

106TH CONGRESS
1ST SESSION

H. R. 2927

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

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 23, 1999

Mr. BROWN of Ohio (for himself, Mr. BERRY, Mr. STARK, Mr. ALLEN, Ms. SCHAKOWSKY, Mr. SANDERS, Mr. KUCINICH, Mr. STRICKLAND, Mr. BARRETT of Wisconsin, and Mr. WYNN) introduced the following bill; which was referred to the Committee on the Judiciary, and in addition to the Committee on 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.

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 Act”.

1 **SEC. 2. COMPULSORY LICENSING OF CERTAIN PATENTED**
2 **MEDICAL INVENTIONS.**

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 CERTAIN PAT-
8 ENTED MEDICAL INVENTIONS.—In the case of any sub-
9 ject invention relating to health in which a patent holder,
10 contractor, exclusive licensee, or assignee has acquired
11 title under this title, the Secretary of Health and Human
12 Services shall have the right to establish other use of the
13 subject matter of the patent without authorization of the
14 right holder if the Secretary makes the determination de-
15 scribed in subsection (b).

16 “(b) DETERMINATION.—The determination of the
17 Secretary of Health and Human Services referred to in
18 subsection (a) is a determination that—

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

24 “(2) such compulsory license is necessary to al-
25 leviate health or safety needs which are not ade-

1 quately satisfied by the patent holder, contractor, li-
2 censee, or assignee; or

3 “(3) the patented material is priced higher than
4 may be reasonably expected based on criteria devel-
5 oped by the Secretary of Commerce.

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

10 “(1) Authorization of such use shall be consid-
11 ered on its individual merits.

12 “(2) Such use may only be permitted if, prior
13 to such use, the proposed user has made efforts to
14 obtain authorization from the right holder on rea-
15 sonable commercial terms and conditions and that
16 such efforts have not been successful within a rea-
17 sonable period of time. This requirement may be
18 waived in the case of a national emergency or other
19 circumstances of extreme urgency or in cases of pub-
20 lic noncommercial use. In situations of national
21 emergency or other circumstances of extreme ur-
22 gency, the right holder shall, nevertheless, be noti-
23 fied as soon as reasonably practicable. In the case
24 of public noncommercial use, where the Government
25 or (if applicable) a contractor of the Government,

1 without making a patent search, knows or has de-
2 monstrable grounds to know that a valid patent is
3 or will be used by or for the Government, the right
4 holder shall be informed promptly.

5 “(3) Such use shall be nonexclusive.

6 “(4) Such use shall be nonassignable, except
7 with that part of the enterprise or goodwill which
8 enjoys such use.

9 “(5) Authorization for such use shall be liable,
10 subject to adequate protection of the legitimate in-
11 terests of the persons so authorized, to be termi-
12 nated if and when the circumstances which led to it
13 cease to exist and are unlikely to recur. The com-
14 petent authority shall have the authority to review,
15 upon appropriate request, the continued existence of
16 such circumstances.

17 “(6) The right holder shall be paid adequate re-
18 muneration in the circumstances of each case, taking
19 into account the economic value of the authorization.

20 “(7) The legal validity of any decision relating
21 to the authorization of such use shall be subject to
22 judicial review or other independent review by a dis-
23 tinct Federal authority.

24 “(8) Any decision relating to the remuneration
25 provided in respect of such use shall be subject to

1 judicial review or other independent review by a dis-
2 tinct Federal authority.

3 “(9) The condition set forth in paragraph (2)
4 is not applicable where such use is permitted to rem-
5 edy a practice determined after judicial or adminis-
6 trative process to be anticompetitive. The need to
7 correct anticompetitive practices may be taken into
8 account in determining the amount of remuneration
9 in such cases. The competent authorities shall have
10 the authority to refuse termination of authorization
11 if and when the conditions which led to such author-
12 ization are likely to recur.

13 “(10) Where such use is authorized to permit
14 the exploitation of a patent (‘the 2nd patent’) which
15 cannot be exploited without infringing another pat-
16 ent (‘the 1st patent’), the following additional condi-
17 tions shall apply:

18 “(A) The invention claimed in the 2nd pat-
19 ent shall involve an important technical advance
20 of considerable economic significance in relation
21 to the invention claimed in the 1st patent.

22 “(B) The owner of the 1st patent shall be
23 entitled to a cross-license on reasonable terms
24 to use the invention claimed in the 2nd patent.

1 “(C) The use authorized in respect of the
 2 1st patent shall be nonassignable except with
 3 the assignment of the 2nd patent.

4 “(d) CONSISTENCY WITH TRIPS.—Regulations
 5 adopted under subsection (a) shall be consistent with pro-
 6 visions of the Agreement on Trade-Related Aspects of In-
 7 tellectual Property Rights referred to in section
 8 101(d)(15) of the Uruguay Round Agreements Act.”.

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

“158. Compulsory licensing.”.

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

13 (a) REPORT REQUIREMENT.—Any person engaged in
 14 the manufacture and sale of any drug approved under sec-
 15 tion 505 or 512 of the Federal Food, Drug, and Cosmetic
 16 Act (21 U.S.C. 355, 360b) for which a patent is still in
 17 effect shall report to the Congress annually an audit of
 18 all financial information relevant to the pricing of that
 19 drug nationally and internationally, including the costs of
 20 research and development, sufficient to assess the reason-
 21 ableness of that pricing, in accordance with specifications
 22 developed by the Secretary of Commerce in consultation
 23 with the Commissioner of Food and Drugs.

24 (b) DISQUALIFICATION FROM PARTICIPATION IN
 25 FEDERAL PROGRAMS AS PENALTY FOR NONCOMPLI-

1 ANCE.—In the case of a person who the Secretary of Com-
2 merce determines has failed to submit a report required
3 under subsection (a) on a timely basis, the person shall
4 be ineligible to receive payment from the Federal Govern-
5 ment or under any Federal program (including under the
6 medicare and medicaid programs) for any prescription
7 drug or biologic it manufactures or sells until the date the
8 Secretary determines that such failure has ceased.

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