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**37 CFR Part 1
Changes To Implement Patent Term
Adjustment Under Twenty-Year Patent
Term; Final Rule**

DEPARTMENT OF COMMERCE**Patent and Trademark Office****37 CFR Part 1**

RIN 0651-AB06

Changes To Implement Patent Term Adjustment Under Twenty-Year Patent Term**AGENCY:** United States Patent and Trademark Office, Commerce.**ACTION:** Final rule.

SUMMARY: The United States Patent and Trademark Office (Office) is revising the rules of practice in patent cases to implement certain provisions of the American Inventors Protection Act of 1999. These provisions of the American Inventors Protection Act of 1999 provide patent term adjustment to compensate patentees for certain delays in the application examination process.

DATES: *Effective Dates:* Sections 1.702 through 1.705 and the amendment to § 1.701 are effective October 18, 2000. The amendment to § 1.18 is effective November 17, 2000.

Applicability Date: Section 1.701 applies to original (non-reissue) patents issued on applications (other than for a design patent) filed on or after June 8, 1995, and before May 29, 2000. Sections 1.702 through 1.705 apply to original applications (other than for a design patent) filed on or after May 29, 2000, and to patents issued on such applications.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: The American Inventors Protection Act of 1999 (Title IV of the Intellectual Property and Communications Omnibus Reform Act of 1999 (S. 1948) as introduced in the 106th Congress on November 17, 1999) was incorporated and enacted into law on November 29, 1999, by § 1000(a)(9), Division B, of Pub. L. 106-113, 113 Stat. 1501 (1999). The American Inventors Protection Act of 1999 contains a number of changes to title 35, United States Code. This final rule changes the rules of practice to implement the provisions of §§ 4401 and 4402 of the American Inventors Protection Act of 1999. These provisions are effective on the date that is six months after the date of enactment of

the American Inventors Protection Act of 1999 (May 29, 2000) and apply to original (non-reissue) applications, other than for a design patent, filed on or after the date that is six months after the date of enactment of the American Inventors Protection Act of 1999 (May 29, 2000).

Section 532(a)(1) of the Uruguay Round Agreements Act (Pub. L. 103-465, 108 Stat. 4809 (1994)) amended 35 U.S.C. 154 to provide that the term of patent protection begins on the date of patent grant and ends on the date twenty years from the filing date of the application, or the earliest filing date for which a benefit is claimed under 35 U.S.C. 120, 121, or 365(c). Pub. L. 103-465 also contained provisions, codified at 35 U.S.C. 154(b), for patent term extension due to certain examination delays.

Section 4402 of the American Inventors Protection Act of 1999 amends 35 U.S.C. 154(b)(1) to provide day-by-day patent term adjustment if the Office fails, within specified time periods, to: (1) initially act on the application; (2) respond to a reply or appeal to the Board of Patent Appeals and Interferences by the applicant; (3) act on an application after a decision by the Board of Patent Appeals and Interferences or a Federal court where at least one allowable claim remains in the application; or (4) issue the application after the issue fee is paid in reply to a notice of allowance and all outstanding requirements are satisfied (35 U.S.C. 154(b)(1)(A)). Section 4402 of the American Inventors Protection Act of 1999 also amends 35 U.S.C. 154(b)(1) to provide day-by-day 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)). Section 4402 of the American Inventors Protection Act of 1999 also amends 35 U.S.C. 154(b)(1) to provide day-by-day patent term adjustment for delays due to interference proceedings under 35 U.S.C. 135(a), imposition of a secrecy order under 35 U.S.C. 181, or successful appellate review by the Board of Patent Appeals and Interferences or a Federal court (35 U.S.C. 154(b)(1)(C)).

Section 4402 of the American Inventors Protection Act of 1999 amends 35 U.S.C. 154(b)(2) to place limitations on the period of patent term adjustment granted under 35 U.S.C. 154(b)(1). First, to the extent that the periods of delay attributed to the grounds specified in 35 U.S.C. 154(b)(1) overlap, the period of adjustment shall not exceed the actual number of days the issuance of the patent was delayed.

Second, no patent, the term of which has been disclaimed beyond a specified date, may be adjusted under 35 U.S.C. 154(b) beyond the expiration date specified in the disclaimer. Third, 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 (or processing or examination) of the application. Section 4402 of the American Inventors Protection Act of 1999, however, does not contain any limit (*e.g.*, of five or ten years) on the total extension or adjustment that may be granted under 35 U.S.C. 154(b).

An applicant is deemed to have failed to engage in reasonable efforts to conclude prosecution of an application with respect to any patent term adjustment under 35 U.S.C. 154(b)(1)(B) (failure to issue a patent within three years of the actual filing date of the application) for the cumulative total of any periods of time in excess of three months that are taken to reply to a notice of any rejection, objection, argument, or other request, measuring the three-month period from the date the notice was mailed or given. In addition, 35 U.S.C. 154(b)(2) directs the Office to prescribe regulations establishing the circumstances that constitute a failure of the applicant to engage in reasonable efforts to conclude processing or examination of an application.

Section 4402 of the American Inventors Protection Act of 1999 also amends 35 U.S.C. 154(b)(3) to establish procedures for patent term adjustment determinations. 35 U.S.C. 154(b)(3) directs the Office to prescribe regulations establishing procedures for the application for and determination of patent term adjustment under 35 U.S.C. 154(b). 35 U.S.C. 154(b)(3), however, requires the Office to: (1) Make a patent term adjustment determination and transmit a notice of that determination with the notice of allowance; and (2) provide the applicant with one opportunity to request reconsideration of that patent term adjustment determination. 35 U.S.C. 154(b)(3) also provides that 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) (for failure to reply to a notice of any rejection, objection, argument, or other request within three months of the date the notice was mailed or given) if, prior to issuance of the patent, the applicant makes a showing that, in spite of all due care, the applicant was unable to reply within the three-month period, except that the

Office may not reinstate more than three additional months for each reply beyond the original three-month period. Section 4402 of the American Inventors Protection Act of 1999 also amends 35 U.S.C. 154(b)(3) to provide that the Office shall proceed to grant the patent after completing its patent term adjustment determination and amends 35 U.S.C. 154(b)(4) to provide for judicial review in the event that the applicant is dissatisfied with that patent term adjustment determination.

Section 4405(a) of the American Inventors Protection Act of 1999 provides that § 4402 shall take effect on the date that is six months after the date of enactment of the American Inventors Protection Act of 1999 (May 29, 2000) and shall apply to any application (other than for a reissue or design) filed on or after the date that is six months after the date of enactment of the American Inventors Protection Act of 1999 (May 29, 2000). Therefore, patents (other than reissue or design) issued on applications filed on or after June 8, 1995, but before May 29, 2000, are subject to the patent term extension provisions of 35 U.S.C. 154(b) as amended by § 532(a)(1) of Pub. L. 103-465 and § 1.701, whereas patents (other than reissue or design) issued on applications filed on or after May 29, 2000, are subject to the patent term adjustment provisions of 35 U.S.C. 154(b) as amended by § 4402 of the American Inventors Protection Act of 1999.

The filing date of a continued prosecution application (CPA) under § 1.53(d) is the date that the request for CPA is filed (§ 1.53(d)(2)), even though the Office uses the filing date of the prior application for identification purposes. Therefore, the patent term adjustment provisions of 35 U.S.C. 154(b) as amended by § 4402 of the American Inventors Protection Act of 1999 apply to any CPA filed on or after May 29, 2000, regardless of the filing date of the prior application of the CPA. While an applicant may file a continuing application under § 1.53(b) on or after May 29, 2000, for the application to be subject to the patent term adjustment provisions of 35 U.S.C. 154(b) as amended by § 4402 of the American Inventors Protection Act of 1999, an applicant need only file a CPA under § 1.53(d) on or after May 29, 2000, for the application to be subject to the patent term adjustment provisions of 35 U.S.C. 154(b) as amended by § 4402 of the American Inventors Protection Act of 1999. The filing of a CPA on or after May 29, 2000, does not, however, entitle an applicant to receive term adjustment

for Office delays before the filing date of the CPA (*i.e.*, before May 29, 2000).

