Chapter 2700 Patent Terms and Extensions

2701 Patent Term

35 U.S.C. 154. Contents and term of patent; provisional rights.

(a) IN GENERAL.—

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(2) TERM.—Subject to the payment of fees under this title, such grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application or applications under section 120, 121, or 365(c) of this title, from the date on which the earliest such application was filed.

(3) PRIORITY.—Priority under section 119, 365(a), or 365(b) of this title shall not be taken into account in determining the term of a patent.

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(c) CONTINUATION.—

(1) DETERMINATION.—The term of a patent that is in force on or that results from an application filed before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act shall be the greater of the 20-year term as provided in subsection (a), or 17 years from grant, subject to any terminal disclaimers.

(2) REMEDIES.—The remedies of sections 283, 284, and 285 of this title shall not apply to acts which —

(A) were commenced or for which substantial investment was made before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act; and

(B) became infringing by reason of paragraph (1).

(3) REMUNERATION.—The acts referred to in paragraph (2) may be continued only upon the payment of an equitable remuneration to the patentee that is determined in an action brought under chapter 28 and chapter 29 (other than those provisions excluded by paragraph (2)) of this title.

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For applications filed on or after June 8, 1995, Section 532(a)(1) of the Uruguay Round Agreements Act (Pub. L. 103-465, 108 Stat. 4809 (1994)) amended 35 U.S.C. 154 to provide that the term of a patent (other than a design patent) begins on the date the patent issues and ends on the date that is twenty years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application or applications under 35 U.S.C. 120, 121, or 365(c), twenty years from the filing date of the earliest of such application(s). This patent term provision is referred to as the "twenty-year term." Design patents have a term of fourteen years from the date of patent grant. See 35 U.S.C 173 and MPEP § 1505.

All patents (other than design patents) that were in force on June 8, 1995, or that issued on an application that was filed before June 8, 1995, have a term that is the greater of the "twenty-year term" or seventeen years from the patent grant. See 35 U.S.C. 154(c). A patent granted on an international application filed

before June 8, 1995, and which entered the national stage under 35 U.S.C. 371 before, on or after June 8, 1995, will have a term that is the greater of seventeen years from the date of grant or twenty years from the international filing date or any earlier filing date relied upon under 35 U.S.C. 120, 121 or 365(c). The terms of these patents are subject to reduction by any applicable terminal disclaimers (discussed below).

CONTINUING APPLICATIONS

A patent granted on a continuation, divisional, or continuation-in-part application that was filed on or after June 8, 1995, will have a term which ends twenty years from the filing date of earliest application for which a benefit is claimed under 35 U.S.C. 120, 121, or 365(c), regardless of whether the application for which a benefit is claimed under 35 U.S.C. 120, 121, or 365(c) was filed prior to June 8, 1995.

INTERNATIONAL APPLICATIONS

A patent granted on an international application filed on or after June 8, 1995 and which enters the national stage under 35 U.S.C. 371 will have a term which ends twenty years from the filing date of the international application. A continuation or a continuation-in-part application claiming benefit under 35 U.S.C. 365(c) of an international application filed under 35 U.S.C. 363 designating the United States will have a term which ends twenty years from the filing date of the parent international application.

FOREIGN PRIORITY

Foreign priority under 35 U.S.C. 119(a)-(d), 365(a), or 365(b) is not considered in determining the term of a patent. Accordingly, an application claiming priority under 35 U.S.C. 365(a) or 365(b) has a term which ends twenty years from the filing date of the application in the United States and not the prior international application.

DOMESTIC PRIORITY UNDER 35 U.S.C. 119(e)

Domestic priority under 35 U.S.C. 119(e) to one or more U.S. provisional applications is not considered in the calculation of the twenty-year term. See 35 U.S.C. 154(a)(3).

EXPIRATION DATE OF PATENTS WITH TERMINAL DISCLAIMERS

To determine the "original expiration date" of a patent subject to a terminal disclaimer, it is generally necessary to examine the language of the terminal disclaimer in the patent file history. If the disclaimer disclaims the terminal portion of the term of the patent which would extend beyond the expiration date of an earlier issued patent, then the expiration date of the earlier issued patent determines the expiration date of the patent subject to the terminal disclaimer. Before June 8, 1995, the terminal disclaimer date was printed on the face of the patent; the date was determined from the expected expiration date of the earlier issued patent based on a seventeen year term measured from grant. When 35 U.S.C. 154 was amended such that all patents (other than design patents) that were in force on June 8, 1995, or that issued on an application that was filed before June 8, 1995, have a term that is the greater of the "twenty year term" or seventeen years from the patent grant, the terminal disclaimer date as printed on many patents became incorrect. If the terminal disclaimer of record in the patent file disclaims the terminal portion of the patent subsequent to the full statutory term of a referenced patent (without identifying a specific date), then the date printed on the face of the patent is incorrect when the full statutory term of the referenced patent is changed as a result of 35 U.S.C. 154(c). That is, the referenced patent's "twenty year term" is longer than the seventeen year term. In such a case, a patentee may request a Certificate of Correction under 37 CFR 1.323 to correct the information printed on the face of the patent. However, if the terminal disclaimer of record in the patent file disclaims the terminal portion of the patent subsequent to a specific date, without reference to the full statutory term of a referenced patent, then the expiration date is the date specified. Several decisions related to disclaimers are posted in the Freedom of Information Act (FOIA) section of the USPTO Internet site (www.uspto.gov).

PATENT TERM EXTENSIONS OR ADJUSTMENTS

See MPEP § 2710, *et seq.,* for patent term extensions or adjustments for delays within the USPTO under 35 U.S.C. 154 for utility and plant patents issuing on applications filed on or after June 8,

1995. Patents that issue from applications filed before June 8, 1995, are not eligible for term adjustment under 35 U.S.C. 154.

See MPEP § 2750 *et. seq.* for patent term extensions available under 35 U.S.C. 156 for premarket regulatory review. The patent term extension that may be available under 35 U.S.C. 156 for premarket regulatory review is separate from and will be added to any extension that may be available under former and current 35 U.S.C. 154. While patents that issue from applications filed before June 8, 1995, are not eligible for term adjustment under 35 U.S.C. 154, such patents may be extended under 35 U.S.C. 156.

2710 Term Extensions or Adjustments for Delays Within the USPTO Under 35 U.S.C. 154

Utility and plant patents issuing on applications filed on or after June 8, 1995, but before May 29, 2000, are eligible for the patent term adjustment (extension) provisions of former 35 U.S.C. 154(b) and 37 CFR 1.701. See MPEP § 2720. Utility and plant patents issuing on applications filed on or after May 29, 2000 are eligible for the patent term adjustment provisions of 35 U.S.C. 154(b)(amended, effective May 29, 2000) and 37 CFR 1.702-1.705. See MPEP § 2730.

Plant and utility patents issuing on applications filed before June 8, 1995 which have a term that is the greater of the "twenty-year term" (see MPEP § 2701) or seventeen years from patent grant are not eligible for term extension or adjustment due to delays in processing the patent application by the United States Patent and Trademark Office.

Since the term of a design patent is not affected by the length of time prosecution takes place, there are no patent term adjustment provisions for design patents.

2720 Applications Filed Between June 8, 1995, and May 28, 2000

Former 35 U.S.C. 154. Contents and term of patent.

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(b) TERM EXTENSION.—

(1) INTERFERENCE DELAY OR SECRECY ORDERS.—If the issue of an original patent is delayed due to a proceeding under section 135(a) of this title, or because the application for patent is placed under an order pursuant to section 181 of this title, the term of the patent shall be extended for the period of delay, but in no case more than 5 years.

(2) EXTENSION FOR APPELLATE REVIEW. —If the issue of a patent is delayed due to appellate review by the Board of Patent Appeals and Interferences or by a Federal court and the patent is issued pursuant to a decision in the review reversing an adverse determination of patentability, the term of the patent shall be extended for a period of time but in no case more than 5 years. A patent shall not be eligible for extension under this paragraph if it is subject to a terminal disclaimer due to the issue of another patent claiming subject matter that is not patentably distinct from that under appellate review.

(3) LIMITATIONS.—The period of extension referred to in paragraph (2)—

(A) shall include any period beginning on the date on which an appeal is filed under section 134 or 141 of this title, or on which an action is commenced under section 145 of this title, and ending on the date of a final decision in favor of the applicant;

(B) shall be reduced by any time attributable to appellate review before the expiration of 3 years from the filing date of the application for patent; and

(C) shall be reduced for the period of time during which the applicant for patent did not act with due diligence, as determined by the Commissioner.

(4) LENGTH OF EXTENSION.—The total duration of all extensions of a patent under this subsection shall not exceed 5 years.

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37 CFR 1.701. Extension of patent term due to examination delay under the Uruguay Round Agreements Act (original applications, other than designs, filed on or after June 8, 1995, and before May 29, 2000).

(a) A patent, other than for designs, issued on an application filed on or after June 8, 1995, is entitled to extension of the patent term if the issuance of the patent was delayed due to:

(1) Interference proceedings under 35 U.S.C. 135(a); and/or

(2) The application being placed under a secrecy order under 35 U.S.C. 181; and/or

(3) Appellate review by the Board of Patent Appeals and Interferences or by a Federal court under 35 U.S.C. 141 or 145, if the patent was issued pursuant to a decision reversing an adverse determination of patentability and if the patent is not subject to a terminal disclaimer due to the issuance of another patent claiming subject matter that is not patentably distinct from that under appellate review.

(b) The term of a patent entitled to extension under paragraph (a) of this section shall be extended for the sum of the periods of delay calculated under paragraphs (c)(1), (c)(2), (c)(3) and (d) of this section, to the extent that these periods are not overlapping, up to a maximum of five years. The extension will run from the expiration date of the patent.

(c)(1) The period of delay under paragraph (a)(1) of this section for an application is the sum of the following periods, to the extent that the periods are not overlapping:

(i) With respect to each interference in which the application was involved, the number of days, if any, in the period beginning on the date the interference was declared or redeclared to involve the application in the interference and ending on the date that the interference was terminated with respect to the application; and

(ii) The number of days, if any, in the period beginning on the date prosecution in the application was suspended by the Patent and Trademark Office due to interference proceedings under 35 U.S.C. 135(a) not involving the application and ending on the date of the termination of the suspension.

(2) The period of delay under paragraph (a)(2) of this section for an application is the sum of the following periods, to the extent that the periods are not overlapping:

(i) The number of days, if any, the application was maintained in a sealed condition under 35 U.S.C. 181;

(ii) The number of days, if any, in the period beginning on the date of mailing of an examiner's answer under § 1.193 in the application under secrecy order and ending on the date the secrecy order and any renewal thereof was removed;

(iii) The number of days, if any, in the period beginning on the date applicant was notified that an interference would be declared but for the secrecy order and ending on the date the secrecy order and any renewal thereof was removed; and

(iv) The number of days, if any, in the period beginning on the date of notification under § 5.3(c) and ending on the date of mailing of the notice of allowance under § 1.311.

(3) The period of delay under paragraph (a)(3) of this section is the sum of the number of days, if any, in the period beginning on the date on which an appeal to the Board of Patent Appeals and Interferences was filed under 35 U.S.C. 134 and ending on the date of a final decision in favor of the applicant by the Board of Patent Appeals and Interferences or by a Federal court in an appeal under 35 U.S.C. 141 or a civil action under 35 U.S.C. 145.

(d) The period of delay set forth in paragraph (c)(3) shall be reduced by:

(1) Any time during the period of appellate review that occurred before three years from the filing of the first national application for patent presented for examination; and

(2) Any time during the period of appellate review, as determined by the Commissioner, during which the applicant for patent did not act with due diligence. In determining the due diligence of an applicant, the Commissioner may examine the facts and circumstances of the applicant's actions during the period of appellate review to determine whether the applicant exhibited that degree of timeliness as may reasonably be expected from, and which is ordinarily exercised by, a person during a period of appellate review.

(e) The provisions of this section apply only to original patents, except for design patents, issued on applications filed on or after June 8, 1995, and before May 29, 2000.

The twenty-year term of a patent issuing from an application filed on or after June 8, 1995, and before May 29, 2000, may be extended for a maximum of five years for delays in the issuance of the patent due to interferences, secrecy orders and/or successful appeals to the Board of Patent Appeals and Interferences or the Federal courts in accordance with 37 CFR 1.701. See former 35 U.S.C. 154(b), as reproduced above. Extensions for successful appeals are limited in that the patent must not be subject to a terminal disclaimer. Further, the period of extension will be reduced by any time attributable to appellate review within three years of the filing date of the application, and the period of extension for appellate review will be reduced by any time during which the applicant did not act with due diligence. The patent term extension that may be available under 35 U.S.C. 156 for premarket regulatory review is separate from and will be added to any extension that may be available under former and current 35 U.S.C. 154. See MPEP § 2750 *et seq*. 35 U.S.C. 154(b) was amended, effective May 29, 2000, to provide for patent term adjustment for applications filed on or after May 29, 2000, but the provisions of former 35 U.S.C. 154(b), as reproduced above, continue to apply to applications filed between and including June 8, 1995 and May 28, 2000.

Examiners make no decisions regarding patent term extensions. Extensions under former 35 U.S.C. 154 will be calculated by PALM and will be printed on the Notice of Allowance and Issue Fee Due. Any patent term extension granted as a result of administrative delay pursuant to 37 CFR 1.701 will also be printed on the face of the patent in generally the same location as the terminal disclaimer information. The term of a patent will be readily discernible from the face of the patent (i.e., from the filing date, continuing data, issue date and any patent term extensions printed on the patent).

If applicant disagrees with the patent term extension or adjustment information printed on the Notice of Allowance and Issue Fee Due, applicant may request review by way of a petition under 37 CFR 1.181. To avoid loss of patent term, however, any such petitions filed during the pendency of the application will not be decided until after issuance of the patent. If the petition is granted, a Certificate of Correction pursuant to 37 CFR 1.322 will be issued. If an error is noted after the patent issues, patentee may seek correction of the patent term extension information by filing a request for a Certificate of Correction pursuant to 37 CFR 1.322.

Petitions and Certificates of Correction regarding patent term extension under former 35 U.S.C. 154(b) should be addressed to the Assistant Commissioner for Patents, Box DAC, Washington, D.C. 20231.

