

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

A BILL

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

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. PATENT TERM RESTORATION REVIEW PROCE-**
4 **DURE FOR CERTAIN DRUG PRODUCTS.**

5 (a) SHORT TITLE.—This Act may be cited as the
6 “Drug Patent Term Restoration Review Procedure Act of
7 1999”.

8 (b) PATENT TERM RESTORATION.—

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

4 **“§ 155B. Patent term restoration review procedure**
5 **for certain drug products**

6 “(a) DEFINITIONS.—For purposes of this section—

7 “(1) the term ‘Commissioner’ means the Com-
8 missioner of Patents and Trademarks; and

9 “(2) the term ‘drug product’ has the meaning
10 given that term under section 156(f)(2)(A), but does
11 not include drugs or products described under sec-
12 tion 156(f)(2)(B).

13 “(b) SPECIAL PATENT TERM REVIEW PROCE-
14 DURE.—

15 “(1) IN GENERAL.—

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

23 “(B) PATENT.—Subparagraph (A) refers
24 to any patent that—

1 “(i) has been extended under section
2 156, subject to the 2-year limitation de-
3 scribed under section 156(g)(6)(c);

4 “(ii) is in force on—

5 “(I) September 24, 1984;

6 “(II) the date of enactment of
7 this section; and

8 “(III) the date of filing an appli-
9 cation under this section; and

10 “(iii) claims a drug product, a method
11 of using a drug product, or a method of
12 manufacturing a drug product.

13 “(2) STANDARDS.—

14 “(A) IN GENERAL.—Upon application by
15 the owner of record of the patent or its agent
16 under paragraph (5) and consideration of the
17 application and all materials submitted by par-
18 ties that would be aggrieved by grant of the
19 restoration of a patent, the term of a patent de-
20 scribed in paragraph (1) shall be restored if the
21 Commissioner determines that—

22 “(i) the period set forth in section
23 156(g)(1)(B)(ii) for the drug product ex-
24 ceeded 60 months;

1 “(ii) the owner of record of the patent
2 or its agent has established by clear and
3 convincing evidence that the patent owner
4 acted with due diligence (as such term is
5 defined in section 156(d)(3) and applied in
6 section 156(d)(2)) during the regulatory
7 review period referred to in section
8 156(g)(1)(B); and

9 “(iii) granting the patent restoration
10 would not be detrimental to the public in-
11 terest and the interest of fairness, as de-
12 fined by the factors set forth in paragraph
13 (7).

14 “(B) DETERMINATION.—

15 “(i) DEDUCTION OF TIME.—If the
16 Commissioner determines there is substan-
17 tial evidence that the patent owner did not
18 act with due diligence during a part of the
19 regulatory review period, that part shall be
20 deducted from the total amount of time in
21 the applicable regulatory review period re-
22 ferred to in section 156(g)(1)(B), and the
23 resulting period, shall be the basis for cal-
24 culating the patent restoration term under
25 paragraph (3) of this subsection.

1 “(ii) FDA CONSULTATION.—The
2 Food and Drug Administration shall be
3 consulted with respect to the Commis-
4 sioner’s determinations under subpara-
5 graph (A) (i), (ii), and (iii). If there is a
6 dispute concerning the underlying facts be-
7 tween the patent owner and the Food and
8 Drug Administration, the Food and Drug
9 Administration shall make the relevant
10 records of the Administration available to
11 the Commissioner.

12 “(3) RESTORATION TERM.—If the Commis-
13 sioner determines that the standards in paragraph
14 (2) have been met for a patent, the term of such
15 patent shall be restored for a period equal to the
16 regulatory review period as defined in section
17 156(g)(1)(B) (taking into account any deduction
18 under paragraph (2)(B)(i)), without taking into ac-
19 count the 2-year limitation described in section
20 156(g)(6)(C), except that—

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

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

3 “(B) any patent term extension previously
4 granted under section 156 shall be subtracted
5 from the period of the patent term restoration
6 granted under this subsection.