The Office published a notice proposing changes to the rules of practice to implement the provisions of § 4402 of the American Inventors Protection Act of 1999. *See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term*, Notice of Proposed Rulemaking, 65 FR 17215 (Mar. 31, 2000), 1233 *Off. Gaz. Pat. Office* 109 (Apr. 25, 2000) (notice of proposed rulemaking). This final rule adopts changes to the rules of practice to implement the provisions of § 4402 of the American Inventors Protection Act of 1999.

Section 4732 of the American Inventors Protection Act of 1999 changed (among other things) the title "Commissioner" to "Director." The title "Commissioner," however, is not being changed to "Director" where it appears in the rules of practice involved in this final rule because legislation is pending before Congress that (if enacted) would restore the former title "Commissioner." *See Intellectual Property Technical Amendments Act of 2000*, H.R. 4870, 106th Cong. (2000).

Discussion of Specific Rules

Sections 1.18(e) and (f) are added to set forth the fees for filing an application for patent term adjustment under § 1.705, and for filing a request for reinstatement of all or part of the term reduced pursuant to § 1.704(b) in an application for patent term adjustment under § 1.705. The fees in § 1.18(e) and (f) are set to recover the estimated average cost to the Office for processing and evaluating an application for patent term adjustment under § 1.705, and for processing and evaluating a request under 35 U.S.C. 154(b)(3)(C) for reinstatement of the term reduced under 35 U.S.C. 154(b)(2)(C), respectively. *See* 35 U.S.C. 41(d).

Section 1.18(e) is added to provide a \$200 fee for filing an application for patent term adjustment under § 1.705. An application for patent term adjustment under § 1.705(b) requires the Office to calculate the applicable patent term adjustment to determine the correct patent term adjustment. Handling such applications for patent term adjustment will involve careful record review and date calculation, but not a great deal of legal analysis. The Office expects them to be as burdensome as petitions of medium level complexity. Based upon activity-based cost estimates (using the costs of treating similar petitions, that is, petitions of medium level burden), a \$200 fee was determined to be the

appropriate fee amount for cost-recovery as provided for in 35 U.S.C. 41(d).

Section 1.18(f) is added to provide a \$400 fee for filing a request for reinstatement of all or part of the term reduced pursuant to § 1.704(b) in an application for patent term adjustment under § 1.705. The request for reinstatement provided for in § 1.705(c) requires the Office to evaluate the merits of the applicant's showing that at least one delay occurred in spite of all due care. Evaluating such "due care" showings is expected to be as burdensome as evaluating the "unavoidable" delay petitions provided for in §§ 1.137(a) and 1.378(b), which are some of the most burdensome petitions. Thus, based upon activity-based cost estimates (using the costs of treating "unavoidable" delay petitions), a \$400 fee was determined to be the appropriate fee amount for cost-recovery as provided for in 35 U.S.C. 41(d).

The Office initially proposed a \$450 fee for filing a request for reinstatement of all or part of the term reduced pursuant to § 1.704(b) in an application for patent term adjustment under § 1.705. The Office, however, has since further refined its cost estimates for processing and evaluating such requests for reinstatement and has determined that \$400 is the appropriate fee amount for cost-recovery as provided for in 35 U.S.C. 41(d).

Subpart F of 37 CFR Part 1 is amended to include a first undesignated center heading to read "Adjustment of Patent Term Due to Examination Delay" followed by an amended § 1.701 and newly added §§ 1.702 through 1.705 concerning patent term adjustment under 35 U.S.C. 154(b), and a second undesignated center heading to read "Extension of Patent Term Due to Regulatory Review" followed by current § 1.710 *et seq.* concerning patent term extension under 35 U.S.C. 156.

Section 1.701 is amended by revising its heading to indicate that its provisions concern the patent term extension provisions of the Uruguay Round Agreements Act (Pub. L. 103-465) and to add a paragraph (e) to specify that the provisions of § 1.701 apply only to original patents issued on applications filed on or after June 8, 1995, and before May 29, 2000. As discussed above, the provisions of 35 U.S.C. 154(b) as amended by § 532(a)(1) of Pub. L. 103-465 and § 1.701 apply to applications (other than for a reissue or design patent) filed on or after June 8, 1995, but before May 29, 2000, and the provisions of § 4402 of the American Inventors Protection Act of 1999 and §§ 1.702 through 1.705 apply to applications (other than for a reissue or

design patent) filed on or after May 29, 2000.

Section 1.702 is added to set forth the bases for patent term adjustment under 35 U.S.C. 154(b)(1). Section 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)). Section 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)). Section 1.702(c) indicates that a patent is entitled to patent term adjustment if the issuance of the patent was delayed by an interference proceeding (35 U.S.C. 154(b)(1)(C)(i)). Section 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)). Section 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)). Section 1.702(f) provides that the provisions of §§ 1.702 through 1.705 apply only to original (*i.e.*, non-reissue) applications, except applications for a design patent, filed on or after May 29, 2000, and patents issued on such applications.

Section 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 § 1.702. When a period is indicated (in § 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 §§ 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 §§ 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.

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

Section 1.703(a)(1) pertains to the provisions of 35 U.S.C. 154(b)(1)(A)(i). Section 1.703(a)(1) 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. A written restriction requirement, a written election of species requirement, a requirement for information under § 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 notices are: a Notice of Incomplete Nonprovisional Application (PTO-1123), a Notice of Omitted Item(s) in a Nonprovisional Application (PTO-1669), a Notice to File Missing Parts of Application (PTO-1533), a Notice of Informal Application (PTO-152), a Notice to File Corrected Application Papers Filing Date Granted (PTO-1660), or a Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures (PTO-1661).

Section 1.703(a)(2) pertains to the provisions of 35 U.S.C. 154(b)(1)(A)(ii). Section 1.703(a)(2) 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 § 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.

Section 1.703(a)(3) also pertains to the provisions of 35 U.S.C. 154(b)(1)(A)(ii). Section 1.703(a)(3) 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 § 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 § 1.113 is a reply to a final Office action, and a reply in compliance with § 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 § 1.113(c).

Section 1.703(a)(4) also pertains to the provisions of 35 U.S.C. 154(b)(1)(A)(ii). Section 1.703(a)(4) 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 § 1.192 was filed and ending on the mailing date of any of an examiner’s answer under § 1.193, an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first. 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 § 1.192” requires that: (1) the appeal brief fee (§ 1.17(c)) be paid (§ 1.192(a)); and (2) the appeal brief complies with § 1.192(c)(1) through (c)(9).

Section 1.703(a)(5) pertains to the provisions of 35 U.S.C. 154(b)(1)(A)(iii). Section 1.703(a)(5) 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 Board of Patent Appeals and Interferences or by a Federal court in an appeal under 35 U.S.C. 141 or a civil action under 35 U.S.C. 145 or 146, where at least one allowable claim remains in the application and ending on the 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 a Board of Patent Appeals and Interferences decision to be a “decision by the Board of Patent Appeals and Interferences under [35 U.S.C.] 134” within the meaning of 35 U.S.C. 154(b)(1)(A)(iii) (and § 1.703(a)(5)), the decision must sustain or reverse the rejection(s) of the claim(s) on appeal. For a Board of Patent Appeals and Interferences decision to be a “decision by the Board of Patent Appeals and Interferences under [35 U.S.C.] 135”

within the meaning of 35 U.S.C. 154(b)(1)(A)(iii) (and § 1.703(a)(5)), the decision must include a decision on the patentability of the claims or priority of invention. A remand or other administrative order by the Board of Patent Appeals and Interferences (even if by a merits panel) is not a "decision" within the meaning of 35 U.S.C. 154(b)(1)(A)(iii) (and § 1.703(a)(5)).

The phrase "final decision" in § 1.703(a)(5) means that: (1) the decision is the last decision in the review by the Board of Patent Appeals and Interferences (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 of Patent Appeals and Interferences decision containing a new ground of rejection under § 1.196(b) requires action by the applicant to avoid termination of proceedings as to the rejected claims and is thus not considered a "final decision" for purposes of § 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 of Patent Appeals and Interferences 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 of Patent Appeals and Interferences) is a "final decision" for purposes of § 1.703(a)(5)).

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:

(1) 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, "allowable claims remain in the application" for purposes of 35 U.S.C. 154(b)(1)(A)(iii).

(2) 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).