2730 Applications Filed on or After May 29, 2000; Grounds for Adjustment

35 U.S.C. 154. Contents and term of patent; provisional rights.

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(b) ADJUSTMENT OF PATENT TERM.—

(1) PATENT TERM GUARANTEES.—

(A) GUARANTEE OF PROMPT PATENT AND TRADEMARK OFFICE RESPONSES.— Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to—

(i) provide at least one of the notifications under section 132 of this title or a notice of allowance under section 151 of this title not later than 14 months after—

(I) the date on which an application was filed under section 111(a) of this title; or

(II) the date on which an international application fulfilled the requirements of section 371 of this title;

(ii) respond to a reply under section 132, or to an appeal taken under section 134, within 4 months after the date on which the reply was filed or the appeal was taken;

(iii) act on an application within 4 months after the date of a decision by the Board of Patent Appeals and Interferences under section 134 or 135 or a decision by a Federal court under section 141, 145, or 146 in a case in which allowable claims remain in the application; or

(iv) issue a patent within 4 months after the date on which the issue fee was paid under section 151 and all outstanding requirements were satisfied, the term of the patent shall be extended 1 day for each day after the end of the period specified in clause (i), (ii), (iii), or (iv), as the case may be, until the action described in such clause is taken.

(B) GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION PENDENCY.— Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States, not including—

(i) any time consumed by continued examination of the application requested by the applicant under section 132(b);

(ii) any time consumed by a proceeding under section 135(a), any time consumed by the imposition of an order under section 181, or any time consumed by appellate review by the Board of Patent Appeals and Interferences or by a Federal court; or

(iii) any delay in the processing of the application by the United States Patent and Trademark Office requested by the applicant except as permitted by paragraph (3)(C), the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.

(C) GUARANTEE OR ADJUSTMENTS FOR DELAYS DUE TO INTERFERENCES, SECRECY ORDERS, AND APPEALS.— Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to—

(i) a proceeding under section 135(a);

(ii) the imposition of an order under section 181; or

(iii) appellate review by the Board of Patent Appeals and Interferences or by a Federal court in a case in which the patent was issued under a decision in the review reversing an adverse determination of patentability, the term of the patent shall be extended 1 day for each day of the pendency of the proceeding, order, or review, as the case may be.

(2) LIMITATIONS.—

(A) IN GENERAL.— To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

(B) DISCLAIMED TERM.— No patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer.

(C) REDUCTION OF PERIOD OF ADJUSTMENT.—

(i) The period of adjustment of the term of a patent under paragraph (1) shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.

(ii) With respect to adjustments to patent term made under the authority of paragraph (1)(B), an applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of 3 months that are taken to respond to a notice from the Office making any rejection, objection, argument, or other request, measuring such 3-month period from the date the notice was given or mailed to the applicant.

(iii) The Director shall prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application.

(3) PROCEDURES FOR PATENT TERM ADJUSTMENT DETERMINATION.—

(A) The Director shall prescribe regulations establishing procedures for the application for and determination of patent term adjustments under this subsection.

(B) Under the procedures established under subparagraph (A), the Director shall—

(i) make a determination of the period of any patent term adjustment under this subsection, and shall transmit a notice of that determination with the written notice of allowance of the application under section 151; and

(ii) provide the applicant one opportunity to request reconsideration of any patent term adjustment determination made by the Director.

(C) The Director shall reinstate all or part of the cumulative period of time of an adjustment under paragraph (2)(C) if the applicant, prior to the issuance of the patent, makes a showing that, in spite of all due care, the applicant was unable to respond within the 3-month period, but in no case shall more than three additional months for each such response beyond the original 3-month period be reinstated.

(D) The Director shall proceed to grant the patent after completion of the Director's determination of a patent term adjustment under the procedures established under this subsection, notwithstanding any appeal taken by the applicant of such determination.

(4) APPEAL OF PATENT TERM ADJUSTMENT DETERMINATION.—

(A) An applicant dissatisfied with a determination made by the Director under paragraph (3) shall have remedy by a civil action against the Director filed in the United States District Court for the District of Columbia within 180 days after the grant of the patent. Chapter 7 of title 5, United States Code, shall apply to such action. Any final judgment resulting in a change to the period of adjustment of the patent term shall be served on the Director, and the Director shall thereafter alter the term of the patent to reflect such change.

(B) The determination of a patent term adjustment under this subsection shall not be subject to appeal or challenge by a third party prior to the grant of the patent.

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37 CFR 1.702. Grounds for adjustment of patent term due to examination delay under the Patent Term Guarantee Act of 1999 (original applications, other than designs, on or after May 29, 2000).

(a) *Failure to take certain actions within specified time frames.* Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to:

(1) Mail at least one of a notification under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151 not later than fourteen months after the date on which the application was filed under 35 U.S.C. 111(a) or fulfilled the requirements of 35 U.S.C. 371 in an international

(2) Respond to a reply under 35 U.S.C. 132 or to an appeal taken under 35 U.S.C. 134 not later than four months after the date on which the reply was or the appeal was taken;

(3) Act on an application not later than four months after the date of a decision by the Board of Patent Appeals and Interferences under 35 U.S.C. 134 or 135 or a decision by a Federal court under 35 U.S.C. 141, 145, or 146 where at least one allowable claim remains in the application; or

(4) Issue a patent not later than four months after the date on which the issue fee was paid under 35 U.S.C. 151 and all outstanding requirements were satisfied.

(b) *Failure to issue a patent within three years of the actual filing date of the application.* Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application, but not including:

(1) Any time consumed by continued examination of the application under 35 U.S.C. 132(b);

(2) Any time consumed by an interference proceeding under 35 U.S.C. 135(a);

(3) Any time consumed by the imposition of a secrecy order under 35 U.S.C. 181;

(4) Any time consumed by review by the Board of Patent Appeals and Interferences or a Federal court; or

(5) Any delay in the processing of the application by the Office that was requested by the applicant.

(c) *Delays caused by interference proceedings*. Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to interference proceedings under 35 U.S.C. 135(a).

(d) *Delays caused by secrecy order*. Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the application being placed under a secrecy order under 35 U.S.C. 181.

(e) *Delays caused by successful appellate review*. Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to review by the Board of Patent Appeals and Interferences under 35 U.S.C. 134 or by a Federal court under 35 U.S.C. 141 or 145, if the patent was issued pursuant to a decision reversing an adverse determination of patentability.

(f) The provisions of this section and §§1.703 through 1.705 apply only to original applications, except applications for a design patent, filed on or after May 29, 2000, and patents issued on such applications.

35 U.S.C. 154(b), as amended effective May 29, 2000, and 37 CFR 1.702-1.705 apply to utility and plant patent applications filed on or after May 29, 2000. All references to 35 U.S.C. 154(b) hereinafter are to 35 U.S.C. 154(b), as amended effective May 29, 2000.

37 CFR 1.702 sets forth the bases for patent term adjustment under 35 U.S.C. 154(b)(1).

37 CFR 1.702(a) indicates that a patent is entitled to patent term adjustment if the Office fails to perform certain acts of examination within specified time frames (35 U.S.C. 154(b)(1)(A)).

37 CFR 1.702(b) indicates that a patent is entitled to patent term adjustment if, subject to a number of limitations, the Office fails to issue a patent within three years of the actual filing date of the application (35 U.S.C. 154(b)(1)(B)). In the case of an international application, the phrase "actual filing date of the application in the United States" means the date the national stage commenced under 35 U.S.C. 371(b) or

(f). See *Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term*, 65 *FR* 56366, 56382-84, (Sept. 18, 2000), 1239 *Off. Gaz. Pat. Office* 14, 28-30 (Oct. 3, 2000).

37 CFR 1.702(c) indicates that a patent is entitled to patent term adjustment if the issuance of the patent was delayed by an interference proceeding (35 U.S.C. 154(b)(1)(C)(i)). 37 CFR 1.702(d) indicates that a patent is entitled to patent term adjustment if the issuance of the patent was delayed by the application being placed under a secrecy order under 35 U.S.C. 181 (35 U.S.C. 154(b)(1)(C)(ii)). 37 CFR 1.702(e) indicates that a patent is entitled to patent term adjustment if the issuance of the patent was delayed by successful appellate review under 35 U.S.C. 134, 141, or 145 (35 U.S.C. 154(b)(1)(C)(iii)).

37 CFR 1.702(f) provides that the provisions of 37 CFR 1.702 through 1.705 apply only to original (i.e., non-reissue) applications, except applications for a design patent, filed on or after May 29, 2000, and patents issued on such applications. Since a continued prosecution application (CPA) filed under 37 CFR 1.53(d) is a new (continuing) application, a CPA filed on or after May 29, 2000, is entitled to the benefits of the patent term adjustment provisions of 35 U.S.C. 154(b) and 37 CFR 1.702 through 1.705. Since a request for continued examination (RCE) filed under 35 U.S.C. 132(b) and 37 CFR 1.114 is **not** a new application (it is a submission in a previously filed application), filing an RCE in an application filed before May 29, 2000, does **not** cause that application to be entitled to the benefits of the patent term adjustment provisions of 35 U.S.C. 154(b) and 37 CFR 1.702 through 1.705.

37 CFR 1.703. Period of adjustment of patent term due to examination delay.

(a) The period of adjustment under § 1.702(a) is the sum of the following periods:

(1) The number of days, if any, in the period beginning on the day after the date that is fourteen months after the date on which the application was under 35 U.S.C. 111(a) or fulfilled the requirements of 35 U.S.C. 371 and ending on the date of mailing of either an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first;

(2) The number of days, if any, in the period beginning on the day after the date that is four months after the date a reply under § 1.111 was and ending on the date of mailing of either an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first;

(3) The number of days, if any, in the period beginning on the day after the date that is four months after the date a reply in compliance with § 1.113(c) was and ending on the date of mailing of either an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first;

(4) The number of days, if any, in the period beginning on the day after the date that is four months after the date an appeal brief in compliance with § 1.192 was and ending on the date of mailing of any of an examiner's answer under § 1.193, an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first;

(5) The number of days, if any, in the period beginning on the day after the date that is four months after the date of a final decision by the Board of Patent Appeals and Interferences or by a Federal court in an appeal under 35 U.S.C. 141 or a civil action under 35 U.S.C. 145 or 146 where at least one allowable claim remains in the application and ending on the date of mailing of either an action under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151, whichever occurs first; and

(6) The number of days, if any, in the period beginning on the day after the date that is four months after the date the issue fee was paid and all outstanding requirements were satisfied and ending on the date a patent was issued.

(b) The period of adjustment under § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application and ending on the date a patent was issued, but not including the sum of the following periods:

(1) The number of days, if any, in the period beginning on the date on which a request for continued examination of the application under 35 U.S.C. 132(b) was and ending on the date the patent was issued;

(2)(i) The number of days, if any, in the period beginning on the date an interference was declared or redeclared to involve the application in the interference and ending on the date that the interference was terminated with respect to the application; and

(ii) The number of days, if any, in the period beginning on the date prosecution in the application was suspended by the Office due to interference proceedings under 35 U.S.C. 135(a) not involving the application and ending on the date of the termination of the suspension;

(3)(i) The number of days, if any, the application was maintained in a sealed condition under 35 U.S.C. 181;

(ii) The number of days, if any, in the period beginning on the date of mailing of an examiner's answer under § 1.193 in the application under secrecy order and ending on the date the secrecy order was removed;

(iii) The number of days, if any, in the period beginning on the date applicant was notified that an interference would be declared but for the secrecy order and ending on the date the secrecy order was removed; and

(iv) The number of days, if any, in the period beginning on the date of notification under § 5.3(c) of this chapter and ending on the date of mailing of the notice of allowance under 35 U.S.C. 151; and,

(4) The number of days, if any, in the period beginning on the date on which a notice of appeal to the Board of Patent Appeals and Interferences was under 35 U.S.C. 134 and § 1.191 and ending on the date of the last decision by the Board of Patent Appeals and Interferences or by a Federal court in an appeal under 35 U.S.C. 141 or a civil action under 35 U.S.C. 145, or on the date of mailing of either an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first, if the appeal did not result in a decision by the Board of Patent Appeals and Interferences.

(c) The period of adjustment under § 1.702(c) is the sum of the following periods, to the extent that the periods are not overlapping:

(1) The number of days, if any, in the period beginning on the date an interference was declared or redeclared to involve the application in the interference and ending on the date that the interference was terminated with respect to the application; and

(2) The number of days, if any, in the period beginning on the date prosecution in the application was suspended by the Office due to interference proceedings under 35 U.S.C. 135(a) not involving the application and ending on the date of the termination of the suspension.

(d) The period of adjustment under § 1.702(d) is the sum of the following periods, to the extent that the periods are not overlapping:

(1) The number of days, if any, the application was maintained in a sealed condition under 35 U.S.C. 181;

(2) The number of days, if any, in the period beginning on the date of mailing of an examiner's answer under § 1.193 in the application under secrecy order and ending on the date the secrecy order was removed;

(3) The number of days, if any, in the period beginning on the date applicant was notified that an interference would be declared but for the secrecy order and ending on the date the secrecy order was removed; and

(4) The number of days, if any, in the period beginning on the date of notification under § 5.3(c) of this chapter and ending on the date of mailing of the notice of allowance under 35 U.S.C. 151.

(e) The period of adjustment under § 1.702(e) is the sum of the number of days, if any, in the period beginning on the date on which a notice of appeal to the Board of Patent Appeals and Interferences was under 35 U.S.C. 134 and § 1.191 and ending on the date of a final decision in favor of the applicant by the Board of Patent Appeals and Interferences or by a Federal court in an appeal under 35 U.S.C. 141 or a civil action under 35 U.S.C. 145.

(f) The adjustment will run from the expiration date of the patent as set forth in 35 U.S.C. 154(a)(2). To the extent that periods of adjustment attributable to the grounds specified in §1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed. The term of a patent entitled to adjustment under § 1.702 and this section shall be adjusted for the sum of the periods calculated under paragraphs (a) through (e) of this section, to the extent that such periods are not overlapping, less the sum of the periods calculated under § 1.704. The date indicated on any certificate of mailing or transmission under § 1.8 shall not be taken into account in this calculation.

(g) No patent, the term of which has been disclaimed beyond a specified date, shall be adjusted under § 1.702 and this section beyond the expiration date specified in the disclaimer.

37 CFR 1.704. Reduction of period of adjustment of patent term.

(a) The period of adjustment of the term of a patent under § 1.703(a) through (e) shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution (processing or examination) of the application.

