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2701 Patent Term [R-07.2015]

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, 365(c), or 386(c) from the date on which the earliest such application was filed.

(3) PRIORITY.—Priority under section 119, 365(a), 365(b), 386(a), or 386(b) 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 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)).

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For applications filed on or after June 8, 1995, Section 532(a)(1) of the Uruguay Round Agreements Act (Public Law 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, except for any design patent issued from applications filed on or after May 13, 2015 (the date of entry into force of the 1999 Geneva Act of the Hague Agreement Concerning the International Registration of Industrial Designs ("Hague Agreement") as to the United States) has a term of fifteen years from the date of patent grant (see Public Law 112-211). See 35 U.S.C. 173 and MPEP § 1505. Under the Hague Agreement, qualified applicants may apply for design protection in the Contracting Parties to the Hague Agreement by filing a single, standardized international design application in a single language. Therefore, the term "design patents" includes patents issued from design applications filed under 35 U.S.C. 111 and international design applications filed under 35 U.S.C. 385. The Patent Law Treaties Implementation Act of 2012, Public Law 112-112, which implemented the provisions of the Hague Agreement, amended 35 U.S.C. 154(a)(2) to delete "section 120, 121, or 365(c)" and to insert "section 120, 121, 365(c), or 386(c)" and 35 U.S.C. 154(a)(3) to delete "section 119, 365(a), or 365(b)" and to insert "section 119, 365(a), 365(b), 386(a), or 386(b)."

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).

I. 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, 365(c), or 386(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.

II. 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.

III. FOREIGN PRIORITY

Foreign priority under 35 U.S.C. 119(a)-(d), 365(a), 365(b), 386(a), or 386(b) is not considered in determining the term of a patent. Accordingly, an application claiming priority under 35 U.S.C. 365(a), 365(b), 386(a), or 386(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 or international design application.

IV. DOMESTIC BENEFIT 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).

V. 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. See *Bayer AG v. Carlsbad Tech., Inc.*, 298 F.3d 1377, 64 USPQ2d 1045 (Fed. Cir. 2002). 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. But a patent term extension under 35 U.S.C. 156 may be applied to patent that is subject to a terminal disclaimer. See *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317, 82 USPQ2d 1203 (Fed. Cir. 2007).

Several decisions related to disclaimers are posted in the Freedom of Information Act (FOIA) section of the USPTO website (**www.uspto.gov**).

VI. 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 patent term extension or patent 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.

2702-2709 [Reserved]

2710 Term Extensions or Adjustments for Delays Within the USPTO Under 35 U.S.C. 154 [R-07.2015]

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 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)(effective May 29, 2000 and amended thereafter) and 37 CFR 1.702 -1.705. See MPEP § 2730. See *Thomas D. Sykes v. Jon W. Dudas*, 573 F.Supp2d 191, 89 USPQ2d 1423 (D.D.C. 2008).

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. The term "design patents" includes patents issued from design applications filed under 35 U.S.C. 111 and international design applications filed under 35 U.S.C. 385.

2711-2719 [Reserved]

2720 Applications Filed Between June 8, 1995, and May 28, 2000 [R-08.2017]

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 or derivation 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 Patent Trial and Appeal Board or by a Federal court under 35 U.S.C. 141 or 145, if the patent was issued pursuant to a decision in the review 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. If an application is remanded by a panel of the Patent Trial and Appeal Board and the remand is the last action by a panel of the Patent Trial and Appeal Board prior to the mailing of a notice of allowance under 35 U.S.C. 151 in the application, the remand shall be considered a decision in the review reversing an adverse determination of patentability as that phrase is used in 35 U.S.C. 154(b)(2) as amended by section 532(a) of the Uruguay Round Agreements Act, Public Law 103-465, 108 Stat. 4809, 4983-85 (1994), and a final decision in favor of the applicant under paragraph (c)(3) of this section. A remand by a panel of the Patent Trial and Appeal Board shall not be considered a decision in the review reversing an adverse determination of patentability as provided in this paragraph if there is filed a request for continued examination under 35 U.S.C. 132(b) that was not first preceded by the mailing, after such remand, of at least one of an action under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151.

(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 or derivation proceeding in which the application was involved, the number of days, if any, in the period beginning on the date the interference or derivation proceeding was instituted to involve the application in the interference or derivation proceeding and ending on the date that the interference or derivation proceeding 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 or derivation 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 § 41.39 of this title 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 or derivation proceeding would be instituted 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 Patent Trial and Appeal Board was filed under 35 U.S.C. 134 and ending on the date of a final decision in favor of the applicant by the Patent Trial and Appeal Board 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 date of the first national application for patent presented for examination; and

(2) Any time during the period of appellate review, as determined by the Director, during which the applicant for patent did not act with due diligence. In determining the due diligence of an applicant, the Director 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 Patent Trial and Appeal Board (Board) 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 first national application for patent, 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. 35 U.S.C. 154 also was amended effective September 16, 2012 and January 14, 2013.

Examiners make no decisions regarding patent term extensions. Any patent term extension granted as a result of administrative delay pursuant to 37 CFR 1.701 will 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 information printed on the front page of the patent, applicant may request review by way of a petition under 37 CFR 1.181. If the petition is granted, a Certificate of Correction pursuant to 37 CFR 1.322 will be issued.

Effective May 24, 2004, 37 CFR 1.701(a)(3) was amended to indicate that certain remands by the Board shall be considered "a decision in the review reversing an adverse determination of patentability" for patent term extension purposes.

Petitions and Certificates of Correction regarding patent term extension under former 35 U.S.C. 154(b) should be addressed to Mail Stop Patent Ext., Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

2721-2729 [Reserved]

2730 Applications Filed on or After May 29, 2000; Grounds for Adjustment [R-07.2015]

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 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); or

(II) the date of commencement of the national stage under section 371 in an international application;

(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 Patent Trial and Appeal Board 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 under section 111(a) in the United States, or, in the case of an international application, the date of commencement of the national stage under section 371 in the international application, 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 Patent Trial and Appeal Board 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 OF ADJUSTMENTS FOR DELAYS DUE TO DERIVATION PROCEEDINGS, 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 Patent Trial and Appeal Board 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 no later than the date of issuance of the patent; 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 the Director's decision on the applicant's request for reconsideration under paragraph (3)(B)(ii) shall have the exclusive remedy by a civil action against the Director filed in the United States District Court for the Eastern District of Virginia within 180 days after the date of the Director's decision on the applicant's request for reconsideration. 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, filed on or after May 29, 2000).

[Editor Note: The provision of 37 CFR 1.702(a)(1), as reproduced below, was effective on April 1, 2013 and applies to patent applications granted on or after January 14, 2013.]

(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 the date the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application;

(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 filed or the appeal was taken;

(3) Act on an application not later than four months after the date of a decision by the Patent Trial And Appeal Board 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) *Three-year pendency.* 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 or derivation 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 Patent Trial and Appeal Board 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 and derivation 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 or derivation 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 Patent Trial and Appeal Board under 35 U.S.C. 134 or by a Federal court under 35 U.S.C. 141 or 145, if the patent was issued under a decision in the review reversing an adverse determination of patentability. If an application is remanded by a panel of the Patent Trial and Appeal Board and the remand is the last action by a panel of the Patent Trial and Appeal Board prior to the mailing of a notice of allowance under 35 U.S.C. 151 in the application, the remand shall be considered a decision by the Patent Trial and Appeal Board as that phrase is used in 35 U.S.C. 154(b)(1)(A)(iii), a decision in the review reversing an adverse determination of patentability as that phrase is used in 35 U.S.C. 154(b)(1)(C)(iii),

and a final decision in favor of the applicant under § 1.703(e). A remand by a panel of the Patent Trial and Appeal Board shall not be considered a decision in the review reversing an adverse determination of patentability as provided in this paragraph if there is filed a request for continued examination under 35 U.S.C. 132(b) that was not first preceded by the mailing, after such remand, of at least one of an action under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151.

(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), was amended effective May 29, 2000, and further amended by Public Law 112-29, enacted on September 16, 2011, known as the Leahy-Smith America Invents Act (AIA) and by Public Law 112-274, enacted on January 14, 2013, known as the AIA Technical Corrections Act. All references to 35 U.S.C. 154(b) hereinafter are to 35 U.S.C. 154(b), as amended effective May 29, 2000 and as further amended by Public Laws 112-29 and 112-274. 37 CFR 1.702-1.705 implement the provisions of 35 U.S.C. 154(b) and apply to utility and plant patent applications filed on or after May 29, 2000.

Due to various effective dates of changes to the provisions of 37 CFR 1.702-1.705, there are several versions currently in place. For example, there is a version of 37 CFR 1.702 that applies only to patents granted on or after January 14, 2013 and another version that applies to patents granted prior to January 14, 2013. For another example, there is a version of the provisions of 37 CFR 1.703(b)(4) and (e) that are only applicable to applications and patents in which a notice of allowance issued on or after September 17, 2012. Office personnel need to carefully consider the effective date provisions in the regulations in order to determine which version to apply to the particular application or patent under consideration.

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)).

Effective September 16, 2012, the Board of Patent Appeals and Interferences has been redesignated the Patent Trial and Appeal Board. Accordingly, 37 CFR 1.702(a)(3) has been amended to reflect the redesignation of the patent appeal board.

For applications in which a patent was granted on or after January 14, 2013, 37 CFR 1.702(a)(1) provides patent term adjustment if the Office fails to mail either a notification under 35 U.S.C. 132 or notice of allowance under 35 U.S.C. 151 not later than 14 months after the date on which the application was filed under 35 U.S.C. 111(a) or the date the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application. For applications filed on or after May 29, 2000 in which the patent was granted prior to January 14 2013, the fourteen month measurement in international applications is based upon the date that the application fulfilled the requirements of 35 U.S.C. 371 and not the date the national stage commenced. See 37 CFR 1.702(a)(1) (pre-2013-04-01).

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, (September 18, 2000), 1239 OG 14, 28-30 (October 3, 2000). On January 14, 2013, section 1(h)(1)(B) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(1)(B) to change "the actual filing date of the application in the United States" to "the actual filing date of the application under section 111(a) in the United States, or, in the case of an international application, the date of commencement of the national stage under section 371 in the international application." The clarification of the meaning of the phrase "actual filing date of the application in the United States" did not require a change to the language of 37 CFR 1.702(b) because the Office had interpreted, by regulation, the language of the former 35 U.S.C. 154(b)(1)(B) to have the same meaning as the current 35 U.S.C. 154(b)(1)(B), as discussed

above. See *Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term*, 65 FR 56366, 56382-84, (September 18, 2000), 1239 OG 14, 28-30 (October 3, 2000). See also *Revisions to Patent Term Adjustment*, 78 FR 19416, 19417 (April 1, 2013), 1389 OG 224 (April 23, 2013).

Effective on September 16, 2012, 37 CFR 1.702(b)(2) was amended to reflect the statutory change in section 3(i) of the AIA that replaced interference proceedings with derivation proceedings for some applications. In addition, section 3(j) of the AIA redesignated the title "Board of Patent Appeals and Interferences" as "Patent Trial and Appeal Board" in 35 U.S.C. 134, 145, 146, 154, and 305. Accordingly, 37 CFR 1.702(b)(4) was amended to reflect the redesignation of the title of the Board. See *Changes to Implement Miscellaneous Post Patent Provisions of the Leahy-Smith America Invents Act*, 77 FR 46615 (August 6, 2012).

37 CFR 1.702(c) also 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)). Effective September 16, 2012, 37 CFR 1.702(c) was amended to reflect the statutory change in section 3(i) of the AIA that replaced interference proceedings with derivation proceedings for certain applications. Specifically, 37 CFR 1.702(c) added derivation proceedings to the guarantees of adjustment for Office delays. In addition, section 3(j) of the AIA redesignated the title "Board of Patent Appeals and Interferences" as "Patent Trial and Appeal Board" in 35 U.S.C. 134, 145, 146, 154, and 305. 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)).

Effective May 24, 2004, 37 CFR 1.702(e) was amended to indicate that certain remands by the Board of Patent Appeals and Interferences shall be considered "a decision in the review reversing an adverse determination of patentability" for patent term adjustment purposes. Effective September 16, 2012, 37 CFR 1.702(e) was amended to implemented section (3)(j) of the AIA by redesignating the title "Board of Patent Appeals and Interferences" as "Patent Trial and Appeal Board".

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 design patents, filed on or after May 29, 2000, and patents issued on such applications. The term ''original application'' includes a continuing application (continuation, divisional, or continuation-in-part, whether the application is filed under 37 CFR 1.53(b) or as a continued prosecution application under 37 CFR 1.53(d)) and an international application under 35 U.S.C. 363 which has entered the national stage. See *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 87 USPQ2d 1705 (Fed. Cir. 2008). In particular, 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, and before July 14, 2003, 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. In regard to international applications, such an application must have an international filing date on or after May 29, 2000 in order for the provisions of 37 CFR 1.702 through 1.705 to apply. The date on which an international application fulfills the requirements of 35 U.S.C. 371 (e.g., enters the national stage) is not the filing date of the international application. See 35 U.S.C. 363. The term "design patents" includes patents issued from design applications filed under 35 U.S.C. 111 and international design applications filed under 35 U.S.C. 385.

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

[Editor Note: 37 CFR 1.703(a)(1), as reproduced below, includes amendments applicable only to patents granted on or after January 14, 2013 and 37 CFR 1.703(b)(4) and (e), as reproduced

below, include amendments applicable only to applications and patents in which a notice of allowance issued on or after September 17, 2012. See 37 CFR 1.703 (2012-09-17 thru 2013-03-31) or 37 CFR 1.703 (pre-2012-09-17) for paragraph (a)(1) applicable to patents granted before January 14, 2013. See 37 CFR 1.703 (pre-2012-09-17) for paragraphs (b)(4) and (e) that apply if the notice of allowance was issued before September 17, 2012.]

(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 filed under 35 U.S.C. 111(a) the date the national stage commenced under 35 U.S.C. 371(b) or (f) in an international 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;

(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 filed 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 filed 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 § 41.37 was filed and ending on the date of mailing of any of an examiner's answer under § 41.39, 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 Patent Trial and Appeal Board 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 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 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 any request for continued examination of the application under 35 U.S.C. 132(b) was filed and ending on the date of mailing of the notice of allowance under 35 U.S.C. 151;

(2)(i) The number of days, if any, in the period beginning on the date an interference or derivation proceeding was instituted to involve the application in the interference or derivation proceeding under 35 U.S.C. 135(a) and ending on the date that the interference or derivation proceeding 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 or derivation 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 § 41.39 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 or derivation proceeding under 35 U.S.C. 135(a) would be instituted 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 jurisdiction over the application passes to the Patent Trial and Appeal Board under § 41.35(a) of this chapter and ending on the date that jurisdiction by the Patent Trial and Appeal Board ends under § 41.35(b) of this chapter or the date of the last decision by a Federal court in an appeal under 35 U.S.C. 141 or civil action under 35 U.S.C. 145, whichever is later.

(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 or derivation proceeding was instituted to involve the application in the interference or derivation proceeding under 35 U.S.C. 135(a) and ending on the date that the interference or derivation proceeding 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 or derivation 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 § 41.39

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 or derivation proceeding under 35 U.S.C. 135(a) would be instituted 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 jurisdiction over the application passes to the Patent Trial and Appeal Board under § 41.45(a) of this chapter and ending on the date of a final decision in favor of applicant by the Patent Trial and Appeal Board or 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 delay 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 1.703 specifies the period of adjustment if a patent is entitled to patent term adjustment under 35 U.S.C. 154(b)(1) and 37 CFR 1.702. See MPEP § 2731 for more information.

On September 16, 2012, 37 CFR 1.703 was amended to reflect the statutory change in section 3(i) of the AIA that replaced interference proceedings with derivation proceedings for certain applications. See AIA section 3(n). 37 CFR 1.702(c) added derivation proceedings to the guarantees of adjustment for Office delays. In addition, section 3(j) of the AIA redesignated the “Board of Patent Appeals and Interferences” as “Patent Trial and Appeal Board” in 35 U.S.C. 134, 145, 146, 154, and 305. 37 CFR 1.703(a)(5) was amended to reflect the change to the title of the Patent Board and 37 CFR 1.703(b)(2), (b)(3), (c)(1), and (d)(3) were amended to reflect the addition of derivation proceedings to the rules providing patent term adjustment for Office delay.

Effective September 17, 2012, any application that receives a notice of allowance on or after such date and issues as a patent, is entitled to patent term adjustment under 37 CFR 1.702(e) for the sum of the number of days, if any, in the period beginning on the date on which jurisdiction passes to the Patent Trial and Appeal Board and ends on the date of a final decision in favor of applicant by the Patent Trial and Appeal Board or a federal court in an appeal under 35 U.S.C. 141 or a civil action under 35 U.S.C. 145. See *Revisions of Patent Term Adjustment Provisions Relating to Appellate Review,* 77 FR 49354 (August 16, 2012).

Effective September 17, 2012, any application that receives a notice of allowance on or after such date and issues as a patent, the three year delay under 37 CFR 1.703(b) does not include the number of days, if any, in the period beginning on the date which jurisdiction passes to the Patent Trial and Appeal Board under 37 CFR 41.35(a) to the date that the jurisdiction of the Patent Trial and Appeal Board ends under 37 CFR 41.35(b) or the date of the last decision by the federal court in an appeal under 35 U.S.C. 141 or civil action under 35 U.S.C. 145.

The Office will also apply the changes to 37 CFR 1.703 in any timely patent term adjustment reconsideration proceeding that is initiated on or after September 17, 2012. To allow patentees to take advantage of changes to this provision relating to appellate review, the Office will consider any of the following timely-filed proceedings to be an eligible "patent term adjustment reconsideration proceeding" if initiated on or after September 17, 2012:

(1) reconsideration proceedings initiated pursuant to a remand from a timely filed civil action in federal court;

(2) reconsideration proceedings initiated pursuant to a timely request for reconsideration of the patent term adjustment indicated in the patent under 37 CFR 1.705(d) (2012) in which the patentee argues that the change to 37 CFR 1.703 in this final rule is applicable to his or her patent; and

(3) reconsideration proceedings initiated pursuant to a request for reconsideration that seeks

reconsideration of the Office's decision under 37 CFR 1.705(d) (2012) regarding patent term adjustment under the Office's former interpretation of the appellate review language of 35 U.S.C. 154(b)(1)(B)(ii) and (C)(iii), if such request is filed within two months of the date of the decision for which reconsideration is requested. See 37 CFR 1.181(f).

For applications in which the patent was granted on or after January 14, 2013, 37 CFR 1.703(a)(1) provides patent term adjustment if the Office fails to 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 14 months after the date on which the application was filed under 35 U.S.C. 111(a) or the date the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application. For applications filed on or after May 29, 2000 in which the patent was granted prior to January 14, 2013, the fourteen month measurement in international applications is based upon the date that application fulfilled the requirements of 35 U.S.C. 371 and not the date the national stage commenced.