(3) If claims 1 and 2 are pending, the decision affirms the rejection of claim 1 and reverses the rejection of claim 2, "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 § 1.703(a)(5) because there is no outstanding objection or requirement as to it until the examiner issues a notice under section 1214.06, paragraph (I)(B) of the *Manual of Patent Examining Procedure* (7th ed.1998) (Rev. 1, Feb. 2000) (MPEP)).

Section 1.703(a)(6) pertains to the provisions of 35 U.S.C. 154(b)(1)(A)(iv). Section 1.703(a)(6) 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. 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. 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).

Section 1.703(b) pertains to the provisions of 35 U.S.C. 154(b)(1)(B). Section 1.703(b) indicates that 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 actual filing date of the application and ending on the date a patent was issued. Section 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). Section 1.703(b) specifically provides that the period of adjustment of the term of a patent under § 1.703(b) 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 § 1.704 as such delays are also circumstances constituting a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application.

Section 1.703(c) pertains to the provisions of 35 U.S.C. 154(b)(1)(C)(i). Section 1.703(c) indicates that the period of adjustment under § 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 was declared or redeclared to involve the application in the interference and ending on the date that the interference was terminated with respect to the application; and (2) the number of days, if any, in the period beginning on the date prosecution in the application was suspended by the Office due to interference proceedings under 35 U.S.C. 135(a) not involving the application and ending on the date of the termination of the suspension.

Section 1.703(d) pertains to the provisions of 35 U.S.C. 154(b)(1)(C)(ii). Section 1.703(d) indicates that the period of adjustment under § 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 § 1.193 in the application under secrecy order and ending on the date the secrecy order was removed; (3) the number of days, if any, in the period beginning on the date applicant was notified that an interference would be declared but for the secrecy order and ending on the date the secrecy order was removed; and (4) the number of days, if any, in the period beginning on the date of notification under § 5.3(c) and ending on the date of mailing of the notice of allowance under 35 U.S.C. 151 and § 1.311.

Section 1.703(e) pertains to the provisions of 35 U.S.C. 154(b)(1)(C)(iii). Section 1.703(e) indicates that the period of adjustment under § 1.702(e) is the sum of the number of days, if any, in the period beginning on the date on which a notice of appeal to the Board of Patent Appeals and Interferences was filed under 35 U.S.C. 134 and § 1.191 and ending on the date of a final decision in favor of the applicant by the

Board of Patent Appeals and Interferences or by a Federal court in an appeal under 35 U.S.C. 141 or a civil action under 35 U.S.C. 145. The phrase "in which the patent was issued under a decision in the review reversing an adverse determination of patentability" (a final decision in favor of the applicant) in 35 U.S.C. 154(b)(1)(C)(iii) requires a Board of Patent Appeals and Interferences or Federal court decision in the review that reverses all of the rejections of at least one claim and that such claim is not subject to a rejection under § 1.196(b). For example:

(1) If claims 1 and 2 are pending, claim 1 stands rejected under 35 U.S.C. 103 and claim 2 was indicated as allowable prior to the appeal, the rejection of claim 1 under 35 U.S.C. 103 is affirmed, and a patent is issued (containing claim 2), the patent was not issued under a decision in the review reversing an adverse determination of patentability.

(2) If claims 1 and 2 are pending, claims 1 and 2 stand rejected under 35 U.S.C. 103, as well as 35 U.S.C. 112, ¶ 2, the rejection of claims 1 and 2 under 35 U.S.C. 103 is affirmed but the rejection of claims 1 and 2 under 35 U.S.C. 112, ¶ 2, is reversed, and a patent is issued as a result of continued examination under the provisions of 35 U.S.C. 132(b) and § 1.114, the patent was not issued under a decision in the review reversing an adverse determination of patentability.

(3) If claims 1 and 2 are pending, claims 1 and 2 stand rejected under 35 U.S.C. 102, the rejection of claims 1 and 2 under 35 U.S.C. 102 is reversed, and the decision by the Board of Patent Appeals and Interferences enters a new ground of rejection of claims 1 and 2 under 35 U.S.C. 103 (§ 1.196(b)), and a patent is issued as a result of further prosecution before the examiner, the patent was not issued under a decision in the review reversing an adverse determination of patentability.

(4) If claims 1 and 2 are pending, claims 1 and 2 stand rejected under 35 U.S.C. 103, the rejection of claim 1 under 35 U.S.C. 103 is affirmed but the rejection of claim 2 under 35 U.S.C. 103 is reversed, and a patent is issued (containing claim 2), the patent was issued under a decision in the review reversing an adverse determination of patentability.

The Committee Reports for the predecessors of the American Inventors Protection Act of 1999 in the 105th Congress (the 21st Century Patent System Improvement Act, H.R. 400, 105th Cong. (1997), and The Omnibus Patent Act of 1997, S. 507, 105th Cong. (1997)) indicate that the Office should

not determine whether "the patent was issued under a decision in the review reversing an adverse determination of patentability" in a mechanistic way, but should consider the particulars of each application after an appeal to determine whether patent term adjustment (restoration) is appropriate. *See* H.R. Rep. No. 105-39, at 66-67 (1997), and S. Rep. No. 105-42, at 102-03 (1997). Nevertheless, this language cannot be relied upon in interpreting the phrase "the patent was issued under a decision in the review reversing an adverse determination of patentability" because: (1) while H.R. 400 was passed by the House of Representatives on April 23, 1997, neither H.R. 400 nor S. 507 were enacted into law; and (2) this language is not contained in the section-by-section analysis of the American Inventors Protection Act of 1999 or the Committee or Conference Reports for its predecessors (the Intellectual Property and Communications Omnibus Reform Act of 1999, H.R. 1554, 106th Cong. (1999), and the American Inventors Protection Act of 1999, H.R. 1907, 106th Cong. (1999)) in the 106th Congress. *See* 145 Cong. Rec. S14,708-26 (1999)(daily ed. Nov. 17, 1999), H.R. Conf. Rep. No. 106-464 (1999), and H.R. Rep. No. 106-287 (1999).

As discussed below, the Office must make its patent term adjustment determinations by a computer program that uses the information recorded in the Office's automated patent application information system (the Patent Application Location and Monitoring system or PALM system). Thus, the Office must determine whether the Board of Patent Appeals and Interferences (or court) decision was of a nature such that "the patent was issued under a decision in the review reversing an adverse determination of patentability" under 35 U.S.C. 154(b)(1)(C)(iii) from information concerning the decision susceptible of being recorded in the PALM system (rather than by a case-by-case review of each decision).

Section 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). Section 1.703(f) also indicates that to the extent that periods of adjustment attributable to the grounds specified in § 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)). Section 1.703(f) also specifically indicates that 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 § 1.703(a) through (e),

to the extent that such periods are not overlapping, less the sum of the periods calculated under § 1.704. Section 1.703(f) also provides that the date indicated on any certificate of mailing or transmission under § 1.8 shall not be taken into account in this calculation. That is, while the date indicated on any certificate of mailing or transmission under § 1.8 will continue to be taken into account in determining timeliness, the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation. Applicant may wish to consider the use of the "Express Mail Post Office to Addressee" service of the United States Postal Service (§ 1.10) or facsimile transmission (§ 1.6(d)) for replies to be accorded the earliest possible filing date for patent term adjustment calculations.

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

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.

Section 1.704(a) implements the provisions of 35 U.S.C. 154(b)(2)(C)(i) and indicates 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.

Section 1.704(b) provides that with respect to the ground for adjustments set forth in §§ 1.702(a) through (e), and in particular § 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 (PTO-1669), 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 § 1.704(b), since the Office does not require a reply to that notice to continue the processing and examination of an application. Section 1.704(b) indicates that 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. As discussed above, a reply is considered filed on the date of its actual receipt in the Office as defined by § 1.6, and the date indicated on any certificate of mailing or transmission under § 1.8 will not be taken into account for patent term adjustment purposes.

The three-month period in § 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 (PTO-1669) as discussed above). These notices include: (1) A Notice of Incomplete Nonprovisional Application (PTO-1123) (except as to any period prior to the filing date ultimately accorded to the application); (2) a Notice to File Missing Parts of Application (PTO-1533); (3) a Notice of Informal Application (PTO-152); (4) a Notice to File Corrected Application Papers Filing Date Granted (PTO-1660); or (5) a Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures (PTO-1661).