(b) With respect to the grounds for adjustment set forth in §§ 1.702(a) through (e), and in particular the ground of adjustment set forth in § 1.702(b), an applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of three months that are taken to reply to any notice or action by the Office making any rejection, objection, argument, or other request, measuring such three-month period from the date the notice or action was mailed or given to the applicant, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date that is three months after the date of mailing or transmission of the Office communication notifying the applicant of the rejection, objection, argument, or other request and ending on the date the reply was filed. The period, or shortened statutory period, for reply that is set in the Office action or notice has no effect on the three-month period set forth in this paragraph.

(c) Circumstances that constitute a failure of the applicant to engage in reasonable efforts to conclude processing or examination of an application also include the following circumstances, which will result in the following reduction of the period of adjustment set forth in § 1.703 to the extent that the periods are not overlapping:

(1) Suspension of action under § 1.103 at the applicant's request, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the date a request for suspension of action under § 1.103 was and ending on the date of the termination of the suspension;

(2) Deferral of issuance of a patent under § 1.314, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the date a request for deferral of issuance of a patent under § 1.314 was filed and ending on the date the patent was issued;

(3) Abandonment of the application or late payment of the issue fee, in which case the period of adjustment set forth in §1.703 shall be reduced by the number of days, if any, beginning on the date of abandonment or the date after the date the issue fee was due and ending on the earlier of:

(i) The date of mailing of the decision reviving the application or accepting late payment of the issue fee; or

(ii) The date that is four months after the date the grantable petition to revive the application or accept late payment of the issue fee was filed;

(4) Failure to file a petition to withdraw the holding of abandonment or to revive an application within two months from the mailing date of a notice of abandonment, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date two months from the mailing date of a notice of abandonment and ending on the date a petition to withdraw the holding of abandonment or to revive the application was filed;

(5) Conversion of a provisional application under 35 U.S.C. 111(b) to a nonprovisional application under 35 U.S.C. 111(a) pursuant to 35 U.S.C. 111(b)(5), in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the date the application was filed under 35 U.S.C. 111(b) and ending on the date a request in compliance with §1.53(c)(3) to convert the provisional application into a nonprovisional application was filed;

(6) Submission of a preliminary amendment or other preliminary paper less than one month before the mailing of an Office action under 35 U.S.C. 132 or notice of allowance under 35 U.S.C. 151 that requires the mailing of a supplemental Office action or notice of allowance, in which case the period of adjustment set forth in § 1.703 shall be reduced by the lesser of:

(i) The number of days, if any, beginning on the day after the mailing date of the original Office action or notice of allowance and ending on the date of mailing of the supplemental Office action or notice of allowance; or

(ii) Four months;

(7) Submission of a reply having an omission (§1.135(c)), in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date the reply having an omission was filed and ending on the date that the reply or other paper correcting the omission was filed;

(8) Submission of a supplemental reply or other paper, other than a supplemental reply or other paper expressly requested by the examiner, after a reply has been filed, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date the initial reply was filed and ending on the date that the supplemental reply or other such paper was filed;

(9) Submission of an amendment or other paper after a decision by the Board of Patent Appeals and Interferences, other than a decision designated as containing a new ground of rejection under § 1.196(b) or statement under § 1.196(c), or a decision by a Federal court, less than one month before the mailing of an Office action under 35 U.S.C. 132 or notice of allowance under 35 U.S.C. 151 that requires the mailing of a supplemental Office action or supplemental notice of allowance, in which case the period of adjustment set forth in § 1.703 shall be reduced by the lesser of:

(i) The number of days, if any, beginning on the day after the mailing date of the original Office action or notice of allowance and ending on the mailing date of the supplemental Office action or notice of allowance; or

(ii) Four months;

(10) Submission of an amendment under § 1.312 or other paper after a notice of allowance has been given or mailed, in which case the period of adjustment set forth in § 1.703 shall be reduced by the lesser of:

(i) The number of days, if any, beginning on the date the amendment under § 1.312 or other paper was and ending on the mailing date of the Office action or notice in response to the amendment under § 1.312 or such other paper; or

(ii) Four months; and

(11) Further prosecution via a continuing application, in which case the period of adjustment set forth in § 1.703 shall not include any period that is prior to the actual filing date of the application that resulted in the patent.

(d) A paper containing only an information disclosure statement in compliance with §§ 1.97 and 1.98 will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under paragraphs (c)(6), (c)(8), (c)(9), or (c)(10) of this section if it is accompanied by a statement that each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement. This thirty-day period is not extendable.

(e) Submission of an application for patent term adjustment under § 1.705(b) (with or without request under § 1.705(c) for reinstatement of reduced patent term adjustment) will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under paragraph (c)(10) of this section.

37 CFR 1.705. Patent term adjustment determination

(a) The notice of allowance will include notification of any patent term adjustment under 35 U.S.C. 154(b).

(b) Any request for reconsideration of the patent term adjustment indicated in the notice of allowance, except as provided in paragraph (d) of this section, and any request for reinstatement of all or part of the term reduced pursuant to § 1.704(b) must be by way of an application for patent term adjustment. An application for patent term adjustment under this section must be filed no later than the payment of the issue fee but may not be filed earlier than the date of mailing of the notice of allowance. An application for patent term adjustment under this section must be accompanied by:

(1) The fee set forth in § 1.18(e); and

(2) A statement of the facts involved, specifying:

(i) The correct patent term adjustment and the basis or bases under § 1.702 for the adjustment;

(ii) The relevant dates as specified in §§ 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in § 1.703(f) to which the patent is entitled;

(iii) Whether the patent is subject to a terminal disclaimer and any expiration date specified in the terminal disclaimer; and

(iv)(A)Any circumstances during the prosecution of the application resulting in the patent that constitute a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in § 1.704; or

(B) That there were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in § 1.704.

(c) Any application for patent term adjustment under this section that requests reinstatement of all or part of the period of adjustment reduced pursuant to § 1.704(b) for failing to reply to a rejection, objection, argument, or other request within three months of the date of mailing of the Office communication notifying the applicant of the rejection, objection, argument, or other request must also be accompanied by:

(1) The fee set forth in § 1.18(f); and

(2) A showing to the satisfaction of the Commissioner that, in spite of all due care, the applicant was unable to reply to the rejection, objection, argument, or other request within three months of the date of mailing of the Office communication notifying the applicant of the rejection, objection, argument, or other request. The Office shall not grant any request for reinstatement for more than three additional months for each reply beyond three months from the date of mailing of the Office communication notifying the applicant of the rejection, objection, argument, or other request.

(d) If the patent is issued on a date other than the projected date of issue and this change necessitates a revision of the patent term adjustment indicated in the notice of allowance, the patent will indicate the revised patent term adjustment. If the patent indicates a revised patent term adjustment due to the patent being issued on a date other than the projected date of issue, any request for reconsideration of the patent term adjustment indicated in the patent must be filed within thirty days of the date the patent issued and must comply with the requirements of paragraphs (b)(1) and (b)(2) of this section.

(e) The periods set forth in this section are not extendable.

(f) No submission or petition on behalf of a third party concerning patent term adjustment under 35 U.S.C. 154(b) will be considered by the Office. Any such submission or petition will be returned to the third party, or otherwise disposed of, at the convenience of the Office.

2750 Patent Term Extension for Delays at other Agencies under 35 U.S.C. 156

The right to a patent term extension based upon regulatory review is the result of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. 355(b), (j), (l); 35 U.S.C. 156, 271, 282)(Hatch-Waxman Act). The act sought to eliminate two distortions to the normal "patent term produced by the requirement that certain products must receive premarket regulatory approval." *Eli Lilly & Co. v. Medtronic Inc.*, 496 U.S. 661, 669, 15 USPQ2d 1121, 1126 (1990). The first distortion was that the patent owner loses patent term during the early years of the patent because the product cannot be commercially marketed without approval from a regulatory agency. The second distortion occurred after the end of the patent term because competitors could not immediately enter the market upon expiration of the patent because they were not allowed to begin testing and other activities necessary to receive FDA approval before patent expiration.

The part of the act codified as 35 U.S.C. 156 was designed to create new incentives for research and development of certain products subject to premarket government approval by a regulatory agency. The statute enables the owners of patents on certain human drugs, food or color additives, medical devices, animal drugs, and veterinary biological products to restore to the terms of those patents some of the time lost while awaiting premarket government approval from a regulatory agency. The rights derived from extension of the patent term are limited to the approved product (as defined in 35 U.S.C. 156(a)(4) and (a)(5)). See 35 U.S.C. 156(b). Accordingly, if the patent claims other products in addition to the approved product, the exclusive patent rights to the additional products expire with the original expiration date of the patent.

In exchange for extension of the term of the patent, Congress legislatively overruled *Roche Products v. Bolar Pharmaceuticals*, 733 F.2d 858, 221 USPQ 937 (Fed. Cir. 1984) as to products covered by 35 U.S.C. 271(e) and provided that it shall not be an act of infringement, for example, to make and test a patented drug solely for the purpose of developing and submitting information for an Abbreviated New Drug Application (ANDA). 35 U.S.C. 271(e)(1). See Donald O. Beers, *Generic and Innovator Drugs: A Guide to FDA Approval Requirements*, Fifth Edition, Aspen Law & Business, 1999, 4.3[2] for a discussion of the Hatch-Waxman Act and infringement litigation. Furthermore, Congress provided that an ANDA cannot be filed until five years after the approval date of the product if the active ingredient or a salt or ester of the active ingredient had not been previously approved under section 505(b) of the Federal Food, Drug and Cosmetic Act. 21 U.S.C. 355(j)(4)(D)(ii). See also Lourie, *Patent Term Restoration: History, Summary, and Appraisal*, 40 Food, Drug and Cosmetic L. J. 351, 353-60 (1985). See also Lourie,

Patent Term Restoration, 66 J. Pat. Off. Soc'y 526 (1984).

On November 16, 1988, 35 U.S.C. 156 was amended by Public Law 100-670, essentially to add animal drugs and veterinary biologics to the list of products that can form the basis of patent term extension. Animal drug products which are primarily manufactured through biotechnology are excluded from the provisions of patent term extension.

On December 3, 1993, 35 U.S.C. 156 was further amended to provide for interim extension of a patent where a product claimed by the patent was expected to be approved, but not until after the original expiration date of the patent. Public Law 103-179, Section 5.

An application for the extension of the term of a patent under 35 U.S.C. 156 must be submitted by the owner of record of the patent or its agent within the sixty-day period beginning on the date the product received permission for commercial marketing or use under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use. See 35 U.S.C. 156(d)(1). The USPTO initially determines whether the application is formally complete and whether the patent is eligible for extension. The statute requires the Commissioner of Patents and Trademarks to notify the Secretary of Agriculture or the Secretary of Health and Human Services of the submission of an application for extension of patent term which complies with 35 U.S.C. 156 within sixty days and to submit to the Secretary a copy of the application. Not later than thirty days after receipt of the application from the Commissioner, the Secretary will determine the length of the applicable regulatory review period and notify the Commissioner of the determination. If the Commissioner determines that the patent is eligible for extension, the Commissioner calculates the length of extension for which the patent is eligible under the appropriate statutory provision and issues an appropriate Certificate of Extension.

Patent term extensions provided by private relief legislation, public laws other than as enacted by 35 U.S.C. 156, such as 35 U.S.C. 155 and 155A, are not addressed herein.

2751 Eligibility Requirements

35 U.S.C. 156. Extension of patent term

(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b) if —

(1) the term of the patent has not expired before an application is submitted under subsection (d)(1) for its extension;

(2) the term of the patent has never been extended under subsection (e)(1) of this section;

(3) an application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirements of paragraphs (1) through (4) of subsection (d);

(4) the product has been subject to a regulatory review period before its commercial marketing or use;

(5)(A) except as provided in subparagraph (B) or (C), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred;

(B) in the case of a patent which claims a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use of the product after such regulatory period is the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent; or

(C) for purposes of subparagraph (A), in the case of a patent which —

(i) claims a new animal drug or a veterinary biological product which (I) is not covered by the claims in any other patent which has been extended, and (II) has received permission for the commercial marketing or use in non-food-producing animals and in food-producing animals, and

(ii) was not extended on the basis of the regulatory review period for use in non-food-producing animals, the permission for the commercial marketing or use of the drug or product after the regulatory review period for use in food-producing animals is the first permitted commercial marketing or use of the drug or product for administration to a food-producing animal.

The product referred to in paragraphs (4) and (5) is hereinafter in this section referred to as the "approved product."

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(f) For purposes of this section:

(1) The term "product" means:

(A) A drug product.

(B) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

(2) The term "drug product" means the active ingredient of—

(A) a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act) or

(B) a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Virus-Serum-Toxin Act) which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques, including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

(3) The term "major health or environmental effects test" means a test which is reasonably related to the evaluation of the health or environmental effects of a product, which requires at least six months to conduct, and the data from which is submitted to receive permission for commercial marketing or use. Periods of analysis or evaluation of test results are not to be included in determining if the conduct of a test required at least six months.

(4)(A)Any reference to section 351 is a reference to section 351 of the Public Health Service Act.

(B) Any reference to section 503, 505, 512, or 515 is a reference to section 503, 505, 512, or 515 of the Federal Food, Drug and Cosmetic Act.

(C) Any reference to the Virus-Serum-Toxin Act is a reference to the Act of March 4, 1913 (21 U.S.C. 151 - 158).

(5) The term "informal hearing" has the meaning prescribed for such term by section 201(y) of the Federal Food, Drug and Cosmetic Act.

(6) The term "patent" means a patent issued by the United States Patent and Trademark Office.

(7) The term "date of enactment" as used in this section means September 24, 1984, for human drug product, a medical device, food additive, or color additive.

(8) The term "date of enactment" as used in this section means the date of enactment of the Generic Animal Drug and Patent Term Restoration Act for an animal drug or a veterinary biological product.

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37 CFR 1.710. Patents subject to extension of the patent term

(a) A patent is eligible for extension of the patent term if the patent claims a product as defined in paragraph (b) of this section, either alone or in combination with other ingredients that read on a composition that received permission for commercial marketing or use, or a method of using such a product, or a method of manufacturing such a product, and meets all other conditions and requirements of this subpart.