Effective January 9, 2015, 37 CFR 1.703(b)(1) was amended to provide that the time consumed by continued examination of the application under 35 U.S.C. 132(b) is the number of days, if any, in the period beginning on the date on which any request for continued examination of the application under 35 U.S.C. 132(b) was filed and ending on the date of mailing of the notice of allowance under 35 U.S.C. 151. This change is effective for any patent granted before, on, or after January 9, 2015. See MPEP § 2731 for more information. See also *Novartis AG v. Lee*, 740 F.3d 593, 109 USPQ2d 1385 (Fed. Cir. 2014).

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

[Editor Note: 37 CFR 1.704(c)(12), as reproduced below, include changes applicable only to applications in which a request for continued examination under 35 U.S.C. 132(b) and 37 CFR 1.114 was filed on or after March 10, 2015. In addition, 37 CFR 1.704(c)(11), (c)(13), (c)(14), and (f), as reproduced below, include changes applicable only to patent applications filed under 35 U.S.C. 111 on or after December 18, 2013, and to international patent applications in which the national stage commenced under 35 U.S.C. 371 on or after December 18, 2013. For 37 CFR 1.704(c)(11) and (c)(12) in effect for applications filed before (and international applications in which the national stage commenced before) December 18, 2013, and in which a notice of appeal was filed on or after September 17, 2012, see 37 CFR 1.704 (2012-09-17 thru 2013-12-17). For 37 CFR 1.704(c)(11) in effect for applications in which there was no notice of appeal filed on or after September 17, 2012, see 37 CFR 1.704 (pre-2012-09-17).37 CFR 1.704(e) below includes changes applicable only to applications in which a notice of allowance was mailed on or after April 1, 2013. For 37 CFR 1.704(e) in effect for applications in which the notice of allowance was mailed prior to April 1, 2013, see 37 CFR 1.704(e) (pre-2013-03-31). 37 CFR 1.704(c)(10)(ii) below includes changes applicable only to patent applications in which a notice of appeal was filed on or after September 17, 2012. For 37 CFR 1.704(c)(10) in effect for applications in which the notice of appeal filed prior to September 17, 2012, see 37 CFR 1.704(c)(10) (pre-2012-09-17).]

(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 filed 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 Patent Trial and Appeal Board, other than a decision designated as containing a new ground of rejection under § 41.50(b) of this title or statement under § 41.50(c) of this title, 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, other than a request for continued examination in compliance with § 1.114, 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 filed 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;

(11) Failure to file an appeal brief in compliance with § 41.37 of this chapter within three months from the date on which a notice of appeal to the Patent Trial and Appeal Board was filed under 35 U.S.C. 134 and § 41.31 of this chapter, 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 three months from the date on which a notice of appeal to the Patent Trial and Appeal Board was filed under 35 U.S.C. 134 and § 41.31 of this chapter, and ending on the date an appeal brief in compliance with § 41.37 of this chapter or a request for continued examination in compliance with § 1.114 was filed;

(12) Submission of a request for continued examination under 35 U.S.C. 132(b) after any notice of allowance under 35 U.S.C. 151 has been mailed, 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 of mailing of the notice of allowance under 35 U.S.C. 151 and ending on the date the request for continued examination under 35 U.S.C. 132(b) was filed;

(13) Failure to provide an application in condition for examination as defined in paragraph (f) of this section within eight months from either the date on which the application was filed under 35 U.S.C. 111(a) or the date of commencement of the national stage under 35 U.S.C. 371(b) or (f) in an international application, 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 eight months from either the date on which the application was filed under 35 U.S.C. 111(a) or the date of commencement of the national stage under 35 U.S.C. 371(b) or (f) in an international application and ending on the date the application is in condition for examination as defined in paragraph (f) of this section; and

(14) 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)(1) 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, and a request for continued examination in compliance with § 1.114 with no submission other than 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 paragraph (c)(12) of this section, if the paper or request for continued examination is accompanied by a statement that each item of information contained in the information disclosure statement:

(i) Was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and 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; or

(ii) Is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office, and 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.

(2) The thirty-day period set forth in paragraph (d)(1) of this section is not extendable.

(e) The submission of a 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.

(f) An application filed under 35 U.S.C. 111(a) is in condition for examination when the application includes a specification, including at least one claim and an abstract (§ 1.72(b)), and has papers in compliance with § 1.52 , drawings (if any) in compliance with § 1.84 , any English translation required by § 1.52(d) or § 1.57(a) , a sequence listing in compliance with § 1.821 through § 1.825 (if applicable), the inventor's oath or declaration or an application data sheet containing the information specified in § 1.63(b) , the basic filing fee (§ 1.16(a) or § 1.16(c)), the search fee (§ 1.16(k) or § 1.16(m)), the examination fee (§ 1.16(o) or § 1.16(q)), any certified copy of the previously filed application required by § 1.57(a) , and any application size fee required by the Office under § 1.16(s) . An international application is in condition for examination when the application has entered the national stage as defined in § 1.491(b), and includes a specification, including at least one claim and an abstract (§ 1.72(b)), and has papers in compliance with § 1.52 , drawings (if any) in compliance with § 1.84 , a sequence listing in compliance with § 1.821 through § 1.825 (if applicable), the inventor's oath or declaration or an application data sheet containing the information specified in § 1.63(b) , the search fee (§ 1.492(b)), the examination fee (§ 1.492(c)), and any application size fee required by the Office under § 1.492(j). An application shall be considered as having papers in compliance with § 1.52 , drawings (if any) in compliance with § 1.84 , and a sequence listing in compliance with § 1.821 through § 1.825 (if applicable) for purposes of this paragraph on the filing date of the latest reply (if any) correcting the papers, drawings, or sequence listing that is prior to 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.

Section 1.704 implements the provisions of 35 U.S.C. 154(b)(2)(C). 35 U.S.C. 154(b)(2)(C) specifies certain circumstances as constituting a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application and also provides for the Office to prescribe regulations establishing circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application. For more information, see MPEP § 2732.

Section 3(j) of the AIA redesignated the title "Board of Patent Appeals and Interferences" as "Patent Trial and Appeal Board" in 35 U.S.C. 134, 145, 146, 154, and 305. Effective September 16, 2012, 37 CFR 1.704(c)(9) was amended to reflect the change to the title of the Board.

Effective December 1, 2011, 37 CFR 1.704(d) was amended to allow the diligent applicant to avoid patent term adjustment reduction for an information disclosure statement (IDS) submission that results from a communication from the Office if submitted within 30 days of receipt of the communication by any individual designated in 37 CFR 1.56(c). See *Revision of Patent Term Adjustment Provisions Relating to Information Disclosure Statements* , 76 FR 74700 (December 1, 2011). Previously, this section only allowed a diligent applicant to avoid patent term adjustment reduction if the IDS was cited as a result from a foreign patent Office. Effective March 10, 2015, 37 CFR 1.704(d)(1) provides that a request for continued examination in compliance with 37 CFR 1.114 with no submission other than an information disclosure statement in compliance with 37 CFR 1.97 and 37 CFR 1.98 will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under 37 CFR 1.704(c)(12), if the request for continued examination under 35 U.S.C. 132(b) is accompanied by the statement provided for in 37 CFR 1.704(d).

Effective September 17, 2012, 37 CFR 1.704(c)(11) was amended to provide that failure to file an appeal brief in compliance with 37 CFR 41.37 within three months from the date that the notice of appeal was filed would constitute a failure to engage in reasonable efforts to conclude processing or

examination of the application. The amended rule is applicable with respect to the filing of an appeal brief in any application (other than design or reissue applications) in which the notice of appeal is filed on or after September 17, 2012.

Prior to September 17, 2012, 37 CFR 1.704(c)(11) contained a provision that further prosecution via a continuing application is a circumstance constituting a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application. Effective September 17, 2012, this provision previously labeled as 37 CFR 1.704(c)(11) was labelled 37 CFR 1.704(c)(12). Effective December 18, 2013, this same provision was amended to be located in 37 CFR 1.704(c)(13), and a new provision regarding the failure to provide an application in condition for examination, as defined in 37 CFR 1.704(f), was added as 37 CFR 1.704(c)(12). Effective March 10, 2015, the same provision formerly labelled as 37 CFR 1.704(c)(13) is now labelled as 37 CFR 1.704(c)(14).

Effective for applications filed under 35 U.S.C. 111 on or after December 18, 2013 and international applications in which the national stage was commenced under 35 U.S.C. 371 on or after December 18, 2013, the following changes to 37 CFR 1.704 were made. On December 18, 2013,37 CFR 1.704(c)(12) was added to provide for a reduction in any earned patent term adjustment in the situation in which an application is not in condition for examination within eight months from when an application under 35 U.S.C. 111 was filed or when an international application commenced the national stage under 35 U.S.C. 371(b) or (f). Effective March 10, 2015, this provision was amended to be labelled as 37 CFR 1.704(c)(13). On December 18, 2013, 37 CFR 1.704(f) was added to define when an application is "in condition for examination" for purposes of 37 CFR 1.704(c)(13). 37 CFR 1.704(c)(11) was modified to delete the "and" at the end of the paragraph because it is no longer the penultimate paragraph of 37 CFR 1.704.

Effective for applications in which a request for continued examination was filed on or after March 10, 2015, 37 CFR 1.704(c)(12) was amended to include a new provision that establishes the submission of a request for continued examination under 35 U.S.C. 132(b) after any notice of allowance under 35 U.S.C. 151 has been mailed as constituting a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application, in which case the period of adjustment set forth in 37 CFR 1.703 shall be reduced by the number of days, if any, beginning on the day after the date of mailing of the notice of allowance under 35 U.S.C. 151 and ending on the date the request for continued examination under 35 U.S.C. 132(b) was filed. See MPEP § 2732 for more information.

37 CFR 1.705 Patent term adjustment determination

[Editor Note: 37 CFR 1.705, as reproduced below, include amendments applicable only to patents granted on or after January 14, 2013. See 37 CFR 1.705(a)-(f) (pre-2013-04-01) in effect with respect to applications granted prior to January 14, 2013.]

(a) The patent 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 on the patent must be by way of an application for patent term adjustment filed no later than two months from the date the patent was granted. This two-month period may be extended under the provisions of § 1.136(a). 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 requests for 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 be filed prior to the issuance of the patent. This time period is not extendable. Any request for reinstatement of

all or part of the period of adjustment reduced pursuant to § 1.704(b) must also be accompanied by:

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

(2) A showing to the satisfaction of the Director 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) 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.

Section 1.705 implements the provisions of 35 U.S.C. 154(b)(3) and (b)(4)(B). See MPEP § 2733 for more information on the patent term adjustment determination under 37 CFR 1.705(a) and MPEP § 2734 for more information on requests for reconsideration under 37 CFR 1.705(b) and the due care showing under 37 CFR 1.705(c).

Any patent granted on or after January 14, 2013 is subject to amended 37 CFR 1.705.

2731 Period of Adjustment [R-07.2015]

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

[Editor Note: 37 CFR 1.703(a)(1), as reproduced below, includes amendments applicable only to patents granted on or after January 14, 2013 and 37 CFR 1.703(b)(4) and (e), as reproduced below, include amendments applicable only to applications and patents in which a notice of allowance issued on or after September 17, 2012. See 37 CFR 1.703 (2012-09-17 thru 2013-03-31) or 37 CFR 1.703 (pre-2012-09-17) for paragraph (a)(1) applicable to patents granted before January 14, 2013. See 37 CFR 1.703 (pre-2012-09-17) for paragraphs (b)(4) and (e) that apply if the notice of allowance was issued before September 17, 2012.]

(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 filed under 35 U.S.C. 111(a) or the date the national stage commenced under 35 U.S.C. 371(b) or (f) in an international 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;

(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 filed 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 filed 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 § 41.37 was filed and ending on the date of mailing of any of an examiner's answer under § 41.39, 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 Patent Trial and Appeal Board 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 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 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 any request for continued examination of the application under 35 U.S.C. 132(b) was filed and ending on the date of mailing of the notice of allowance under 35 U.S.C. 151;

(2)(i) The number of days, if any, in the period beginning on the date an interference or derivation proceeding was instituted to involve the application in the interference or derivation proceeding under 35 U.S.C. 135(a) and ending on the date that the interference or derivation proceeding 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 or derivation 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 § 41.39 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

or derivation proceeding under 35 U.S.C. 135(a) would be instituted 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 jurisdiction over the application passes to the Patent Trial and Appeal Board under § 41.35(a) of this chapter and ending on the date that jurisdiction by the Patent Trial and Appeal Board ends under § 41.35(b) of this chapter or the date of the last decision by a Federal court in an appeal under 35 U.S.C. 141 or civil action under 35 U.S.C. 145, whichever is later.

(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 or proceeding was instituted to involve the application in the interference or derivation proceeding under 35 U.S.C. 135(a) and ending on the date that the interference or derivation proceeding 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 or derivation 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 § 41.39 of this title 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 or derivation proceeding would be instituted 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 jurisdiction over the application passes to the Patent Trial and Appeal Board under § 41.35(a) of this chapter and ending on the date of a final decision in favor of applicant by the Patent Trial and Appeal Board or 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 delay 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 1.703 specifies the period of adjustment if a patent is entitled to patent term adjustment under 35 U.S.C. 154(b)(1) and 37 CFR 1.702. When a period is indicated (in 37 CFR 1.703 or 1.704) as "beginning" on a particular day, that day is included in the period, in that such day is "day one" of the period and not "day zero." For example, a period beginning on April 1 and ending on April 10 is ten (and not nine) days in length.

35 U.S.C. 154(b)(1)(A) and (B) provide for an adjustment of one day for each day after the end of the period set forth in 35 U.S.C. 154(b)(1)(A)(i), (ii), (iii), (iv), and (B) until the prescribed action is taken, whereas 35 U.S.C. 154(b)(1)(C) provides for an adjustment of one day for each day of the pendency of the proceeding, order, or review prescribed in 35 U.S.C. 154(b)(1)(C)(i) through (iii). Therefore, the end of the period set forth in 37 CFR 1.703(a) and 1.703(b) (which correspond to 35 U.S.C. 154(b)(1)(A) and (B)) is "day zero" (not "day one") as to the period of adjustment, whereas the first day of the proceeding, order, or review set forth in 37 CFR 1.703(c), 1.703(d), and 1.703(e) (which correspond to 35 U.S.C. 154(b)(1)(C)(i) through (iii)) is "day one" of the period of adjustment.

37 CFR 1.703(a) pertains to 35 U.S.C. 154(b)(1)(A) and indicates that the period of adjustment under 37 CFR 1.702(a) is the sum of the periods specified in 37 CFR 1.703(a)(1) through 37 CFR 1.703(a)(6).

37 CFR 1.703(a)(1) pertains to the provisions of 35 U.S.C. 154(b)(1)(A)(i) and specifies that the period is the number of days, if any, beginning on the date after the day that is 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 application and ending on the mailing date of either an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first. For purposes of 35 U.S.C. 154(b)(1)(A)(i)(II) in effect prior to enactment of the AIA Technical Corrections Act, an international application fulfills the requirements of 35 U.S.C. 371 on the date of commencement of the national stage under 35 U.S.C. 371(b) or (f), or the date the application fulfills the requirements of 35 U.S.C. 371(c) if that date is later than the date of commencement of the national stage under 35 U.S.C. 371(b) or (f). In other words, the requirements of 35 U.S.C. 371 are met when applicant has met all of the requirements of 35 U.S.C. 371(c) and, unless applicant requests early processing under 35 U.S.C. 371(f), the time limit set forth in the applicable one of PCT Articles 22 and 39 has expired. Accordingly, the requirements of 35 U.S.C. 371 are met when the Office can begin examination of the patent application. If, for example, an applicant files the required oath or declaration (35 U.S.C. 115) and any necessary English translation after the expiration of the time limit set forth in Article 22 of the PCT or the time limit under Article 39 of the PCT, the date the requirements of 35 U.S.C. 371 are met is the date the requirements of 35 U.S.C. 371(c) are met. If, however, an applicant files the required declaration (or oath), filing fee, and any required English translation before the expiration of the relevant PCT Article 22 or Article 39 time period, but does not request early processing under 35 U.S.C. 371, the requirements of 35 U.S.C. 371 will be met once the applicable time period has expired.

For patents issuing from international application that are granted on or after January 14, 2013, 37 CFR 1.703(a)(1) in effect on April 1, 2013 applies. The AIA Technical Corrections Act and the changes to 37 CFR 1.703(a)(1) revised the date that begins the fourteen-month measurement from the date on which the international application fulfilled the requirements of 35 U.S.C. 371 to the date of commencement of the national stage under 35 U.S.C. 371. The change to 35 U.S.C. 154(b)(1)(A)(i)(II) means that the time period will begin sooner in international applications where the inventor does not file the inventor's oath or declaration (35 U.S.C. 371(c)(4)) or other requirements at the time of the commencement.

A written restriction requirement, a written election of species requirement, a requirement for information under 37 CFR 1.105, an action under *Ex parte Quayle*, 1935 Comm'r Dec. 11 (1935), and a notice of allowability (PTOL-37) are each an action issued as a result of the examination conducted pursuant to 35 U.S.C. 131. As such, each of these Office actions is a notification under 35 U.S.C. 132. Office notices and letters issued as part of the pre-examination processing of an application are not notices issued as a result of an examination conducted pursuant to 35 U.S.C. 131, and thus are not notifications under 35 U.S.C. 132. Examples of such pre-examination processing notices are: a Notice of Incomplete Nonprovisional Application, a Notice of Omitted Item(s) in a Nonprovisional Application, a Notice to File Missing Parts of Application, a Notice of Informal Application, a Notice to File Corrected Application Papers Filing Date Granted, or a Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures.

