

SEC. ____.

(a) IN GENERAL.—Section 156 of title 35, United States Code, is amended by adding at the end the following:

“(i) AUTHORITY TO ACCEPT LATE FILINGS IN CERTAIN CASES OF UNINTENTIONAL DELAY AND PROVISION FOR FEE PAYMENTS.—

“(1) IN GENERAL.—The Director shall accept an application under this section that is filed not later than 3 business days after the expiration of the 60-day period provided in subsection (d)(1) if the applicant files a petition, not later than 5 business days after the expiration of that 60-day period, showing, to the satisfaction of the Director, that the delay in filing the application was unintentional.

“(2) FEE FOR LATE FILINGS.—

“(A) IN GENERAL.—In order to effect a patent term extension under this subsection, the patent holder shall pay a fee to the United States Treasury in the amount prescribed under subparagraph (B).

“(B) FEE AMOUNT.—

“(i) FEE AMOUNT.—The patent holder shall pay a fee equal to—

“(I) \$65,000,000 with respect to any application for a patent term extension, filed with the United States Patent and Trademark Office before the date of the enactment of this subsection, for a drug intended for use in humans that is in the anticoagulant class of drugs; or

“(II) the amount estimated under clause (ii) with respect to any other application for a patent term extension.

“(ii) CALCULATION OF ALTERNATE AMOUNT.—The Director shall estimate the amount referred to in clause (i)(II) as the amount equal to the sum of—

“(I) any net increase in direct spending arising from the extension of the patent term (including direct spending of the United States Patent and Trademark Office and any other department or agency of the Federal Government);

“(II) any net decrease in revenues arising from such patent term extension; and

“(III) any indirect reduction in revenues associated with payment of the fee under this subsection.

The Director, in estimating the amount under this subparagraph, shall consult with the Director of the Office of Management and Budget, the Secretary of the Treasury, and either the Secretary of Health and Human Services or (in the case of a drug product subject to the Act commonly referred to as the ‘Virus-Serum-Toxin Act’; 21 U.S.C. 151-158) the Secretary of Agriculture.

“(C) NOTICE OF FEE.—The Director shall inform the patent holder of the fee determined under subparagraph (B) at the time the Director provides notice to the patent holder of the period of extension of the patent term that the patent holder may effect under this subsection.

“(D) ACCEPTANCE REQUIRED.—Unless, within 15 days after the Director provides notice to the patent holder under subparagraph (C), the patent holder accepts the patent term extension in writing to the Director, the patent term extension is rescinded and no fees shall be due under this subsection by reason of the petition under this subsection, under which the Director provided the notice.

“(E) PAYMENT OF FEE.—The extension of a patent term of which notice is provided under subparagraph (C) shall not become effective unless the patent holder pays the fee required under subparagraph (B) not later than 60 days after the date on which the notice is provided.

“(F) DIRECTOR DEFINED.—Except as otherwise provided, in this subsection, the term ‘Director’ means the

Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office.

“(3) APPLICABILITY.—

“(A) IN GENERAL.—This subsection shall apply
to any application—

“(i) that is made on or after the date of the
enactment of this subsection; or

“(ii) that, on such date of enactment, is
pending before the Director, that is described in
paragraph (2)(B)(i)(I), or as to which a decision of
the Director is eligible for judicial review.

“(B) TREATMENT OF CERTAIN
APPLICATIONS.—In the case of any application
described in subparagraph (A)(ii), the 5-day period
prescribed in subsection (i)(1) shall be deemed to begin on
the date of the enactment of this subsection.”

(b) TECHNICAL AND CONFORMING AMENDMENT.—
Section 156(d)(1) of title 35, United States Code, is amended in the second
sentence, by inserting “or subsection (i)” after “paragraph (5)”.