(b) The term *product* referred to in paragraph (a) of this section means —

(l) The active ingredient of a new human drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act) including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient; or

(2) The active ingredient of a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Virus-Serum-Toxin Act) that is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes including site specific genetic manipulation techniques, including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient; or

(3) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

37 CFR 1.720. Conditions for extension of patent term

The term of a patent may be extended if:

(a) The patent claims a product or a method of using or manufacturing a product as defined in § 1.710;

(b) The term of the patent has never been previously extended, except for extensions issued pursuant to §§ 1.701, 1.760, or 1.790;

(c) An application for extension is submitted in compliance with § 1.740;

(d) The product has been subject to a regulatory review period as defined in 35 U.S.C. 156(g) before its commercial marketing or use;

(e) The product has received permission for commercial marketing or use and —

(1) The permission for the commercial marketing or use of the product is the first received permission for commercial marketing or use under the provision of law under which the applicable regulatory review occurred, or

(2) In the case of a patent other than one directed to subject matter within § 1.710(b)(2) claiming a method of manufacturing the product that primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use is the first received permission for the commercial marketing or use of a product manufactured under the process claimed in the patent, or

(3) In the case of a patent claiming a new animal drug or a veterinary biological product that is not covered by the claims in any other patent that has been extended, and has received permission for the commercial marketing or use in non-food-producing animals and in food-producing animals, and was not extended on the basis of the regulatory review period for use in non-food-producing animals, the permission for the commercial marketing or use of the drug or product after the regulatory review period for use in food-producing animals is the first permitted commercial marketing or use of the drug or product for administration to a food-producing animal.

(f) The application is submitted within the sixty-day period beginning on the date the product first received permission for commercial marketing or use under the provisions of law under which the applicable regulatory review period occurred; or in the case of a patent claiming a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the application for extension is submitted within the sixty-day period beginning on the date of the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent; or in the case of a patent that claims a new animal drug or a veterinary biological product that is not covered by the claims in any other patent that has been extended, and said drug or product has received permission for the commercial marketing or use in non-food-producing animals, the

application for extension is submitted within the sixty-day period beginning on the date of the first permitted commercial marketing or use of the drug or product for administration to a food-producing animal;

(g) The term of the patent, including any interim extension issued pursuant to § 1.790, has not expired before the submission of an application in compliance with § 1.741; and

(h) No other patent term has been extended for the same regulatory review period for the product.

35 U.S.C. 156(a) sets forth what patents can be extended and the conditions under which they may be extended. 37 CFR 1.710 also addresses the patents that may be extended, and 37 CFR 1.720 describes the conditions under which a patent may be extended. As set forth in 35 U.S.C. 156 and 37 CFR 1.710, a patent which claims a human drug product, medical device, food or color additive first approved for marketing or use after September 24, 1984, or an animal drug or veterinary biological product (which was not primarily manufactured through biotechnology) first approved for marketing or use after November 16, 1988, may qualify for patent term extension. Furthermore, 35 U.S.C. 156(a)(1) - (5) require that the applicant establish that:

(1) the patent has not expired before an application under 35 U.S.C. 156(d) was filed (this may be an application for patent term extension under subsection (d)(1) or an application for interim extension under subsection (d)(5));

(2) the patent has never been extended under 35 U.S.C. 156(e)(1);

(3) the application for extension is submitted by the owner of record of the patent or its agent to the Office within 60 days of regulatory agency approval of the commercial marketing application and the application includes details relating to the patent, the approved product, and the regulatory review time spent in securing regulatory agency approval;

(4) the product has been subject to a regulatory review period within the meaning of 35 U.S.C. 156(g) before its commercial marketing or use;

(5) the approval is the first permitted commercial marketing or use of the product (35 U.S.C. 156(a)(5)(A)), except in the case of human drug products manufactured using recombinant DNA technology where the provisions of 35 U.S.C. 156(a)(5)(B) apply, or in the case of a new animal drug or a veterinary biological product where the provisions of 35 U.S.C. 156(a)(5)(C) apply.

35 U.S.C. 156(c)(4) also requires that no other patent term has been extended for the same regulatory review period for the product. See MPEP § 2761.

MEANING OF "PRODUCT" AS DEFINED IN 35 U.S.C. 156(f)

As required by 35 U.S.C. 156(a), patents eligible for extension of patent term are those which:

(A) claim a "product" as defined in 35 U.S.C. 156(f)(1), either alone or in combination with other ingredients, wherein the product reads on a composition (product) that received permission for commercial marketing or use, or a method of using such a product, or a method of manufacturing such a product, and

(B) meet all other conditions and requirements of the statute.

The term "claims a product" is not synonymous with "infringed by a product." A patent which claims a metabolite of an approved drug does not claim the approved drug. *Hoechst-Roussel Pharmaceuticals Inc. v. Lehman*, 109 F.3d 756, 759, 42 USPQ2d 1220, 1223 (Fed. Cir. 1997).

The term "product" means:

(A) The active ingredient of a new human drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act) including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient; or

(B) The active ingredient of a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Virus-Serum-Toxin Act) that is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes including site specific genetic manipulation techniques, including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient; or

(C) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

See 21 CFR 60.3(b) for definitions of terms such as active ingredient, color additive, food additive, human drug product, and medical device.

Essentially, a "product" is a "drug product," medical device, food additive, or color additive requiring Food and Drug Administration or Department of Agriculture (Plant and Animal Inspection Service) approval of an order or regulation prior to commercial marketing or use. "Drug product" is the active ingredient of a human drug, animal drug (excluding those primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes including site specific genetic manipulation techniques), or biological product (as defined by the Federal Food, Drug and Cosmetics Act and the Public Health Service Act) including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient. Animal biological products are approved by the Plant and Animal Inspection Service of the Department of Agriculture.

A "drug product" means the active ingredient found in the final dosage form prior to administration of the product to the patient, not the resultant form the drug may take after administration. In this regard, a drug in the ester form which is used for oral administration is a different drug product from the same active moiety in a salt form which is administered by injection, even though both the salt and the ester are used to treat the same disease condition. The ester form is a different active ingredient from the salt form. Both the ester and the salt active ingredient may each support an extension of patent term of different patents provided the acid itself has not previously been approved. See *Glaxo Operations UK Ltd. v. Quigg*, 706 F.Supp. 1224, 1232-33, 10 USPQ2d 1100, 1107 (E.D. Va. 1989); *aff'd.*, 894 F.2d 392, 13 USPQ2d 1628 (Fed. Cir. 1990).

Furthermore, a "drug product" is the active ingredient of a particular new drug, rather than the entire composition of the drug product approved by the Food and Drug Administration. See *Fisons plc v. Quigg*, 1988 U.S. Dist. LEXIS 10935; 8 USPQ2d 1491, 1495 (D.D.C. 1988); *aff'd.*, 876 F2d 99, 110; 10 USPQ2d 1869, 1870 (Fed. Cir. 1989). An active ingredient of a drug is the ingredient in the drug product that becomes therapeutically active when administered. *Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392, 393, 13 USPQ2d 1628, 1629 (Fed. Cir. 1990); *but c.f.*, *Abbott Laboratories v. Young*, 920 F.2d 984, 989 n.7 (D.C. Cir. 1990), *cert denied*, 112 S. Ct. 76 (1991) (The court rejected the approach of *Glaxo* in considering whether *Abbott* was entitled to exclusivity).

A patent is considered to claim the product at least in those situations where the patent claims the active ingredient per se, or claims a composition or formulation which contains the active ingredient(s) and reads on the composition or formulation approved for commercial marketing or use.

NO PREVIOUS EXTENSIONS (WITH LIMITED EXCEPTIONS)

37 CFR 1.720(b) explains that patent term extension pursuant to 35 U.S.C. 156 is available only if the term of the patent has never been previously extended, except for extensions issued pursuant to 37 CFR 1.701, 1.760, or 1.790. An extension issued pursuant to 37 CFR 1.701 is an extension of the patent due to administrative delay within the Office. Note that the term of a patent is "adjusted," not extended, pursuant to 37 CFR 1.702-1705. An extension issued pursuant to 37 CFR 1.760 is an interim extension under 35 U.S.C. 156(e)(2). An extension issued pursuant to 37 CFR 1.790 is an interim extension under 35 U.S.C. 156(d)(5).

REGULATORY REVIEW PERIOD

37 CFR 1.720(d) restates the statutory requirement set forth in 35 U.S.C. 156(a)(4). The regulatory review period must have been a regulatory review period defined by the statute. A regulatory review period under section 510(k) of the Federal Food, Drug and Cosmetic Act is not a regulatory review period which gives rise to eligibility for patent term extension under 35 U.S.C. 156. *In re Nitinol Medical Technologies Inc.,* 17 USPQ2d 1492, 1492-1493 (Comm'r Pat. & Tm. 1990). See also *Baxter Diagnostics v. AVL Scientific Corp*. 798 F. Supp. 612, 619-620; 25 USPQ2d 1428,1434 (CD CA 1992)(Congress intended only Class III medical devices to be eligible for patent term extension).

If the product is alleged to be a medical device, then regulatory review must have occurred under section 515, and not section 505, of the Federal Food, Drug and Cosmetic Act. Drug products are not reviewed under section 515.

If more than one application for patent term extension is filed based upon a single regulatory review period, election will be required of a single patent. See MPEP § 2761.

FIRST PERMITTED MARKETING OR USE

37 CFR 1.720(e) follows 35 U.S.C. 156(a)(5), and sets forth that the approval under the relevant provision of law must have been the first permitted marketing or use of the product under the provision of law, unless the product is for use in food producing animals as explained below. See *In re Patent Term Extension Application, U.S. Patent No. 3,849,549*, 226 USPQ 283, 284 (Pat. & Tm. Office 1985). If the product is a human drug product, then the approval of the active ingredient must be the first permitted commercial marketing or use of the active ingredient as a single entity or in combination with another active ingredient under the provision of law under which regulatory review occurred.

Where a product contains multiple active ingredients, if any one active ingredient has not been previously approved, it can form the basis of an extension of patent term provided the patent claims that ingredient. See *In re Alcon Laboratories Inc.*, 13 USPQ2d 1115, 1121 (Comm'r Pat. & Tm. 1989) for examples of products having different combinations of active ingredients. A different ratio of hormones is not a different active ingredient for purposes of 35 U.S.C. 156. Furthermore, an approved product having two active ingredients, which are not shown to have a synergistic effect or have pharmacological interaction, will not be considered to have a single active ingredient made of the two active ingredients.

As to 35 U.S.C. 156(a)(5)(C), which is addressed in 37 CFR 1.720(e)(3), the term of a patent directed to a new animal drug or veterinary biological product may be extended based on a second or subsequent approval of the active ingredient provided all the following conditions exist:

(A) the patent claims the drug or product;

(B) the drug or product is not covered by the claims in any other patent that has been extended;

(C) the patent term was not extended on the basis of the regulatory review period for use in non-food producing animals; and

(D) the second or subsequent approval was the first permitted commercial marketing or use of the drug or product for administration to a food-producing animal. In this case, the application must be filed within sixty days of the first approval for administration to a food-producing animal.

For animal drugs or products, prior approval for use in a non-food producing animal will not make a patent ineligible for patent term extension based upon a later approval of the drug or product for use in food producing animals, if the later approval is the first approval of the drug or product for use in food producing animals.

2752 Patent Term Extension Applicant

35 U.S.C. 156. Extension of patent term

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(d)(1) To obtain an extension of the term of a patent under this section, the owner of record of the patent or its agent shall submit an application to the Director. Except as provided in paragraph (5), such an application may only be submitted within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use. The application shall contain —

(A) the identity of the approved product and the Federal statute under which regulatory review occurred;

(B) the identity of the patent for which an extension is being sought and the identity of each claim of such patent;

(C) information to enable the Director to determine under subsections (a) and (b) the eligibility of a patent for extension and the rights that will be derived from the extension and information to enable the Director and the Secretary of Health and Human Services or the Secretary of Agriculture to determine the period of the extension under subsection (g);

(D) a brief description of the activities undertaken by the applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities; and

(E) such patent or other information as the Director may require.

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37 CFR 1.730. Applicant for extension of patent term; signature requirements.

(a) Any application for extension of a patent term must be submitted by the owner of record of the patent or its agent and must comply with the requirements of § 1.740.

(b) If the application is submitted by the patent owner, the application must be signed either by:

(1) The patent owner in compliance with § 3.73(b) of this chapter; or

(2) A registered practitioner on behalf of the patent owner.

(c) If the application is submitted on behalf of the patent owner by an agent of the patent owner (*e.g.*, a licensee of the patent owner), the application must be signed by a registered practitioner on behalf of the agent. The Office may require proof that the agent is authorized to act on behalf of the patent owner.

(d) If the application is signed by a registered practitioner, the Office may require proof that the practitioner is authorized to act on behalf of the patent owner or agent of the patent owner.

35 U.S.C. 156(d)(1) requires that the application for extension of the patent term must be submitted by the owner of record of the patent or its agent. If the application is filed by an assignee, the application papers should refer to the reel and frame number of the recorded assignment. A power of attorney from the patent owner to any patent attorney or agent submitting the patent term extension application papers should be filed, if the attorney or agent is not already of record in the patent (see 37 CFR 1.34(b)).

If the applicant for patent term extension was not the marketing applicant before the regulatory agency, then there must be an agency relationship between the patent owner and the marketing applicant during the regulatory review period. To show that such an applicant is authorized to rely upon the activities of the marketing applicant before the Food and Drug Administration or the Department of Agriculture, it is advisable for the applicant for patent term extension to obtain a letter from the marketing applicant specifically authorizing such reliance.

2753 Application Contents

37 CFR 1.740. Formal requirements for application for extension of patent term; correction of informalities.

(a) An application for extension of patent term must be made in writing to the Commissioner. A formal application for the extension of patent term must include:

(1) A complete identification of the approved product as by appropriate chemical and generic name, physical structure or characteristics;

(2) A complete identification of the Federal statute including the applicable provision of law under which the regulatory review occurred;

(3) An identification of the date on which the product received permission for commercial marketing or use under the provision of law under which the applicable regulatory review period occurred;

(4) In the case of a drug product, an identification of each active ingredient in the product and as to each active ingredient, a statement that it has not been previously approved for commercial marketing or use under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Virus-Serum-Toxin Act, or a statement of when the active ingredient was approved for commercial marketing or use (either alone or in combination with other active ingredients), the use for which it was approved, and the provision of law under which it was approved.