Written restriction requirements are notifications under 35 U.S.C. 132. In considering whether a restriction requirement under 35 U.S.C. 121 was appealable under 35 U.S.C. 134, the Court of Customs and Patent Appeals (CCPA) noted that: (1) 35 U.S.C. 121 denoted its restriction procedure as a ''requirement''; (2) 35 U.S.C. 132 stated that the Commissioner shall give notice to the applicant whenever ''any claim for a patent is rejected, or any objection or requirement made''; and (3) 35 U.S.C. 134 provided for an appeal only by an applicant whose claims have been ''twice rejected.'' See *In re Hengehold*, 440 F.2d 1395, 1402–03, 169 USPQ 473,479 (CCPA 1971). Thus, the CCPA concluded that Congress intended to differentiate between objections and requirements (35 U.S.C. 132) and actual rejections of claims (35 U.S.C. 132) and made appeal applicable only to the latter. See *Hengehold*, 440 F.2d at 1403, 169 USPQ at 479. Since the CCPA cited with approval the "requirement" language of 35 U.S.C. 121 and evaluated rejections, objections, and requirements together under 35 U.S.C. 132 when discussing and differentiating among them to determine whether a restriction requirement was

appealable under 35 U.S.C. 134, the CCPA must have considered a restriction requirement to be a requirement under 35 U.S.C. 132. In other words, the CCPA's analysis determined that the making of a written restriction (or election) requirement is a notification under 35 U.S.C. 132. See also *Digital Equipment Corp. v. Diamond*, 653 F.2d 701, 713 n.13, 210 USPQ 521, 535–36 n.13 (1st Cir. 1981) (35 U.S.C. 132 when noting that the terms ''requirement'' and ''objection'' are distinct from ''rejection'' and as such, objections were not appealable under 35 U.S.C. 134). In addition, the Office has long considered a written restriction requirement containing no action on the merits to be a notice under 35 U.S.C. 132. For example, MPEP § 710.02(b) instructs examiners to set a shortened statutory period for reply of one month for a written restriction requirement containing no action on the merits under the authority given by 35 U.S.C. 133. 35 U.S.C. 133 would not apply to the period for reply to a written restriction requirement, if a written restriction requirement containing no action on the merits is not a notice under 35 U.S.C. 132.

37 CFR 1.703(a)(2) pertains to the provisions of 35 U.S.C. 154(b)(1)(A)(ii) and specifies that the period is the number of days, if any, beginning on the day after the date that is four months after the date a reply under 37 CFR 1.111 was filed and ending on the mailing date of either an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first.

37 CFR 1.703(a)(3) also pertains to the provisions of 35 U.S.C. 154(b)(1)(A)(ii) and specifies that the period is the number of days, if any, beginning on the day after the date that is four months after the date a reply in compliance with 37 CFR 1.113(c) was filed 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. A reply under 37 CFR 1.113 is a reply to a final Office action, and a reply in compliance with 37 CFR 1.113 is a reply that cancels all of the rejected claims and removes all outstanding objections and requirements or otherwise places the application in condition for allowance. Any amendment after final that does not cancel all of the rejected claims and remove all outstanding objections and requirements or otherwise place the application in condition for allowance is not a reply in compliance with 37 CFR 1.113(c) and will not trigger the four-month requirement under 37 CFR 1.703(a)(3) for the Office to act on the after-final reply.

37 CFR 1.703(a)(4) also pertains to the provisions of 35 U.S.C. 154(b)(1)(A)(ii) and specifies that the period is the number of days, if any, beginning on the day after the date that is four months after the date an appeal brief in compliance with 37 CFR 41.37 was filed and ending on the mailing date of any of an examiner's answer under 37 CFR 41.39, an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first. As discussed below, the phrase "the date on which" an "appeal was taken" in 35 U.S.C. 154(b)(1)(A)(ii) means the date on which an appeal brief (and not a notice of appeal) was filed. The phrase "appeal brief in compliance with 37 CFR 41.37" requires that: (1) the appeal brief fee (37 CFR 1.17(b)) be paid (37 CFR 41.20); and (2) the appeal brief complies with the requirements in 37 CFR 41.37(c). However, for applications in which the appeal brief was filed on or after March 19, 2013, the fee required to accompany the appeal brief is set to zero dollars in amended 37 CFR 41.37(a), and accordingly, the phrase "appeal brief in compliance with 37 CFR 41.37" no longer requires the filing of the appeal brief fee. See *Setting and Adjusting Patent Fees*, 78 FR 4212, 4291 (January 18, 2013).

37 CFR 1.703(a)(5) pertains to the provisions of 35 U.S.C. 154(b)(1)(A)(iii) and specifies that the period is the number of days, if any, beginning on the day after the date that is four months after the date of a final decision by the Patent Trial and Appeal Board (Board) 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 mailing date of either an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first.

The phrase "allowable claims remain in the application" for purposes of 35 U.S.C. 154(b)(1)(A)(iii) means that after the decision there is at least one pending claim (for purposes of statutory construction, "words importing the plural include the singular" (1 U.S.C. 1)) that is not

withdrawn from consideration and is not subject to a rejection, objection, or other requirement. This applies in the following situations: (1) at least one claim is allowable (not merely objected to) at the time the examiner's answer is mailed and is not canceled before, or made subject to a rejection as a result of, the appellate review; or (2) when all of the rejections applied to at least one claim are reversed, and such claim is not made subject to a rejection, as a result of the appellate review. For example:

(A) If claims 1 and 2 (both independent) are pending, the decision affirms the rejection of claim 1, and claim 2 was indicated as allowable prior to the appeal, then "allowable claims remain in the application" for purposes of 35 U.S.C. 154(b)(1)(A)(iii).

(B) If claims 1 and 2 are pending, the decision affirms the rejection of claim 1, and claim 2 was objected to by the examiner prior to the appeal as being allowable except for its dependency from claim 1, "allowable claims" do not "remain in the application" for purposes of 35 U.S.C. 154(b)(1)(A)(iii) (claim 2 is not allowable because there is an outstanding objection to it).

(C) If claims 1 and 2 are pending (claim 2 either depending from claim 1 or is an independent claim), and the decision affirms the rejection of claim 1 and reverses the rejection of claim 2, then "allowable claims remain in the application" for purposes of 35 U.S.C. 154(b)(1)(A)(iii) (claim 2 is "allowable" within the meaning of 37 CFR 1.703(a)(5)) because there is no outstanding objection or requirement as to it (see MPEP § 1214.06, subsection II).

For a Board decision to be a ''decision by the Patent Trial and Appeal Board under [35 U.S.C.] 134'' within the meaning of 35 U.S.C. 154(b)(1)(A)(iii) (and 37 CFR 1.703(a)(5)), the decision must sustain or reverse the rejection(s) of the claim(s) on appeal, or in limited circumstances as further described below, a remand may be deemed a decision for purposes of 37 CFR 1.703(a)(5). For a Board decision to be a ''decision by the Patent Trial and Appeal Board under [35 U.S.C.] 135''within the meaning of 35 U.S.C. 154(b)(1)(A)(iii) (and 37 CFR 1.703(a)(5)), the decision must include a decision on the patentability of the claims, derivation, or priority of invention.

If an application is remanded by a panel and the remand is the last action by a panel of the Board prior to the mailing of a notice of allowance under 35 U.S.C. 151, the remand generally shall be considered a decision by the Patent Trial and Appeal Board as that phrase is used in 35 U.S.C. 154(b)(1)(A)(iii), a decision in the review reversing an adverse determination of patentability as that phrase is used in 35 U.S.C. 154(b)(1)(C)(iii), and a final decision in favor of the applicant as that phrase is used in 37 CFR 1.703(e). However, a remand by a panel of the Board shall not be considered a decision in the review reversing an adverse determination of patentability, as provided in this paragraph, if there is filed a request for continued examination under 35 U.S.C. 132(b) that was not first preceded by the mailing, after the remand, of at least one of an action under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151.

The phrase ''final decision'' in 37 CFR 1.703(a)(5) means that: (1) the decision is the last decision in the review by the Board (or by a federal court); and (2) the decision does not require further action by the applicant to avoid termination of proceedings as to the rejected claims. Thus, a Board decision containing a new ground of rejection under 37 CFR 41.50(b) requires action by the applicant to avoid termination of proceedings as to the rejected claims and is, thus, is not considered a ''final decision'' for purposes of 37 CFR 1.703(a)(5). The phrase ''final decision,'' however, does not require that the decision be final for purposes of judicial review (*e.g.* , a Board decision reversing the rejection of all of the claims on appeal is not ''final'' for purposes of judicial review, but (absent a subsequent decision by the Board) is a ''final decision'' for purposes of 37 CFR 1.703(a)(5)).

37 CFR 1.703(a)(6) pertains to the provisions of 35 U.S.C. 154(b)(1)(A)(iv) and specifies that the period is the number of days, if any, 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 the patent was issued. Thus, the period of adjustment under 35 U.S.C. 154(b)(1)(A)(iv), if any, is ascertained by looking back from the issue date to the most recent time at which the issue fee or another requirement was outstanding, determining the succeeding date

on which the issue fee was paid and all outstanding requirements were satisfied, and measuring the number of days, if any, in the period beginning on the day after the date that is four months after such date the issue fee was paid and all outstanding requirements were satisfied and ending on the date a patent was issued. The date the issue fee was paid and all outstanding requirements were satisfied is the later of the date the issue fee was paid or the date all outstanding requirements were satisfied. Note that the filing of a priority document (and processing fee) is not considered an outstanding requirement under 35 U.S.C. 154(b)(1)(A)(iv) and 37 CFR 1.703(a)(6) because, if the priority document is not filed, the patent simply issues without the priority claim (the application is not abandoned). If prosecution in an application is reopened after allowance (see MPEP § 1308), all outstanding requirements are not satisfied until the application is again in condition for allowance as indicated by the issuance of a new notice of allowance under 35 U.S.C. 151 (see MPEP § 1308) and the form PTOL-85(b) from the latest notice of allowance is returned to the Office along with any outstanding requirements, such as payment of any additional fees owed and/or additional required drawings to be submitted by the applicant. For example, if prosecution in an application is reopened after a notice of allowance as the result of an applicant filing a request for continued examination, the date on which the issue fee was paid and all outstanding requirements were satisfied is the date on which the Issue Fee Transmittal Form (PTOL-85(b)) from the ultimate notice of allowance under 35 U.S.C. 151 is returned to the Office (or a later date if there remain additional outstanding requirements, such as payment of any additional fees owed or required drawings to be submitted). See MPEP § 2732.

Applicant is also provided patent term adjustment for Office delay under 37 CFR 1.702(a)(2) when the Office fails to act on a request for continued examination within four months of the filing of the request for continued examination. The period of adjustment for Office delay, if any, begins on the date that is the day after the date that is four months from the filing of the request for continued examination and ends on the date of mailing of the date of an action under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151.

37 CFR 1.703(b) pertains to the provisions of 35 U.S.C. 154(b)(1)(B) and indicates that the period of adjustment under 37 CFR 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 actual filing date of the application and ending on the date a patent was issued. 37 CFR 1.703(b) also sets forth the limitations on patent term adjustment specified in 35 U.S.C. 154(b)(1)(B)(i) and (ii). Specifically, 37 CFR 1.703(b) provides that the period of adjustment of the term of a patent shall not include the period equal to the sum of the following periods: (1) the period of pendency consumed by continued examination of the application under 35 U.S.C. 132(b) (35 U.S.C. 154(b)(1)(B)(i)); (2) the period of pendency consumed by interference proceedings (35 U.S.C. 154(b)(1)(B)(ii)); (3) the period of pendency consumed by imposition of a secrecy order (35 U.S.C. 154(b)(1)(B)(ii)); and (4) the period of pendency consumed by appellate review under 35 U.S.C. 134, 141, 145, whether successful or unsuccessful (35 U.S.C. 154(b)(1)(B)(ii)). The provisions of 35 U.S.C. 154(b)(1)(B)(iii) concerning the period of pendency consumed by delays in the processing of the application requested by the applicant are treated in 37 CFR 1.704 as such applicant delays are also circumstances constituting a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application.

The U.S. Court of Appeals for the Federal Circuit (Federal Circuit) decided that, with respect to the provisions of 35 U.S.C. 154(b)(1)(B)(i), that: (1) any time consumed by continued examination under 35 U.S.C. 132(b) is subtracted in determining the extent to which the period defined in 35 U.S.C. 154(b)(1)(B) exceeds three years, regardless of when the continued examination under 35 U.S.C. 132(b) was initiated; but (2) the time consumed by continued examination under 35 U.S.C. 132(b) does not include the time after a notice of allowance is mailed, unless the Office actually resumes examination of the application after allowance. See *Novartis AG v. Lee*, 740 F.3d 593, 109 USPQ2d 1385 (Fed. Cir. 2014).

Effective January 9, 2015, 37 CFR 1.703(b)(1) was amended to provide that the time consumed by continued examination of the application under 35

U.S.C. 132(b) is the number of days, if any, in the period beginning on the date on which any request for continued examination of the application under 35 U.S.C. 132(b) was filed and ending on the date of mailing of the notice of allowance under 35 U.S.C. 151. The changes to 37 CFR 1.703(b)(1) apply to any patent granted before, on, or after January 9, 2015. The time period between a request for continued examination and a notice of allowance is "time consumed by continued examination of the application requested by the applicant under section 132(b)" regardless of whether the Office issues an Office action under 35 U.S.C. 132. Thus, any period of examination after the mailing of a notice of allowance resulting from the filing of a subsequent request for continued examination would also be considered "time consumed by continued examination," but a period of examination after the mailing of a notice of allowance resulting from the Office *sua sponte* reopening prosecution would not be considered "time consumed by continued examination" (unless the applicant subsequently files a request for continued examination).

For example, if a first request for continued examination is filed before a notice of allowance has been mailed and a second request for continued examination is filed after a notice of allowance has been mailed, the time consumed by continued examination of the application under 35 U.S.C. 132(b) is the number of days in the period beginning on the date on which the first request for continued examination was filed and ending on the date of mailing of the notice of allowance following the first request for continued examination, plus the number of days in the period beginning on the date on which the second request for continued examination was filed and ending on the date of mailing of the notice of allowance following the second request for continued examination. Note that the "time consumed by continued examination" as measured by 37 CFR 1.703(b)(1) may include non-contiguous periods if the applicant files a subsequent request for continued examination after a notice of allowance is mailed.

In contrast, if a second request for continued examination is filed without a notice of allowance having been mailed between the filing of the first and second requests for continued examination and a notice of allowance is mailed after the second request for continued examination, the time consumed by continued examination of the application under 35 U.S.C. 132(b) is the number of days in the period beginning on the date on which the first request for continued examination was filed and ending on the date of mailing of the notice of allowance. 35 U.S.C. 154(b)(1)(B)(i) provides that the period under 35 U.S.C. 154(b)(1)(B) does not include "**any** time consumed by continued examination of the application requested by the applicant under section 132(b)" (emphasis added). Therefore, a second or subsequent request for continued examination will be treated the same as the first request for continued examination with respect to period between the filing of the request for continued examination and a notice of allowance being considered "time consumed by continued examination of the application requested by the applicant under section 132(b)."

The "time consumed by continued examination of the application requested by the applicant under section 132(b)" is the number of days, if any, in the period beginning on the date on which a request for continued examination was filed and ending on the date of mailing of the notice of allowance (PTOL-85), regardless of whether the notice of allowability (PTOL-37) and notice of allowance (PTOL-85) are mailed or issued on different days, and also regardless of whether the Office has issued multiple consecutive notices of allowability (PTOL-37). As background, the Office issues a notice of allowability (PTOL-37) and a notice of allowance (PTOL-85) when an application is in condition for allowance. These notices are generally mailed or issued on the same day, but the notice of allowability (PTOL-37) and notice of allowance (PTOL-85) are occasionally mailed or issued on different days. The Office also occasionally mails or issues multiple consecutive notices of allowability (PTOL-37) (e.g., a notice of allowability and then a supplemental notice of allowability) and rarely issues multiple consecutive notices of allowance (e.g., a notice of allowance (PTOL-85) and then a supplemental notice of allowance (PTOL-85)). In the rare instance in which the Office issues multiple consecutive notices of allowance (PTOL-85), the "time consumed by continued examination of the application requested by the applicant under section

132(b)" is the number of days, if any, in the period beginning on the date on which a request for continued examination was filed and ending on the date of mailing of the first notice of allowance (PTOL-85).

37 CFR 1.703(c) pertains to the provisions of 35 U.S.C. 154(b)(1)(C)(i) and indicates that the period of adjustment under 37 CFR 1.702(c) is the sum of the following periods (to the extent that such periods are not overlapping): (1) the number of days, if any, in the period beginning on the date an interference or derivation proceeding was instituted to involve the application in the interference or deviation proceeding and ending on the date that the interference or deviation proceeding 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 or derivation proceedings under 35 U.S.C. 135(a) not involving the application and ending on the date of the termination of the suspension.

37 CFR 1.703(d) pertains to the provisions of 35 U.S.C. 154(b)(1)(C)(ii) and indicates that the period of adjustment under 37 CFR 1.702(d) is the sum of the following periods (to the extent that such 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 37 CFR 41.39 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 or derivation proceeding under 35 U.S.C. 135(a) would be instituted 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 37 CFR 5.3(c) and ending on the date of mailing of the notice of allowance under 35 U.S.C. 151 and 37 CFR 1.311.

37 CFR 1.703(e) pertains to the provisions of 35 U.S.C. 154(b)(1)(C)(iii) and indicates that the period of adjustment under 37 CFR 1.702(e) is the sum of the number of days, if any, in the period beginning on the date on which a jurisdiction over the application passes to the Patent Trial and Appeal Board under 37 CFR 41.35(a) or 37 CFR 41.31 if the notice of allowance was issued prior to September 17, 2012, and ending on the date of a final decision in favor of the applicant by the Board or by a federal court in an appeal under 35 U.S.C. 141 or a civil action under 35 U.S.C. 145.

37 CFR 1.703(f) indicates that the adjustment will run from the expiration date of the patent as set forth in 35 U.S.C. 154(a)(2) and also indicates that to the extent that periods of delay attributable to the grounds specified in 37 CFR 1.702 overlap, the period of adjustment will not exceed the actual number of days the issuance of the patent was delayed (35 U.S.C. 154(b)(2)(A)). 35 U.S.C. 154(b)(2)(A) provides that "[t]o the extent that periods of delay attributable to grounds specified in [35 U.S.C. 154(b)(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." The USPTO previously had interpreted this provision as covering situations in which a delay by the USPTO contributes to multiple bases for adjustment (the "pre-Wyeth" interpretation of 35 U.S.C. 154(b)(2)(A)). See *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, 69 FR 34283 (June 21, 2004), 1284 OG 56 (July 13, 2004). The United States Court of Appeals for the Federal Circuit, however, held that the USPTO's earlier interpretation of 35 U.S.C. 154(b)(2)(A) was erroneous, and that periods of delay overlap under 35 U.S.C. 154(b)(2)(A) only if the periods which measure the amount of adjustment under 35 U.S.C. 154(b)(1) occur on the same calendar day. See *Wyeth v. Kappos*, 591 F.3d 1364, 93 USPQ2d 1257 (Fed. Cir. 2010).

37 CFR 1.703(f) also specifically indicates that the term of a patent entitled to adjustment under 37 CFR 1.702 and 1.703 shall be adjusted for the sum of the periods calculated under 37 CFR 1.703(a) through (e), to the extent that such periods are not overlapping, less the sum of the periods calculated under 37 CFR 1.704.