In addition, the three-month period in 35 U.S.C. 154(b)(2)(C)(ii) and § 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 one-month period for reply (restriction requirement), the applicant may obtain a two-month extension of time under § 1.136(a) before being subject to a reduction of patent term adjustment under 35 U.S.C. 154(b)(2)(C)(ii) and § 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 § 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.

Section 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. Sections 1.704(c)(1) through (c)(11) set forth actions or inactions by an applicant that interfere with the Office's ability to process or examine an application (and thus 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 § 1.703 shall be reduced if an applicant engages in any of the enumerated actions or inactions.

Sections 1.704(c)(1) through 1.704(c)(11) address situations that occur with sufficient frequency to warrant being specifically provided for in the rules of practice. An attempt to provide an exhaustive listing of actions or inactions that interfere with the Office's ability to process or examine an application is impractical, 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 § 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 § 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 § 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 § 1.704(c).

Section 1.704(c)(1) establishes suspension of action under § 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. Section 1.704(c)(1) also provides that in such a 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.

Section 1.704(c)(2) establishes deferral of issuance of a patent under § 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 § 1.314, the Office is precluded from issuing the application as a result of an action by the applicant. When a petition under § 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. Section 1.704(c)(2) also provides that in such a 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 issue date of the patent.

Section 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. Section 1.704(c)(3) also provides that in such a 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 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.

Section 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 § 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), paragraph (I). Section 1.704(c)(4) also provides that in such a 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.

Section 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)) as a circumstance that constitutes a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application. Section 4801(a) of the American Inventors Protection Act of 1999, which provides for the conversion of a provisional application under 35 U.S.C. 111(b) and § 1.53(c) to a nonprovisional application under 35 U.S.C. 111(a) and § 1.53(b), is being implemented in a separate rulemaking. 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. Section 1.704(c)(5) also provides that in such a 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.

Section 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. Section 1.704(c)(6) also provides that in such a case the period of adjustment set forth in § 1.703 shall be reduced by the lesser of the number of days, if any, beginning on 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 § 1.704(c)(6) if the Office takes longer than four months to issue a supplemental Office action or notice of allowance.

Section 1.704(c)(7) establishes submission of a reply having an omission (§ 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 § 1.135(c) and await and process the applicant's reply to the action under § 1.135(c) before the initial reply (as corrected) can be treated on its merits. Section 1.704(c)(7) also provides that in such a 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 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 “§ 1.135(c)” is parenthetical because § 1.704(c)(7) is not limited to Office actions under § 1.135(c) but applies 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 § 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 § 1.821 *et seq.*

Section 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. Section 1.704(c)(8) does not apply to a supplemental reply or other paper that was expressly requested by the examiner. Section 1.704(c)(8) also provides that in such a 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 initial reply was filed and ending on the date that the supplemental reply or such other paper was filed.

Section 1.704(c)(9) establishes submission of an amendment or other paper in an application containing allowed claims after a decision by the Board of Patent Appeals and Interferences (other than a decision containing a rejection under § 1.196(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 of Patent Appeals and Interferences 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. Section 1.704(c)(9) also provides that in such a case the period of adjustment set forth in § 1.703 shall be reduced by the lesser of the number of days, if any, beginning on 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 § 1.704(c)(9) if the Office takes longer than four months to issue a

supplemental Office action or notice of allowance.

Section 1.704(c)(10) establishes submission of an amendment under § 1.312 or other paper 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. The submission of amendments (or other papers) after an application is allowed causes substantial interference with the patent issue process. See *Filing of Continuing Applications, Amendments, or Petitions after Payment of Issue Fee*, Notice, 1221 *Off. Gaz. Pat. Office* 14 (Apr. 6, 1999); and *Patents to Issue More Quickly After Issue Fee Payment*, Notice, 1220 *Off. Gaz. Pat. Office* 42 (Mar. 9, 1999). Thus, to continue to permit applicants to submit an amendment or other paper after a notice of allowance is mailed or given, the Office must establish submission of such papers as circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application. Section 1.704(c)(10) also provides that in such a case the period of adjustment set forth in § 1.703 shall be reduced by the lesser of: (1) the number of days, if any, beginning on the date the amendment under § 1.312 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 (2) four months. The phrase "lesser of * * * or [f]our months" is to provide a four-month cap for a reduction under § 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 § 1.312 or other paper.

Section 1.704(c)(11) 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 § 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. Thus, the Office is establishing 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 § 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 § 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.

As discussed above, an applicant may file a CPA under § 1.53(d) on or after May 29, 2000, for the application to be subject to the patent term adjustment provisions of 35 U.S.C. 154(b) as amended by § 4402 of the American Inventors Protection Act of 1999. The period of patent term adjustment set forth in § 1.703 (if any), however, will not include any period that is prior to the filing date of the request for that CPA.

Section 1.704(d) provides that a paper containing only an information disclosure statement in compliance with §§ 1.97 and 1.98 will not be considered (result in a reduction) under §§ 1.704(c)(6), 1.704(c)(8), 1.704(c)(9), or 1.704(c)(10) if it is accompanied by a certification that each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement. This provision will permit applicants to submit information cited in a

communication from a foreign patent office in a counterpart application to the Office without a reduction in patent term adjustment if an information disclosure statement is promptly (within thirty days of receipt of the communication) submitted to the Office. Obviously, compliance with the certification requirement of § 1.704(d) does not substitute for compliance with any relevant requirement of §§ 1.97 or 1.98. Section 1.704(d) also provides that this thirty-day period is not extendable.

Section 1.704(e) provides that submission of an application for patent term adjustment under § 1.705(b) (with or without request under § 1.705(c) for reinstatement of reduced patent term adjustment) will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under § 1.704(c)(10). Due to the time constraints on the Office under 35 U.S.C. 154(b)(1)(A)(iv) and (B) to complete its patent term adjustment determination and issue the patent, the Office must require applicants to follow the specific procedure set forth in § 1.705 for requesting reconsideration of the Office's initial patent term adjustment determination and for requesting reinstatement of patent term adjustment reduced under § 1.704(b). Thus, while submission of an application for patent term adjustment under § 1.705(b) (regardless of whether it contains a request under § 1.705(c) for reinstatement of reduced patent term adjustment) will interfere with the patent printing process, submission of the application will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under § 1.704(c)(10). Other papers concerning patent term adjustment (e.g., status letters, untimely applications for patent term adjustment, requests for reconsideration of the Office's decisions on applications for patent term adjustment, petitions under §§ 1.181, 1.182, or 1.183 concerning patent term adjustment, or miscellaneous letters concerning patent term adjustment), however, will be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under § 1.704(c)(10).

Section 1.705 implements the provisions of 35 U.S.C. 154(b)(3) and (b)(4)(B).

Section 1.705(a) indicates that the notice of allowance will include notification of any patent term adjustment under 35 U.S.C. 154(b) (35 U.S.C. 154(b)(3)(B)(i)). Since the Office now issues over 160,000 patents each year, the only practical way to make the

patent term adjustment determinations required by 35 U.S.C. 154(b)(3)(B)(i) is by a computer program that uses the information (dates of receipt and nature of applicant correspondence and of the dates of mailing and nature of Office actions or notices) recorded in the PALM system.

Section 1.705(b) provides that any request for review or reconsideration of the patent term adjustment indicated in the notice of allowance (except as provided in § 1.705(d)) and any request for reinstatement of all or part of the term reduced pursuant to § 1.704(a) must be filed no later than the payment of the issue fee but may not be filed earlier than the date of mailing of the notice of allowance. Section 1.705(b) provides that any such request must be by way of an application for patent term adjustment accompanied by the fee set forth in § 1.18(e) and a statement of the facts involved. Section 1.705(b) also provides that such statement of facts must specify: (1) The basis or bases under § 1.702 for the adjustment; (2) 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; (3) whether the patent is subject to a terminal disclaimer and any expiration date specified in the terminal disclaimer; and (4) 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 a statement that there were no such circumstances). Since the Office must complete its determination of patent term adjustment before proceeding to issue the patent (35 U.S.C. 154(b)(3)(D)), the Office must require that such application for patent term adjustment be filed within a non-extendable time period and setting forth with particularity why the Office's patent term adjustment determination is not correct. In the absence of these requirements, the issuance of the patent will be further delayed by a protracted patent term adjustment determination proceeding.