(5) A statement that the application is being submitted within the sixty day period permitted for submission pursuant to § l.720(f) and an identification of the date of the last day on which the application could be submitted;

(6) A complete identification of the patent for which an extension is being sought by the name of the inventor, the patent number, the date of issue, and the date of expiration;

(7) A copy of the patent for which an extension is being sought, including the entire specification (including claims) and drawings;

(8) A copy of any disclaimer, certificate of correction, receipt of maintenance fee payment, or reexamination certificate issued in the patent;

(9) A statement that the patent claims the approved product, or a method of using or manufacturing the approved product, and a showing which lists each applicable patent claim and demonstrates the manner in which at least one such patent claim reads on:

(i) The approved product, if the listed claims include any claim to the approved product;

(ii) The method of using the approved product, if the listed claims include any claim to the method of using the approved product; and

(iii) The method of manufacturing the approved product, if the listed claims include any claim to the method of manufacturing the approved product;

(10) A statement beginning on a new page of the relevant dates and information pursuant to 35 U.S.C. 156(g) in order to enable the Secretary of Health and Human Services or the Secretary of Agriculture, as appropriate, to determine the applicable regulatory review period as follows:

(i) For a patent claiming a human drug, antibiotic, or human biological product:

(A) The effective date of the investigational new drug (IND) application and the IND number;

(B) The date on which a new drug application (NDA) or a Product License Application (PLA) was initially submitted and the NDA or PLA number; and

(C) The date on which the NDA was approved or the Product License issued;

(ii) For a patent claiming a new animal drug:

(A) The date a major health or environmental effects test on the drug was initiated, and any available substantiation of that date, or the date of an exemption under subsection (j) of Section 512 of the Federal Food, Drug, and Cosmetic Act became effective for such animal drug;

(B) The date on which a new animal drug application (NADA) was initially submitted and the NADA number; and

(C) The date on which the NADA was approved;

(iii) For a patent claiming a veterinary biological product:

(A) The date the authority to prepare an experimental biological product under the Virus-Serum-Toxin Act became effective;

(B) The date an application for a license was submitted under the Virus-Serum-Toxin Act; and

(C) The date the license issued;

(iv) For a patent claiming a food or color additive:

(A) The date a major health or environmental effects test on the additive was initiated and any available substantiation of that date;

(B) The date on which a petition for product approval under the Federal Food, Drug and Cosmetic Act was initially submitted and the petition number; and

(C) The date on which the FDA published a *Federal Register* notice listing the additive for use;

(v) For a patent claiming a medical device:

(A) The effective date of the investigational device exemption (IDE) and the IDE number, if applicable, or the date on which the applicant began the first clinical investigation involving the device, if no IDE was submitted, and any available substantiation of that date;

(B) The date on which the application for product approval or notice of completion of a product development protocol under Section 515 of the Federal Food, Drug and Cosmetic Act was initially submitted and the number of the application; and

(C) The date on which the application was approved or the protocol declared to be completed;

(11) A brief description beginning on a new page of the significant activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities;

(12) A statement beginning on a new page that in the opinion of the applicant the patent is eligible for the extension and a statement as to the length of extension claimed, including how the length of extension was determined;

(13) A statement that applicant acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services or the Secretary of Agriculture any information which is material to the determination of entitlement to the extension sought (see § 1.765);

(14) The prescribed fee for receiving and acting upon the application for extension (see § 1.20(j)); and

(15) The name, address, and telephone number of the person to whom inquiries and correspondence relating to the application for patent term extension are to be directed.

(b) The application under this section must be accompanied by two additional copies of such application (for a total of three copies).

(c) If an application for extension of patent term is informal under this section, the Office will so notify the applicant. The applicant has two months from the mail date of the notice, or such time as is set in the notice, within which to correct the informality. Unless the notice indicates otherwise, this time period may be extended under the provisions of § 1.136.

37 CFR 1.740 sets forth the requirements for a formal application for extension of patent term. See MPEP § 2752 for a discussion of who may apply for a patent term extension. See 37 CFR 1.741 and MPEP § 2754 for a description of the information that must be submitted in the patent term extension application in order to be accorded a filing date.

37 CFR 1.740(a)(1) requires a complete identification of the approved product as by appropriate chemical and generic name, physical structure or characteristics so as to enable the Commissioner to make a determination of whether the patent claims the approved product, or a method of using or manufacturing the approved product.

37 CFR 1.740(a)(2) requires a complete identification of the federal statute including the applicable provision of law under which the regulatory review occurred. When the regulatory review of the product took place under more than one Federal statute, each appropriate statute should be listed. This could apply to a situation where a human biological product is tested under an investigational new drug (IND) application pursuant to the Federal Food, Drug, and Cosmetic Act, but is approved under the Public Health Service Act; or to a situation where approval is sought for use of a particular medical device with a specific drug product which may require approval under more than a single provision of law. The product that forms the basis of an application for patent term extension must be either a medical device or a drug product; it cannot be a combination of those separate products. See the file history of U.S. Patent No. 4,428,744 for an example of the application of this principle.

The date that a product receives permission for commercial marketing or use (which must be identified pursuant to 37 CFR 1.740(a)(3)) is generally the mailing date of the letter from the regulatory agency indicating regulatory approval. For a food additive, the approval date is generally the effective date stated in the regulation and the date the regulation is published.

37 CFR 1.740(a)(4) provides that for drug products, each active ingredient must be identified and there must be an indication of the use for which the product was approved. For each active ingredient, a statement must be made that either the active ingredient was not previously approved for commercial marketing or use under the Federal Food, Drug and Cosmetic Act, or that the active ingredient was approved for commercial marketing or use (either alone or in combination with other active ingredients) and the provision of law under which it was approved. The information is

especially necessary for a determination of eligibility where, for example, the application is based on a second or subsequent approval of an active ingredient, but the first approval for administration to a food-producing animal.

In accordance with 37 CFR 1.740(a)(5), the application must be submitted within the sixty day period permitted for submission pursuant to 37 CFR 1.720(f). If the sixty day period ends on a Saturday, Sunday or Federal holiday, then the last day on which the application could be submitted will be considered to be the next business day following the Saturday, Sunday or Federal holiday. See 37 CFR 1.7. However, applicants are cautioned to avoid filing an application for patent term extension on the last day for filing to avoid the application being denied because the filing deadline was inadvertently missed.

The expiration date of the patent for which an extension is sought as identified pursuant to 37 CFR 1.740(a)(6) should be the expiration date according to the law (35 U.S.C. 154) at the time of filing of the application for patent term extension, and should include any patent term adjustment under 35 U.S.C. 154(b).

Pursuant to 37 CFR 1.740(a)(9), the application for patent term extension need only explain how one product claim of the patent claims the approved product, if there is a claim to the product. In addition, the application need only explain how one method of use claim of the patent claims the method of use of the approved product, if there is a claim to the method of use of the product. Lastly, the application need only explain how one claim of the patent claims the method of manufacturing the approved product, if there is a claim to the method of manufacturing the approved product. At most, a showing explaining three claims is required. However, each claim that claims the approved product, the method of use of the approved product, or the method of manufacturing the approved product must be listed. See 35 U.S.C. 156(d)(1)(B).

The showing should clearly explain how each listed claim reads on the approved product. For example, where a generic chemical structure is used in the claim to define the claimed invention, a listing of variables and substituents which correspond to the approved product is appropriate. Where a claim uses the "means for" language permitted by 35 U.S.C. 112, paragraph 6, reference to the column and line number of the patent text and any drawing reference numbers, as well as a description of any relevant equivalents, is also appropriate.

Pursuant to 37 CFR 1.740(a)(10), the patent term extension applicant must provide a statement to enable the Secretary of Health and Human Services or the Secretary of Agriculture, as appropriate, to determine the applicable regulatory period. In cases where there is no regulatory event to reflect the commencement of the testing or approval phase of the regulatory review period, applicants should include in the application the dates that they claim initiate either the approval or the testing phases and an explanation of their reasonable bases for why they conclude that these dates are the relevant dates. For instance, when the clinical trials are conducted outside of the United States, the testing phase for a medical device begins on the date the clinical investigation involving the device began. An applicant should include an explanation as to why the date claimed is the date on which such clinical investigations had commenced. If the applicant has any means of substantiating that date, that information should be included in the application.

37 CFR 1.740(a)(11) requires a brief description of the activities of the marketing applicant before the regulatory agency. This description should include an identification of significant communications of substance with the regulatory agency and the dates related to such communications. For example, these activities would include the dates of the submissions of new data to the FDA, communications between FDA and the applicant with respect to the appropriate protocols for testing the product, and communications between FDA and the applicant that are attempts to define the particular requirements for premarketing approval for this particular product. The applicant is not required to establish the existence of due diligence during the regulatory review period in order to have a complete application.

As stated above, the marketing applicant must have been an agent of the patent owner, if not the same entity as the patent owner. Accordingly, the Office will not assist the patent owner in obtaining information required in an application for patent term extension from the marketing applicant. It is sufficient that the description of the activities briefly identify those significant activities undertaken by the marketing

applicant directed toward regulatory approval, and a submission of insignificant details or identification of non-substantive communications is not required.

37 CFR 1.740(a)(12) requires that the extension applicant state the length of extension claimed and show how the length of extension was calculated, including whether the 14-year limit of 35 U.S.C. 156(c)(3) or the two or three limit of 35 U.S.C. 156(g)(6)(C) applies.

37 CFR 1.740(a)(15) requires the patent term extension applicant to provide a correspondence address. A fax number should also be provided. Normally only communications regarding the application for patent term extension will be sent to the address specified in the patent term extension application. If the address is changed after filing the application for patent term extension, the change of address should be sent to Box Patent Extension, since changing the address for the patent file will not cause the address for the patent term extension application to also be changed.

In order to change the address of all correspondence, including maintenance fee reminders, a change of address should also be filed. A change of address must be signed by the patent applicant, the assignee of the entire interest, or an attorney or agent of record. 37 CFR 1.33(a). Accordingly, if the patent term extension application is signed by the marketing applicant, as an agent of the patent owner, a power of attorney from the patent owner to any attorney for the marketing applicant would be necessary for the attorney for the marketing applicant to be able to sign a change of address for the patent file.

Pursuant to 37 CFR 1.740(b), two additional copies of the application for patent term extension must be filed with the application. In addition, applicants are requested to file an additional two copies of the application, for a total of five copies. The original copy is placed into the patent application file after the Notice of Final Determination is mailed. Two copies of the application are forwarded to the regulatory agency, one copy is made available for public inspection in the Office of Patent Legal Administration, and the fifth copy is used by the Legal Advisor.

2754 Filing Date

37 CFR 1.741. Complete application given a filing date; petition procedure.

(a) The filing date of an application for extension of a patent term is the date on which a complete application is received in the Office or filed pursuant to the procedures set forth in §1.8 or § 1.10. A complete application must include:

(1) An identification of the approved product;

(2) An identification of each Federal statute under which regulatory review occurred;

(3) An identification of the patent for which an extension is being sought;

(4) An identification of each claim of the patent which claims the approved product or a method of using or manufacturing the approved product;

(5) Sufficient information to enable the Commissioner to determine under subsections (a) and (b) of 35 U.S.C. 156 the eligibility of a patent for extension, and the rights that will be derived from the extension, and information to enable the Commissioner and the Secretary of Health and Human Services or the Secretary of Agriculture to determine the length of the regulatory review period; and

(6) A brief description of the activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities.

(b) If an application for extension of patent term is incomplete under this section, the Office will so notify the applicant. If applicant requests review of a notice that an application is incomplete, or review of the filing date accorded an application under this section, applicant must file a petition pursuant to this paragraph accompanied by the fee set forth in § 1.17(h) within two months of the mail date of the notice that the application is incomplete, or the notice according the filing date complained of. Unless the notice indicates otherwise, this time period may be extended under the provisions of § 1.136.

FILING DATE ACCORDED

An application for patent term extension under 35 U.S.C. 156 may be filed by mail addressed to the Assistant Commissioner for Patents, Box **Patent Ext.**, Washington, D.C. 20231 or may be hand carried to the Office of Patent Legal Administration. Applicants are encouraged to use the post card receipt practice described in MPEP § 502.

As set forth in 37 CFR 1.741(a), the filing date of an application for patent term extension is the date on which a complete application is received in the USPTO or filed pursuant to the certificate of mailing provisions of 37 CFR 1.8 (see MPEP § 512 for suggested formats for a certificate of mailing) or the Express Mail provisions of 37 CFR 1.10. Patent term extension applications should not be filed

by facsimile, however correspondence setting forth a change of address and other papers relating to a patent term extension may be sent by facsimile to the Office of Patent Legal Administration.

COMPLETE APPLICATION

The term "complete application" is defined in 37 CFR 1.741(a) and is an application meeting the requirements set forth in 35 U.S.C. 156(d)(1). For the establishment of a filing date, the distinction between the requirements of 37 CFR 1.740 and the requirements of 37 CFR 1.741 are important. While the requirements of 37 CFR 1.740 may be satisfied outside the 60 day filing period, the requirements of 37 CFR 1.741 are mandated by 35 U.S.C. 156 and must be satisfied within the 60 day filing period for the establishment of the filing date. The Office will consider each of these statutory requirements to be satisfied in an application which provides sufficient information, directed to each requirement, to act on the application, even though further information may be desired by the USPTO or the regulatory agency before a final determination of eligibility and length of patent term extension is made.

INFORMAL APPLICATION

37 CFR 1.740. Formal requirements for application for extension of patent term; correction of informalities.

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(c) If an application for extension of patent term is informal under this section, the Office will so notify the applicant. The applicant has two months from the mail date of the notice, or such time as is set in the notice, within which to correct the informality. Unless the notice indicates otherwise, this time period may be extended under the provisions of § 1.136.

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If the application does not meet all the formal requirements of 37 CFR 1.740(a) (see MPEP § 2753), the applicant will be notified of the informalities and may seek to have that holding reviewed under 37 CFR 1.740(c) or to correct the informality. The time periods set forth therein are subject to the provisions of 37 CFR 1.136, unless otherwise stated in the notice.

Note that if the application satisfies the requirements of 37 CFR 1.741, the application filing date will have been established even if the application is held to be informal under 37 CFR 1.740.