Moreover, 37 CFR 1.703(f) provides that the date indicated on any certificate of mailing or transmission under 37 CFR 1.8 shall not be taken

into account in this calculation. The date indicated on a certificate of mailing is used only to determine whether the correspondence is timely (including whether any extension of the time and fee are required) so as to avoid abandonment of the application or termination or dismissal of proceedings. The actual date of receipt of the correspondence in the Office is used for all other purposes. See 37 CFR 1.8(a). Thus, while the date indicated on any certificate of mailing or transmission under 37 CFR 1.8 will continue to be taken into account in determining timeliness, the date of filing (37 CFR 1.6) will be the date used in a patent term adjustment calculation. Applicant may wish to consider the use of the electronic filing system (EFS), the Priority Mail Express® Post Office to Addressee service of the United States Postal Service (37 CFR 1.10) or facsimile transmission (37 CFR 1.6(d)), when permitted, for replies to be accorded the earliest possible filing date for patent term adjustment calculations. Alternatively, applicant may choose to mail correspondence with sufficient time to ensure that the correspondence is received in the Office (and stamped with a date of receipt) before the expiration of the three-month period. Applicants are encouraged to check PAIR to verify the date of deposit entered in PALM for the correspondence. Applicants should contact the Office for correction of any such entries prior to the grant of the patent. At the time of the grant of the patent, the patent term adjustment calculation will be made with the dates in PALM. Thereafter, a patent term adjustment accompanied by the requisite fee and statement or showing, will be necessary to have any reduction of patent term under 37 CFR 1.704 reinstated.

Finally, 37 CFR 1.703(g) indicates that no patent, the term of which has been disclaimed beyond a specified date, shall be adjusted under 37 CFR 1.702 and 1.703 beyond the expiration date specified in the disclaimer (35 U.S.C. 154(b)(2)(B)).

2732 Reduction of Period of Adjustment of Patent Term [R-07.2015]

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

[Editor Note: 37 CFR 1.704(c)(12), as reproduced below, include changes applicable only to applications in which a request for continued examination under 35 U.S.C. 132(b) and 37 CFR 1.114 was filed on or after March 10, 2015. In addition,37 CFR 1.704(c)(11), (c)(13) , (c)(14), and (f), as reproduced below, include changes applicable only to patent applications filed under 35 U.S.C. 111 on or after December 18, 2013, and to international patent applications in which the national stage commenced under 35 U.S.C. 371 on or after December 18, 2013. For 37 CFR 1.704(c)(11) and (c)(12) in effect for applications filed before (and international applications in which the national stage commenced before) December 18, 2013, and in which a notice of appeal was filed on or after September 17, 2012, see 37 CFR 1.704 (2012-09-17 thru 2013-12-17). For 37 CFR 1.704(c)(11) in effect for applications in which there was a notice of appeal filed prior to September 17, 2012, see 37 CFR 1.704(c)(11) (pre-2012-09-17).37 CFR 1.704(e) below includes changes applicable only to applications in which a notice of allowance was mailed on or after April 1, 2013. For 37 CFR 1.704(e) in effect for applications in which there was a notice of allowance mailed prior to April 1, 2013, see 37 CFR 1.704(e) (pre-2013-03-31). 37 CFR 1.704(c)(10)(ii) below includes changes applicable only to patent applications in which a notice of appeal was filed on or after September 17, 2012. For 37 CFR 1.704(c)(10) in effect for applications in which there was a notice of appeal filed prior to September 17, 2012, see 37 CFR 1.704(c)(10) (pre-2012-09-17).]

(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 filed 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 Patent Trial and Appeal Board, other than a decision designated as containing a new ground of rejection under § 41.50(b) of this title or statement under § 41.50(c) of this title, 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, other than a request for continued examination in compliance with § 1.114, 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 filed 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;

(11) Failure to file an appeal brief in compliance with § 41.37 of this chapter within three months from the date on which a notice of appeal to the Patent Trial and Appeal Board was filed under 35 U.S.C. 134 and § 41.31 of this chapter, 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 three months from the date on which a notice of appeal to the Patent Trial and Appeal Board was filed under 35 U.S.C. 134 and § 41.31 of this chapter, and ending on the date an appeal brief in compliance with § 41.37 of this chapter or a request for continued examination in compliance with § 1.114 was filed;

(12) Submission of a request for continued examination under 35 U.S.C. 132(b) after any notice of allowance under 35 U.S.C. 151 has been mailed, 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 of mailing of the notice of allowance under 35 U.S.C. 151 and ending on the date the request for continued examination under 35 U.S.C. 132(b) was filed;

(13) Failure to provide an application in condition for examination as defined in paragraph (f) of this section within eight months from either the date on which the application was filed under 35 U.S.C. 111(a) or the date of commencement of the national stage under 35 U.S.C. 371(b) or (f) in an international application, 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 eight months from either the date on which the application was filed under 35 U.S.C. 111(a) or the date of commencement of the national stage under 35 U.S.C. 371(b) or (f) in an international application

and ending on the date the application is in condition for examination as defined in paragraph (f) of this section; and

(14) 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)(1) 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, and a request for continued examination in compliance with § 1.114 with no submission other than 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 paragraph (c)(12) of this section, if the paper or request for continued examination is accompanied by a statement that each item of information contained in the information disclosure statement:

(i) Was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by an individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement; or

(ii) Is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office, and 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.

(2) The thirty-day period set forth in paragraph (d)(1) of this section is not extendable.

(e) The submission of a 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.

(f) An application filed under 35 U.S.C. 111(a) is in condition for examination when the application includes a specification, including at least one claim and an abstract (§ 1.72(b)), and has papers in compliance with § 1.52, drawings (if any) in compliance with § 1.84, any English translation required by § 1.52(d) or § 1.57(a), a sequence listing in compliance with § 1.821 through § 1.825 (if applicable), the inventor's oath or declaration or an application data sheet containing the information specified in § 1.63(b), the basic filing fee (§ 1.16(a) or § 1.16(c)), the search fee (§ 1.16(k) or § 1.16(m)), the examination fee (§ 1.16(o) or § 1.16(q)), any certified copy of the previously filed application required by § 1.57(a), and any application size fee required by the Office under § 1.16(s). An international application is in condition for examination when the application has entered the national stage as defined in § 1.491(b), and includes a specification, including at least one claim and an abstract (§ 1.72(b)), and has papers in compliance with § 1.52, drawings (if any) in compliance with § 1.84, a sequence listing in compliance with § 1.821 through § 1.825 (if applicable), the inventor's oath or declaration or an application data sheet containing the information specified in § 1.63(b), the search fee (§ 1.492(b)), the examination fee (§ 1.492(c)), and any application size fee required by the Office under § 1.492(j). An application shall be considered as having papers in compliance with § 1.52, drawings (if any) in compliance with § 1.84, and a sequence listing in compliance with § 1.821 through § 1.825 (if applicable) for purposes of this paragraph on the filing date of the latest reply (if any) correcting the papers, drawings, or sequence listing that is prior to 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.

37 CFR 1.704 implements the provisions of 35 U.S.C. 154(b)(2)(C) which provides that the period of patent term adjustment under 35 U.S.C. 154(b)(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 (processing or examination) of the application," and specifies certain circumstances as constituting a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application. Further, 35 U.S.C. 154(b)(2)(C)(iii) gives the Office the authority to prescribe regulations establishing circumstances that constitute "a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application." 35 U.S.C. 154(b)(2)(C) does not require the applicant's action or inaction (that amounts to a failure to engage in reasonable efforts to conclude prosecution of the application) to have caused or contributed to patent term adjustment for the period of adjustment to be reduced due to such action or inaction. The patent term adjustment provisions of 35 U.S.C. 154(b) create a balanced system allowing for patent term adjustment due to Office delays for a reasonably diligent applicant. Since the public has an interest in the technology disclosed and covered by a patent being available to the public at the earliest possible date, 35 U.S.C. 154(b)(2)(C)(i) provides that patent term adjustment is reduced by any period of time during which applicant failed to engage in reasonable efforts to conclude prosecution of the application, regardless of whether the applicant's actions or inactions caused or contributed to patent term adjustment.

37 CFR 1.704(a) implements the provisions of 35 U.S.C. 154(b)(2)(C)(i) and sets forth that the period of adjustment 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 (i.e., processing or examination) of an application.

37 CFR 1.704(b) provides that with respect to the ground for adjustments set forth in 37 CFR 1.702(a) through (e), and in particular 37 CFR 1.702(b), an applicant shall be deemed to have failed to engage in reasonable efforts to conclude prosecution 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. A Notice of Omitted Items in a Nonprovisional Application, however, is not a notice or action by the Office making a rejection, objection, argument, or other request within the meaning of 35 U.S.C. 154(b)(2)(C)(ii) or 37 CFR 1.704(b), since the Office does not require a reply to that notice to continue the processing and examination of an application. 37 CFR 1.704(b) indicates that the period of adjustment set forth in 37 CFR 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. As discussed above, a reply is considered filed on the date of its actual receipt in the Office as defined by 37 CFR 1.6, and the date indicated on any certificate of mailing or transmission under 37 CFR 1.8 will not be taken into account for patent term adjustment purposes.

The three-month period in 37 CFR 1.704(b) applies to the Office notices and letters issued as part of the pre-examination processing of an application (except a Notice of Omitted Items in a Nonprovisional Application as discussed above). These notices include: (1) a Notice of Incomplete Nonprovisional Application (except as to any period prior to the filing date ultimately accorded to the application); (2) a Notice to File Missing Parts of Non-Provisional Application; (3) a Notice of Informal Application; (4) a Notice to File Corrected Application Papers Filing Date Granted; or (5) a Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures.

In addition, the three-month period in 35 U.S.C. 154(b)(2)(C)(ii) and 37 CFR 1.704(b) applies regardless of the period for reply set in the Office action or notice. For example, if an Office action sets a two-month period for reply (restriction requirement), the applicant may obtain a one-month extension of time under 37 CFR 1.136(a) before being subject to a reduction of patent term adjustment under 35 U.S.C. 154(b)(2)(C)(ii) and 37 CFR 1.704(b). If, however, an Office action sets a six-month period for reply, as is commonly set in applications subject to secrecy orders (see MPEP § 130), the applicant is subject to a reduction of patent term adjustment under 35 U.S.C. 154(b)(2)(C)(ii) and 37 CFR 1.704(b) if the applicant does not reply to the Office action within three months, notwithstanding that a reply may be timely filed six months after the mailing date of the Office action. If the last day of the three-month time period from the Office communication notifying the applicant of the rejection, objection, argument, or other request falls on a Saturday, Sunday, or federal holiday within the District of Columbia, then action, may be taken, or fee paid, on the next succeeding secular or business day without loss of any patent term adjustment under 37 CFR 1.704(b). See *ArQule v. Kappos*, 793 F.Supp2d 214 (D.D.C. 2011). For example, no reduction in patent term adjustment would occur if an applicant's three-month reply time period expires on a Saturday and the applicant files a reply that is received by the Office on the following Monday, which is not a federal holiday within the District of Columbia. In this case, any patent term adjustment would not be reduced under 37 CFR 1.704(b) because the reply was received on Monday, the next succeeding secular or business day after the expiration of the three-month reply time. If applicant files his reply on Tuesday, then any patent term adjustment for the patent issuing from the application would be reduced under 37 CFR 1.704(b) by one day.

37 CFR 1.704(c) establishes further circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application. 37 CFR 1.704(c)(1) through (c)(13) set forth actions or inactions by an applicant that interfere with the Office's ability to process or examine an application (and, thus, are circumstances that constitute a failure of an applicant

to engage in reasonable efforts to conclude processing or examination of an application), as well as the period by which a period of adjustment set forth in 37 CFR 1.703 shall be reduced if an applicant engages in any of the enumerated actions or inactions. 37 CFR 1.704(c) requires that an applicant refrain from engaging in actions or inactions that prevent or interfere with the Office's ability to process or examine an application. An applicant who is engaging in actions or inactions that prevent or interfere with the Office's ability to process or examine an application cannot reasonably be characterized as "engag[ing] in reasonable efforts to conclude processing or examination of an application" (35 U.S.C. 154(b)(2)(C)(i)).

37 CFR 1.704(c)(1) through 1.704(c)(14) address situations that occur with sufficient frequency to warrant being specifically provided for in the rules of practice. These situations do not represent an exhaustive list of actions or inactions that interfere with the Office's ability to process or examine an application, since there are a myriad of actions or inactions that occur infrequently but will interfere with the Office's ability to process or examine an application (e.g., applicant files and persists in requesting reconsideration of a meritless petition under 37 CFR 1.10; parties to an interference obtain an extension for purposes of settlement negotiations which do not result in settlement of the interference; and when the scope of the broadest claim in the application at the time an application is placed in condition for allowance is substantially the same as suggested or allowed by the examiner more than six months earlier than the date the application was placed in condition for allowance). Thus, the actions or inactions set forth in 37 CFR 1.704(c) are exemplary circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application. The Office may also reduce a period of adjustment provided in 37 CFR 1.703 on the basis of conduct that interferes with the Office's ability to process or examine an application under the authority provided in 35 U.S.C. 154(b)(2)(C)(iii), even if such conduct is not specifically addressed in 37 CFR 1.704(c).

37 CFR 1.704(c)(1) establishes suspension of action under 37 CFR 1.103 at the applicant's request as a circumstance that constitutes a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application. Obviously, if action is suspended at the applicant's request, the Office is precluded from processing or examining the application as a result of an action by the applicant. 37 CFR 1.704(c)(1) also provides that in such a case the period of adjustment set forth in 37 CFR 1.703 shall be reduced by the number of days, if any, beginning on the date a request for suspension of action under 37 CFR 1.103 was filed and ending on the date of the termination of the suspension.

37 CFR 1.704(c)(2) establishes deferral of issuance of a patent under 37 CFR 1.314 as a circumstance that constitutes a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application. Obviously, if issuance of the patent is deferred under 37 CFR 1.314, the Office is precluded from issuing the application as a result of an action by the applicant. When a petition under 37 CFR 1.314 is granted, the petition decision generally states that the application will be held for a period of a month to await the filing of a paper. At the end of the period, the application is returned to the issue process without a further communication from the Office to the applicant. 37 CFR 1.704(c)(2) also provides that in such a case the period of adjustment set forth in 37 CFR 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 37 CFR 1.314 was filed and ending on the issue date of the patent.

37 CFR 1.704(c)(3) establishes abandonment of the application or late payment of the issue fee as a circumstance that constitutes a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application. Obviously, if the application is abandoned (either by failure to prosecute or late payment of the issue fee), the Office is precluded from processing or examining the application as a result of an action or inaction by the applicant. 37 CFR 1.704(c)(3) also provides that in such a case the period of adjustment set forth in 37 CFR 1.703 shall be reduced by the number of days, if any, beginning on the date of abandonment or the date after the day the issue fee was due, and ending on the earlier of: (1) the date

of mailing of the decision reviving the application or accepting late payment of the issue fee; or (2) 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. The phrase "earlier of… [t]he 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" is to place a cap (measured from the filing date of the grantable petition) on the reduction if the Office does not act on (grant) the grantable petition to revive within four months of the date it was filed.

37 CFR 1.704(c)(4) establishes failure to file a petition to withdraw a holding of abandonment or to revive an application within two months from the mailing date of a notice of abandonment as a circumstance that constitutes a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application. Any applicant who considers an application to have been improperly held abandoned (the reduction in 37 CFR 1.704(c)(3) is applicable to the revival of an application properly held abandoned) is expected to file a petition to withdraw the holding of abandonment (or to revive the application) within two months from the mailing date of a notice of abandonment. See MPEP § 711.03(c), subsection I. 37 CFR 1.704(c)(4) also provides that in such a case the period of adjustment set forth in 37 CFR 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.

If a petition to withdraw the holding of abandonment is granted, the Office's PALM system records should be checked to ensure that the correct term adjustment determination is made. Applicants are encouraged to check the Office's PALM system records for their applications through PAIR (see MPEP § 2733). For example, if applicant shows in the petition that a reply was filed in the Office on March 2, but the March 2 reply was never matched with the file, when the petition to withdraw the holding of abandonment is granted, the receipt of a paper on March 2 should be recorded on the Office's PALM system records. If the papers or dates are recorded incorrectly, applicant should contact the examiner, the examiner's supervisor or the Technology Center customer service representative to have the entry corrected. If an applicant receives a Notice of Abandonment and does not request that the holding of abandonment be withdrawn within two months of the mailing date of the notice, the applicant has failed to engage in reasonable efforts to conclude prosecution and any patent term adjustment will be reduced pursuant to 37 CFR 1.704(c)(4).

37 CFR 1.704(c)(5) establishes 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); (see MPEP § 201.04)) as a circumstance that constitutes a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application. Conversion of a provisional application to a nonprovisional application will require the Office to reprocess the application (as a nonprovisional application) up to one year after the filing date that will be accorded to such nonprovisional application as a result of an action by the applicant. 37 CFR 1.704(c)(5) also provides that in such a case the period of adjustment set forth in 37 CFR 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 37 CFR 1.53(c)(3) to convert the provisional application into a nonprovisional application was filed.

37 CFR 1.704(c)(6) establishes 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 a notice of allowance under 35 U.S.C. 151 that requires the mailing of a supplemental Office action or notice of allowance as a circumstance that constitutes a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application. If the submission of a preliminary amendment or other paper requires the Office to issue a supplemental Office action or notice of allowance, the submission of that preliminary amendment or other paper has interfered with the processing and examination of an application. 37 CFR 1.704(c)(6) also provides that in such a case the period of adjustment set forth in 37 CFR 1.703 shall be reduced by the lesser of

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 four months. The phrase "lesser of… or [f]our months" is to provide a four-month cap for a reduction under 37 CFR 1.704(c)(6) if the Office takes longer than four months to issue a supplemental Office action or notice of allowance.

37 CFR 1.704(c)(7) establishes submission of a reply having an omission (e.g., 37 CFR 1.135(c)) as a circumstance that constitutes a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application. Submitting a reply having an omission requires the Office to issue an action under 37 CFR 1.135(c) and await and process the applicant's reply to the action under 37 CFR 1.135(c) before the initial reply (as corrected) can be treated on its merits. In addition, 37 CFR 1.704(c)(7) provides that in such a case the period of adjustment set forth in 37 CFR 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. The reference to 37 CFR 1.135(c) is parenthetical because 37 CFR 1.704(c)(7) is not limited to Office actions under 37 CFR 1.135(c) but applies also when the Office issues any action or notice indicating that a reply has an omission which must be corrected: e.g., (1) a decision on a petition under 37 CFR 1.47 dismissing the petition as lacking an item necessary to grant the petition; or (2) a notice indicating that the computer readable format sequence listing filed in reply to a Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures (PTO-1661) does not comply with 37 CFR 1.821 *et seq.* The filing of a non-compliant appeal brief, however, will not be deemed an omission under 37 CFR 1.704(c)(7) if the notice of appeal was filed on or after September 17, 2012. This situation is covered under 37 CFR 1.704(c)(11).