7 “(4) INFRINGEMENT.—During the period of
8 any restoration granted under this subsection, the
9 rights derived from a patent the term of which is re-
10 stored shall be determined in accordance with sec-
11 tions 156(b) and 271.

12 “(5) PROCEDURE.—

13 “(A) TIME FOR FILING.—Any application
14 under this section shall be filed with the Com-
15 missioner within 90 days after the date of en-
16 actment of this section.

17 “(B) FILING.—Upon submission of an ap-
18 plication to the Commissioner by the owner of
19 record of a patent referred to in paragraph (1)
20 or its agent for a determination in accordance
21 with paragraph (3)—

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

1 application and make the application avail-
2 able to the public upon request;

3 “(ii) any interested party may submit
4 comments on the application within the 60-
5 day period beginning on the date of publi-
6 cation of the notice;

7 “(iii) within 7 days following the expi-
8 ration of that 60-day period, the Commis-
9 sioner shall forward a copy of all com-
10 ments received to the applicant, who shall
11 be entitled to submit a response to such
12 comments to the Commissioner within 45
13 days after receipt of such comments;

14 “(iv) within 30 days following receipt
15 of the applicant’s response to comments or,
16 if there are no such comments, within 30
17 days following expiration of the 60-day
18 comment period, the Commissioner shall,
19 in writing—

20 “(I) determine whether to grant
21 the application; and

22 “(II) make specific findings re-
23 garding the criteria set forth in para-
24 graph (2) (including, where appro-
25 priate, findings regarding the public

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

3 “(v) if the Commissioner determines
4 that the standards set forth in paragraph
5 (2) have been met, the Commissioner
6 shall—

7 “(I) issue to the applicant a cer-
8 tificate of restoration, under seal, for
9 the period prescribed under paragraph
10 (3); and

11 “(II) record the certificate in the
12 official file of the patent, which cer-
13 tificate shall be in effect from the date
14 it issues and shall be considered a
15 part of the original patent.

16 “(C) PATENT TERM DURING REVIEW.—If
17 the term of a patent for which an application
18 has been submitted under this section would ex-
19 pire before a determination to issue a certificate
20 of restoration is made under subparagraph (B),
21 the Commissioner may extend, until such deter-
22 mination is made (but not to exceed 1 year) the
23 term of the patent if the Commissioner deter-
24 mines that the patent likely would be eligible
25 for restoration.

1 “(D) RECORD AND REVIEW.—The Com-
2 missioner’s determination under subparagraph
3 (B)(iv) shall be based solely on the record devel-
4 oped under this subsection. Except as provided
5 in section 141, the Commissioner’s determina-
6 tion shall not be reviewable in any court.

7 “(6) APPLICATION FEE.—The applicant shall
8 pay a fee for an application made under this sub-
9 section which shall be determined in accordance with
10 the same criteria as the fees established under sec-
11 tion 156(h).

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

17 “(A) Whether grant of the application
18 would result in the public having no other com-
19 mercially available alternatives to treat the
20 same disease or condition as the drug claimed
21 in the patent that is the subject of the patent
22 term restoration request.

23 “(B) Whether grant of the application
24 would disserve society’s interest in the avail-
25 ability of innovative drugs at competitive prices.

1 “(C) Whether denial of the application
2 would disserve society’s interest in encouraging
3 and rewarding pharmaceutical research and in-
4 novation.

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

11 “(E) Whether other manufacturers, before
12 the date of enactment of this section, have sub-
13 mitted applications under sections 505(b)(2) or
14 (j) of the Federal Food, Drug, and Cosmetic
15 Act that are sufficiently complete to permit
16 substantive review and have made substantial
17 investments to manufacture a generic version of
18 the particular drug that is the subject of the
19 patent term restoration application, which
20 would not receive the compensation specified
21 under subsection (e) of the Drug Patent Term
22 Restoration Review Procedure Act of 1999.”.

23 (2) TECHNICAL AND CONFORMING AMEND-
24 MENT.—The table of sections for chapter 14 of title

1 35, United States Code, is amended by inserting
2 after the item relating to section 155A the following:
“155B. Patent term restoration review procedure for certain drug products.”.