Section 1.705(c) implements the provisions of 35 U.S.C. 154(b)(3)(C). Section 1.705(c) specifically provides that a 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 mailing of the Office communication notifying the applicant of the rejection, objection, argument, or other request must include: (1) The fee

set forth in § 1.18(f); and (2) a showing to the satisfaction of the Commissioner that, in spite of all due care, the applicant was unable to reply to the rejection, objection, argument, or other request within three months of the date of mailing of the Office communication notifying the applicant of the rejection, objection, argument, or other request. Section 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)).

Since the Office is obligated to provide a determination of patent term adjustment under 35 U.S.C. 154(b) in the notice of allowance (*i.e.*, before the actual patent issue date), the Office must project (or estimate) the actual patent issue date and base its patent term adjustment determination on that projection. Thus, § 1.705(d) provides for the situation in which the patent is issued on a date other than the projected date of issue and this change necessitates a revision of the patent term adjustment indicated in the notice of allowance. Section 1.705(d) specifically provides that if the patent is issued on a date other than the projected date of issue and this change necessitates a revision of the patent term adjustment indicated in the notice of allowance, the patent will indicate the revised patent term adjustment. Section 1.705(d) also provides that if the patent indicates a revised patent term adjustment due to the patent being issued on a date other than the projected date of issue, any request for reconsideration of the patent term adjustment indicated in the patent must be filed within thirty days of the date the patent issued and must comply with the requirements of § 1.705(b)(1) and § 1.705(b)(2).

Section 1.705(e) provides that the periods set forth in this section are not extendable. As discussed above, the Office must set non-extendable time periods in § 1.705 to avoid delay in the issuance of the patent.

Section 1.705(f) 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.

Response to comments: The Office received twenty-three written comments (from Intellectual Property

Organizations, Businesses, Law Firms, Patent Practitioners, and others) in response to the notice of proposed rulemaking. Comments generally in support of a change are not discussed. The comments and the Office's responses to those comments follow:

Comment 1: One comment argued that charging a fee as set forth in § 1.18(e) to correct an Office error was unfair. In addition, several comments argued that the fee for a patent term adjustment calculation should be refundable if the Office does not calculate the term adjustment correctly.

Response: 35 U.S.C. 154(b)(3) provides for the Office to establish procedures for the application for and determination of patent term adjustment under 35 U.S.C. 154(b). The Office will provide an initial determination of the patent term adjustment in the notice of allowance. If, however, an applicant wishes to request reconsideration of the initial determination in the notice of allowance, the applicant must file an application for patent term adjustment. 35 U.S.C. 41(d) authorizes the Office to establish a fee to recover the estimated average cost of treating applications for patent term adjustment (as well as a fee for treating a request for reinstatement of patent term adjustment), and the cost of treating an application for patent term adjustment is about the same regardless of whether the Office's initial determination of patent term adjustment indicated in the notice of allowance is correct. In any event, refunding the fee under § 1.18(e) when the application for patent term adjustment is correct would: (1) Require the Office to raise the fee set forth in § 1.18(e) (to enable the Office to recover the same aggregate amount); and (2) add further complication to a review process that must take place in a limited period of time.

Comment 2: One comment argued that the fees under §§ 1.18(e) and (f) should be reduced for small entities.

Response: As discussed above, 35 U.S.C. 41(d) authorizes the Office to establish a fee to recover the estimated average cost of treating applications for patent term adjustment (as well as a fee for treating a request for reinstatement of patent term adjustment). The small entity discount in 35 U.S.C. 41(h)(1) applies only to fees charged under 35 U.S.C. 41(a) and (b). Thus, the Office has no authority to apply the small entity discount to the fees set forth in §§ 1.18(e) and (f).

Comment 3: One comment noted that the heading of § 1.701 was inconsistent with § 1.701(e), and suggested that "and before May 29, 2000" be added to the heading of § 1.701.

Response: The phrase “and before May 29, 2000” has been added to the heading of § 1.701.

Comment 4: Several comments argued that for purposes of § 1.702(a)(1), a restriction requirement or an election of species requirement should not be considered a notification under 35 U.S.C. 132. The comments stated an Office action containing only a restriction requirement or an election of species requirement should be issued only after there has been an attempt to make the restriction requirement or the election of species requirement by telephone, and that treating a restriction requirement or election of species requirement as an action under 35 U.S.C. 132 will further exacerbate a concern of applicants that a restriction requirement is not proper.

Response: The comment cannot be adopted. The Office did not “decide” to treat restriction requirements and election of species requirements as notifications under 35 U.S.C. 132; they 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 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 (under 35 U.S.C. 132) and actual rejections of claims (under 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 discussed and differentiated between rejections, objections, and requirements under 35 U.S.C. 132 in determining 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, thus making a written restriction (or election) requirement 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) (citing 35 U.S.C. 132 when noting that the terms “requirement” and “objection” are distinct from “rejection” (as used in title 35, U.S.C.) and that requirements and

objections were not appealable under 35 U.S.C. 134).

In addition, the Office has long considered (at least implicitly) a written restriction requirement containing no action on the merits to be a notice under 35 U.S.C. 132. *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).

The Office encourages examiners to make an oral restriction requirement. Many applicants, however, prefer a written restriction requirement because it gives them more time to consider the requirement.

Comment 5: One comment requested a definition of the term “original application” as used in § 1.702(f) and asked whether the term refers to a parent application or a divisional or continuation. Several comments expressed confusion as to whether term adjustment for a first-filed application would result in the same term adjustment in a continuation of that application. One comment suggested that the term “applications other than reissue applications” be used instead of “original applications.”

Response: An “original application” is any application other than a reissue application. See *Guidelines Concerning the Implementation of Changes to 35 U.S.C. 102(g) and 103(c) and the Interpretation of the Term “Original Application” in the American Inventors Protection Act of 1999*, 1233 *Off. Gaz. Pat. Office* 54 (Apr. 11, 2000). Thus, the term “original application” includes a continuing application (continuation, divisional, or continuation-in-part, whether the application is filed under § 1.53(b) or as a continued prosecution application under § 1.53(d)), and the national stage of an international application. Since a request for continued examination under 35 U.S.C. 132(b) and § 1.114 is not an application (but a submission in a previously filed application), the term “original application” does not include a request for continued examination under 35 U.S.C. 132(b) and § 1.114.

While 35 U.S.C. 154(b) does not use the term “original application,” its provisions concern the situation in which the issue of an original patent is delayed due to the failure of the Office to take certain actions in the application that issued as the patent. Patent term

adjustment events in one application may not be relied upon as giving rise to patent term adjustment in another application, even if the other application claims the benefit of the first application under 35 U.S.C. 120, 121, or 365(c) (*i.e.*, patent term adjustment events in a parent application do not carry over to a child application).

Comment 6: One comment stated that § 1.702(f) should also provide that the provisions apply to international applications in which the requirements of 35 U.S.C. 371 are met on or after May 29, 2000.

Response: The date on which an international application fulfills the requirements of 35 U.S.C. 371 is not the filing date, or even relevant to the filing date, of the international application. Section 4405 of the American Inventors Protection Act of 1999 provides that the amendments relating to patent term adjustment shall apply to any application filed on or after May 29, 2000, but does not provide that its patent term adjustment provisions apply to international applications filed before May 29, 2000, that complied with the requirements of 35 U.S.C. 371 on or after May 29, 2000.

Comment 7: As to § 1.703(a)(6), one comment requested clarification as to whether the filing of a priority document would be an “outstanding requirement” which would cause a delay in the beginning of the “four months after payment of the issue fee and all outstanding requirements were satisfied” period. The comment argued that filing of a priority document should not be considered an outstanding requirement because if the priority document is not filed the patent simply issues without the priority claim (the application is not abandoned).

Response: Section 1.55 has been amended to eliminate the need for a petition to accept a priority document filed after payment of the issue fee, as well as the need for the Office to evaluate the priority claim before a patent is granted. Therefore, 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 § 1.703(a)(6).