37 CFR 1.704(c)(8) establishes submission of a supplemental reply or other paper after a reply has been filed as a circumstance that constitutes a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application. The submission of a supplemental reply or other paper (e.g., an information disclosure statement (IDS) or petition) after an initial reply was filed requires the Office to restart consideration of the initial reply in view of the supplemental reply or other paper, which will result in a delay in the Office's response to the initial reply. The submission of an information disclosure statement that is filed after a reply to a restriction requirement (and prior to the subsequent Office action and without a safe harbor statement under 37 CFR 1.704(d)) is an applicant delay. See *Gilead Sciences Inc. v. Lee,* 778 F.3d 1341, 113 USPQ2d 1837 (Fed. Cir. 2015). Similarly, the filing of an information disclosure statement after a request for continued examination (RCE) but prior to a subsequent Office action is deemed an applicant delay under 37 CFR 1.704(c)(8). 37 CFR 1.704(c)(8) does not apply to a supplemental reply or other paper that was expressly requested by the examiner. If an amendment is requested by an examiner, the examiner will have the paper processed so that it is included as part of an interview summary or examiner's amendment and not a separate paper for PALM to flag in the patent term adjustment calculation. 37 CFR 1.704(c)(8) also provides that in such a case the period of adjustment set forth in 37 CFR 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 such other paper was filed.

Applicant's submission of an information disclosure statement pursuant to 37 CFR 1.97(c) or an amendment under 37 CFR 41.33 after a notice of appeal has been filed but prior to jurisdiction passing to the Patent Trial and Appeal Board is deemed an applicant delay under 37 CFR 1.704(c)(8). Under 37 CFR 1.97(c), an applicant who submits an information disclosure statement meeting the requirements of 37 CFR 1.97 and 1.98 will have such submission considered by the examiner if it is accompanied by a statement under 37 CFR 1.97(e) and the fee under 37 CFR 1.17(p). Moreover, the Office may admit an amendment after notice of appeal if it meets the applicable requirements in 37 CFR 41.33(a) and (b) for consideration. Because the treatment of these papers may delay the Board taking jurisdiction of the application, the Office will treat such papers similarly to how the Office treats a

supplemental reply under this provision, in that the papers will be considered as a circumstance that constitutes a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application.

37 CFR 1.704(c)(9) establishes submission of an amendment or other paper (other than a statement under 37 CFR 41.50(c)) in an application after a decision by the Patent Trial and Appeal Board (other than a decision containing a rejection under 37 CFR 41.50(b)) or 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 as a circumstance that constitutes a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application. The submission of an amendment or other paper (e.g., IDS or petition) in an application after a Board decision or court decision requires the Office to restart consideration of the application in view of the amendment or other paper, which will result in a delay in the Office's taking action on the application. 37 CFR 1.704(c)(9) also provides that in such a case the period of adjustment set forth in 37 CFR 1.703 shall be reduced by the lesser of 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 four months. The phrase "lesser of…or [f]our months" is to provide a four-month cap for a reduction under 37 CFR 1.704(c)(9) if the Office takes longer than four months to issue a supplemental Office action or notice of allowance. If the amendment is requested by an examiner, the examiner will have the paper processed so that it is included as part of an interview summary or examiner's amendment and not a separate paper for PALM to flag in the patent term adjustment calculation.

37 CFR 1.704(c)(10) establishes submission of an amendment under 37 CFR 1.312 or other paper, other than a request for continued examination in compliance with 37 CFR 1.114, after a notice of allowance has been given or mailed as a circumstance that constitutes a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application. Effective March 10, 2015, 37 CFR 1.704(c)(10) was amended to change "other paper" to "other paper, other than a request for continued examination in compliance with § 1.114," to clarify that the filing of a request for continued examination under 35 U.S.C. 132(b) in compliance with 37 CFR 1.114 is treated under 37 CFR 1.704(c)(12) rather than 37 CFR 1.704(c)(10). See the final rule *Changes to Patent Term Adjustment in view of the Federal Circuit Decision in Novartis v. Lee,* 80 FR 1346 (January 9, 2015). Prior to March 10, 2015, the submission of a request for continued examination after the mailing date of a notice of allowance was not considered an applicant delay under 37 CFR 1.704. The submission of amendments (or other papers) after an application is allowed may cause substantial interference with the patent issue process. Certain papers filed after allowance are not considered to be a failure to engage in reasonable efforts to conclude processing or examination of an application. See *Clarification of 37 CFR 1.704(c)(10) – Reduction of Patent Term Adjustment for Certain Types of Papers Filed After a Notice of Allowance has been Mailed,* 1247 OG 111 (June 26, 2001). 37 CFR 1.704(c)(10) provides that in such a case the period of adjustment set forth in 37 CFR 1.703 shall be reduced by the lesser of: (1) the number of days, if any, beginning on the date the amendment under 37 CFR 1.312 or other paper was filed and ending on the mailing date of the Office action or notice in response to the amendment under 37 CFR 1.312 or such other paper; or (2) four months. The phrase "lesser of …or [f]our months" is to provide a four-month cap for a reduction under 37 CFR 1.704(c)(10) if the Office takes longer than four months to issue an Office action or notice in response to the amendment under 37 CFR 1.312 or other paper. If the Office does not mail a response to the paper that triggered the delay under this provision and the patent issues in less than four months, then the applicant delay under this provision will end on the date of the patent issuance. The Office will treat the issuance of the patent as the response to the paper that triggered the delay.

In the final rule *Changes to Patent Term Adjustment in view of the Federal Circuit Decision in Novartis v. Lee,* 80 FR 1346 (January 9, 2015), the Office

further revised policies regarding 37 CFR 1.704(c)(10) and no longer considers submission of a written (or other type of) status inquiry, request for refund, or an inventor's oath or declaration to be a failure to engage in reasonable efforts to conclude processing and examination of the application under 37 CFR 1.704(c)(10) due to the changes that have been brought about by the electronic filing and processing of patent applications.

The submission of the following papers after a "Notice of Allowance" is **not** considered a failure to engage in reasonable efforts to conclude processing or examination of an application: (1) Fee(s) Transmittal (PTOL-85B); (2) power of attorney; (3) power to inspect; (4) change of address; (5) change of status (micro/small/not small entity status); (6) a response to the examiner's reasons for allowance or a request to correct an error or omission in the "Notice of Allowance" or "Notice of Allowability;" (7) status letters; (8) requests for a refund; (9) an inventor's oath or declaration; (10) an information disclosure statement with a statement in compliance with 37 CFR 1.704(d); (11) the resubmission by applicant of unlocatable paper(s) previously filed in the application (37 CFR 1.251); (12) a request for acknowledgment of an information disclosure statement in compliance with 37 CFR 1.97 and 1.98, provided that the applicant had requested that the examiner acknowledge the information disclosure statement prior to the notice of allowance, or the request for acknowledgement was applicant's first opportunity to request that the examiner acknowledge the information disclosure statement; (13) comments on the substance of an interview where the applicant-initiated interview resulted in a notice of allowance; and (14) letters related to government interests (e.g., those between NASA and the Office).

Under 37 CFR 1.704(c)(10), papers that **will be** considered a failure to engage in reasonable efforts to conclude processing or examination of an application include: (1) an amendment under 37 CFR 1.312; (2) a paper containing a claim for priority or benefit or request to correct priority or benefit information (e.g., a new or supplemental application data sheet filed to correct foreign priority or domestic benefit information); (3) a request for a corrected filing receipt; (4) a certified copy of a priority document; (5) drawings; (6) a letter related to biologic deposits; (7) a request to change or correct inventorship; and (8) an information disclosure statement not accompanied by a statement in compliance with 37 CFR 1.704(d).

Effective for applications in which a notice of appeal was filed on or after September 17, 2012, 37 CFR 1.704(c)(11) establishes that failure to file an appeal brief in compliance with 37 CFR 41.37 within three months from the date on which a notice of appeal to the Patent Trial and Appeal Board was filed under 35 U.S.C. 134 and 37 CFR 41.31 is a circumstance that constitutes a failure to engage in reasonable efforts to conclude processing or examination of the application. It is noted that although the appeal brief is due within two months of the filing of the notice of appeal under 37 CFR 41.37, 37 CFR 1.704(c)(11) provides three months before any patent term adjustment under 37 CFR 1.703 will be reduced for the late submission of an appeal brief. If applicant files a non-compliant appeal brief and thereafter files a compliant appeal brief, the period of time from the filing of a non-compliant appeal brief to the filing of the compliant appeal brief will not be considered a failure to engage in reasonable efforts to conclude processing or examination of the application under 37 CFR 1.704(c)(8). However, if the compliant appeal brief is filed more than three months from the date on which the notice of appeal was filed, the provisions of 37 CFR 1.704(c)(11) may result in reduction of any patent term adjustment under 37 CFR 1.703. 37 CFR 1.704(c)(11) provides that the period of adjustment set forth in 37 CFR 1.703 shall be reduced by the number of days, if any, beginning on the day after the date three months from the date on which the notice of appeal to the Patent Trial and Appeal Board was filed and ending on the date an appeal brief in compliance with 37 CFR 41.37 or a request for continued examination in compliance with 37 CFR 1.114 was filed.

If the Office reopens prosecution of the application more than three months after the filing of the notice of appeal but prior to the submission of a compliant appeal brief, the Office will not deem the period of time from the day after three months from the filing of the notice of appeal to the date the Office reopens prosecution to be an applicant delay under 37 CFR 1.704(c)(11). In addition, the Office's reopening of

prosecution after appeal will not be considered as vacating any previous response that potentially increases patent term adjustment under 35 U.S.C. 154(b)(1)(A)(i) through (iv). As discussed above, the change to 37 CFR 1.704(c)(11) is applicable to any applications that includes an appeal brief in which the notice of appeal was filed on or after September 17, 2012.

Effective for applications in which a request for continued examination was filed on or after March 10, 2015, 37 CFR 1.704(c)(12) was amended to provide a new provision that establishes the submission of a request for continued examination under 35 U.S.C. 132(b) after any notice of allowance under 35 U.S.C. 151 has been mailed as constituting a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application, in which case the period of adjustment set forth in 37 CFR 1.703 shall be reduced by the number of days, if any, beginning on the day after the date of mailing of the notice of allowance under 35 U.S.C. 151 and ending on the date the request for continued examination under 35 U.S.C. 132(b) was filed. See the final rule *Changes to Patent Term Adjustment in view of the Federal Circuit Decision in Novartis v. Lee*, 80 FR 1346 (January 9, 2015). This new provision ensures that an applicant does not obtain additional patent term adjustment under 35 U.S.C. 154(b)(1)(B) for the time after a notice of allowance has been mailed as a consequence of delaying issuance of the patent by filing a request for continued examination under 35 U.S.C. 132(b) after a notice of allowance has been mailed. Moreover, the filing of a request for continued examination after the mailing of a notice of allowance removes the application from the issue process, prevents the Office from issuing the patent, and requires the Office to determine if the submission affects the patentability of the application, which adds to the pendency of the application in which the request for continued examination is filed (as well as other applications since examination resources must be diverted from other applications to the application in which the request for continued examination is filed). "An applicant who is engaging in actions or inactions that prevent or interfere with the Office's ability to process or examine an application cannot reasonably be characterized as 'engag[ing] in reasonable efforts to conclude processing or examination of an application' (35 U.S.C. 154(b)(2)(C)(i))." See *Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term*, 65 FR at 56379 (response to comment 17). Therefore, the Office considers it appropriate to expressly define the filing of a request for continued examination after the mailing of any notice of allowance as a failure to engage in reasonable efforts to conclude processing or examination of an application. See 35 U.S.C. 154(b)(2)(C)(iii) (provides for the Office to 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).

Nevertheless, the Office considers it appropriate to permit applicants to submit information cited in a patent office communication in a counterpart application to the Office without a reduction in patent term adjustment if an information disclosure statement is submitted to the Office within thirty days (not three months) of the date the patent office communication was received by an individual designated in 37 CFR 1.56(c). Accordingly, 37 CFR 1.704(d) was revised to provide that a request for continued examination in compliance with 37 CFR 1.114 with no submission other than an information disclosure statement in compliance with 37 CFR 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 37 CFR 1.704(c)(12), if the request for continued examination is accompanied by a statement in compliance with 37 CFR 1.704(d).

Effective for applications in which a request for continued examination was filed on or after March 10, 2015, if such a request for continued examination is filed after payment of the issue fee, any patent term adjustment would be reduced by the number of days in the period starting on the day after the date of mailing of the notice of allowance and ending on the date the request for continued examination was filed. 35 U.S.C. 154(b)(1)(A)(iv) provides that, subject to the limitations under 35 U.S.C. 154(b)(2), if the issue of an original patent is delayed due to the failure of the Office to issue a patent within four months after the date on which the issue fee was paid under 35 U.S.C. 151 and all outstanding

requirements were satisfied, the term of the patent shall be extended one day for each day after the date on which the issue fee was paid and all outstanding requirements were satisfied until the patent is issued. Thus, the period of adjustment under 35 U.S.C. 154(b)(1)(A)(iv), if any, is ascertained by looking back from the issue date to the most recent time at which the issue fee or another requirement was outstanding, determining the succeeding date on which the issue fee was paid and all outstanding requirements were satisfied, and measuring the number of days, if any, in the period beginning on the day after the date that is four months after such date the issue fee was paid and all outstanding requirements were satisfied and ending on the date a patent was issued. Where prosecution in an application is reopened after a notice of allowance (before or after payment of the issue fee), either by the Office *sua sponte* or as the result of an applicant filing a request for continued examination, the date on which the issue fee was paid and all outstanding requirements were satisfied is the date on which the Issue Fee Transmittal Form (PTOL-85(b)) from the ultimate notice of allowance under 35 U.S.C. 151 is returned to the Office (or a later date if there remain additional outstanding requirements, such as payment of any additional fees owed or required drawings to be submitted). See MPEP § 2731. The mailing of a notice of allowance by the Office subsequent to the reopening of prosecution is the Office's indication that the application is (again) in condition to be issued as a patent, and the applicant's return of the Issue Fee Transmittal Form (PTOL-85(b)) is the applicant's indication or confirmation that the applicant wants any previously paid issue fee to be applied as the issue fee for the patent. See MPEP § 1306. Thus, if prosecution in an application is reopened after a notice of allowance as the result of an applicant filing a request for continued examination, the date on which the issue fee was paid and all outstanding requirements were satisfied is the date on which the Issue Fee Transmittal Form (PTOL-85(b)) from the ultimate notice of allowance under 35 U.S.C. 151 is returned to the Office (or a later date if there remain additional outstanding requirements, such as payment of any additional fees owed or required drawings to be submitted). Applicants should note that 37 CFR 1.114 does not permit an applicant to file a request for continued examination under 35 U.S.C. 132(b) after the date the issue fee is paid as a matter of right. See 37 CFR 1.114(a)(1).

Effective March 10, 2015, the provisions in 37 CFR 1.704(c)(12) and 37 CFR 1.704(c)(13) were relabeled as 37 CFR 1.704(c)(13) and 37 CFR 1.704(c)(14), respectively. See the final rule *Changes to Patent Term Adjustment in view of the Federal Circuit Decision in Novartis v. Lee*, 80 FR 1346 (January 9, 2015).

For applications filed under 35 U.S.C. 111(a) on or after December 18, 2013 and international patent applications in which the national stage was commenced under 35 U.S.C. 371 on or after December 18, 2013, 37 CFR 1.704(c)(13) establishes that the circumstances that constitute a failure of the applicant to engage in reasonable efforts to conclude processing or examination of an application also include the failure to provide an application in condition for examination within eight months from the date on which the application was filed under 35 U.S.C. 111(a) or the date of commencement of the national stage under 35 U.S.C. 371(b) or (f) in an international application. Section 1.704(c)(13) does not require that applications be in condition for examination on filing (or commencement of national stage in an international application) in order for an applicant to avoid a reduction of patent term adjustment.

37 CFR 1.704(c)(13) establishes that where there is a failure to provide an application in condition for examination within eight months from the date on which the application was filed under 35 U.S.C. 111(a) or the date of commencement of the national stage under 35 U.S.C. 371(b) or (f) in an international application, the period of adjustment set forth in 37 CFR 1.703 shall be reduced by the number of days, if any, beginning on the day after the date that is eight months from the date on which the application was filed under 35 U.S.C. 111(a) or the date of commencement of the national stage under 35 U.S.C. 371(b) or (f) in an international application and ending on the date the application is in condition for examination.

37 CFR 1.704(c)(14) (which was formerly 37 CFR 1.704(c)(11),(c)(12), and (c)(13)) establishes further prosecution via a continuing application as a

circumstance that constitutes a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application. Currently, a continuing application may be used to: (1) obtain further examination of an invention disclosed and claimed in the prior application (continuation application); (2) obtain examination (for the first time) of an invention disclosed but not claimed or not elected for examination in the prior application (divisional application); or (3) obtain examination of an invention neither disclosed nor claimed in the prior application (continuation-in-part application). The provisions of 35 U.S.C. 132(b) and 37 CFR 1.114 permit an applicant to obtain further or continued examination of an invention disclosed and claimed in an application, which renders it unnecessary for an applicant whose application is eligible for patent term adjustment under 35 U.S.C. 154(b) to file a continuing application to obtain further examination of an invention disclosed and claimed in an application. If an applicant is filing a continuing application to obtain examination (for the first time) of an invention disclosed but not claimed or not elected for examination in the prior application or an invention neither disclosed nor claimed in the prior application, it is not appropriate for that applicant to obtain any benefit in the continuing application for examination delays that might have occurred in the prior application. See *Mohsenzadeh v. Lee,* 115 USPQ2d 1483 (Fed. Cir. 2015) where the district court upheld the Office's position that patent term adjustment does not carry over to a continuing or divisional application. Thus, the Office has established further prosecution via a continuing application as a circumstance that constitutes a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application, in that the period of adjustment set forth in 37 CFR 1.703 shall not include any period that is prior to the actual filing date of the application that resulted in the patent. Thus, if the application that resulted in the patent is a continuing application (including a CPA), the period of adjustment set forth in 37 CFR 1.703 (if any) will not include any period that is prior to the actual filing date of the application (in the case of a CPA, the filing date of the request for a CPA) that resulted in the patent.

A CPA under 37 CFR 1.53(d) filed on or after May 29, 2000 and before July 14, 2003 is entitled to the patent term adjustment provisions of 35 U.S.C. 154(b) as amended by section 4402 of the American Inventors Protection Act of 1999 (CPAs can only be filed in design patent applications on or after July 14, 2003, and design applications are not entitled to PTA). The period of patent term adjustment set forth in 37 CFR 1.703 (if any), however, will not include any period that is prior to the filing date of the request for that CPA.

Delays before the filing date of an application are not relevant to whether an application is entitled to patent term adjustment. Patent term adjustment will not be reduced by applicant actions or inactions (that amount to a failure to engage in reasonable efforts to conclude processing or examination of the application) occurring in a prior (or other) application.

