II

106TH CONGRESS
1ST SESSION

S. 1172

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

IN THE SENATE OF THE UNITED STATES

MAY 27, 1999

Mr. TORRICELLI introduced the following bill; which was read twice and 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. PATENT TERM RESTORATION REVIEW PROCEDURE FOR CERTAIN DRUG PRODUCTS.

(a) SHORT TITLE.—This Act may be cited as the ''Drug Patent Term Restoration Review Procedure Act of 1999''.

(b) 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 that term under section 156(f)(2)(A), but does not include drugs or products described under section 156(f)(2)(B).

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

''(1) IN GENERAL.—

''(A) PATENT RESTORED.—The term of any patent described under subparagraph (B) shall be restored under paragraph (3) from the expiration date determined under section 154 (including any extension granted under section 156), if the Commissioner determines that the standards under paragraph (2) have been met.

''(B) PATENT.—Subparagraph (A) refers to any patent that—

''(i) has been extended under section 156, subject to the 2–year limitation described under section 156(g)(6)(c);

''(ii) is in force on—

''(I) September 24, 1984;

''(II) the date of enactment of this section; and

''(III) the date of filing an application under this section; and

''(iii) claims a drug product, a method of using a drug product, or a method of manufacturing a drug product.

''(2) STANDARDS.—

''(A) IN GENERAL.—Upon application by the owner of record of the patent or its agent under paragraph (5) and consideration of the application and all materials submitted by parties that would be aggrieved by grant of the restoration of a patent, the term of a patent described in paragraph (1) shall be restored if the Commissioner determines that—

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

"(ii) the owner of record of the patent or its agent has established by clear and convincing evidence that the patent owner acted with due diligence (as such term is defined in section 156(d)(3) and applied in section 156(d)(2)) during the regulatory review period referred to in section 156(g)(1)(B); and

"(iii) granting the patent restoration would not be detrimental to the public interest and the interest of fairness, as defined by the factors set forth in paragraph (7).

"(B) DETERMINATION.—

"(i) DEDUCTION OF TIME.—If the Commissioner determines there is substantial evidence that the patent owner did not act with due diligence during a part of the regulatory review period, that part shall be deducted from the total amount of time in the applicable regulatory review period referred to in section 156(g)(1)(B), and the resulting period, shall be the basis for calculating the patent restoration term under paragraph (3) of this subsection.

"(ii) FDA CONSULTATION.—The Food and Drug Administration shall be consulted with respect to the Commissioner's determinations under subparagraph (A) (i), (ii), and (iii). If there is a dispute concerning the underlying facts between the patent owner and the Food and Drug Administration, the Food and Drug Administration shall make the relevant records of the Administration available to the Commissioner.

"(3) 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 period equal to the regulatory review period as defined in section 156(g)(1)(B) (taking into account any deduction under paragraph (2)(B)(i)), without taking into account the 2-year limitation described in section 156(g)(6)(C), except that—

"(A) the total of the period of the patent term restoration granted under this section and any patent term extension previously granted under section 156 shall be subject to the time

period limitations described in section 156(c)(2)–156 (c)(4) and (g)(6)(A); and

"(B) any patent term extension previously granted under section 156 shall be subtracted from the period of the patent term restoration granted under this subsection.

"(4) 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.

"(5) PROCEDURE.—

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

"(B) FILING.—Upon submission of an application to the Commissioner by the owner of record of a patent referred to in paragraph (1) or its agent for a determination in accordance with paragraph (3)—

"(i) the Commissioner shall publish within 30 days after the submission in the Federal Register a notice of receipt of an

application and make the application available to the public upon request;

''(ii) any interested party may submit comments on the application within the 60-day period beginning on the date of publication of the notice;

''(iii) within 7 days following the expiration of that 60-day 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 45 days after receipt of such comments;

''(iv) within 30 days following receipt of the applicant's response to comments or, if there are no such comments, within 30 days following expiration of the 60-day comment period, the Commissioner shall, in writing—

''(I) determine whether to grant the application; and

''(II) make specific findings regarding the criteria set forth in paragraph (2) (including, where appropriate, findings regarding the public

interest and fairness factors set forth in paragraph (7)); and

''(v) if the Commissioner determines that the standards set forth in paragraph (2) have been met, the Commissioner shall—

''(I) issue to the applicant a certificate of restoration, under seal, for the period prescribed under paragraph (3); and

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

''(C) PATENT TERM DURING REVIEW.—If the term of a patent for which an application has been submitted under this section would expire before a determination to issue a certificate of restoration is made under subparagraph (B), the Commissioner may extend, until such determination is made (but not to exceed 1 year) the term of the patent if the Commissioner determines that the patent likely would be eligible for restoration.

