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106TH CONGRESS
1ST SESSION

H. R. 1598

To provide a patent term restoration review procedure for certain drug products.

IN THE HOUSE OF REPRESENTATIVES

APRIL 28, 1999

Mr. BRYANT (for himself, Mr. MCDERMOTT, Mrs. BONO, Mr. DUNCAN, Mr. WICKER, Mr. JENKINS, Mr. FRANKS of New Jersey, Mr. FORD, Mr. BLUNT, Mr. WAMP, Mr. HOYER, Mr. ROTHMAN, Mr. MENENDEZ, Mr. GORDON, Mrs. TAUSCHER, Mr. DELAHUNT, Ms. JACKSON-LEE of Texas, Ms. ESHOO, Mr. PASTOR, Mr. CONYERS, Mr. SMITH of Texas, Mr. PAYNE, Mrs. EMERSON, Mr. HILLEARY, and Mr. FRELINGHUYSEN) introduced the following bill; which was referred to the Committee on the Judiciary

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A BILL

To provide a patent term restoration review procedure for certain drug products.

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 "Patent Fairness Act of 1999".

SEC. 2. PATENT TERM RESTORATION REVIEW PROCEDURE FOR CERTAIN DRUG PRODUCTS.

(a) PATENT TERM RESTORATION.—

(1) IN GENERAL.—Chapter 14 of title 35, United States Code, is amended by inserting after section 155A the following new section:

"§ 155B. Patent term restoration review procedure for certain drug products

''(a) DEFINITIONS.—For purposes of this section—

''(1) the term 'Commissioner' means the Commissioner of Patents and Trademarks; and

(2) the term 'drug product' has the meaning given such term under section 156(f)(2)(A).

''(b) SPECIAL PATENT TERM REVIEW PROCEDURE.—

''(1) IN GENERAL.—The term of any patent, in force on September 24, 1984, and on the date of the filing of an application under this section, that claims—

''(A) a drug product,

''(B) a method of using a drug product, or

''(C) a method of manufacturing a drug product,

shall be restored under paragraph (4) from the expiration date of the patent term determined under section 154 (including any extension granted under sec-

tion 156) if the Commissioner determines that the standards under paragraph (2) have been met.

''(2) STANDARDS.—Upon application, filed under paragraph (6), by the owner of record of a patent described in paragraph (1) or its agent and consideration of the application and all materials submitted by parties that would be aggrieved by grant of the restoration of the term of such patent, the term of such patent shall be restored if the Commissioner determines that—

''(A) the period set forth in section 156(g)(1)(B)(ii) for the drug product exceeded 60 months; and

''(B) there is no substantial evidence overcoming the rebuttable presumption that the applicant for patent term restoration for the drug product acted with due diligence (as such term is defined in section 156(d)(3)) during the period referred to in section 156(g)(1)(B)(ii).

If the Commissioner determines there is substantial evidence that the applicant for patent term restoration did not act with due diligence during a part of the period referred to in section 156(g)(1)(B)(ii) that part shall be deducted from the total amount

of time in such period for purposes of paragraph (4).

''(3) RECORDS.—The Commissioner may request and obtain relevant records from the Food and Drug Administration to verify the facts underlying the Commissioner's determinations under paragraph (2). Such records shall be afforded the same protections against public disclosure that apply to such records when in the possession of the Food and Drug Administration.

''(4) RESTORATION TERM.—If the Commissioner determines that the standards in paragraph (2) have been met for a patent, the term of such patent shall be restored for a restoration period equal to the period set forth in section 156(g)(1)(B)(ii) for the drug product that is the subject of an application under paragraph (6), except that—

''(A) the restoration period shall be reduced by any deduction made pursuant to paragraph (2);

''(B) if the sum of—

''(i) the remaining term of such patent after the date of the approval of the drug product covered by the patent under

the provision of law under which the regulatory review occurred, and

"(ii) the restoration period as revised under subparagraph (A),

exceeds 14 years, the restoration period shall be reduced so that the total of such periods does not exceed 14 years; and

"(C) the restoration period, after any adjustment required by subparagraph (A) or (B) plus any previous extension of the patent term under section 156(c), shall not exceed 5 years.

"(5) INFRINGEMENT.—During the period of any restoration granted under this subsection, the rights derived from a patent the term of which is restored shall be determined in accordance with sections 156(b) and 271.

"(6) PROCEDURE.—

"(A) TIME FOR FILING.—An application under this section shall be filed with the Commissioner within 90 days after the date of the enactment of this section.