37 CFR 1.704(d) provides that a paper containing only an information disclosure statement in compliance with 37 CFR 1.97 and 1.98 will not be considered (result in a reduction) under 37 CFR 1.704(c)(6), 1.704(c)(8), 1.704(c)(9), or 1.704(c)(10) if it is accompanied by a statement that each item of information:

(i) was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by an individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the information disclosure statement; or

(ii) is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office, and this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the information disclosure statement.

The above-mentioned statement(s) should accompany the submission of the information disclosure statement.

Effective March 10, 2015, 37 CFR 1.704(d)(1) was amended to also provide that a request for continued examination in compliance with 37 CFR 1.114 with

no submission other than an information disclosure statement in compliance with 37 CFR 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 37 CFR 1.704(c)(12), if the request for continued examination under 35 U.S.C. 132(b) is accompanied by the statement provided for in 37 CFR 1.704(d). See the final rule *Changes to Patent Term Adjustment in view of the Federal Circuit Decision in Novartis v. Lee*, 80 FR 1346 (January 9, 2015).

The provision in 37 CFR 1.704(d) will permit applicants to submit information first cited in a communication from a patent office in a counterpart foreign or international application or from the Office in another application without a reduction in patent term adjustment if an information disclosure statement is promptly (within thirty days of receipt of the first communication) submitted to the Office. This provision also permits an application to submit communications that were issued by a patent office in a counterpart foreign or international application or by the Office that were not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the information disclosure statement to avoid a reduction in any patent term adjustment.

Compliance with the statement requirement of 37 CFR 1.704(d) does not substitute for compliance with any relevant requirement of 37 CFR 1.97 or 1.98. 37 CFR 1.704(d) also provides that this thirty-day period is not extendable.

The determination of when the thirty day period in 37 CFR 1.704(d)(1)(i) or (ii) begins to run is dependent on the role of each entity involved in the prosecution of the U.S. and foreign applications, and the role that each plays (if any) vis-à-vis the application being examined by the USPTO. The inventors, the assignee and the U.S. patent counsel are all individuals designated in 37 CFR 1.56(c). The issue is whether the foreign patent counsel is also an individual designated in 37 CFR 1.56(c).

37 CFR 1.56(c) provides that individuals associated with the filing or prosecution of a patent application within the meaning of 37 CFR 1.56 are:

1. Each inventor named in the application;

2. Each attorney or agent who prepares or prosecutes the application; and

3. Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

Based on these elements of 37 CFR 1.56(c), the following three examples provide guidance in regard to the discussed situations.

Example A:

An applicant based in Chicago, Illinois, directs U.S. counsel to prepare, file and prosecute an application in the United States Patent and Trademark Office (USPTO). The U.S. counsel subsequently sends the application to foreign counsel for filing and prosecution in foreign jurisdictions. The U.S. counsel directs foreign counsel to provide copies of all communications from the foreign office (by fax or overnight mail) within seven days of receipt thereof, and expressly reserves all decision-making authority as to prosecution of the U.S. and foreign applications.

On January 5, 2002, a foreign counsel in Germany receives a communication from the European Patent Office (EPO) that includes a list of citations of patents. On January 8, the foreign counsel, pursuant to the standing instructions of U.S. counsel, sends by overnight mail, a copy of the communication from the EPO. The document is received by U.S. counsel on January 12, 2002. On January 30, the U.S. counsel reviews the document and discovers a previously uncited patent. A copy of the patent and an IDS is then prepared and filed by the U.S. counsel, which was received at the USPTO on February 11, 2002.

Answer to Example A:

The thirty-day period would be calculated from January 12, 2002. As such, the IDS received on February 11, 2002 would be filed within the thirty-day period in 37 CFR 1.704(d), and thus would not result in a reduction of any patent term adjustment pursuant to 37 CFR 1.704(c)(6), (c)(8), (c)(9), or (c)(10).

In this example, the foreign counsel has no substantive role in the prosecution of the U.S. application. The explicitly defined role of the foreign counsel relative to the U.S. counsel in combination with the practice in the described fact pattern removes any potential doubt as to the role of the foreign counsel. For these reasons, the foreign counsel is not deemed a person who is substantially involved in the U.S. application under 37 CFR 1.56(c).

Example B:

An applicant based in Paris, France, directs French counsel to prepare, file and prosecute an application in the European Patent Office (EPO). The EPO application is then sent to U.S. counsel

by French counsel to be reviewed, edited, and prepared for filing in the United States Patent and Trademark Office (USPTO). The U.S. counsel works with the French counsel to review the edited application, and then files the application at the USPTO. The review and editing of the U.S. application filed at the USPTO also leads the French counsel to amend its EPO application.

On January 5, 2002, the French counsel receives a search report from the European Patent Office that includes a list of six patents. On January 20, 2002, the U.S. counsel receives from French counsel (by overnight mail) a copy of the communication from the EPO and suggests that the U.S. counsel review the search report and "take appropriate action." On January 25, 2002, the French counsel provides a copy of the search report to the applicant. On January 30, 2002, the U.S. counsel reviews the document and discovers a previously uncited patent. A copy of the patent and an IDS is then prepared and filed by the U.S. counsel, which is received at the USPTO on February 14, 2002

Answer to Example B:

The thirty-day period would be calculated from **January 5, 2002**. As such, the submission of the IDS would not be received within the thirty-day window in 37 CFR 1.704(d), and thus could result in a reduction of any patent term pursuant to37 CFR 1.704(c)(6), (c)(8), (c)(9), or (c)(10).

In this example, the USPTO would consider the French counsel to have been a party within the meaning of 37 CFR 1.56(c). The French counsel, based on the above facts, played a substantive role in the preparation and prosecution of the U.S. application (e.g., the French counsel drafted the original application, worked with U.S. counsel to edit the application and subsequently amended the EPO application based on the work product produced with U.S. counsel).

Example C:

An applicant based in Chicago, Illinois, hires U.S. counsel to prepare an application suitable for filing in the United States Patent and Trademark Office (USPTO) and the European Patent Office (EPO). The U.S. counsel engages a German attorney to assist in the review and editing of the application to take account of issues relevant to EPO practice. The U.S. counsel then reviews the edited application, approves the changes, and files it at the USPTO. The U.S. counsel then directs the German attorney to file the application in the EPO. During prosecution of the U.S. case, the U.S. counsel receives an Office action citing three patents.

On December 1, 2001, the U.S. counsel sends the three patents to the German attorney for review and appropriate action. On January 5, 2002, the German attorney receives a search report from the EPO that cites the three previously cited patents, plus a fourth patent, which are all designated as "X" references. On January 15, 2002, the German attorney reviews the fourth patent and compares it to the three patents cited in the U.S. prosecution. The German attorney concludes that the fourth patent is duplicative of one of the three patents, and takes no further action.

On March 1, 2002, during a routine status inquiry, the U.S. counsel is informed of the citation of the fourth patent by the EPO and the decision of the German attorney that the information in the newly cited patent was duplicative of the three patents previously cited by the USPTO. The U.S. counsel also obtains copies of the newly cited patent on this date. On March 5, 2002, the U.S. counsel files an IDS containing the newly cited patent, which is received at the USPTO on the same date.

Answer to Example C:

The thirty-day period would be calculated from January 5, 2002. As such, the submission of the IDS would be determined to have not been received within the thirty-day period in 37 CFR 1.704(d), and thus could result in a reduction of any patent term pursuant to 37 CFR 1.704(c)(6), (c)(8), (c)(9), or (c)(10).

In this example, the USPTO would consider the participation of the German attorney in the prosecution and decision-making as to the relevance of the newly cited art vis-à-vis the previously cited three patents to be a substantive participation in the U.S. prosecution. As such, the German attorney would be considered by the USPTO to be a party covered by 37 CFR 1.56(c). Accordingly, evaluation of compliance with 37 CFR 1.704(d) would consider the date that the foreign counsel first learned of the fourth patent (i.e., the newly cited reference).

37 CFR 1.704(e) provides that a submission of a request under 37 CFR 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 37 CFR 1.704(c)(10). The Office will not deem such a failure to engage in reasonable efforts to conclude processing or examination of the application under 37 CFR 1.704(c)(10) because the statute expressly requires that all such requests be filed prior to the issuance of the patent. See 35 U.S.C. 154(b)(3)(C).

For applications filed under 35 U.S.C. 111(a) on or after December 18, 2013 and international patent applications in which the national stage was commenced under 35 U.S.C. 371 on or after December 18, 2013, 37 CFR 1.704(f) was added to define what is meant by "condition for examination" for purposes of 37 CFR 1.704(c)(13). Specifically, 37 CFR 1.704(f) defines that an application filed under 35 U.S.C. 111(a) is in condition for examination when the application includes a specification, including at least one claim and an abstract (37 CFR 1.72(b)), and has papers in compliance with 37 CFR 1.52, drawings in compliance with 37 CFR 1.84, any English

translation required by 37 CFR 1.52(d) or 37 CFR 1.57(a), a sequence listing incompliance with 37 CFR 1.821 through 37 CFR 1.825 (if applicable), the inventor's oath or declaration or application data sheet containing the information specified in 37 CFR 1.63(b), the basic filing fee (37 CFR 1.16(a) or 37 CFR 1.16(c)), the search fee (37 CFR 1.16(k) or 37 CFR 1.16(m)), the examination fee (37 CFR 1.16(o) or 37 CFR 1.16(q)), any certified copy of the previously filed application required by 37 CFR 1.57(a), and any application size fee required by the Office under 37 CFR 1.16(s).

37 CFR 1.704(f) also provides that an international application is in condition for examination when the application has entered the national stage as defined in 37 CFR 1.491(b), and includes a specification, including at least one claim and an abstract (37 CFR 1.72(b)), and has papers in compliance with 37 CFR 1.52, drawings in compliance with 37 CFR 1.84, a sequence listing in compliance with 37 CFR 1.821 through 37 CFR 1.825 (if applicable), the inventor's oath or declaration or application data sheet containing the information specified 37 CFR 1.63(b), the search fee (37 CFR 1.492(b)), the examination fee (37 CFR 1.492(c)), and any application size fee required by the Office under 37 CFR 1.492(j). 37 CFR 1.704(f) as adopted in this final rule also provides that an application shall be considered as having papers in compliance with 37 CFR 1.52, drawings (if any) in compliance with 37 CFR 1.84, and a sequence listing in compliance with 37 CFR 1.821 through 37 CFR 1.825 (if applicable) for purposes of 37 CFR 1.704(f) on the filing date of the latest reply (if any) correcting the papers, drawings, or sequence listing that is prior to 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.

2733 Patent Term Adjustment Determination [R-08.2017]

37 CFR 1.705 Patent term adjustment determination.

Editor Note: 37 CFR 1.705(a) below includes amendments applicable only to patents granted on or after January 14, 2013. See 37 CFR 1.705(a) (pre-2013-04-01) with respect to patents granted prior to January 14, 2013.]

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

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The AIA Technical Corrections Act was enacted on January 14, 2013. See Public Law 112-274, 126 Stat. 2456 (2013). Section 1(h) of the AIA Technical Corrections Act revises the patent term adjustment provisions of 35 U.S.C. 154(b) and is effective for any patent granted on or after January 14, 2013. Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to change "shall transmit a notice of that [patent term adjustment] determination with the written notice of allowance of the application under section 151" to "shall transmit a notice of that [patent term adjustment] determination no later than the date of issuance of the patent." See 126 Stat. at 2457. This change eliminates the need for the Office to provide an initial patent term adjustment determination with the notice of allowance and before the patent term adjustment under 35 U.S.C. 154(b)(1)(A)(iv) and 154(b)(1)(B) is known. See *Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term*, 65 FR 56365, 56374 (September 18, 2000) (explaining that a two-part process is required because the Office is obliged under 35 U.S.C. 154(b)(3) to provide a patent term adjustment determination before the issue date, and thus the patent term adjustment, is known). 37 CFR 1.705(a) has been amended to reflect that the Office will provide notification of the patent term adjustment on the patent. The Office will no longer provide a notification of the patent term adjustment with the mailing of the notice of allowance for any patent granted on or after January 14, 2013.

The Office has revised 37 CFR 1.705 to implement the statutory changes to 35 U.S.C. 154(b)(3)(B)(i). The amendment to the statute provides that the Office shall transmit a determination of the patent term adjustment no later than the date of issuance of the patent. Accordingly, the Office is no longer required to transmit a determination at the time of the mailing of the notice of allowance which occurs before all of the guarantees of the statute could be calculated. The Office, however, will continue to provide a preliminary patent term adjustment calculation with the issue notification that is mailed to applicant prior to issuance of the patent, but the patent term adjustment indicated on the patent is the "official" notification of the Office's patent term adjustment determination under 35 U.S.C. 154(b).

Accordingly, patentee should wait until the grant of the patent to determine whether or not a request for reconsideration of the patent term adjustment indicated on the patent is warranted. See MPEP § 2734 for a discussion of the requirements of any such request.

If a registered practitioner receives a patent term adjustment indicated on the front of the patent that is longer than expected, the practitioner may disclose the error to the Office in a letter in compliance with the practitioner's duty of candor and good faith in practice before the Office. The Office will treat letters submitted by patentees stating that Office's determination of patent term adjustment indicated on the patent is greater than what the applicant or patentee believes is appropriate by placing these letters in the file of the patent without comment. See *Treatment of Letters Stating That the USPTO's Patent Term Adjustment Determination Is Greater Than What the Applicant or Patentee Believes Is Appropriate* , 75 FR 42079 (July 20, 2010), 1357 OG 262 (August 24, 2010). The Office will not review these letters or issue certificates of correction under either 35 U.S.C. 254 or 255 on the basis of these letters. In addition, the Office will not grant a request for a certificate of correction under either 35 U.S.C. 254 or 255 to revise the patent term adjustment indicated in a patent, unless the certificate of correction is issued to revised the patent for consistency with (1) the patent term adjustment determined via a decision on the request for reconsideration under 37 CFR 1.705; or (2) the total patent term adjustment indicated on the Patent Application Information Retrieval (PAIR) screen that displays the patent term adjustment calculation for the patent. If patentee submits a request for a certificate of correction under either 35 U.S.C. 254 or 255 to revise the patent term adjustment indicated in a patent that also includes changes in the patent for which a certificate of correction would be appropriate, the request for a certificate of correction will not be granted unless the patentee submits a new request for a certificate of correction that does not also attempt to revise the patent term adjustment indicated in the patent.

If patentee wants the Office to reconsider its patent term adjustment determination, the patentee must use the procedures set forth in 37 CFR 1.705(b) for requesting reconsideration of a patent term adjustment determination. Specifically, the procedures set forth in 37 CFR 1.705(b) must be used whether the USPTO's patent term adjustment determination is greater than or less than the adjustment that the applicant or patentee believes to be appropriate.

A patentee may also file a terminal disclaimer at any time disclaiming any period considered in excess of the appropriate patent term adjustment. See 35 U.S.C. 253 and 37 CFR 1.321.

Note that the Office does not require patentee to file either a request for reconsideration under 37 CFR 1.705(b) or a terminal disclaimer when the patent term adjustment indicated on the patent is greater than what the patentee believes is appropriate. As discussed above, the patentee or the appointed registered practitioner may disclose the alleged error to the Office in a letter in compliance with the practitioner's duty of candor and good faith.

Information as to how the patent term adjustment calculation has been made will be available through Patent Application Information Retrieval (PAIR) at **www.uspto.gov/learning-and-resources/portal-applications**. Applicants may routinely use PAIR to check the accuracy of the data entered in the PALM system for their applications (i.e., the type of the paper and date of receipt in the Office) throughout prosecution. If any errors are detected, they should be brought to the Office's attention (e.g., by contacting the examiner or the Technology Center's customer service representative) as soon as possible to ensure that they are corrected before allowance of the application and the determination of the patent term adjustment. In checking Office records, applicants should keep in mind that the date that should be recorded in the Office computer records is the date of receipt of the paper, not the date that it was mailed under 37 CFR 1.8. In addition, if an original paper is misplaced by the Office and a duplicate is filed with a post card receipt showing the date of receipt of the original paper, the date shown on the post-card receipt for the original paper is the date that should be shown in the Office computer records. If Priority Mail Express® service was used, then the date shown as the "date accepted" on the Priority Mail

Express® label will be entered into the Office computer records. Otherwise, the date reflected in the Office computer records for a duplicate copy of correspondence will normally be the date that the duplicate was received in the Office.

2734 Application for Patent Term Adjustment; Due Care Showing [R-07.2015]

37 CFR 1.705 Patent term adjustment determination.

[Editor Note: 37 CFR 1.705(b) and (c) below include amendments applicable only to patents granted on or after January 14, 2013. See 37 CFR 1.705 (pre-2013-04-01) with respect to patents granted prior to January 14, 2013.]

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(b) Any request for reconsideration of the patent term adjustment indicated on the patent must be by way of an application for patent term adjustment filed no later than two months from the date the patent was granted. This two-month period may be extended under the provisions of § 1.136(a). 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 request for 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 the mailing of the Office communication notifying the applicant of the rejection, objection, argument, or other request must be filed prior to the issuance of the patent. This time period is not extendable. Any request for reinstatement of all or part of the period of adjustment pursuant to § 1.704(b) must be accompanied by:

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

(2) A showing to the satisfaction of the Director 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.

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I. OFFICE PROCEDURE FOR THE TREATMENT OF REQUESTS FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT

37 CFR 1.705(b) provides that any request for reconsideration of the patent term adjustment indicated on the patent must be by way of an application for patent term adjustment which must filed within two months of the date the patent was granted and accompanied by the fee set forth in 37 CFR 1.18(e) and a statement of the facts involved. 37 CFR 1.705(b)(2) provides that such statement of facts involved must specify: (1) the correct patent term adjustment and the basis or bases under 37 CFR 1.702 for the adjustment; (2) the relevant dates as specified in 37 CFR 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in 37 CFR 1.703(f) to which the patent is entitled; (3) whether the patent is subject to a terminal disclaimer and any expiration date specified in the terminal disclaimer; and (4) any circumstances, if any, 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 37 CFR 1.704 (or a statement that there were no such circumstances). The two month period set in 37 CFR 1.705(b) is extendable under 37 CFR 1.136 for up to five additional months (permitting patentee to request reconsideration of the patent term adjustment indicated on the patent as late as within seven months after the date the patent was granted).