"(D) RECORD AND REVIEW.—The Commissioner's determination under subparagraph (B)(iv) shall be based solely on the record developed under this subsection. Except as provided in section 141, the Commissioner's determination shall not be reviewable in any court.

"(6) APPLICATION FEE.—The applicant shall pay a fee for an application made under this subsection which shall be determined in accordance with the same criteria as the fees established under section 156(h).

"(7) PUBLIC INTEREST AND FAIRNESS.—When required to make a determination under paragraph (2)(A)(iii), the Commissioner shall consider each of the following factors and shall not rely solely on any single factor:

"(A) Whether grant of the application would result in the public having no other commercially available alternatives to treat the same disease or condition as the drug claimed in the patent that is the subject of the patent term restoration request.

"(B) Whether grant of the application would disserve society's interest in the availability of innovative drugs at competitive prices.

"(C) Whether denial of the application would disserve society's interest in encouraging and rewarding pharmaceutical research and innovation.

"(D) Whether denial of the application would be unfair to the applicant, in comparison to others who have experienced the benefits of a 5-year patent restoration under section 156 while experiencing similar regulatory review delays.

"(E) Whether other manufacturers, before the date of enactment of this section, have submitted applications under sections 505(b)(2) or (j) of the Federal Food, Drug, and Cosmetic Act that are sufficiently complete to permit substantive review and have made substantial investments to manufacture a generic version of the particular drug that is the subject of the patent term restoration application, which would not receive the compensation specified under subsection (e) of the Drug Patent Term Restoration Review Procedure Act of 1999.".

(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.".

(c) APPEAL OF DETERMINATIONS OF THE COMMISSIONER.—Section 141 of 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 under section 155B, may appeal the determination of the Commissioner under such section to the United States Court of Appeals for the Federal Circuit.".

(d) COURT JURISDICTION.—

(1) COURT OF APPEALS FOR THE FEDERAL CIRCUIT.—Section 1295(a)(4) of title 28, United States Code, is amended—

(A) in subparagraph (B), by striking "or" after the semicolon;

(B) in subparagraph (C), by adding "or" after the semicolon; and

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

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

(2) JURISDICTION BASED ON INFRINGEMENT OF PATENT.—Section 271(e) of title 35, United

States Code, is amended by adding at the end the following:

''(5) In any action brought under paragraph (2) involving a patent, the term of which has been restored under section 155B, the alleged infringer shall have the right to seek compensation under subsection (e) of the Drug Patent Term Restoration Review Procedure Act of 1999.''.

(e) 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 $2,000,000 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 appli-

cation shall be entitled to compensation of $1,000,000 by the patent owner.

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

(A) $10,000,000 to persons submitting applications described in such paragraph, or

(B) $5,000,000 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.

(f) EFFECT OF FILING OF ABBREVIATED APPLICATIONS.—The fact that 1 or more abbreviated applications have been filed under section 505 (b) or (j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 (b) or (j)) for approval of a drug product, which is covered by a patent that is the subject of an application for term restoration under this section, shall not preclude the grant of such term restoration.

(g) REPORT TO CONGRESS.—Not later than 1 year after the effective date of this section, the Commissioner of Patents and Trademarks shall—

(1) submit to Congress a report evaluating the patent term restoration review procedure established under this section; and

(2) include in such report a recommendation whether Congress should consider establishing such a patent term restoration review procedure for other patents.

(h) EFFECTIVE DATE.—This section shall take effect on the date of enactment of this section and an owner of record of a patent referred to under section 155B(b)(1) of title 35, United States Code (as added by this section); or an agent of the owner shall be immediately eligible on such a date to submit an application to the Commissioner for a determination in accordance with subsection (b)(3) of such section.

SEC. 2. AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

(a) LIMITATION ON USE OF PATENTS TO PREVENT ANDA APPROVAL.—

(1) APPLICATION.—Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2)) is amended by adding at the end the following:

''For an approved product claimed in a patent, the term of which has been restored pursuant to section 155B of

title 35, United States Code, the certification required by subparagraph (A) is limited to any patent that claims an active ingredient, including any salt or ester of the active ingredient, of the approved product, alone or in combination with another active ingredient.''.

(2) ABBREVIATED APPLICATION.—Section 505(j)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)(A)) is amended by adding at the end the following:

''For an approved product claimed in a patent, the term of which has been restored pursuant to section 155B of title 35, United States Code, the certification required by clause (vii) is limited to any patent that claims an active ingredient, including any salt or ester of the active ingredient, of the approved product, alone or in combination with another active ingredient.''.

(b) EXCLUSIVITY FOR GENERIC DRUG.—Section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iv)) is amended by inserting after ''containing such certification'' the following: ''and for which an action for infringement of a patent which is the subject of such a certification has been brought before the expiration of 45 days from the date of the notice provided under paragraph (2)(B)(i) is received''.

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