component of a health care product that in-
15 volves patents, and the licensing terms for the
16 patent on the invention are not reasonable and
17 deter innovation or product development, con-
18 trary to the public interest.

19 “(4) An invention covered by a patent (the ‘sec-
20 ond patent’) cannot be exploited without infringing
21 upon the patent described in subsection (a) (the
22 ‘first patent’), insofar as the invention claimed in
23 the second patent involves an important technical
24 advance.



1 “(5) The invention claimed in the patent is
2 needed for research purposes that would benefit the
3 public health, and is not licensed on reasonable
4 terms and conditions.

5 “(c) FACTORS IN AUTHORIZING OTHER USE.—In ex-
6 ercising the right under subsection (a) to authorize other
7 use of the subject matter of a patent, the following shall
8 apply:

9 “(1) In cases involving commercial use, such
10 use may be permitted only if, prior to such use, the
11 proposed user has made efforts to obtain authoriza-
12 tion from the right holder on reasonable commercial
13 terms and conditions and such efforts have not been
14 successful within a reasonable period of time.

15 “(2) The right holder shall be paid adequate re-
16 muneration for the use of the patent.

17 “(3) Where such use is authorized under sub-
18 section (b)(4), the owner of the first patent shall be
19 entitled to a license on reasonable terms to use the
20 invention claimed in the second patent.

21 “(d) CONSIDERATIONS FOR DETERMINING REMU-
22 NERATION FOR USE OF A PATENT.—In determining the
23 reasonableness of licensing terms and the remuneration
24 for the use of a patent under subsection (c), the Secretary



1 of Health and Human Services or the Federal Trade Com-
2 mission (as the case may be) shall consider—

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

6 “(2) the efficacy and innovative nature and im-
7 portance to the public health of the invention or
8 products using the invention;

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

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

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

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

17 “(e) CONSISTENCY WITH TRIPS.—The Secretary of
18 Health and Human Services and the Federal Trade Com-
19 mission may adopt regulations jointly to implement the
20 purposes of this section, consistent with the Agreement
21 on Trade-Related Aspects of Intellectual Property Rights
22 referred to in section 101(d)(15) of the Uruguay Round
23 Agreements Act.

24 “(f) DEFINITION.—In this section, the term ‘health
25 care product’ means any drug or device (as those terms



1 are defined in section 201 of the Federal Food, Drug, and
2 Cosmetic Act), any biological product (as defined in sec-
3 tion 351 of the Public Health Service Act), or any tech-
4 nology or process to the extent the technology or process
5 is applied to health or health care.”.

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

“158. Compulsory licensing.”.

9 **SEC. 3. REPORT ON PHARMACEUTICAL COSTS AND SALES.**

10 (a) REPORT REQUIREMENT.—Any person engaged in
11 the manufacture and sale of any drug approved under sec-
12 tion 505 or 512 of the Federal Food, Drug, and Cosmetic
13 Act (21 U.S.C. 355, 360b) for which a patent is still in
14 effect shall report to the Secretary of Health and Human
15 Services annually an audit of all financial information rel-
16 evant to the pricing of that drug nationally and inter-
17 nationally, including, in formats specified by the Sec-
18 retary, an accounting of the costs allocated to research
19 and development of that drug, as well as costs allocated
20 to other research and development activities. The Sec-
21 retary shall transmit the reports filed under this sub-
22 section to the Congress.

23 (b) CIVIL PENALTY.—

24 (1) PENALTY.—Any person who fails to submit
25 a report under subsection (a) by the date specified



1 pursuant to subsection (c) shall be liable to the
2 United States for a civil penalty in an amount not
3 to exceed \$25,000 for each such violation. Each day
4 such a violation continues shall, for purposes of this
5 subsection, constitute a separate violation of sub-
6 section (a).

7 (2) PROCEDURES.—A civil penalty for a viola-
8 tion of subsection (a) shall be assessed by order of
9 the Secretary of Health and Human Services after
10 opportunity (provided in accordance with this para-
11 graph) for a hearing in accordance with section 554
12 of title 5, United States Code. Before issuing such
13 an order, the Secretary shall give written notice to
14 the person to be assessed a civil penalty under such
15 order of the Secretary's proposal to issue such order
16 and provide such person an opportunity to request,
17 within 15 days of the date the notice is received by
18 such person, such a hearing on the order.

19 (3) JUDICIAL REVIEW.—Any person who re-
20 quested a hearing in accordance with paragraph (2)
21 a hearing and who is aggrieved by an order assess-
22 ing a civil penalty pursuant to the hearing may seek
23 judicial review of the order by filing a petition for
24 judicial review in the appropriate United States dis-



1 trict court not later than 30 days after the date on
2 which the order was issued.

3 (4) FAILURE TO PAY PENALTY.—If any person
4 fails to pay an assessment of a civil penalty—

5 (A) after the order making the assessment
6 has become a final order and if such person
7 does not file a petition for judicial review of the
8 order, or

9 (B) after a court in an action for judicial
10 review of the order has entered a final judg-
11 ment in favor of the Secretary of Health and
12 Human Services,

13 the Attorney General shall recover the amount as-
14 sessed (plus interest at currently prevailing rates
15 from the date of the expiration of the 30-day period
16 referred to in paragraph (3) or the date of such final
17 judgment, as the case may be) in an action brought
18 in any appropriate district court of the United
19 States. In such an action, the validity, amount, and
20 appropriateness of such penalty shall not be subject
21 to review.

22 (c) REGULATIONS.—The Secretary of Health and
23 Human Services shall issue such regulations as are nec-
24 essary to carry out this section, including specifying the



- 1 dates by which the reports under subsection (a) must be
- 2 submitted.