The Office will conduct a manual redetermination of patent term adjustment in response to a request for reconsideration of the patent term adjustment. The Office makes the patent term adjustment determination indicated in the patent by a computer program that uses the information recorded in the Office's Patent Application Locating and Monitoring (PALM) system, except when an applicant requests reconsideration pursuant to 37 CFR 1.705. See

Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 FR 56365, 56370, 56380-81 (September 18, 2000) (final rule). The PALM system was not originally designed for the purpose of calculating patent term adjustment as provided in 35 U.S.C. 154(b). The patent term adjustment provisions of 35 U.S.C. 154(b) are complex, with numerous types of communications exchanged between applicants and the Office during the patent application process. Thus, a manual redetermination of patent term adjustment could result in (1) an amount of patent term adjustment that is the amount of patent term adjustment requested by the applicant; (2) the same amount of patent term adjustment as indicated in the patent (i.e., there being no change); or (3) a different amount of patent term adjustment that may be higher or lower than the patent term adjustment as indicated in the patent.

If the patent term adjustment redetermination results in the amount of patent term adjustment requested by the applicant, the Office will issue a decision granting the request for reconsideration and a certificate of correction that indicates the revised patent term adjustment. If the patent term adjustment redetermination results in the same amount of patent term adjustment as indicated in the patent (i.e., there being no change) and the Office does not require any additional information to render a decision on the request for reconsideration, the Office will issue a decision denying the request for reconsideration, and this decision is the Director's decision on the applicant's request for reconsideration within the meaning of 35 U.S.C. 154(b)(4) .

If the patent term adjustment redetermination results in a different amount of patent term adjustment (higher or lower than the patent term adjustment indicated in the patent), the Office will issue a redetermination of patent term adjustment that explains how the Office arrived at the different amount of patent term adjustment. This redetermination of patent term adjustment is not the Director's decision on the applicant's request for reconsideration within the meaning of 35 U.S.C. 154(b)(4) , but is simply a new patent term adjustment determination (e.g., a redetermination). If the Office issues such a redetermination of patent term adjustment in response to the request for reconsideration, the applicant has two months from the date of the redetermination to file a renewed request for reconsideration of the patent term adjustment that addresses the issues included in the Office's redetermination of patent term adjustment. No additional fee under 37 CFR 1.18(e) is required. The two-month period to file a renewed request for reconsideration of patent term adjustment is extendable under 37 CFR 1.136(a).

If the patent term adjustment redetermination results in the same amount of patent term adjustment as indicated in the patent (i.e., there being no change) but the Office requires additional information to render a decision on the request for reconsideration of the patent term adjustment, the Office will issue a requirement for information to obtain the additional information. This requirement for information is not the Director's decision on the applicant's request for reconsideration within the meaning of 35 U.S.C. 154(b)(4). If the Office issues a requirement for information in response to the request for reconsideration of the patent term adjustment, the applicant has two months from the date of the requirement for information to file a renewed request for reconsideration of the patent term adjustment. The renewed request should supply the required information and no additional fee is required. This two-month period is extendable under 37 CFR 1.136(a).

The Office will again conduct a redetermination of patent term adjustment in response to any renewed request for reconsideration, which is filed in response to a redetermination of patent term adjustment and/or a requirement for information. If this redetermination of patent term adjustment results in the amount of patent term adjustment requested by the applicant, the Office will issue a decision granting the request for reconsideration and a certificate of correction that indicates the revised patent term adjustment. If this redetermination of patent term adjustment results in the same amount of patent term adjustment as indicated in the previous redetermination of patent term adjustment or in the patent, the Office will generally issue a decision denying the request for reconsideration and a certificate of correction, if necessary, indicating the revised patent term adjustment as the result of a redetermination of patent term adjustment. The decision denying the

request for reconsideration is the Director's decision on the applicant's request for reconsideration within the meaning of 35 U.S.C. 154(b)(4). In certain, limited circumstances, the redetermination may result in another redetermination of patent term adjustment or requirement for information. In such a case, applicant will be given another opportunity to file a renewed request for reconsideration as described above.

Only if the Office issues a decision denying patentee's request for reconsideration, then patentee may appeal such decision to the District Court for the Eastern District of Virginia by filing a civil complaint within 180 days of the date of the decision on the request for reconsideration of patent term adjustment (within the meaning of 35 U.S.C. 154(b)(4)).

Section 1(h)(3) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(4) to provide that "[a]n applicant dissatisfied with the Director's decision on the applicant's request for reconsideration under paragraph (3)(B)(ii) shall have exclusive remedy by a civil action against the Director filed in the United States District Court for the Eastern District of Virginia within 180 days after the date the Director's decision on the applicant's request for reconsideration." The change to 35 U.S.C. 154(b)(4) clarifies that (1) a civil action under 35 U.S.C. 154(b)(4) is not an alternative to requesting reconsideration of the patent term adjustment under 35 U.S.C. 154(b)(3) but is the remedy for an applicant who is dissatisfied with the Director's decision on the applicant's request for reconsideration under 35 U.S.C. 154(b)(3); and (2) a civil action provided in 35 U.S.C. 154(b)(4) is the **exclusive** remedy for an applicant who is dissatisfied with the Director's decision on the applicant's request for reconsideration. In other words, an applicant that is dissatisfied with the patent term adjustment determination on the patent must first request reconsideration under 35 U.S.C. 154(b)(3) and 37 CFR 1.705(b). Only after receiving a decision denying the request for reconsideration, may the applicant file a civil action, proscribed in 35 U.S.C. 154(b)(4), if the applicant is dissatisfied with the decision on the request for reconsideration. This statutory change is applicable for all patents that issue on or after January 14, 2013.

For patents that issued prior to January 14, 2013, 35 U.S.C. 154(b)(4) previously required that patentee commence a civil action within 180 days of the grant of the patent. Patentee is not entitled to equitable tolling of the 180-day period to commence the civil action in the district court where patentee did not lack sufficient facts on which it could sue but instead waited until another, unrelated party secured a favorable ruling on a legal theory in another court proceeding. See *Novartis AG v. Lee*, 740 F.3d 539, 109 USPQ2d 1385 (Fed. Cir. 2014). It is noted, however, that the U.S. District Court for the District of Columbia affirmed a prior decision of the court holding that the 180-day deadline under 35 U.S.C. 154(b)(4)(A) for filing a lawsuit challenging a PTA determination was tolled in the circumstances of that case by the patent holders' timely requests for reconsideration of the PTA determinations set forth in the patents at issue. See *Bristol-Myers Squibb Co. v. Kappos*, 891 F.Supp.2d 135 (D.D.C. 2012) (denying reconsideration of the decision published at 841 F. Supp.2d 238 (D.D.C. 2012)). Section 1(n) of the AIA Technical Corrections Act provides that amendments made in section 1(h) shall take effect on January 14, 2013 (the date of enactment) and shall apply to the proceedings commenced on or after January 14, 2013. Section 1(n) of the Technical Corrections Act does not limit the applicability of the changes in section 1(h) to applications filed on or after January 14, 2013. Cf. Section 4405(a) of the American Inventors Protection Act of 1999 (AIPA), Public Law 106-113, 113 Stat. 1501, 1501A-552 through 1501A-591 (limiting the applicability of the patent term adjustment provisions of the AIPA to applications filed on or after May 29, 2000 (the date that is six months after the enactment of AIPA)). Patent term adjustment proceedings are not "commenced" until the Office notifies the applicant of the Office's patent term adjustment determination under 35 U.S.C. 154(b)(3), which now occurs when the patent is granted. Accordingly, the changes to 35 U.S.C. 154 in section 1(h) of the AIA Technical Corrections Act apply to any patent granted on or after January 14, 2013.

II. DUE CARE SHOWING

37 CFR 1.705(c) implements the provisions of 35 U.S.C. 154(b)(3)(C) and specifically provides that a request for reinstatement of all or part of the period

of adjustment reduced pursuant to 37 CFR 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 include: (1) the fee set forth in 37 CFR 1.18(f); and (2) a showing to the satisfaction of the Director 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. 37 CFR 1.705(c) also provides that the Office shall not grant any request for reinstatement for more than three additional months for each reply beyond three months of the date of mailing of the Office communication notifying the applicant of the rejection, objection, argument, or other request (35 U.S.C. 154(b)(3)(C)). 35 U.S.C. 154(b)(3)(C) and 37 CFR 1.705(c) also requires that the request for reinstatement be filed prior to the issuance of the patent. Because 35 U.S.C. 154(b)(3)(C) requires that the request be filed prior to the issuance of the patent, the Office will not consider or act on a request for reinstatement in a paper filed after the patent is issued. For example, a request for reinstatement cannot be made as part of a request for reconsideration under 37 CFR 1.705(b). Applicants are aware during the pendency of the application of situations where the reply was filed more than three months after the Office communication notifying the applicant of the rejection, objection, argument, or other request. If applicants believe that they can make the required showing that, in spite of all due care, the applicant was unable to rely to the rejection, objection, argument or other Office request within three months, then applicants should file the request for reinstatement promptly and no later than at least one day prior to the issuance of the patent. Applicants need not review of the patent term adjustment calculation to establish a request for reinstatement under 37 CFR 1.705(c). The Office will not delay issuance of the patent but will make a decision on the request for reinstatement after the grant of the patent and if appropriate, issue a certificate of correction to revise the patent term adjustment determination on the patent.

As noted *supra*, 37 CFR 1.705(c) continues to require that any request for reinstatement of all or part of the cumulative period of time of an adjustment reduced under 35 U.S.C. 154(b)(2)(C), on the basis of a showing that, in spite of all due care, the applicant was unable to respond within the three-month period, must be filed prior to the issuance of the patent. Thus, where an applicant is seeking reinstatement under 35 U.S.C. 154(b)(3)(C) of patent term adjustment reduced under 35 U.S.C. 154(b)(2)(C), the showing required by 35 U.S.C. 154(b)(3)(C) must be filed prior to the issuance of the patent. However, where the patentee is not seeking reinstatement under 35 U.S.C. 154(b)(3)(C) of patent term adjustment reduced under 35 U.S.C. 154(b)(2)(C), but is simply contending that the Office's patent term adjustment determination is in error with respect to the three-month timeframe in 35 U.S.C. 154(b)(2)(C)(ii) (e.g., a reply is filed within the three-month timeframe in 35 U.S.C. 154(b)(2)(C)(ii), but the Office's patent term adjustment determination treats the reply as having been filed outside the three-month period in 35 U.S.C. 154(b)(2)(C)(ii)), any request for reconsideration or review of a patent term adjustment determination is by way of an application for patent term adjustment under 37 CFR 1.705(b) filed no later than two months from the date the patent was granted (this two-month period being extendable under the provisions of 37 CFR 1.136(a)).

Filing a reply outside of three months after an Office action is *per se* a failure to engage in reasonable efforts to conclude prosecution under 35 U.S.C. 154(b)(2)(C)(ii) unless applicant can establish that the delay was “in spite of all due care.” The provisions of 35 U.S.C. 21(b) are applicable to the determination of three-month period for reply. If the last day of the three-month period from the Office communication notifying the applicant of the rejection, objection, argument, or other request falls on a Saturday, Sunday, or federal holiday within the District of Columbia, then action, may be taken, or the fee paid, on the next succeeding secular or business day without loss of any patent term adjustment under 37 CFR 1.704(b). See *ArQule v. Kappos*, 793 F.Supp2d 214 (D.D.C. 2011). For example, an applicant’s three-month reply time period expires on a Saturday and the applicant files a reply that is received by the Office on the following

Monday, which is not a federal holiday within the District of Columbia. In this case, any patent term would not be reduced under 37 CFR 1.704(b) because the reply was received on Monday, the next succeeding secular or business day after the expiration of the three-month reply time. Accordingly, a request for reinstatement of all or part of the period of adjustment under 37 CFR 1.705(c) would not be applicable since applicant would not have been deemed to reply more than three months from the date of the Office action.

The Office "shall reinstate all or part of the cumulative period of time of an adjustment reduced under [35 U.S.C. 154(b)(2)(C)] if the applicant… makes a showing that, in spite of all due care, the applicant was unable to respond within the 3-month period…." See 35 U.S.C. 154(b)(3)(C). The "due care" of a reasonably prudent person standard has been applied in deciding petitions under the "unavoidable delay" standard of 35 U.S.C. 133. See *In re Mattullath*, 38 App. D.C. 497, 514-15 (1912) ("the word 'unavoidable' … is applicable to ordinary human affairs, and requires no more or greater care or diligence than is generally used and observed by prudent and careful men in relation to their most important business") (quoting and adopting *Ex parte Pratt*, 1887 Dec. Comm'r Pat. 31, 32-33); see also *Ray v. Lehman*, 55 F.3d 606, 609, 34 USPQ2d 1786, 1787 (Fed. Cir. 1995) ("in determining whether a delay…was unavoidable, one looks to whether the party…exercised the due care of a reasonably prudent person"). While the legislative history of the American Inventors Protection Act of 1999 is silent as to the meaning of the phrase "in spite of all due care," the phrases "all due care" and "unable to respond" invoke a higher degree of care than the ordinary due care standard of 35 U.S.C. 133, as well as the "reasonable efforts to conclude processing or examination [or prosecution] of an application" standard of 35 U.S.C. 154(b)(2)(C)(i) and (iii). Therefore, applicants should not rely upon decisions relating to the "unavoidable delay" standard of 35 U.S.C. 133 as controlling in a request to reinstate reduced patent term adjustment on the basis of a showing that the applicant was unable to respond within the three-month period in spite of all due care.

Examples

The following are examples of showings that may establish that the applicant was unable to respond within the three-month period in spite of all due care:

(A) a showing that the original three-month period was insufficient to obtain the test data necessary for an affidavit or declaration under 37 CFR 1.132 that was submitted with a reply filed outside the original three-month period;

(B) a showing that the applicant was unable to reply within the original three-month period due to a natural disaster;

(C) a showing that applicant was unable to reply within the original three-month period because testing was required to reply to an Office action, and the testing necessarily took longer than three months; or

(D) a showing that the applicant was unable to reply within the original three-month period due to illness or death of a sole practitioner of record who was responsible for prosecuting the application.

The patent term adjustment reinstated would be limited to the period in which the showing establishes that the applicant was acting with all due care to reply to the Office notice or action, but circumstances (outside applicant's control) made applicant unable to reply in spite of such due care. An applicant will not be able to show that he or she was unable to reply within the three-month period "in spite of all due care" if the reply was not filed within the three-month period due to reasons within the control of applicant or agencies within the applicant's control.

Examples of circumstances that would **NOT** establish that the applicant was unable to respond within the three-month period in spite of all due care are:

(A) an applicant's or representative's preoccupation with other matters (e.g., an *inter partes* lawsuit or interference) that is given priority over prosecution of the application;

(B) illness or death of the practitioner in charge of the application if the practitioner is associated (in a law firm) with other practitioners (since the other

practitioners could have taken action to reply within the three-month period);

(C) time consumed with communications between the applicant and his or her representative, regardless of whether the applicant resides in the United States or chooses to communicate with the United States representative via a foreign representative;

(D) vacation or other non-attention to an application that results in a failure to reply within the three-month period;

(E) applicant filing a reply on or near the last day of the three-month period using first class mail with a certificate of mailing under 37 CFR 1.8, rather than by electronic filing, Priority Mail Express® under 37 CFR 1.10 or facsimile (if permitted), and the reply is not received (filed) in the Office until after the three-month period; or

(F) failure of clerical employees of applicant or applicant's representative to properly docket the Office action or notice for reply or perform other tasks necessary for reply within the three-month period.

Rarely is the power of attorney given to a single attorney and often many attorneys are given power of attorney in an application. An attorney in litigation, working on an interference or taking a vacation is generally aware of that fact before the event and should make plans for another to take over his or her work so that it is completed and filed in the Office within the three-month period. Thus, failure to reply within the three-month period in 35 U.S.C. 154(b)(2)(C)(ii) due to preoccupation with other matters (e.g., an *inter partes* lawsuit or interference) given priority over the application, or vacation or other non-attention to an application, cannot be relied upon to show that applicant was unable to reply "in spite of all due care" under 35 U.S.C. 154(b)(3)(C).

III. OPTIONAL PROCEDURE FOR SEEKING A PATENT TERM ADJUSTMENT CALCULATION FOR INTERNATIONAL APPLICATIONS THAT ISSUE BETWEEN JANUARY 14, 2013 AND MAY 13, 2014

The Office experienced a delay in modifying the computer program used to calculate patent term adjustment with respect to measuring the fourteen-month patent term adjustment period from the date of commencement of the national stage under 35 U.S.C. 371 in international applications. In contrast, the change to 35 U.S.C. 154(b)(1)(B) with respect to measuring the three-year patent term adjustment period from the date of commencement of the national stage under 35 U.S.C. 371 in international applications did not require a change to the computer program used to calculate patent term adjustment because the Office interpreted the phrase ``actual filing date of the application in the United States" in former 35 U.S.C. 154(b)(1)(B) as meaning the date of commencement of the national stage under 35 U.S.C. 371 in an international application. This software modification required for measuring the fourteen-month patent term adjustment period from the date of commencement of the national stage was completed in April of 2014. Therefore, patent term adjustment determinations for patents issued on or after May 20, 2014 will be consistent with the changes to 35 U.S.C. 154(b) in the AIA Technical Corrections Act.

Due to significant delay in modifying the computer program the Office uses to calculate patent term adjustments with respect to the change in 35 U.S.C. 154(b) in the AIA Technical Corrections Act, the Office provided an optional procedure for patentees to request a recalculation of their patent term adjustment without a fee as an alternative to the petition and fee otherwise required to request reconsideration of a patent term adjustment determination under 37 CFR 1.705(b). Specifically, the optional procedure is for patents issued between January 14, 2013 and May 20, 2014, which resulted directly from international applications (i.e., applications that have entered the national stage under 35 U.S.C. 371). The optional procedure is not applicable to patents that resulted from applications under 35 U.S.C. 111(a), including bypass continuations of international applications or continuations of international applications that entered the national stage under 35 U.S.C. 371. Any request for recalculation of patent term adjustment under the optional procedure must have been filed no later than July 31, 2014. See *Revisions to Implement the Patent Term Adjustment Provisions of the Leahy-Smith America Invents Act Technical Corrections Act*, 79 FR 21736 (May 15, 2014).

Under the optional procedure, the Office provided a Request for Recalculation of Patent Term Adjustment form (PTO/SB/132) for use in making such a request. A copy of form PTO/SB/132 is reproduced at the end of this subsection. As discussed previously, this optional procedure and Request for Recalculation of Patent Term Adjustment form (PTO/SB/132) are applicable only for patents issued between January 14, 2013 and May 20, 2014, that resulted directly from an international application. Any request under the optional procedure must have been filed no later than July 31, 2014.

The fee specified in 37 CFR 1.18(e) and any fee for a petition under 37 CFR 1.136(a) required for a timely request for reconsideration under 37 CFR 1.705(b) is not a fee paid by mistake or in excess of that required, and the Office may only refund fees paid by mistake or in excess of that required (35 U.S.C. 42(d)). Therefore, the optional procedure is not a basis for requesting a refund of the fee specified in 37 CFR 1.18(e) or the fee necessary for any petition under 37 CFR 1.136(a) for any request for reconsideration under 37 CFR 1.705(b), including any previously filed request that was solely based on the Office's alleged error pertaining to the fourteen-month patent term adjustment period.