"(B) FILING AND DETERMINATION.—Upon the filing of an application to the Commissioner under this section—

"(i) the Commissioner shall publish within 30 days of its filing a notice in the Federal Register of receipt of the application;

"(ii) any party who would be aggrieved by the granting of a patent term restoration under the application may submit comments on the application within the 30-day period beginning on the date of publication of the notice under clause (i);

"(iii) within 7 days following the expiration of the 30-day comment period, the Commissioner shall forward a copy of all comments received to the applicant who shall be entitled to submit a response to such comments to the Commissioner within 30 days after receipt of the comments from the Commissioner;

"(iv) within 30 days following the receipt of the applicant's response to comments or, if there are no such comments, within 30 days following expiration of the 30-day comment period, the Commissioner shall, in writing—

''(I) determine whether to grant the patent term restoration for which the application was filed; and

''(II) make specific findings regarding the criteria set forth in paragraph (2); and

''(V) if the Commissioner grants such patent term restoration, on the same date that the Commissioner makes the determination under clause (iv) the Commissioner shall—

''(I) issue to the applicant a certificate of patent term restoration, under seal, for the period prescribed under paragraph (4); and

''(II) record the certificate in the official file of the patent, which certificate shall be in effect from such date and shall be considered a part of the original patent.

''(C) INTERIM RESTORATION.—If the term of a patent that is the subject of an application filed under this section would otherwise expire before a determination under subparagraph

(B)(iv) is made, the Commissioner shall extend the term of such patent until—

"(i) a determination is made under such subparagraph to restore the term of such patent, or

"(ii) 60 days after a determination is made under such subparagraph to not restore the patent term,

as applicable. If the Commissioner determines not to restore the patent term, then during the 60-day period described in clause (ii), an applicant may apply to the United States Court of Appeals for the Federal Circuit for an order directing the Commissioner to extend the patent pending judicial review and subsequent Commissioner action following that review.

"(D) RECORD.—The Commissioner's determination under subparagraph (B)(iv) shall be based solely on the record developed under this subsection.

"(7) APPLICATION FEE.—The applicant shall pay a fee for an application made under paragraph (6) which shall be established in accordance with the same criteria applicable to fees required under section 156(h). If no such fee has been established at

the time of the application, the applicant may provide the Commissioner with an undertaking, satisfactory to the Commissioner, to pay the subsequently established fee.''.

(2) TECHNICAL AND CONFORMING AMENDMENT.—The table of sections for chapter 14 of title 35, United States Code, is amended by inserting after the item relating to section 155A the following:

''155B. Patent term restoration review procedure for certain drug products.''.

(b) APPEAL OF DETERMINATIONS OF THE COMMISSIONER.—Section 141 of the title 35, United States Code, is amended by adding at the end the following: ''The applicant under section 155B or any aggrieved party that made a submission commenting on an application made under such section may appeal the determination of the Commissioner with respect to the application involved under such section only to the United States Court of Appeals for the Federal Circuit.''.

(c) COURT JURISDICTION.—Section 1295(a)(4) of title 28, United States Code, is amended—

(1) in subparagraph (B), by striking ''or'' after the semicolon;

(2) in subparagraph (C), by adding ''or'' after the semicolon; and

(3) by inserting after subparagraph (C) the following:

"(D) the Commissioner of Patents and Trademarks under section 155B of title 35;".

(d) COMPENSATION.—

(1) IN GENERAL.—In the event a person has submitted an application described in section 505(b)(2) or 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2),(j)) for a drug product covered by a patent for which a patent term restoration was provided under section 155B of title 35, United States Code (as added by subsection (a)(1)) and such application has been found by the Food and Drug Administration on or before the date of the enactment of this section to be sufficiently complete to permit substantive review, such person shall be entitled to compensation of $1,000,000 by the patent owner. Any holder of a Type II Drug Master File that has permitted a reference to its Type II Drug Master File to be made in such application shall be entitled to compensation of $500,000 by the patent owner.

(2) LIMITS ON LIABILITY.—A patent owner shall not be required to make under paragraph (1) payments exceeding—

(A) $5,000,000 to persons submitting applications described in such paragraph, or

(B) $2,500,000 to holders of Type II Drug Master Files.

If the aggregate limits are insufficient to pay the applicants or holders the full amounts specified in paragraph (1), each such applicant or holder shall be paid its per capita share of the aggregate liability imposed by paragraph (1) upon the patent holder.

(e) EFFECT OF FILING OF ABBREVIATED APPLICATIONS.—The fact that one or more applications have been filed under section 505(b)(2) or 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2),(j)) for approval of a drug or a method of using a drug which is claimed by a patent that is the subject of an application under section 155B of title 35, United States Code, for restoration of the patent term shall not affect the grant of such patent term restoration.

(f) REPORT.—Not later than 1 year after the date of the enactment of this section, the Commissioner of Patents and Trademarks shall submit to Congress a report evaluating the patent term restoration review procedure established under section 155B of title 35, United States Code, and shall include in such report a recommendation whether Congress should consider establishing such a patent term review procedure for patents not covered by such section.

(g) EFFECTIVE DATE.—The owner of record of a patent referred to in section 155B(b)(1) of title 35, United States Code (as added by subsection (a)(1)) or an agent of the owner shall be immediately eligible on the date of the enactment of this section to submit an application to the Commissioner of Patents and Trademarks for a determination in accordance with section 155B(b)(6) of such title.

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