Comment 8: One comment objected to the exclusion from the three-year period in § 1.703(b)(1) of the period of time in which a request for continued examination under 35 U.S.C. 132(b) and § 1.114 is processed. The comment argues that filing a request for continued examination should not preclude an applicant from obtaining a term adjustment for printing delays of a patent.

Response: 35 U.S.C. 154(b)(1)(B) provides that an applicant may receive a term adjustment if the application is not issued within three years of the filing date of the application, excluding (among other things) any time consumed by continued examination requested under 35 U.S.C. 132(b). Once a request for continued examination under 35 U.S.C. 132(b) and § 1.114 is filed in an application, any further processing or examination of the application, including granting of a patent, is by virtue of the continued examination given to the application under 35 U.S.C. 132(b) and § 1.114. Nevertheless, if a request for continued examination is filed in an application, the applicant may still accrue patent term adjustment under 35 U.S.C. 154(b)(1)(A) or (C). Accordingly, if two years after the filing date of an application, a request for continued examination is filed, and three years after the filing date of the application, the issue fee is paid (and all outstanding requirements are satisfied), but the patent does not issue as a patent until four years after the application's filing date, applicant may be entitled to an eight-month term adjustment because the application did not issue within four months of payment of the issue fee. Since the request for continued examination was filed within three years of the filing date of the application, applicant cannot accrue any term adjustment under the "three-year" statutory basis (35 U.S.C. 154(b)(1)(B)), but may accrue patent term adjustment under the other bases (e.g., 35 U.S.C. 154(b)(1)(A)(iv)).

Comment 9: One comment asked whether "a final decision in favor of applicant" as used in § 1.703(e) and "a decision in the [appellate] review reversing an adverse determination of patentability" as used in 35 U.S.C. 154(b)(1)(C)(iii) is limited to successful appeals on purely statutory grounds or would also include non-statutory grounds (e.g., obviousness-type double patenting).

Response: A "final decision in favor of applicant" is understood to include any final decision of the Board of Patent Appeals and Interferences or Federal court that reverses all of the rejections of at least one claim (without subjecting the claim to a new rejection). The type of rejection (i.e., whether the rejection is based upon a statutory or judicial basis) is not relevant.

Comment 10: A number of comments objected to the provision in § 1.703(f) that the certificate of mailing date under § 1.8 will not be used for determining when applicant is considered to "respond to a notice from the Office

making any rejection, objection argument or other request." The comments included suggestions, objections, or arguments that: (1) the date set forth in the § 1.8 statement should be used as the date when applicant is considered to have responded within three months of the Office action; (2) applicants should not be compelled to hand-carry papers to the Office or to use the Express Mail service of the United States Postal Service in order to be able to meet the three-month timeliness goal or reduce a period of time in which they are considered to have "failed to engage in reasonable efforts to conclude processing or examination of an application"; (3) a certificate of mailing is now accepted for purposes of a filing date; (4) using the date of receipt rather than the date of mailing by a practitioner would require the Office to keep "separate books" of the date of mailing and date of receipt of papers; and (5) United States Postal Service delays are insignificant compared to Office mailroom delays.

Response: The suggestion is not adopted. 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 § 1.8(a). In addition, a certificate of mailing date under § 1.8 cannot be relied upon for purposes of according a filing date to a patent application. See § 1.8(a)(2)(i)(A). Rather, correspondence is considered filed in the Office on the date of its actual receipt in the Office (§ 1.6(a)) or the date it was deposited with the United States Postal Service under § 1.10 as shown by the "date-in" on the Express Mail mailing label. Nevertheless, § 1.8 will continue to be used in determining whether correspondence is timely filed and whether an extension of time and fee for an extension of time are due.

Section 1.703(f) does not compel applicants to hand-carry papers to the Office or to use the Express Mail service of the United States Postal Service to ensure that correspondence is received within three months of an Office action and avoid a reduction in any patent term adjustment. Most correspondence that can be submitted using the benefit of § 1.8 can also be submitted to the Office by facsimile transmission (§ 1.6(d)) to avoid mail delays and ensure that correspondence is received within three months of an Office action

or notice. In addition, applicants can also 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 who chose to use first-class mail at the end of the period for reply instead of a quicker means of submitting correspondence to the Office have no complaint concerning consequences of their decision on patent term adjustment.

The Office practice of using the date of receipt of papers rather than the date of mailing of papers as the filing date of the papers is well established and changing this practice would have undesirable results. For example, when a notice of appeal is filed, the filing date accorded the notice of appeal is the date of receipt of the notice of appeal in the Office, not the certificate of mailing date under § 1.8 indicated on the notice of appeal. An appeal brief must then be filed within two months of the date of receipt of the notice of appeal. See § 1.191(a) and MPEP 1206. If the suggested change to Office practice were adopted, the date on the certificate of mailing under § 1.8 would be used as the "receipt date" of the notice of appeal to determine whether applicant replied within three months of the Office action for patent term adjustment purposes, and the appeal brief would be required to be filed within two months of the date on the certificate of mailing under § 1.8 (now the "receipt date"), unless the period for reply to the Office action is later. For many applicants, this would lead to the appeal brief being required to be filed several days earlier, which would be an undesirable result.

The certificate of mailing date is not recorded in the Office's PALM system. The Office's PALM system records contain a single date: the date of receipt in the Office (as defined by § 1.6). The certificate of mailing date may be noted on the date received/mailed column of the contents of the application's file wrapper with an entry such as "1-31-00 (c.o.m. 1/26/00)." Thus, adopting the suggested change to § 1.703(f) would require the Office to keep "separate books" of the date of mailing and date of receipt of correspondence.

Finally, whether United States Postal Service delays are insignificant compared to Office mailroom delays is immaterial. The purpose of the patent term adjustment provisions of the American Inventors Protection Act of 1999 is to compensate applicants for certain administrative delays by the Office, and any delays (whether significant or insignificant) by United States Postal Service in delivering

correspondence to the Office is not a delay by the Office.

Comment 11: One comment was received objecting to the provision in § 1.703(f) as unfair because applicants were responsible for a reply within a set time from the mailing date by the Office, whereas the Office is held to a standard for reply from the filing date of papers filed by the applicant.

Response: 35 U.S.C. 154(b)(2)(C)(ii) establishes the standard of reply by applicants to within three months of the date a notice is given or mailed to applicants. In addition, 35 U.S.C. 154(b)(1)(A)(i) and (ii) measure the deadline for the Office's reply from the date an application or a reply is filed. These different standards established by Congress are considered important because they are both dates that are contained in the Office's PALM system records.

Comment 12: One comment also stated that if the certificate of mailing date was not used for establishing a date of receipt under § 1.703(f), the patent term adjustment procedure would be more difficult because applicant would not know when the paper was received by the Office.

Response: Applicants may use a postcard receipt to establish when a paper is received by the Office. Not only does a postcard receipt provide evidence of a date of receipt, but it also provides *prima facie* evidence of receipt in the Office of all items listed thereon on the date stamped by the Office. See MPEP 503. In addition, applicants may check the Office's PALM system records (which shows the date of receipt of papers) through the Patent Application Information Retrieval (PAIR) system at <http://pair.uspto.gov>.

If the date of mailing under § 1.8 were to be used for determining if applicant has replied within three months of the date of an Office action, the Office's PALM system would have to record two different dates for patent term adjustment calculation purposes. This is because the measurements of whether the Office has taken action within a set time would not run from the same date (e.g., fourteen months from the filing date of the application or four months of the date on which a reply was filed or an appeal is taken). Such a patent term adjustment calculation would be unnecessarily complex.

Comment 13: One comment stated that the reduction in § 1.703(f) for failure to reply within three months even where the Office sets a longer period is a subtle point which should be mentioned in the rules as well as being stated in any communication setting a

period for reply of longer than three months.

Response: The suggestion to expressly mention in any communication warning applicants that any reply not received within three months of an Office action may result in a reduction to any patent term adjustment, even where the Office action sets forth a longer period for reply, has been adopted. The Office is planning to modify forms used by patent examiners to include this warning.

Comment 14: One comment argued that the phrase "processing or examination" in 35 U.S.C. 154(b)(2)(C)(ii) and (iii) means the same thing as "prosecution" in 35 U.S.C. 154(b)(2)(C)(i).

Response: The Office agrees with this interpretation of 35 U.S.C. 154(b)(2)(C). Section 1.704(a) uses the term "prosecution (processing or examination)" for this reason.