Applicants seeking a revised patent term adjustment in a patent issued after May 20, 2014, must file a request for reconsideration under 37 CFR 1.705(b) that complies with the requirements of 37 CFR 1.705(b)(1) and (b)(2) within two months of the date the patent issued.

Under the optional procedure, to the extent that the procedures adopted under the authority of 35 U.S.C. 2(b)(2) and 154(b)(3) require that any request for reconsideration of the patent term adjustment indicated in the patent must be filed within two months of the date the patent issued and include the information required by 37 CFR 1.705(b)(2) and the fee required by 37 CFR 1.18(e), these requirements were *sua sponte* waived for patents that met all of the following criteria: (1) The patent issued between January 14, 2013 and May 20, 2014; (2) the patent resulted directly from an international application that has entered the national stage under 35 U.S.C. 371; and (3) the Request for Recalculation of the Patent Term Adjustment form (PTO/SB/132) was filed no later than July 31, 2014. See 37 CFR 1.183. This waiver does not apply to patents issued on or after May 20, 2014, and does not apply to requests that the Office recalculate the patent term adjustment for alleged errors other than the above-identified errors.

A request for recalculation of patent term adjustment under the optional procedure to request a recalculation of patent term adjustment is not a request for reconsideration within the meaning of 35 U.S.C. 154(b)(3), and a recalculation of patent term adjustment under the optional procedure is not the Director's decision on an applicant's request for reconsideration within the meaning of 35 U.S.C. 154(b)(3) and (b)(4). Rather, a recalculation of patent term adjustment under the optional procedure is simply a new patent term adjustment determination under 35 U.S.C. 154(b)(3). Any request for reconsideration under 35 U.S.C. 154(b)(3) and 37 CFR 1.705(b) of a new patent term adjustment determination under the optional procedure must comply with the requirements of 37 CFR 1.705(b)(1) and (b)(2) and be filed no later than two months from the date of the new patent term adjustment determination resulting from the recalculation of patent term adjustment. This two-month time period may be extended under the provisions of 37 CFR 1.136(a).

Nothing in this optional procedure shall be construed as a waiver of the requirement of 35 U.S.C. 154(b)(4) that an applicant dissatisfied with the Director's decision on the applicant's request for reconsideration under 35 U.S.C. 154(b)(3)(B)(ii) shall have exclusive remedy by a civil action against the Director filed in the United States District Court for the Eastern District of Virginia within 180 days after the date of the Director's decision on the applicant's request for reconsideration under 35 U.S.C. 154(b)(3)(B)(ii).

Doc Code: PET.PTA.AIA1
Document Description: Request for Recalculation in view of AIA

PTO/SB/132 (03-14)

REQUEST FOR RECALCULATION OF PATENT TERM ADJUSTMENT IN VIEW OF *AIA TECHNICAL CORRECTIONS ACT*

Attorney Docket Number:	Patent Number:
Filing Date (or 371(b) or (f) Date):	Issue Date:
First Named Inventor:	
Title:	

Patentee hereby requests Recalculation of the Patent Term Adjustment (PTA) under 35 U.S.C. 154(b) indicated on the above-identified patent. The international application issued as a patent after January 13, 2013 and before May 28, 2014.

A Request for Recalculation of Patent Term Adjustment under this optional procedure is not considered a Request for Reconsideration within the meaning of 35 U.S.C. 154(b)(3) and a Recalculation of Patent Term Adjustment under this procedure in not the Director's decision on an applicant's request for reconsideration within the meaning of 35 U.S.C. 154(b)(3)and (b)(4).

NOTE: This form must be filed prior to August 1, 2014. On or after August 1, 2014, patentee cannot use this optional procedure and must comply with the requirements of 37 CFR 1.705(b).

Signature	Date
Name (Print/Typed)	Registration Number

***Note**: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required in accordance with 37 CFR 1.33 and 11.18. Please see 37 CFR 1.4(d) for the form of the signature. If necessary, submit multiple forms for more than one signature, see below*.*

☐ *Total of _____ forms are submitted.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/SB/132 (03-14)

Instruction Sheet for:
REQUEST FOR RECALCULATION OF PATENT TERM ADJUSTMENT
IN VIEW OF *AIA TECHNICAL CORRECTIONS ACT*
(Not to be submitted to the USPTO)

This form is available for utility and plant patents that that are (1) international applications issued between January 14, 2013 and May 27, 2014 and (2) have a filing date or after May 29, 2000. Patentees seeking reconsideration of any patent issued after May 27, 2014 must comply with the procedure set forth in 37 CFR §§ 1.705(b)(1) and (b)(2).

This form is inapplicable to design applications, reissue applications, reexamination applications, supplemental examination applications, and any plant or utility application that has a filing date prior to May 29, 2000.

The Office is providing patentee a form titled Request for Recalculation of Patent Term Adjustment in view of AIA Technical Corrections Act (PTP/SB/132) for use in making such request. Any patentee who uses form PTO/SB/132 may request that the Office recalculate the patent term adjustment without a request under 37 CFR 1.705(b) or (fee). Any request for recalculation that make use of this alternative procedure by filing the form must do so no later than July 31, 2014.

It is noted that that nothing in this procedure shall be construed as a waiver of the requirement of 35 U.S.C. 154(b)(4) that any civil action by an applicant dissatisfied with a determination made by the Director under 35 U.S.C. 154(b)(3) be filed in the United States District Court for the Eastern District of Virginia within 180 day after the date of the Director's decision on an applicant's request for reconsideration under 35 U.S.C. 154(b)(3).

For more information, see "Revision to Patent Term Adjustment" available on the USPTO Web site at http://www.uspto.gov/news/fedreg/fr 2014.jsp.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

2735 [Reserved]

2736 Third Party Papers [R-07.2015]

37 CFR 1.705 Patent term adjustment determination.

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Editor Note: 37 CFR 1.705(d) below includes amendments applicable only to patents granted on or after January 14, 2013. See 37 CFR 1.705(f) (pre-2013-04-01) with respect to patents granted prior to January 14, 2013.]

(d) 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.

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For patents granted on or after January 14, 2013,37 CFR 1.705(d) implements the provisions of 35 U.S.C. 154(b)(4)(B) and provides that 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, and that any such submission or petition will be returned to the third party, or otherwise disposed of, at the convenience of the Office. For patents granted before January 14, 2013, 37 CFR 1.705(f) (pre-2013-04-01) similarly provided that no submission or petition on behalf of a third party concerning patent term adjustment under35 U.S.C. 154(b) will be considered by the Office, and that any such submission or petition will be returned to the third party, or otherwise disposed of, at the convenience of the Office.

2737-2749 [Reserved]

2750 Patent Term Extension for Delays at other Agencies under 35 U.S.C. 156 [R-11.2013]

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, Public Law 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 under 35 U.S.C. 156(a) are defined in 35 U.S.C. 156(b), but are not limited to a claim-by-claim basis. Rather, subsection(a) of 156 indicates that "[t]he term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended." See *Genetics Institute LLC v. Novartis Vaccines and Diagnostics Inc.*, 655 F.3d 1291, 99 USPQ2d 1713 (Fed. Cir. 2011). However, pursuant to 35 U.S.C. 156(b) , 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 *et al.*, *Generic and Innovator Drugs: A Guide to FDA Approval Requirements*,

Eighth Edition, Wolters Kluwer Law & Business, 2013, 4.05 for a discussion of the Hatch-Waxman Act and infringement litigation. Furthermore, Congress provided that an ANDA that the FDA will grant to the marketing applicant a period of 5 years of data exclusivity for any active ingredient or salt or ester of the active ingredient which 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). This language regarding the sixty-day period has been clarified by the America Invents Act where the Act provides that, "[f]or purposes of determining the date on which a product receives permission under the second sentence of this paragraph, if such permission is transmitted after 4:30 P.M., Eastern Time, on a business day, or is transmitted on a day that is not a business day, the product shall be deemed to receive such permission on the next business day. For purposes of the preceding sentence, the term 'business day' means any Monday, Tuesday, Wednesday, Thursday, or Friday, excluding any legal holiday under section 6103 of title 5." See Section 37 of the AIA and 35 U.S.C. 156. The USPTO initially determines whether the application is formally complete and whether the patent is eligible for extension. The statute requires the Director of the United States Patent and Trademark Office 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 Director, the Secretary will determine the length of the applicable regulatory review period and notify the Director of the determination. If the Director determines that the patent is eligible for extension, the Director 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 [R-11.2013]

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 —

(1) 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.

I. TERMINALLY DISCLAIMED PATENTS ARE ELIGIBLE

A patent may be extended under 35 U.S.C. 156, even though it has been terminally disclaimed. A patent

term extension under 35 U.S.C. 156 is a limited extension of the patent rights associated with the approved product that is attached onto the original term of the patent. See 35 U.S.C. 156(b). Only one patent may be extended for a regulatory review period for any product, and 35 U.S.C. 156 sets the expiration date of a patent term extension. Although 35 U.S.C. 154(b)(2) (June 8, 1995) precludes a patent from being extended under 35 U.S.C. 154(b) if the patent has been terminally disclaimed due to an obviousness-type double patenting rejection (see MPEP § 2720), there is no such exclusion in 35 U.S.C. 156. Additionally, 35 U.S.C. 154(b)(2)(B)) (May 29, 2000) provides that a patent cannot be adjusted beyond the date set by the disclaimer (see MPEP § 2730), but there is no similar provision in 35 U.S.C. 156. Thus patents may receive a patent term extension under 35 U.S.C. 156 beyond an expiration date set by a terminal disclaimer. See *Merck & Co., Inc. v. Hi-Tech Pharmacal, Co., Inc.*, 482 F3d 1317, 82 USPQ2d 1203 (Fed. Cir. 2007).

II. 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. See *Hoechst-Roussel*, 109 F.3d at 759 n.3 ("For purposes of patent term extension, this active ingredient must be present in the drug product when administered."). In addition, a patent to a drug product having one form of an active ingredient may qualify for an extension even though another form of the

underlying chemical moiety was previously approved and commercially marketed or used. For example, a drug product having the ester form of a particular chemical moiety is a different drug product from the same chemical moiety in a salt form, even though both the salt and the ester are used to treat the same disease condition. See *PhotoCure v. Kappos*, 603 F.3d 1372, 95 USPQ2d 1250 (Fed. Cir. 2010); see also *Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392, 13 USPQ2d 1628 (Fed. Cir. 1990) (holding that a patent which claimed an ester of the acid cefuroxime was eligible for extension regardless of previous approvals of two salts of cefuroxime). Thus, eligibility for patent term extension for a patent which claims a product subject to regulatory review as set forth in 35 U.S.C. 156(b) turns on the question of whether the product, i.e., the active ingredient of the drug product, present in the final dosage form was previously approved by FDA. If neither it, nor any salt or ester of that active ingredient has been previously approved by FDA, then the patent should be eligible for patent term extension.

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).

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.

III. 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 1.702-1.705. 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).

IV. 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 Cal. 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.

V. 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 will not be considered to have a single active ingredient made of the two active ingredients. See *Arnold Partnership v. Dudas*, 362 F.3d 1338, 70 USPQ2d 1311 (Fed. Cir. 2004). In considering whether a patent claiming an enantiomer, where the enantiomer was subject to pre-market regulatory review, is barred from receiving patent term extension in light of the previous approval of the racemate of the drug product, the court indicated that an enantiomer was a separate drug product from the racemate and each could support a patent term extension. See *Ortho-McNeil Pharmaceutical Inc. v. Lupin Pharmaceuticals Inc.*, 603 F3d 1377, 95 USPQ2d 1246 (Fed. Cir. 2010).

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 [R-08.2017]

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, or in the case of a drug product described in subsection (i), within the sixty-day period beginning on the covered date (as defined in subsection (i)). 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 which claims the approved product or a method of using or manufacturing the approved product;

(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.

For purposes of determining the date on which a product receives permission under the second sentence of this paragraph, if such permission is transmitted after 4:30 P.M., Eastern Time, on a business day, or is transmitted on a day that is not a business day, the product shall be deemed to receive such permission on the next business day. For purposes of the preceding sentence, the term "business day" means any Monday, Tuesday, Wednesday, Thursday, or Friday, excluding any legal holiday under section 6103 of title 5.

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(i)(1) For purposes of this section, if the Secretary of Health and Human Services provides notice to the sponsor of an application or request for approval, conditional approval, or indexing of a drug product for which the Secretary intends to recommend controls under the Controlled Substances Act, beginning on the covered date, the drug product shall be considered to—

(A) have been approved or indexed under the relevant provision of the Public Health Service Act or Federal Food, Drug, and Cosmetic Act; and

(B) have permission for commercial marketing or use.

(2) In this subsection, the term "covered date" means the later of—

(A) the date an application is approved—

(i) under section 351(a)(2)(C) of the Public Health Service Act; or

(ii) under section 505(b) or 512(c) of the Federal Food, Drug, and Cosmetic Act;

(B) the date an application is conditionally approved under section 571(b) of the Federal Food, Drug, and Cosmetic Act;

(C) the date a request for indexing is granted under section 572(d) of the Federal Food, Drug, and Cosmetic Act; or

(D) the date of issuance of the interim final rule controlling the drug under section 201(j) of the Controlled Substances Act.

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 [R-11.2013]

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 Director. 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 § 1.720(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 Director of the United States Patent and Trademark Office 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 Director 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; any extension will be granted based upon the review of the product as 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. The starting date of the sixty-day period as recited in 35 U.S.C. 156(d)(1) has been clarified by the America Invents Act where the Act provides that, "[f]or purposes of determining the date on which a product receives permission under the second sentence of this paragraph, if such permission is transmitted after 4:30 P.M., Eastern Time, on a business day, or is transmitted on a day that is not a business day, the product shall be deemed to receive such permission on the next business day. For purposes of the preceding sentence, the term 'business day' means any Monday, Tuesday, Wednesday, Thursday, or Friday, excluding any legal holiday under section 6103 of title 5." See Section 37 of the American Invents Act and 35 U.S.C. 156. 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, or 35 U.S.C. 112(f) for patents granted on AIA applications, 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 five-year limit of 35 U.S.C. 156(g)(6)(A) 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 Mail Stop Hatch-Waxman PTE, 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. The original copy, along with the patent file (if not already scanned into the Image File Wrapper system), is scanned into the Image File Wrapper system so that all patent prosecution and patent term extension documents are available in PUBLIC PAIR. One copy of the application is forwarded to the regulatory agency and the second copy is used by the Legal Advisor in the Office of Patent Legal Administration.

2754 Filing Date [R-11.2013]

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 Director 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 Director 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.

I. FILING DATE ACCORDED

An application for patent term extension under 35 U.S.C. 156 may be filed by mail addressed to Mail Stop Hatch-Waxman PTE, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 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 Priority Mail Express® provisions of 37 CFR 1.10. Patent term extension applications must not be filed by facsimile or the Office's electronic filing system (EFS-Web). 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 or via EFS-Web.

II. 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.

III. 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.

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) [R-11.2013]

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). For purposes of determining the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use, if such permission is transmitted after 4:30 P.M., Eastern Time, on a business day, or is transmitted on a day that is not a business day, the product shall be deemed to have received such permission on the next business day. The term "business day" in this context means any Monday, Tuesday, Wednesday, Thursday, or Friday, excluding any legal holiday under 5 U.S.C. 6103.

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 generally is 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) [R-8.2012]

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), identification of the date the product received permission for commercial marketing or

use, 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) [R-8.2012]

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 [R-8.2012]

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 Director 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 Director 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 [R-11.2013]

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

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(e)(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 Director 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 Director 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 Director. The length of any interim extension is discretionary with the Director 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 Director 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.

2755.02 Interim Extension of Patent Term Before Product Approval [R-08.2017]

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

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(d)

(5)(A) If the owner of record of the patent or its agent 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, 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 regulatory 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 date 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

In re___

Request for Patent Term Extension ORDER GRANTING U.S. Patent No.___ 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 [R-11.2013]

It is the Director'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 FR 17830 (May 12, 1987); *Memorandum of Understanding Between the Patent and Trademark Office and the Animal and Plant Health Inspection Service*, 54 FR 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 extension 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.

I. 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 to request 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.

II. 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). 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 [R-11.2013]

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) (regarding U.S. Patent No. 4,215,113). To determine the regulatory review period for an animal drug where the New Animal Drug Application (NADA) components were submitted to FDA in a phased review, the approval phase, as defined by 35 U.S.C. 156(g)(4)(B)(ii), begins on the date of the submission of the administrative NADA. See *Wyeth Holdings Corp. v. Sebelius*, 603 F.3d 1291, 1299-1300, 95 USPQ2d 1233,1240 (Fed. Cir. 2010).

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 [R-11.2013]

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 will proceed with the final eligibility determination. See 21 CFR Ch. 1, Subparts D and E.

2758 Notice of Final Determination - Calculation of Patent Term Extension [R-08.2017]

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)(1) for the same regulatory review period for any product.

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(g) For purposes of this section, the term "regulatory review period" has the following meanings:

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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 environmental 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 the 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 Office then calculates 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 website (**www.uspto.gov**) with other Decisions of the Director. 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 dismisses the application and sets forth the basis for the dismissal. 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 Director 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 = RRP - PGRRP - DD - ½ (TP - PGTP)1

[1]Consistent with 35 U.S.C. 156(c), "RRP" is the total number of days in the regulatory review period, "PGRRP" is the number of days of the RRP which were on and before the date on which the patent issued, "DD" is the number of days of the RRP that the applicant did not act with due diligence, "TP" is the testing phase period described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g) of 35 U.S.C. 156, and "PGTP" is the number of days of the TP which were

on and before the date on which the patent issued, wherein half days are ignored for purposes of the subtraction of ½ (TP - PGTP).

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 former 35 U.S.C. 154(b) (for applications filed between June 8, 1995 and May 28, 2000) and patent term adjustment under 35 U.S.C. 154(b) (for applications filed on or after May 29, 2000).

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.

I. 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 CFR 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*, 917 F2d 522, 525, 16 USPQ2d 1549, 1551 (Fed. Cir. 1990).

2759 Certificate of Extension of Patent Term [R-11.2013]

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 Director. 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 website (**www.uspto.gov**) and which is also available in the "Patent Term Extension (Restoration)" section of the electronic FOIA Reading Room of USPTO's website at **www.uspto.gov/ip/boards/foia_rr/resources/patents/pte.jsp**.

2760 Trade Secret, Confidential, and Protective Order Material [R-8.2012]

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 [R-08.2017]

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)(1) 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 information 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 [R-08.2012]

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 Director of the United States Patent and Trademark Office, 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 [R-08.2012]

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.

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 Director, 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 [R-08.2012]

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.