2754.01 Deadline for Filing an Application Under 35 U.S.C. 156(d)(1)

An application for patent term extension under 35 U.S.C. 156(d)(1) may only be filed within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use. The statutory time period is not extendable and cannot be waived or excused. See U.S. Patent No. 4,486,425 (application for patent term extension filed after the end of the 60-day period and was therefore denied). The sixty-day period begins on the regulatory agency approval date which marks the end of the regulatory review period. The statute takes into account only the regulatory review carried out by the Food and Drug Administration or the Department of Agriculture and no other government obstacles to marketing or use. See *Unimed, Inc. v. Quigg*, 888 F2d 826, 828; 12 USPQ2d 1644, 1646 (Fed. Cir. 1989). For drug products the approval date is the date of a letter by the Food and Drug Administration indicating that the application has been approved, even if the letter requires further action before the drug can be marketed. *Mead Johnson Pharmaceutical Group v. Bowen*, 838 F2d 1332, 1336; 6 USPQ2d 1565, 1568 (D.C. Cir. 1988). For food or color additives, the relevant date is the effective date of the regulation or order, which is set forth in the regulation or order, and which is generally the date that the regulation or order is published, e.g., in the Federal Register. See 21 U.S.C. 348(e). This date will generally be later than the date the approval is communicated to the marketing applicant.

2754.02 Filing Window for an Application Under 35 U.S.C. 156(d)(5)

A first application for interim extension under 35 U.S.C. 156(d)(5) (to extend the patent term before product approval) must be filed within the period beginning six months and ending fifteen days before the patent is due to expire. Each subsequent application for interim extension must be filed during the period beginning sixty days before and ending thirty

days before the expiration of the preceding interim extension. 35 U.S.C. 156(d)(5)(C). An interim extension granted under 35 U.S.C. 156(d)(5) terminates sixty days after permission for commercial marketing or use of the product is granted, except, if within the sixty-day period any additional information needed for an application for patent term extension under 35 U.S.C. 156(d)(1) is submitted, the patent may be further extended. 35 U.S.C. 156(d)(5)(E). The additional information required to be submitted includes the fee for an application for patent term extension under 35 U.S.C. 156(d)(1) and identification of the date the product received permission for commercial marketing or use and a statement that the application is being submitted within sixty days of such date and identification of the last date that the application could be submitted. See 37 CFR 1.740(a)(3) and (5). However, if the product is not approved within the period of interim extension, a new request for interim extension must be filed and another interim extension granted to keep the patent in force. An applicant is generally limited to four one-year interim extensions.

See MPEP § 2755.02 for additional information pertaining to the interim extension of patent term under 35 U.S.C. 156(d)(5).

2754.03 Filing of a Request for an Extension Under 35 U.S.C. 156(e)(2)

A request for an interim extension under 35 U.S.C. 156(e)(2) (to extend the patent term during the processing of the patent term extension application) should be made at least three months before the patent is due to expire. See MPEP § 2755.01 for information pertaining to the interim extension of patent term under 35 U.S.C. 156(e)(2).

2755 Eligibility Determination

37 CFR 1.750. Determination of eligibility for extension of patent term

A determination as to whether a patent is eligible for extension may be made by the Commissioner solely on the basis of the representations contained in the application for extension filed in compliance with § 1.740 or § 1.790. This determination may be delegated to appropriate Patent and Trademark Office officials and may be made at any time before the certificate of extension is issued. The Commissioner or other appropriate officials may require from applicant further information or make such independent inquiries as desired before a final determination is made on whether a patent is eligible for extension. In an application for extension filed in compliance with § 1.740, a notice will be mailed to applicant containing the determination as to the eligibility of the patent for extension and the period of time of the extension, if any. This notice shall constitute the final determination as to the eligibility and any period of extension of the patent. A single request for reconsideration of a final determination may be made if filed by the applicant within such time as may be set in the notice of final determination or, if no time is set, within one month from the date of the final determination. The time periods set forth herein are subject to the provisions of § 1.136.

The determination as to whether a patent is eligible for an extension will normally be made solely from the representations contained in the application for patent term extension. However, further information may be required or inquiry made of applicant before a final determination is made on whether a patent is eligible for extension. In circumstances where further information is required by the Office, the applicant will be given a time period within which to respond. The failure to provide a response within the time period provided may result in a final determination adverse to the granting of an extension of patent term unless the response period is extended. An extension of time to respond may be requested under the provisions of 37 CFR 1.136. Under appropriate circumstances, e.g., if time is of the essence for a particular reason, a request for information may contain a statement that the provisions of 37 CFR 1.136(a) are not available. The intentional failure to provide the information requested may result in an adverse final determination.

A final determination may be made at any time after an application is filed. A single request for reconsideration of a final determination may be filed within one month or within such other time period set in the final determination. A notice will be mailed to applicant containing the determination as to eligibility of the patent for extension and the period of time of the extension of the term, if any. This notice shall constitute the final determination as to eligibility and any period of extension of the patent term. If no request for reconsideration is filed within the time period set in the notice of final determination, the certificate of patent term extension will be issued in due course. See MPEP § 2758.

2755.01 Interim Extension of Patent Term During the Processing of the Application

35 U.S.C. 156. Extension of patent term.

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(2) If the term of a patent for which an application has been submitted under subsection (d)(1) would expire before a certificate of extension is issued or denied under paragraph (1) respecting the application, the Director shall extend, until such determination is made, the term of the patent for periods of up to one year if he determines that the patent is eligible for extension.

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37 CFR 1.760. Interim extension of patent term under 35 U.S.C. 156(e)(2).

An applicant who has filed a formal application for extension in compliance with § 1.740 may request one or more interim extensions for periods of up to one year each pending a final determination on the application pursuant to § 1.750. Any such request should be filed at least three months prior to the expiration date of the patent. The Commissioner may issue interim extensions, without a request by the applicant, for periods of up to one year each until a final determination is made. The patent owner or agent will be notified when an interim extension is granted and notice of the extension will be published in the *Official Gazette of the United States Patent and Trademark Office*. The notice will be recorded in the official file of the patent and will be considered as part of the original patent. In no event will the interim extensions granted under this section be longer than the maximum period for extension to which the applicant would be eligible.

If the original term of the patent for which extension is sought will expire before a final decision to issue a certificate of extension can be made, and a determination is made that the patent is eligible for extension, 35 U.S.C. 156 provides that the Commissioner may issue an interim extension of the patent term for up to one year pending a final decision on the application for extension. Should additional time be necessary, additional interim extensions of up to one year may be granted by the Commissioner. The length of any interim extension is discretionary with the Commissioner so long as it is for one year or less. Its length should be set to provide time for completion of any outstanding requirements. See *In re Reckitt & Colman Products Ltd.*, 230 USPQ 369, 372 (Comm'r Pat. & Tm. 1986). The Commissioner may issue an interim extension under 35 U.S.C. 156(e)(2) with or without a request from the applicant.

Where a determination is made that the patent is not eligible for patent term extension, an interim extension of the patent term is not warranted under 35 U.S.C. 156(e)(2). See *In re Alcon Laboratories Inc.*, 13 USPQ2d 1115, 1123 (Comm'r. Pat.& Tm. 1989).

Where an interim extension has been granted and it is subsequently determined that the patent is not eligible for patent term extension, the interim extension may be vacated *ab initio* as ineligible under 35 U.S.C. 156(e)(2). See *In re Reckitt,* 230 USPQ at 370.

While 37 CFR 1.760 provides that a request for an interim extension by the applicant "should" be filed three months prior to the expiration of the patent, this time frame is not mandatory. Any request filed within a shorter period of time will be considered, upon a proper showing, where it is not possible to make an earlier request. However, for an interim extension to be granted, the application for extension, in compliance with 37 CFR 1.741, must have been filed prior to the expiration date of the patent. In no event will an interim extension be granted for a period of patent term extension longer than the period of extension to which the patent would be eligible.

A notice of each interim extension granted will be issued to the applicant for patent term extension. The notice will be recorded in the official file of the patent and will be considered as part of the original patent. Notification of the issuance of the interim extension will be published in the Official Gazette of the Patent and Trademark Office.

2755.02 Interim Extension of Patent Term Before Product Approval

35 U.S.C. 156. Extension of patent term.

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(5)(A) If the owner of record of the patent or its agent reasonably expects that the applicable regulatory review period described in paragraphs (1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii) of subsection (g) that began for a product that is the subject of such patent may extend beyond the expiration of the patent term in effect, the owner or its agent may submit an application to the Director for an interim extension during the period beginning 6 months, and ending 15 days before such term is due to expire. The application shall contain—

(i) the identity of the product subject to regulating review and the Federal statute under which such review is occurring;

(ii) the identity of the patent for which interim extension is being sought and the identity of each claim of such patent which claims the product under regulatory review or a method of using or manufacturing the product;

(iii) information to enable the Director to determine under subsection (a)(1), (2), and (3) the eligibility of a patent for extension;

(iv) a brief description of the activities undertaken by the applicant during the applicable regulatory review period to date with respect to the product under review and the significant dates applicable to such activities; and

(v) such patent or other information as the Director may require.

(B) If the Director determines that, except for permission to market or use the product commercially, the patent would be eligible for an extension of the patent term under this section, the Director shall publish in the Federal Register a notice of such determination, including the identity of the product under regulatory review, and shall issue to the applicant a certificate of interim extension for a period of not more than 1 year.

(C) The owner of record of a patent, or its agent, for which an interim extension has been granted under subparagraph (B), may apply for not more than 4 subsequent interim extensions under this paragraph, except that, in the case of a patent subject to subsection (g)(6)(C), the owner of record of the patent, or its agent, may apply for only 1 subsequent interim extension under this paragraph. Each such subsequent application shall be made during the period beginning 60 days before, and ending 30 days before, the expiration of the preceding interim extension.

(D) Each certificate of interim extension under this paragraph shall be recorded in the official file of the patent and shall be considered part of the original patent.

(E) Any interim extension granted under this paragraph shall terminate at the end of the 60-day period beginning on the day on which the product involved receives permission for commercial marketing or use, except that, if within that 60-day period, the applicant notifies the Director of such permission and submits any additional information under paragraph (1) of this subsection not previously contained in the application for interim extension, the patent shall be further extended, in accordance with the provisions of this section—

(i) for not to exceed 5 years from the date of expiration of the original patent term; or

(ii) if the patent is subject to subsection (g)(6)(C), from the date on which the product involved receives approval for commercial marketing or use.

(F) The rights derived from any patent the term of which is extended under this paragraph shall, during the period of interim extension—

(i) in the case of a patent which claims a product, be limited to any use then under regulatory review;

(ii) in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent then under regulatory review; and

(iii) in the case of a patent which claims a method of manufacturing a product, be limited to the method of manufacturing as used to make the product then under regulatory review.

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37 CFR 1.790. Interim extension of patent term under 35 U.S.C. 156(d)(5).

(a) An owner of record of a patent or its agent who reasonably expects that the applicable regulatory review period described in paragraph (1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii) of subsection (g) that began for a product that is the subject of such patent may extend beyond the expiration of the patent term in effect may submit one or more applications for interim extensions for periods of up to one year each. The initial application for interim extension must be filed during the period beginning 6 months and ending 15 days before the patent term is due to expire. Each subsequent application for interim extension must be filed during the period beginning 60 days before and ending 30 days before the expiration of the preceding interim extension. In no event will the interim extensions granted under this section be longer than the maximum period of extension to which the applicant would be entitled under 35 U.S.C. 156(c).

(b) A complete application for interim extension under this section shall include all of the information required for a formal application under § 1.740 and a complete application under § 1.741. Sections (a)(1), (a)(2), (a)(4), and (a)(6) - (a)(17) of § 1.740 and § 1.741 shall be read in the context of a product currently undergoing regulatory review. Sections (a)(3) and (a)(5) of § 1.740 are not applicable to an application for interim extension under this section.

(c) The content of each subsequent interim extension application may be limited to a request for a subsequent interim extension along with a statement that the regulatory review period has not been completed along with any materials or information required under §§ 1.740 and 1.741 that are not present in the preceding interim extension application.

37 CFR 1.791. Termination of interim extension granted prior to regulatory approval of a product for commercial marketing or use.

Any interim extension granted under 35 U.S.C. 156(d)(5) terminates at the end of the 60-day period beginning on the date on which the product involved receives permission for commercial marketing or use. If within that 60-day period the patent owner or its agent files an application for extension under §§ 1.740 and 1.741 including any additional information required under 35 U.S.C. 156(d)(1) not contained in the application for interim extension, the patent shall be further extended in accordance with the provisions of 35 U.S.C. 156.

If a patent that claims a product which is undergoing the approval phase of regulatory review as defined by 35 U.S.C. 156(g)(1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), and (5)(B)(ii) is expected to expire before approval is granted, interim patent term extension is available under 35 U.S.C. 156(d)(5). The application

for patent term extension that must be submitted is generally the same as would be filed had the product been approved, except that the approval date is not required to be set forth. Once the product is approved, the application must be converted to an application for patent term extension under 35 U.S.C. 156(d)(1) to obtain patent term extension under that subsection.

Processing of an application for interim patent term extension under 35 U.S.C. 156(d)(5) is performed in the Office of Patent Legal Administration and is similar to other applications for patent term extension, except that the Office is not required to seek the advice of the relevant regulatory agency. The relevant agency, however, is normally consulted before an interim extension is granted or before the application is denied. The fee for an application for patent term extension under 35 U.S.C. 156(d)(5) is set forth in 37 CFR 1.20(j)(2), and the fee for a subsequent application is set forth in 37 CFR 1.20(j)(3). Copies of an application for interim extension are maintained in the same manner as applications for patent term extension. As required by 35 U.S.C. 156(d)(5)(B), a determination that a patent is eligible for extension under 35 U.S.C. 156, but for regulatory approval, is published in the Federal Register. A sample order granting a second interim extension follows:

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE COMMISSIONER OF PATENTS AND TRADEMARKS

In re___

Request for Patent Term Extension
U.S. Patent No.___

ORDER GRANTING
INTERIM EXTENSION

On __, patent owner __, filed an application under 35 U.S.C. 156(d)(5) for interim extension of the term of U.S. Patent No. __. The patent claims the active ingredient __ in the human drug product "___." The application indicates that the product is currently undergoing a regulatory review before the Food and Drug Administration for permission to market or use the product commercially. The original term of the patent expired on ___ On ___, the patent was granted an first interim extension under 35 U.S.C. 156(d)(5) for a period of one year.

Review of the application indicates that except for receipt of permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. 156. Since it is apparent that the regulatory review period may extend beyond the date of expiration of the patent, as extended by the first interim extension, a second interim extension of the patent term under 35 U.S.C. 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. 156(d)(5) of the term of U.S. Patent No. __ is granted for a period of one year from the extended expiration date of the patent.

