

104TH CONGRESS
2D SESSION

S. 2154

To provide equitable treatment for pharmaceutical patents on certain pipeline drugs in order to encourage continued development of new drugs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 28, 1996

Mr. SPECTER (for himself, Mr. JOHNSTON, Mr. HEFLIN, and Mr. SANTORUM) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

A BILL

To provide equitable treatment for pharmaceutical patents on certain pipeline drugs in order to encourage continued development of new drugs, and for other purposes.

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 “Pharmaceutical Equity
5 Act of 1996”.

6 **SEC. 2. EXTENSION OF PATENTS RELATING TO CERTAIN**
7 **PIPELINE DRUGS.**

8 (a) IN GENERAL.—The term of any patent in force
9 on September 24, 1984, and on the effective date of this

1 Act, that claims a drug product, a method of using a drug
2 product, or a method of manufacturing a drug product,
3 shall be extended pursuant to subsection (b) from the expi-
4 ration date determined pursuant to section 154 of title 35,
5 United States Code, if:

6 (1) an exemption described in section
7 156(g)(1)(B)(i) or section 156(g)(4)(B)(i) of title
8 35, United States Code, became effective for the
9 drug product before September 24, 1984;

10 (2) the regulatory review period set forth in sec-
11 tion 156(g)(1)(B) or section 156(g)(4)(B) of title
12 35, United States Code, for the drug product, ex-
13 ceeded 120 months; and

14 (3) the regulatory review period described in
15 section 156(g)(1)(B)(ii) or section 156(g)(4)(B)(ii)
16 of title 35, United States Code, for the drug prod-
17 uct, exceeded 60 months.

18 (b) TERM.—The term of any patent described in sub-
19 section (a) shall be extended by a period of two years.

20 (c) INFRINGEMENT.—During any extension granted
21 pursuant to subsection (b), the rights in the patent so ex-
22 tended shall be determined in accordance with section
23 156(b) of title 35, United States Code.

1 (d) DEFINITION.—For the purpose of the Act, the
2 term “drug product” shall be defined in accordance with
3 section 156(f)(2) of title 35, United States Code.

4 (e) NOTIFICATION.—No later than 90 days after the
5 date of enactment of this Act, the patentee of a patent
6 extended pursuant to subsection (b) shall notify the Com-
7 missioner of Patents and Trademarks of the number of
8 any patent extended pursuant to subsection (b). On re-
9 ceipt of this notice, the Commissioner shall confirm the
10 patent extension by placing a notice thereof in the official
11 file of the patent, and publishing an appropriate notice
12 of this extension in the Official Gazette of the Patent and
13 Trademark Office.

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