3 (c) APPEAL OF DETERMINATIONS OF THE COMMIS-
4 SIONER.—Section 141 of title 35, United States Code, is
5 amended by adding at the end the following: “The appli-
6 cant under section 155B, or any aggrieved party that
7 made a submission commenting on an application under
8 section 155B, may appeal the determination of the Com-
9 missioner under such section to the United States Court
10 of Appeals for the Federal Circuit.”.

11 (d) COURT JURISDICTION.—

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

15 (A) in subparagraph (B), by striking “or”
16 after the semicolon;

17 (B) in subparagraph (C), by adding “or”
18 after the semicolon; and

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

21 “(D) the Commissioner of Patents and
22 Trademarks under section 155B of title 35;”.

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

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

3 “(5) In any action brought under paragraph (2)
4 involving a patent, the term of which has been re-
5 stored under section 155B, the alleged infringer
6 shall have the right to seek compensation under sub-
7 section (e) of the Drug Patent Term Restoration Re-
8 view Procedure Act of 1999.”.

9 (e) COMPENSATION.—

10 (1) IN GENERAL.—In the event a person has
11 submitted an application described in section
12 505(b)(2) or 505(j) of the Federal Food, Drug, and
13 Cosmetic Act (21 U.S.C. 355(b)(2),(j)) for a drug
14 product covered by a patent for which a patent term
15 restoration was provided under section 155B of title
16 35, United States Code (as added by subsection
17 (a)(1)) and such application has been found by the
18 Food and Drug Administration on or before the date
19 of the enactment of this section to be sufficiently
20 complete to permit substantive review, such person
21 shall be entitled to compensation of \$2,000,000 by
22 the patent owner. Any holder of a Type II Drug
23 Master File that has permitted a reference to its
24 Type II Drug Master File to be made in such appli-

1 cation shall be entitled to compensation of
2 \$1,000,000 by the patent owner.

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

6 (A) \$10,000,000 to persons submitting ap-
7 plications described in such paragraph, or

8 (B) \$5,000,000 to holders of Type II Drug
9 Master Files.

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

15 (f) EFFECT OF FILING OF ABBREVIATED APPLICA-
16 TIONS.—The fact that 1 or more abbreviated applications
17 have been filed under section 505 (b) or (j) of the Federal
18 Food, Drug, and Cosmetic Act (21 U.S.C. 355 (b) or (j))
19 for approval of a drug product, which is covered by a pat-
20 ent that is the subject of an application for term restora-
21 tion under this section, shall not preclude the grant of
22 such term restoration.

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

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

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

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

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

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

20 (1) APPLICATION.—Section 505(b)(2) of the
21 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
22 355(b)(2)) is amended by adding at the end the fol-
23 lowing:

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

1 title 35, United States Code, the certification required by
2 subparagraph (A) is limited to any patent that claims an
3 active ingredient, including any salt or ester of the active
4 ingredient, of the approved product, alone or in combina-
5 tion with another active ingredient.”.

6 (2) ABBREVIATED APPLICATION.—Section
7 505(j)(2)(A) of the Federal Food, Drug, and Cos-
8 metic Act (21 U.S.C. 355(j)(2)(A)) is amended by
9 adding at the end the following:

10 “For an approved product claimed in a patent, the term
11 of which has been restored pursuant to section 155B of
12 title 35, United States Code, the certification required by
13 clause (vii) is limited to any patent that claims an active
14 ingredient, including any salt or ester of the active ingre-
15 dient, of the approved product, alone or in combination
16 with another active ingredient.”.

17 (b) EXCLUSIVITY FOR GENERIC DRUG.—Section
18 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic
19 Act (21 U.S.C. 355(j)(5)(B)(iv)) is amended by inserting
20 after “containing such certification” the following: “and
21 for which an action for infringement of a patent which
22 is the subject of such a certification has been brought be-
23 fore the expiration of 45 days from the date of the notice
24 provided under paragraph (2)(B)(i) is received”.

○