As seen from the example given, a series of one-year interim extensions may be granted if requested in a timely manner (in the window of time between thirty and sixty days before the extended expiration date).

An interim extension granted under 35 U.S.C. 156(d)(5) terminates sixty days after permission for commercial marketing or use of the product is granted, except, if within the sixty day period any additional information needed for an application for patent term extension under 35 U.S.C. 156(d)(1) is submitted, the patent may be further extended. 35 U.S.C. 156(d)(5)(E).

2756 Correspondence Between the USPTO and the Regulatory Agency

It is the Commissioner's responsibility to decide whether an applicant has satisfied the requirements of the statute and whether the patent qualifies for patent term extension. The regulatory agency possesses expertise and records regarding some of the statutory requirements and has certain direct responsibilities under 35 U.S.C. 156 for determining the length of the regulatory review period. Consequently, to facilitate eligibility decisions and permit the regulatory agency and the Office to carry out their responsibilities under 35 U.S.C. 156, both the Food and Drug Administration and the Department of Agriculture have entered into an "agreement" of cooperation with the Office. *Memorandum of Understanding Between the Patent and Trademark Office and the Food and Drug Administration*, 52 Fed. Reg. 17830 (May 12, 1987); *Memorandum of Understanding Between the Patent and Trademark Office and the Animal and Plant Health Inspection Service*, 54 Fed. Reg. 26399 (June 23, 1989); 1104 OG 18 (July 11, 1989). The agreements establish the procedures whereby the regulatory agency assists the Office in determining a patent's eligibility for patent term restoration under 35 U.S.C. 156. It also establishes procedures for exchanging information between the regulatory agency and the Office regarding regulatory review

period determinations, due diligence petitions and informal regulatory agency hearings under the law. The patent term extension applicant receives a copy of all correspondence between the Office and the regulatory agency.

The Animal and Health Inspection Service of the Department of Agriculture is responsible for assisting the Office in determining the eligibility of patent claiming a veterinary biological product that has been subject to the Virus-Serum-Toxin Act (21 U.S.C. 151-59) and for determining the regulatory review period of the veterinary biological product. The Secretary of Health and Human Services of the Food and Drug Administration is responsible for assisting the Office in determining the eligibility of patents claiming any other product for which regulatory review gives rise to eligibility for patent term extension. 21 CFR 60.10.

INFORMATION REGARDING ELIGIBILITY FOR EXTENSION

If the Office has no clear reason to deny eligibility for patent term extension (even if there are questions concerning eligibility), or if the applicant has been notified of any informalities and it is anticipated that the informalities will be corrected or explained, a first letter is sent to the regulatory agency requesting information regarding eligibility. The letter is accompanied by a copy of the patent term extension application. This letter does **not** request the determination of the applicable regulatory review period.

The regulatory agency reply is usually in the form of a written response:

(A) verifying whether the product has undergone a regulatory review period within the meaning of 35 U.S.C. 156(g) prior to commercial marketing or use;

(B) stating whether the marketing permission was for the first permitted commercial marketing or use of that product, or, in the case of recombinant DNA technology, whether such commercial marketing or use was the first permitted under the process claimed in the patent;

(C) informing the Office whether the patent term extension application was submitted within sixty days after the product was approved for marketing or use; and

(D) providing the Office with any other information relevant to the Office determination of whether a patent related to a product is eligible for patent term extension.

While the Office has primary responsibility for the eligibility determination, the regulatory agency often possesses information which is not readily available to the Office. The assistance on the part of the regulatory agency enables both the Office and the agency to process applications efficiently and to conserve resources.

PRELIMINARY ELIGIBILITY DECISION

Upon receipt of a reply from the regulatory agency to the first letter from the Office requesting assistance on determining eligibility, a preliminary eligibility decision (not the final decision) is made as to whether the patent is eligible for an extension of its term. As noted above, the reply from the regulatory agency will usually inform the Office as to whether the permission for commercial marketing and use of the product on which the application for patent term extension is based is the first such approval for that product. Furthermore, the regulatory agency usually provides information regarding the date of product approval to permit a determination as to whether the application was filed within the sixty-day statutory period. The information provided by the regulatory agency is then compared with the related information from the application. If no major discrepancies are found and the patent is determined to be eligible for patent term extension, a second letter requesting a determination of the length of the regulatory review period of the product is mailed to the regulatory agency not later than sixty (60) days after the Office receipt date of the reply from the regulatory agency. In the interest of efficiency, if the patent is determined to be ineligible for patent term extension, the Office will dismiss the application rather than request a determination of the regulatory review period. *In re Allen & Hansbury, Ltd.*, 227 USPQ 955, 960 n. 9 (Comm'r Pat. & Tm. 1985). A certified copy of the application for patent term extension is sent to the regulatory agency along with the second letter. The second letter states that, subject to final review, the patent is considered eligible for patent term extension and requests a determination of the applicable regulatory review period.

2757 Regulatory Agency Determination of the Length of the Regulatory Review Period

Under 35 U.S.C. 156, the regulatory agency is responsible for the determination of the length of the regulatory review period for the approved product on which the application for patent term extension is based. The determination by the regulatory agency is made based on the application as well as the official regulatory agency records for the approved product. See, e.g., 21 CFR Ch. 1, Subpart C. The determination of the length of the regulatory review period is solely the responsibility of the regulatory agency. *Aktiebolaget Astra v. Lehman*, 71 F.3d 1578, 1580-81, 37 USPQ2d 1212, 1214-15 (Fed. Cir. 1995); U.S. Patent No. 4,215,113.

Once the determination has been made, the regulatory agency publishes the information in the Federal Register and forwards a letter to the Office with the same information. Included in both the Federal Register Notice and the letter to the Office are the total length of the regulatory review period and the relevant dates on which the determination is based. Both the letter to the Office and the Federal Register Notice separate the total regulatory period into the initial or testing phase and the final approval phase. This provides the Office with the information necessary to determine the actual length of extension for which the patent may be eligible. The Federal Register Notice also sets a date, 180 days after publication of the notice, as a deadline for filing written comments concerning any of the information set forth in the notice or a petition for a determination regarding whether the marketing applicant has acted with due diligence during the regulatory review period. The letter to the Office makes clear that the determination does not take into account the issue date of the patent nor does it exclude one-half of the testing phase.

The regulatory review period determination is not final until due diligence petitions and informal hearings, if any, have been resolved. A certificate for extension of the term of a patent may not issue from the Office until the regulatory review period determination is final unless an interim extension appears warranted under 35 U.S.C. 156(d)(5) and (e)(2).

2757.01 Due Diligence Determination

If a due diligence petition is filed during the 180-day period following publication of the regulatory agency determination of the regulatory review period, the regulatory agency (e.g., FDA) makes the determination under 35 U.S.C. 156(d)(2)(B) whether the applicant for patent term extension acted with due diligence during the regulatory review proceedings. The term "due diligence" is defined in 35 U.S.C. 156(d)(3) as "that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period." After affirming or revising the determination of the regulatory review period, the regulatory agency notifies the Office and publishes the results in the Federal Register. If no comment or petition is filed in the time period provided, the regulatory agency notifies the Office that the period for filing a due diligence petition pursuant to the notice has expired and that the regulatory agency therefore considers its determination of the regulatory review period for the product to be final. Following notification from the regulatory agency, the Office proceeds with the final eligibility determination. See 21 CFR Ch. 1, Subparts D and E.

2758 Notice of Final Determination - Calculation of Patent Term Extension

35 U.S.C. 156. Extension of patent term.

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(c) The term of a patent eligible for extension under subsection (a) shall be extended by the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued, except that—

(1) each period of the regulatory review period shall be reduced by any period determined under subsection (d)(2)(B) during which the applicant for the patent extension did not act with due diligence during such period of the regulatory review period;

(2) after any reduction required by paragraph (1), the period of extension shall include only one-half of the time remaining in the periods described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g);

(3) if the period remaining in the term of a patent after the date of the approval of the approved product under the provision of law under which such regulatory review occurred when added to the regulatory review period as revised under paragraphs (1) and (2) exceeds fourteen years, the period of extension shall be

reduced so that the total of both such periods does not exceed fourteen years, and

(4) in no event shall more than one patent be extended under subsection (e)(i) for the same regulatory review period for any product.

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(6) A period determined under any of the preceding paragraphs is subject to the following limitations:

(A) If the patent involved was issued after the date of the enactment of this section, the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.

(B) If the patent involved was issued before the date of the enactment of this section and —

(i) no request for an exemption described in paragraph (1)(B) or (4)(B) was submitted and no request for the authority described in paragraph (5)(B) was submitted,

(ii) no major health or environment effects test described in paragraph (2)(B) or (4)(B) was initiated and no petition for a regulation or application for registration described in such paragraph was submitted, or

(iii) no clinical investigation described in paragraph (3) was begun or product development protocol described in such paragraph was submitted, before such date for the approved product the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.

(C) If the patent involved was issued before the date of the enactment of this section and if an action described in subparagraph (B) was taken before the date of enactment of this section with respect to the approved product and the commercial marketing or use of the product has not been approved before such date, the period of extension determined on the basis of the regulatory review period determined under such paragraph may not exceed two years or in the case of an approved product which is a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act or the Virus-Serum-Toxin Act), three years.

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After reviewing the information provided by the regulatory agency, if the Office determines the patent to be eligible for extension, the calculation is made of the length of extension for which the patent is eligible under the appropriate statutory provisions (35 U.S.C. 156(c); 37 CFR 1.750). The length of extension is subject to the limitations of 35 U.S.C. 156(c)(3) and 35 U.S.C. 156(g)(6). A Notice of Final Determination is mailed to applicant which states the length of extension for which the application has been determined to be eligible and the calculations used to determine the length of extension. Recently mailed Notices of Final Determination are posted in the Freedom of Information (FOIA) section of the USPTO web site (www.uspto.gov) with other Decisions of the Commisssioner. The notice provides a period, usually one month, in which the applicant can request reconsideration of any aspect of the Office determination as to eligibility or the length of extension for which the application has been found eligible.

If the application has been determined to be ineligible for patent term extension, an appropriate Notice of Final Determination is mailed to applicant which denies the application and sets forth the basis for the denial. The applicant is given a period, usually one month, in which to seek reconsideration of the determination.

If the patent is found to be eligible for extension, the Notice of Final Determination may include text similar to the following:

> A determination has been made that U.S. Patent No. ___, which claims the human drug ___, is eligible for patent term extension under 35 U.S.C. 156. The period of extension has been determined to be ___.
>
> A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of ___ days.
>
> The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of ___. Under 35 U.S.C. 156(c).
>
> Period of Extension = 1/2 (Testing Phase) + Approval Phase
>
> = 1/2 (___ -___) + ___
>
> = ___ days
>
> Since the regulatory review period began __, before the patent issued ___, only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. 156(c). (From __ to ___) is___ days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. 156(c)(1) was made.

The 14 year exception of 35 U.S.C. 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product (___) when added to the period of extension calculated above (___ days) cannot exceed fourteen years. The period of extension is thus limited to ___, by operation of 35 U.S.C. 156(c)(3). Since the patent term (35 U.S.C. 154) would expire on ___, the period of extension is the number of days to extend the term of the patent from its expiration date to and including ___, or ___ days.

The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension determined above.

See MPEP § 2759 for further information pertaining to the issuance of a certificate of extension.

A patent term extension generally extends the patent from its "original expiration date," as defined by 35 U.S.C. 154 to include extension under 35 U.S.C. 154(b). Patents "in force on June 8, 1995 only because of a Hatch-Waxman extension are not entitled to re-apply a restoration extension to a 20-year from filing term." *Merck & Co. v. Kessler*, 80 F.3d 1543, 1553, 38 USPQ2d 1347, 1354 (Fed. Cir. 1996). However, if the patent received an interim extension under 35 U.S.C. 156(d)(5) and the patent is eligible for either a two- or a three-year extension, the extension would run from the approval date of the product, not the original expiration date of the patent. See 35 U.S.C. 156(d)(5)(E)(ii).

No certificate or extension will be issued if the term of a patent cannot be extended, even though the patent is otherwise determined to be eligible for extension. In such situations the final determination would issue indicating that no certificate will issue.

CALCULATION OF PATENT TERM EXTENSION

The procedure for calculating the length of the patent term extension is set forth for human drugs, antibiotic drugs, and human biological products in 37 FR 1.775; for food or color additives in 37 CFR 1.776; for medical devices in 37 CFR 1.777; for animal drug products in 37 CFR 1.778; and for veterinary biological products in 37 CFR 1.779. The length of patent term extension is the length of the regulatory review period as determined by the Secretary of Health and Human Services or the Secretary of Agriculture, but reduced, where appropriate, by the time periods provided in 37 CFR 1.775 - 1.779. The Office will rely on the Secretary's determination of the length of the regulatory review period when calculating the length of the extension period under 37 CFR 1.775 - 1.779.

Any part of the regulatory review period which occurs before the patent was granted will not be counted toward patent term extension. Any period in which the marketing applicant failed to exercise due diligence, thereby unnecessarily adding to the length of the regulatory review period after the patent issued, will not be considered in determining the length of the extension period. In making the calculation of the extension period, half days will be ignored and thus will not be subtracted from the regulatory review period.

For products other than animal drug or veterinary biological products, the calculated extension period cannot exceed any of the following statutory maximum periods of extension:

(A) If the period remaining in the term of the patent after the date of approval of the approved product when added to the calculated regulatory review period exceeds fourteen years, the period of extension shall be reduced so that the total of both such periods does not exceed fourteen years;

(B) If the patent involved was issued after September 24, 1984, (the date of enactment of the statute), the calculated period of extension may not exceed five years;

(C) If the patent involved was issued before September 24, 1984, (the date of enactment of the statute), and the regulatory review period proceeding started after this date, the calculated period of extension may not exceed five years; and

(D) If the patent involved was issued before September 24, 1984, (the date of enactment of the statute), and the regulatory review period proceeding started before this date, and the commercial marketing or use of the product has been approved after such date, the calculated period of extension may not exceed two years.