Comment 15: One comment objected to § 1.704(b), arguing that foreign applicants, especially those from non-English speaking countries, need more time to reply to an Office action than United States applicants and argued that one additional month should be considered as not being a failure to engage in reasonable efforts to conclude prosecution.

Response: The language in § 1.704(b) is taken directly from 35 U.S.C. 154(b)(2)(C)(ii), wherein Congress stated that a delay in a reply beyond three months is *per se* a failure to engage in reasonable efforts. Moreover, Congress provided that if applicant makes a showing that in spite of all due care applicant was unable to reply within the three-month period, the adjustment may be reinstated. Since Congress provided that applicants must make a showing explaining that the delay was in spite of all due care for a reply beyond three months not to be a failure to engage in reasonable efforts, the Office cannot by rule provide that a reply within a longer period is not failure to engage in reasonable efforts to conclude prosecution (absent a showing explaining that the delay was in spite of all due care).

Comment 16: Another comment objected to the use of "or given" in the phrase "measuring such three-month period from the date the notice or action was mailed or given to the applicant" in § 1.704(b), and argued that § 1.2 requires all correspondence to be in writing, and allowing an oral restriction requirement to start a period for the applicant to reply would not be consistent with § 1.2. In addition, the comment argued that sometimes a message is left on an answering machine and such a message

should not be considered notice of an objection or other requirement.

Response: The phrase "measuring such three-month period from the date the notice [or action] was mailed or given to the applicant" (emphasis added) is taken almost directly from 35 U.S.C. 154(b)(2)(C)(ii). The Office is using the statutory language "mailed or given," rather than "mailed," because the Office envisions that it may one day issue (or "give") actions or notices by means other than mailing (e.g., by facsimile transmission or e-mail message over the Internet). The Office, however, does not envision that it would issue (or "give") actions or notices by non-written means (e.g., a telephone conversation). Thus, a telephone message left on an answering machine would not constitute the giving notice of an objection or other requirement.

Comment 17: One comment suggested that setting forth "strict examples" in § 1.704(c) of circumstances of when applicant has failed to engage in reasonable efforts to conclude prosecution (or processing or examination) of an application is inconsistent with the legislative intent of Congress in enacting the provisions of 35 U.S.C. 154(b)(2)(C)(iii). The comment suggested that a reduction of patent term adjustment under 35 U.S.C. 154(b)(2)(C) should occur to prevent only "the few applicants who engage in intentional or unjustifiable delay tactics" from abusing the system, such that "only the most egregious and obvious delay tactics will go unrewarded," citing to H.R. Rep. No. 105-39 at 66 (1997). The comment suggested that the regulations are so strict as to require the applicant to be a "perfect" applicant rather than a "diligent" or "reasonable" applicant. The comment suggested that the Office should instead review each application on a case-by-case basis to determine a reduction of patent term adjustment is warranted due to the applicant's failure to engage in reasonable efforts to conclude prosecution (or processing or examination) of an application.

Response: 35 U.S.C. 154(b)(2)(C) provides that: (1) The Office is 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 (35 U.S.C. 154(b)(2)(C)(iii)); and (2) 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 of an application (35 U.S.C.

154(b)(2)(C)(i)). Thus, promulgating regulations that set forth "strict examples" of circumstances of when applicant has failed to engage in reasonable efforts to conclude prosecution (or processing or examination) of an application (rather than considering applications on an *ad hoc* or case-by-case basis) is not only consistent with 35 U.S.C. 154(b)(2)(C), it is what the Office is required to do under 35 U.S.C. 154(b)(2)(C)(iii).

The cited House Report (H.R. Rep. No. 105-39) is of questionable reliability in interpreting the patent term adjustment provisions of the American Inventors Protection Act of 1999 concerning the Office's authority 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 (35 U.S.C. 154(b)(2)(C)(iii)). H.R. Rep. No. 105-39 is the Committee Report for the 21st Century Patent System Improvement Act, H.R. 400, 105th Cong., (1997), which was passed by the House of Representatives on April 23, 1997, but was not enacted into law.

The American Inventors Protection Act of 1999 is title IV of the Intellectual Property and Communications Omnibus Reform Act of 1999 (S. 1948), and S. 1948 was incorporated and enacted into law as part of Pub. L. 106-113. The Conference Report for H.R. 3194, 106th Cong., 1st Sess. (1999), which resulted in Pub. L. 106-113, does not contain any discussion (other than the incorporated language) of S. 1948. See H.R. Conf. Rep. No. 106-497, at 37 and 1089-174 (1999). A section-by-section analysis of S. 1948, however, was printed in the Congressional Record at the request of Senator Lott. See 145 Cong. Rec. S14,708-26 (1999) (daily ed. Nov. 17, 1999). This section-by-section analysis of the patent term adjustment provisions of the American Inventors Protection Act of 1999 provides, in relevant part, that:

Subtitle D amends the provisions in the Patent Act that compensate patent applicants for certain reductions in patent term that are not the fault of the applicant. The provisions that were initially included in the term adjustment provisions of patent bills in the 105th Congress only provided adjustments for up to 10 years for secrecy orders, interferences, and successful appeals. Not only are these adjustments too short in some cases, but no adjustments were provided for administrative delays caused by the [Office] that were beyond the control of the applicant. Accordingly, subtitle D removes the 10 year caps from the existing provisions, adds a new provision to compensate applicants fully for [Office]-caused administrative delays, and, for good measure, includes a new provision

guaranteeing diligent applicants at least a 17-year term by extending the term of any patent not granted within three years of filing. Thus, no patent applicant diligently seeking to obtain a patent will receive a term of less than the 17 years as provided under the pre-GATT standard; in fact, most will receive considerably more. Only those who purposely manipulate the system to delay the issuance of their patents will be penalized under subtitle D, a result that the Conferees believe entirely appropriate.

* * * * *

Section 4402 amends [35 U.S.C.] 154(b) of the Patent Act covering term.

First, new [35 U.S.C.] 154(b)(1)(A)(i)-(iv) guarantees day-for-day restoration of term lost as a result of delay created by the [Office] when the [Office] fails to:

(1) Make a notification of the rejection of any claim for a patent or any objection or argument under [35 U.S.C.] 132, or give or mail a written notice of allowance under [35 U.S.C.] 151, within 14 months after the date on which a non-provisional application was actually filed in the [Office];

(2) Respond to a reply under [35 U.S.C.] 132, or to an appeal taken under [35 U.S.C.] 134, within four months after the date on which the reply was filed or the appeal was taken;

(3) Act on an application within four months after the date of a decision by the Board of Patent Appeals and Interferences under [35 U.S.C.] 134 or 135 or a decision by a Federal court under [35 U.S.C.] 141, 145, or 146 in a case in which allowable claims remain in the application; or

(4) 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.

Further, subject to certain limitations, *infra*, [35 U.S.C.] 154(b)(1)(B) guarantees a total application pendency of no more than three years. Specifically, day-for-day restoration of term is granted if the [Office] has not issued a patent within three years after "the actual date of the application in the United States." This language was intentionally selected to exclude the filing date of an application under the Patent Cooperation Treaty (PCT). Otherwise, an applicant could obtain up to a 30-month extension of a U.S. patent merely by filing under PCT, rather than directly in the [Office], gaining an unfair advantage in contrast to strictly domestic applicants. Any periods of time—

(1) Consumed in the continued examination of the application under [35 U.S.C.] 132(b);

(2) Lost due to an interference under [35 U.S.C.] 135(a), a secrecy order under [35 U.S.C.] 181, or appellate review by the Board of Patent Appeals and Interferences or by a Federal court (irrespective of the outcome); and

(3) Incurred at the request of an applicant in excess of the three months to respond to a notice from the Office permitted by [35 U.S.C.] 154(b)(2)(C)(ii) unless excused by a showing by the applicant under [35 U.S.C.] 154(b)(3)(C) that in spite of all due care the applicant could not respond within three months shall not be considered a delay by

the [Office] and shall not be counted for purposes of determining whether the patent issued within three years from the actual filing date.

Day-for-day restoration is also granted under new [35 U.S.C.] 154(b)(1)(C) for delays resulting from interferences, secrecy orders, and appeals by the Board of Patent Appeals and Interferences or a Federal court in which a patent was issued as a result of a decision reversing an adverse determination of patentability.

