Calendar No. 640

104TH CONGRESS
2D SESSION

S. 1277

[Report No. 104–394]

A BILL

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

OCTOBER 1, 1996

Reported with an amendment

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IN THE SENATE OF THE UNITED STATES

SEPTEMBER 27 (legislative day, SEPTEMBER 25), 1995

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

OCTOBER 1, 1996

Reported by Mr. HATCH, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

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 in-

~~gredient 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.~~

SECTION 1. SHORT TITLE.

This Act may be cited as the "Pharmaceutical Industry Special Equity Act of 1996".

SEC. 2. APPROVAL OF GENERIC DRUGS.

(a) IN GENERAL.—With respect to any patent, the term of which is modified under section 154(c)(1) of title 35, United States Code, as amended by the Uruguay Round Agreements Act (Public Law 103–465; 108 Stat. 4983), the remedies of section 271(e)(4) of title 35, United States Code, shall not apply if—

(1) such patent is the subject of a certification described under—

(A) section 505 (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV)); or

(B) section 512(n)(1)(H)(iv) of such Act (21 U.S.C. 360b(n)(1)(H)(iv));

(2) on or after the date of enactment of this section, such a certification is made in an application that was filed under section 505 or 512 of the Federal Food, Drug, and Cosmetic Act and accepted for filing by the Food and Drug Administration prior to June 8, 1995; and

(3) a final order, from which no appeal is pending or may be made, has been entered in an action brought under chapter 28 or 29 of title 35, United States Code—

(A) finding that the person who submitted such certification made a substantial investment of the type described under section 154(c)(2) of title 35, United States Code, as amended by the Uruguay Round Agreements Act; and

(B) establishing the amount of equitable remuneration of the type described under section 154(c)(3) of title 35, United States Code, as amended by the Uruguay Round Agreements Act,

that is required to be paid by the person who submitted such certification to the patentee for the product that is the subject of the certification.

(b) DETERMINATION OF SUBSTANTIAL INVESTMENT.—In determining whether a substantial investment has been made in accordance with this section, the court shall find that—

(1) a complete application submitted under section 505 or 512 of the Federal Food, Drug, and Cosmetic Act was found by the Secretary of Health and Human Services on or before June 8, 1995 to be sufficiently complete to permit substantive review; and

(2) the total sum of the investment made by the person submitting such an application—

(A) is specifically related to the research, development, manufacture, sale, marketing, or other activities undertaken in connection with, the product covered by such an application; and

(B) does not solely consist of that person's expenditures related to the development and submission of the information contained in such an application.

(c) COMPENSATION.—(1) In connection with the entry of the order described in subsection (a) (3), the court may order that the patentee pay equitable compensation, to the

person that submitted such an application, for the period commencing on the date a certification described in subsection (a)(1) was first made and ending on the date of the entry of the order described in subsection (a)(3).

(2) The court may order payment of equitable compensation under paragraph (1) if marketing of the product that is the subject of the certification was delayed as a result of an action brought pursuant to this section.

(d) EFFECTIVE DATE OF APPROVAL OF APPLICATION.—In no event shall the Food and Drug Administration make the approval of an application under sections 505 or 512 of the Federal Food, Drug, and Cosmetic Act, which is subject to the provisions of this Act, effective prior to the entry of the order described in subsection (a)(3).

(e) APPLICABILITY.—The provisions of this section shall not apply to any patent the term of which, inclusive of any restoration period provided under section 156 of title 35, United States Code, would have expired on or after June 8, 1998, under the law in effect on the date before December 8, 1994.

SEC. 3. APPLICATION OF CERTAIN BENEFITS AND TERM EXTENSIONS TO ALL PATENTS IN FORCE ON A CERTAIN DATE.

For the purposes of this Act and the provisions of title 35, United States Code, all patents in force on June 8,

1995, including those in force by reason of section 156 of title 35, United States Code, are entitled to the full benefit of the Uruguay Round Agreements Act of 1994 and any extension granted before such date under section 156 of title 35, United States Code.

SEC. 4. EXTENSION OF PATENTS RELATING TO NONSTEROIDAL ANTI-INFLAMMATORY DRUGS.

(a) IN GENERAL.—Notwithstanding section 154 of title 35, United States Code, the term of patent shall be extended for any patent which encompasses within its scope of composition of matter known as a nonsteroidal anti-inflammatory drug if—

(1) during the regulatory review of the drug by the Food and Drug Administration the patentee—

(A) filed a new drug application in 1982 under section 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355); and

(B) awaited approval by the Food and Drug Administration for at least 96 months; and

(2) such new drug application was approved in 1991.

(b) TERM.—The term of any patent described in subsection (a) shall be extended from its current expiration date for a period of 2 years.

(c) NOTIFICATION.—No later than 90 days after the date of enactment of this Act, the patentee of any patent described in subsection (a) shall notify the Commissioner of Patents and Trademarks of the number of any patent extended under such subsection. On receipt of such notice, the Commissioner shall confirm such extension by placing a notice thereof in the official file of such patent and publishing an appropriate notice of such extension in the Official Gazette of the Patent and Trademark Office.

SEC. 5. SENSE OF THE SENATE.

It is the sense of the Senate that litigation pursuant to this Act will be concluded as expeditiously as possible.