For animal drug or veterinary biological products, the calculated extension period cannot exceed any of the following statutory maximum periods of extension:

(A) If the period remaining in the term of the patent after the date of approval of the approved product when added to the calculated regulatory review period exceeds fourteen years, the period of extension shall be reduced so that the total of both such periods does not exceed fourteen years;

(B) If the patent involved was issued after November 16, 1988, the calculated period of extension may not exceed five years;

(C) If the patent involved was issued before November 16, 1988, and the regulatory review period proceeding started after this date, the calculated period of extension may not exceed five years; and

(D) If the patent involved was issued before November 16, 1988, and the regulatory review period proceeding started before this date, and the commercial marketing or use of the product has been approved after such date, the calculated period of extension may not exceed three years.

The patent term extension of a patent that issued before September 24, 1984, where the regulatory review period began and ended before September 24, 1984, would only be a function of the regulatory review period and the fourteen-year limit, and may be extended for more than five years. *Hoechst Aktiengesellschaft v. Quigg*, 916 F2d 522, 525, 16 USPQ2d 1549, 1551 (Fed. Cir. 1990).

2759 Certificate of Extension of Patent Term

35 U.S.C. 156. Extension of patent term.

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(e)(1) A determination that a patent is eligible for extension may be made by the Director solely on the basis of the representations contained in the application for the extension. If the Director determines that a patent is eligible for extension under subsection (a) and that the requirements of paragraphs (1) through (4) of subsection (d) have been complied with, the Director shall issue to the applicant for the extension of the term of the patent a certificate of extension, under seal, for the period prescribed by subsection (c). Such certificate shall be recorded in the official file of the patent and shall be considered as part of the original patent.

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37 CFR 1.780. Certificate or order of extension of patent term.

If a determination is made pursuant to § 1.750 that a patent is eligible for extension and that the term of the patent is to be extended, a certificate of extension, under seal, or an order granting interim extension under 35 U.S.C. 156(d)(5), will be issued to the applicant for the extension of the patent term. Such certificate or order will be recorded in the official file of the patent and will be considered as part of the original patent. Notification of the issuance of the certificate or order of extension will be published in the *Official Gazette of the United States Patent and Trademark Office*. Notification of the issuance of the order granting an interim extension under 35 U.S.C. 156(d)(5), including the identity of the product currently under regulatory review, will be published in the *Official Gazette of the United States Patent and Trademark* Office and in the *Federal Register*. No certificate of, or order granting, an extension will be issued if the term of the patent cannot be extended, even though the patent is otherwise determined to be eligible for extension. In such situations, the final determination made pursuant to § 1.750 will indicate that no certificate or order will issue.

Once a determination is made pursuant to 37 CFR 1.750 that a patent is eligible for extension of its term, a certificate of extension, under seal, will be issued to the patent owner at the correspondence address specified in the application for patent term extension. Following the one-month period provided in the Notice of Final Determination, and where an extension is appropriate, the Certificate of Extension is signed by the Commissioner. The original certificate is mailed or delivered to the applicant and a copy is sent to the regulatory agency. A copy of the certificate is placed in the two files (official file/patent file and public file) maintained for the patent term extension application.

Upon issuance of the certificate of extension, a notice is published in the *Official Gazette*. A sample *Official Gazette* Notice Follows:

PATENT TERM EXTENDED UNDER 35 U.S.C. 156

A Certificate extending the term of the following patent was issued on __.

U.S. Patent No.: __ Granted: __; Applicant: __; Owner of Record: __; Title: ___; Classification: __ Product Trade Name: __; Original Expiration Date: __; Term Extended: ____; Extended Expiration Date: __.

All original papers from the application for patent term extension in the official file are transferred to the official patent file of the subject patent and become a part of the permanent record. A copy of the certificate

of extension of patent term is added to the patent electronic database as part of the patent record in the same manner as is a certificate of correction or a terminal disclaimer. The patent is also added to the list of patents extended under 35 U.S.C. 156, a copy of which is posted on the USPTO web site (www.uspto.gov) and which is also available in the Reading Room of the Public Search Room and from the Office of Patent Legal Administration. The public file for the application for patent term extension is stored in the Office of Patent Legal Administration.

2760 Trade Secret, Confidential, and Protective Order Material

There is no provision in the statute or the rules for withholding from the public any information that is submitted to the Office or the regulatory agency relating to an application for patent term extension. While one submitting such materials to the Office in relation to a pending application for patent term extension must generally assume that such materials will be made of record in the file and be made public, the Office is not unmindful of the difficulties this sometimes imposes. Proprietary or trade secret information should be submitted generally in accordance with the procedures set forth in MPEP § 724.02. Identification of the propriety or trade secret material should be made by page, line, and word, as necessary. The Office will not in the first instance undertake the task of determining the precise material in the application which is proprietary or trade secret information. Only the applicant is in a position to make this determination. See *In re Schering-Plough Corp.*, 1 USPQ2d 1926, 1926 (Comm'r Pat. & Tm. 1986).

The information will not be made public as part of the patent file before a certificate of patent extension is issued. Should the Office receive a Freedom of Information Act (FOIA) request for the material, the applicant will be provided notice and an opportunity to substantiate its claim that the material is proprietary before the Office determines whether disclosure of the material is required under the FOIA. If such information was material to a determination of eligibility or any other Office responsibility under 35 U.S.C. 156, it will be made public at the time the certificate of extension is issued. Otherwise, if a suitable petition to expunge is filed before the issuance of the certificate, the trade secret or confidential information will be expunged from the file and returned to the patent term extension applicant. If a petition to expunge is not filed prior to the issuance of the certificate, all of the information will be open to public inspection.

2761 Multiple Applications for Extension of Term of the Same Patent or of Different Patents for the Same Regulatory Review Period for a Product

35 U.S.C. 156. Extension of patent term.

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(c)(4) in no event shall more than one patent be extended under subsection (e)(i) for the same regulatory review period for any product.

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37 CFR 1.785. Multiple applications for extension of term of the same patent or of different patents for the same regulatory review period for a product.

(a) Only one patent may be extended for a regulatory review period for any product § 1.720 (h). If more than one application for extension of the same patent is filed, the certificate of extension of patent term, if appropriate, will be issued based upon the first filed application for extension.

(b) If more than one application for extension is filed by a single applicant which seeks the extension of the term of two or more patents based upon the same regulatory review period, and the patents are otherwise eligible for extension pursuant to the requirements of this subpart, in the absence of an election by the applicant, the certificate of extension of patent term, if appropriate, will be issued upon the application for extension of the patent term having the earliest date of issuance of those patents for which extension is sought.

(c) If an application for extension is filed which seeks the extension of the term of a patent based upon the same regulatory review period as that relied upon in one or more applications for extension pursuant to the requirements of this subpart, the certificate of extension of patent term will be issued on the application only if the patent owner or its agent is the holder of the regulatory approval granted with respect to the regulatory review period.

(d) An application for extension shall be considered complete and formal regardless of whether it contains the identification of the holder of the regulatory approval granted with respect to the regulatory review period. When an application contains such information, or is amended to contain such information, it will be considered in determining whether an application is eligible for an extension under this section. A request may be made of any applicant to supply such information within a non-extendable period of not less than one month whenever multiple applications for extension of more than one patent are received and rely upon the same regulatory review period. Failure to provide such infor-

mation within the period for reply set shall be regarded as conclusively establishing that the applicant is not the holder of the regulatory approval.

(e) Determinations made under this section shall be included in the notice of final determination of eligibility for extension of the patent term pursuant to § 1.750 and shall be regarded as part of that determination.

Only one patent may be extended for a regulatory review period for any product. If more than one application for extension is filed for a single patent by different applicants, the certificate of extension of the term of the patent, if appropriate, would be issued based upon the first filed application for extension of patent term. If a single applicant files more than one application for patent term extension for a single patent based upon the regulatory review period of different products, then the final determination under 37 CFR 1.750 will provide a period of time (usually one month) for the patent owner to elect the product for which extension is desired. An express withdrawal of the applications for extension of the nonelected products should accompany the election. The final determination will indicate that if the patent owner fails to elect a single product within the set time period, the Office will issue a certificate of extension for the patent for a specified one of the products.

If more than one application for extension is filed by a single applicant for the extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension will be issued on the application for extension of the patent having the earliest date of issuance of those for which extension is sought unless all but one application for extension is voluntarily withdrawn by the applicant. When plural patents are found to be eligible for patent term extension based on the same regulatory review of a product, the final determination under 37 CFR 1.750 will provide a period of time (usually one month) for the patent owner to elect the patent for which extension is desired. An express withdrawal of the application(s) for extension of the nonelected patent(s) should accompany the election. A failure to elect within the set time period will result in issuance of a certificate of extension for the patent having the earliest date of issue.

If applications for extension are filed by different applicants for the extension of the terms of different patents based upon the same regulatory review period of a product, the certificate of extension will be issued on the application of the holder of the regulatory approval (marketing applicant). If the marketing applicant is not an applicant for extension, the certificate of extension will issue to the applicant for extension which holds an express authorization from the marketing applicant to rely upon the regulatory review period as the basis for the application for extension. See also 37 CFR 1.785(d).

2762 Duty of Disclosure in Patent Term Extension Proceedings

37 CFR 1.765. Duty of disclosure in patent term extension proceedings.

(a) A duty of candor and good faith toward the Patent and Trademark Office and the Secretary of Health and Human Services or the Secretary of Agriculture rests on the patent owner or its agent, on each attorney or agent who represents the patent owner and on every other individual who is substantively involved on behalf of the patent owner in a patent term extension proceeding. All such individuals who are aware, or become aware, of material information adverse to a determination of entitlement to the extension sought, which has not been previously made of record in the patent term extension proceeding must bring such information to the attention of the Office or the Secretary, as appropriate, in accordance with paragraph (b) of this section, as soon as it is practical to do so after the individual becomes aware of the information. Information is material where there is a substantial likelihood that the Office or the Secretary would consider it important in determinations to be made in the patent term extension proceeding.

(b) Disclosures pursuant to this section must be accompanied by a copy of each written document which is being disclosed. The disclosure must be made to the Office or the Secretary, as appropriate, unless the disclosure is material to determinations to be made by both the Office and the Secretary, in which case duplicate copies, certified as such, must be filed in the Office and with the Secretary. Disclosures pursuant to this section may be made to the Office or the Secretary, as appropriate, through an attorney or agent having responsibility on behalf of the patent owner or its agent for the patent term extension proceeding or through a patent owner acting on his or her own behalf. Disclosure to such an attorney, agent or patent owner shall satisfy the duty of any other individual. Such an attorney, agent or patent owner has no duty to transmit information which is not material to the determination of entitlement to the extension sought.

(c) No patent will be determined eligible for extension and no extension will be issued if it is determined that fraud on the Office or the Secretary was practiced or attempted or the duty of disclosure was violated through bad faith or gross negligence in connection with the patent term extension proceeding. If it is established by clear and convincing evidence that any fraud was practiced or attempted on the Office or the Secretary in connection with the patent term extension proceeding or that there was any violation of the duty of disclosure through bad faith or gross

negligence in connection with the patent term extension proceeding, a final determination will be made pursuant to § 1.750 that the patent is not eligible for extension.

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A duty of candor and good faith toward the USPTO, the Secretary of Health and Human Services, and the Secretary of Agriculture rests on the patent owner or its agent, on each attorney or agent who represents the patent owner, and on every other individual who is substantively involved on behalf of the patent owner in a patent term extension proceeding. All such individuals who are aware, or become aware, of material information adverse to a determination of entitlement to the extension sought, which has not been previously made of record in the patent term extension proceeding, must bring such information to the attention of the Office or the Secretary, as appropriate, as soon as it is practicable to do so after the individual becomes aware of the information. Information is "material" when there is a substantial likelihood that the Office or the Secretary would consider it important in determinations to be made in the patent term extension proceeding. Any such material information should be submitted to the Commissioner of Patents and Trademarks, the Secretary of Health and Human Services, or the Secretary of Agriculture, as appropriate, accompanied by a copy of each written document being disclosed. The information may be submitted through a patent attorney or agent.

A determination of eligibility for an extension or the issuance of a certificate will not be made if clear and convincing evidence of fraud or attempted fraud on the Office or a Secretary is determined to be present, or the duty of disclosure is determined to have been violated through bad faith or gross negligence in connection with the patent term extension proceeding. Since the determination as to whether a patent is eligible for extension may be made solely on the basis of the representations made in the application for extension, a final determination to refuse a patent term extension because of fraud or a violation of the duty of disclosure is expected to be rare. See MPEP § 2010.

2763 Limitation of Third Party Participation

37 CFR 1.765. Duty of disclosure in patent term extension proceedings.

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(d) The duty of disclosure pursuant to this section rests on the individuals identified in paragraph (a) of this section and no submission on behalf of third parties, in the form of protests or otherwise, will be considered by the Office. Any such submissions by third parties to the Office will be returned to the party making the submission, or otherwise disposed of, without consideration by the Office.

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Although the statute specifically provides for public input into the determination of the regulatory review period, i.e., the filing of a due diligence petition before the regulatory agency, no such provision was made for proceedings before the Office. Since applicant already has a duty of disclosure to both the Office and the regulatory agency, and Congress expected that it would be an administratively simple proceeding, no input from third parties is permitted. Absent an invitation from the Commissioner, any such submission would be inappropriate. Accordingly, 37 CFR 1.765(d) precludes submissions to the Office by or on behalf of third parties, thereby making patent term extension proceedings in the Office an *ex parte* matter between the patent owner or its agent and the Office. Submissions by third parties not requested by the Office will be returned, or otherwise disposed of, without consideration. See *In re Dubno*, 12 USPQ2d 1153, 1154 (Comm'r Pat. & Tm. 1989).

2764 Express Withdrawal of Application for Extension of Patent Term

37 CFR 1.770. Express withdrawal of application for extension of patent term.

An application for extension of patent term may be expressly withdrawn before a determination is made pursuant to § 1.750 by filing in the Office, in duplicate, a written declaration of withdrawal signed by the owner of record of the patent or its agent. An application may not be expressly withdrawn after the date permitted for reply to the final determination on the application. An express withdrawal pursuant to this section is effective when acknowledged in writing by the Office. The filing of an express withdrawal pursuant to this section and its acceptance by the

Office does not entitle applicant to a refund of the filing fee (§ 1.20(j)) or any portion thereof.

Any request for withdrawal of an application for extension of patent term after a determination has been made pursuant to 37 CFR 1.750 must be submitted on or before the date permitted for reply to the final determination, and be accompanied by a petition under 37 CFR 1.182 with the appropriate petition filing fee.