104TH CONGRESS
1ST SESSION

S. 1277

To provide equitable relief for the generic drug industry, and for other purposes.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 27 (legislative day, SEPTEMBER 25), 1995

Mr. BROWN (for himself and Mr. PRYOR) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

---

A BILL

To provide equitable relief for the generic drug industry, and for other purposes.

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 ''Prescription Drug Equity Act of 1995''.

SEC. 2. EQUITABLE TREATMENT FOR THE GENERIC DRUG INDUSTRY.

(a) SENSE OF THE SENATE.—It is the sense of the Senate that the generic drug industry should be provided equitable relief in the same manner as other industries are

provided with such relief under the patent transitional provisions of section 154(c) of title 35, United States Code, as amended by section 532 of the Uruguay Round Agreements Act of 1994 (Public Law 103–465; 108 Stat. 4983).

(b) APPROVAL OF APPLICATIONS OF GENERIC DRUGS.—For purposes of acceptance and consideration by the Secretary of an application under subsections (b), (c), and (j) of section 505, and subsections (b), (c), and (n) of section 512, of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 (b), (c), and (j), and 360b (b), (c), and (n)), the expiration date of a patent that is the subject of a certification under section 505(b)(2)(A) (ii), (iii), or (iv), section 505(j)(2)(A)(vii) (II), (III), or (IV), or section 512(n)(1)(H) (ii), (iii), or (iv) of such Act, respectively, made in an application submitted prior to June 8, 1995, or in an application submitted on or after that date in which the applicant certifies that substantial investment was made prior to June 8, 1995, shall be deemed to be the date on which such patent would have expired under the law in effect on the day preceding December 8, 1994.

(c) MARKETING GENERIC DRUGS.—The remedies of section 271(e)(4) of title 35, United States Code, shall not apply to acts—

(1) that were commenced, or for which a substantial investment was made, prior to June 8, 1995; and

(2) that became infringing by reason of section 154(c)(1) of such title, as amended by section 532 of the Uruguay Round Agreements Act (Public Law 103–465; 108 Stat. 4983).

(d) EQUITABLE REMUNERATION.—For acts described in subsection (c), equitable remuneration of the type described in section 154(c)(3) of title 35, United States Code, as amended by section 532 of the Uruguay Round Agreements Act (Public Law 103–465; 108 Stat. 4983) shall be awarded to a patentee only if there has been—

(1) the commercial manufacture, use, offer to sell, or sale, within the United States of an approved drug that is the subject of an application described in subsection (b); or

(2) the importation by the applicant into the United States of an approved drug or of active ingredient used in an approved drug that is the subject of an application described in subsection (b).

SEC. 3. APPLICABILITY.

The provisions of this Act shall govern—

(1) the approval or the effective date of approval of applications under section 505(b)(2), 505(j), 507, or 512(n), of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 (b)(2) and (j), 357, and 360b(n)) submitted on or after the date of enactment of this Act; and

(2) the approval or effective date of approval of all pending applications that have not received final approval as of the date of enactment of this Act.

○