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107TH CONGRESS
1ST SESSION

H. R. 1708

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

IN THE HOUSE OF REPRESENTATIVES

MAY 3, 2001

Mr. BROWN of Ohio (for himself, Mr. BERRY, Mr. STARK, Mr. ALLEN, Mr. SANDERS, Mr. BONIOR, Ms. LEE, Mr. LATOURETTE, Mr. WYNN, Mr. LANGEVIN, Mr. DAVIS of Illinois, Mr. BARRETT, Mr. BALDACCI, Ms. SCHAKOWSKY, Mr. GREEN of Texas, Mrs. JONES of Ohio, Mr. NADLER, Mr. LEWIS of Georgia, Mr. GEORGE MILLER of California, and Mr. DEFAZIO) 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

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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.

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 ''Affordable Prescription Drugs and Medical Inventions Act''.

SEC. 2. COMPULSORY LICENSING OF PATENTED INVENTIONS.

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

"§ 158. Compulsory licensing

''(a) COMPULSORY LICENSING OF PATENTED INVENTIONS.—In the case of any invention relating to health care, in which a patent holder, contractor, exclusive licensee, or assignee has acquired title under this title, the Secretary of Health and Human Services and the Federal Trade Commission shall each have the right to establish other use of the subject matter of the patent without authorization of the right holder if the Secretary or the Commission (as the case may be) makes the determination described in subsection (b).

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

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

''(2) Establishing other use of the subject matter of the patent is necessary to alleviate health or safety needs which are not adequately satisfied by the patent holder, contractor, licensee, or assignee.

''(3) The patent holder has engaged in anti-competitive behavior. Such determination may include, but is not limited to, a determination that—

''(A) the patented invention is priced excessively relative to the median price for developed countries or by other reasonable standards, and that such pricing contravenes the public interest; or

''(B) the patented invention is an essential component of a health care product that involves patents, and the licensing terms for the patent on the invention are not reasonable and deter innovation or product development, contrary to the public interest.

''(4) An invention covered by a patent (the 'second patent') cannot be exploited without infringing upon the patent described in subsection (a) (the 'first patent'), insofar as the invention claimed in the second patent involves an important technical advance.

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

''(c) FACTORS IN AUTHORIZING OTHER USE.—In exercising the right under subsection (a) to authorize other use of the subject matter of a patent, the following shall apply:

''(1) In cases involving commercial use, such use may be permitted only if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and such efforts have not been successful within a reasonable period of time.

''(2) The right holder shall be paid adequate remuneration for the use of the patent.

''(3) Where such use is authorized under subsection (b)(4), the owner of the first patent shall be entitled to a license on reasonable terms to use the invention claimed in the second patent.

''(d) CONSIDERATIONS FOR DETERMINING REMUNERATION FOR USE OF A PATENT.—In determining the reasonableness of licensing terms and the remuneration for the use of a patent under subsection (c), the Secretary

of Health and Human Services or the Federal Trade Commission (as the case may be) shall consider—

''(1) the risks and costs associated with the invention claimed in the patent and the commercial development of products that use the invention;

''(2) the efficacy and innovative nature and importance to the public health of the invention or products using the invention;

''(3) the degree to which the invention benefited from publicly funded research;

''(4) the need for adequate incentives for the creation and commercialization of new inventions;

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

''(6) the public health benefits of expanded access to the invention.

''(e) CONSISTENCY WITH TRIPS.—The Secretary of Health and Human Services and the Federal Trade Commission may adopt regulations jointly to implement the purposes of this section, consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights referred to in section 101(d)(15) of the Uruguay Round Agreements Act.

''(f) DEFINITION.—In this section, the term 'health care product' means any drug or device (as those terms

are defined in section 201 of the Federal Food, Drug, and Cosmetic Act), any biological product (as defined in section 351 of the Public Health Service Act), or any technology or process to the extent the technology or process is applied to health or health care.''.

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

''158. Compulsory licensing.''.

SEC. 3. REPORT ON PHARMACEUTICAL COSTS AND SALES.

(a) REPORT REQUIREMENT.—Any person engaged in the manufacture and sale of any drug approved under section 505 or 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360b) for which a patent is still in effect shall report to the Secretary of Health and Human Services annually an audit of all financial information relevant to the pricing of that drug nationally and internationally, including, in formats specified by the Secretary, an accounting of the costs allocated to research and development of that drug, as well as costs allocated to other research and development activities. The Secretary shall transmit the reports filed under this subsection to the Congress.

(b) CIVIL PENALTY.—

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

pursuant to subsection (c) shall be liable to the United States for a civil penalty in an amount not to exceed $25,000 for each such violation. Each day such a violation continues shall, for purposes of this subsection, constitute a separate violation of subsection (a).

(2) PROCEDURES.—A civil penalty for a violation of subsection (a) shall be assessed by order of the Secretary of Health and Human Services after opportunity (provided in accordance with this paragraph) for a hearing in accordance with section 554 of title 5, United States Code. Before issuing such an order, the Secretary shall give written notice to the person to be assessed a civil penalty under such order of the Secretary's proposal to issue such order and provide such person an opportunity to request, within 15 days of the date the notice is received by such person, such a hearing on the order.

(3) JUDICIAL REVIEW.—Any person who requested a hearing in accordance with paragraph (2) a hearing and who is aggrieved by an order assessing a civil penalty pursuant to the hearing may seek judicial review of the order by filing a petition for judicial review in the appropriate United States dis-

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

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

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

(B) after a court in an action for judicial review of the order has entered a final judgment in favor of the Secretary of Health and Human Services,

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

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

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

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