Section 4402 imposes limitations on restoration of term. In general, pursuant to [35 U.S.C.] 154(b)(2)(A)-(C), total adjustments granted for restorations under [35 U.S.C. 154](b)(1) are reduced as follows:

(1) To the extent that there are multiple grounds for extending the term of a patent that may exist simultaneously (*e.g.*, delay due to a secrecy order under [35 U.S.C.] 181 and administrative delay under [35 U.S.C.] 154(b)(1)(A)), the term should not be extended for each ground of delay but only for the actual number of days that the issuance of a patent was delayed;

(2) The term of any patent which has been disclaimed beyond a date certain may not receive an adjustment beyond the expiration date specified in the disclaimer; and

(3) Adjustments shall be reduced by a period equal to the time in which the applicant failed to engage in reasonable efforts to conclude prosecution of the application, based on regulations developed by the Director, and an applicant shall be deemed to have failed to engage in such reasonable efforts for any periods of time in excess of three months that are taken to respond to a notice from the Office making any rejection or other request;

New [35 U.S.C.] 154(b)(3) sets forth the procedures for the adjustment of patent terms. [35 U.S.C. 154(b)](3)(A) empowers the Director to establish regulations by which term extensions are determined and contested. Paragraph (3)(B) requires the Director to send a notice of any determination with the notice of allowance and to give the applicant one opportunity to request reconsideration of the determination. Paragraph (3)(C) requires the Director to reinstate any time the applicant takes to respond to a notice from the Office in excess of three months that was deducted from any patent term extension that would otherwise have been granted if the applicant can show that he or she was, in spite of all due care, unable to respond within three months. In no case shall more than an additional three months be reinstated for each response. Paragraph (3)(D) requires the Director to grant the patent after completion of determining any patent term extension irrespective of whether the applicant appeals.

New [35 U.S.C.] 154(b)(4) regulates appeals of term adjustment determinations made by the Director. Paragraph (4)(A) requires a dissatisfied applicant to seek remedy in the District Court for the District of Columbia under the Administrative Procedures Act within 180 days after the grant of the patent. The Director shall alter the term of the patent to reflect any final judgment. Paragraph (4)(B) precludes a third party from challenging the determination of a patent term prior to patent grant.

See 145 Cong. Rec. S14,718 (footnotes omitted).

In addition, since the patent term adjustment provisions of the American Inventors Protection Act of 1999 contained in Pub. L. 106-113 are identical to the patent term adjustment provisions in title IV of the Intellectual Property and Communications Omnibus Reform Act of 1999 (H.R. 1554), the joint statement in the Conference Report for H.R. 1554 may also be useful in interpreting the patent term adjustment provisions of the American Inventors Protection Act of 1999. The joint statement in the Conference Report for H.R. 1554 contains an identical discussion of its patent term adjustment provisions. See H.R. Conf. Rep. No. 106-464, at 125-27 (1999).

The language relied upon for the position that the provisions of § 1.704(c) (establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application) are inconsistent with the legislative intent of Congress in enacting the provisions of 35 U.S.C. 154(b)(2)(C)(iii) is not included in either the section-by-section analysis of S. 1948 by Senator Lott or the Conference Report for H.R. 1554 (H.R. Conf. Rep. No. 106-464). In addition, while H.R. 400 is one of the forerunners of the patent term adjustment provisions enacted into law in the American Inventors Protection Act of 1999, the provision concerning the establishment of circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application contained in the American Inventors Protection Act of 1999 is not the same as the corresponding provision in H.R. 400.

In any event, the provisions of § 1.704(c) do not require an applicant to be "perfect" or even "diligent" when prosecuting an application to avoid a reduction of patent term adjustment; § 1.704(c) simply 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)).

That conduct (an action or inaction) has been established in § 1.704 as circumstances constituting a failure of

an applicant to engage in reasonable efforts to conclude processing or examination of an application should not be taken as an indication that such conduct is unreasonable *per se*. If Congress considered taking longer than three months to reply to an Office action or notice to be unreasonable *per se*, Congress would simply have amended title 35, U.S.C., to provide a statutory period of three months to reply to all Office actions or notices. The patent statute (and specifically the fee extension provisions of 35 U.S.C. 41(a)(8)), however, permits applicants to take longer than three months to reply to an Office action or notice even in the absence of showing that, in spite of all due care, the applicant was unable to reply within a three-month period. Nevertheless, 35 U.S.C. 154(b)(2)(C)(ii) provides that 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. Thus, Congress concluded that there is conduct during the prosecution of an application that is not unreasonable *per se*, but which is a failure to engage in reasonable efforts to conclude processing or examination of an application. Conversely, that conduct is permitted by the patent statute and rules of practice does not imply that such conduct is not a failure to engage in reasonable efforts to conclude processing or examination of an application.

Comment 18: One comment objected to § 1.704(c) as being overly broad and not being limited to the situations where applicant's actions or inactions have hindered the Office's ability to process or examine the application. Several other comments argued that § 1.704(c) sets off an applicant delay against unrelated Office delays (*e.g.*, one comment noted that if in an application the Office does not issue a first Office action until fifteen months after the application's filing date and later applicant files a notice of appeal followed by an appeal brief two months later, and an examiner's answer is mailed two months after the appeal brief is filed, the applicant would receive no term adjustment, and argued that there was "no logical reason" for such a setoff). Another comment argued that the result is that applicants are penalized twice for actions which are characterized as a failure to engage in reasonable efforts to conclude prosecution: once because their patent

issues later than it would have had the applicant not delayed and a second time because they receive a lesser term adjustment than they would have without their delay.

Response: Section 1.704 as adopted (*i.e.*, not adopting proposed §§ 1.704(c)(6), 1.704(c)(7), 1.704(c)(8), 1.704(c)(9), and 1.704(c)(13)) will result in fewer situations in which patent term adjustment is reduced by an action or inaction that did not cause or contribute to the patent term adjustment.

Nevertheless, 35 U.S.C. 154(b) 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 of the application." See 35 U.S.C. 154(b)(2)(C)(i). 35 U.S.C. 154(b)(1)(C)(i) 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, it is appropriate to reduce patent term adjustment 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.

Comment 19: One comment objected to § 1.704(c) not being limited to the proposed sixteen enumerated events that would result in reduction in term adjustment, but being also applicable to situations where an applicant acts in a manner which would delay the conclusion of prosecution (arguing, *e.g.*, that an applicant should not have to accept a "picture claim" or face a reduction to any term adjustment). In addition, the comment stated that it is unclear what petitions the Office considers meritless since the Office does not publish petition decisions.

Response: The Office anticipates that some applicants will seek out ways to manipulate the system to their advantage no matter how exhaustive a listing of circumstances the Office were to set forth in § 1.704(c). Thus, the Office must provide that the enumerated circumstances in § 1.704(c) are

exemplary (and not exhaustive) to avoid always being one step behind such applicants.

As discussed above, the Office plans to calculate patent term adjustment with a computer program that uses the PALM system records of the dates of receipt and nature of applicant correspondence and of the dates of mailing and nature of Office actions or notices. This automated approach will not lend itself to basing a reduction of patent term adjustment on circumstances not enumerated in § 1.704(c) except in the most peculiar situations (*e.g.*, unsuccessfully seeking reconsideration or judicial review of a petition decision designated as final agency action). Finally, while the Office does not submit petition decisions for publication in the United States Patent Quarterly as a matter of course, the Office does post a variety of petition decisions on its Internet Web site (on the FOIA Web page, FOIA Reading Room (<http://www.uspto.gov/web/offices/com/sol/foia/readroom.htm>), Final Decisions of the Office of the Commissioner).

Comment 20: One comment argued that the reduction in § 1.704(c)(1) being equal to the time between the date a request for suspension of action under § 1.103 was filed and ending on the date the suspension was terminated should only be applied against any period where an adjustment is caused (*e.g.*, against the three-year period).

Response: As discussed above, 35 U.S.C. 154(b)(2)(C)(i) provides that the Office shall reduce any term adjustment by the period of time in which applicant has failed to engage in reasonable efforts to conclude prosecution, regardless of whether the applicant's actions or inactions caused or contributed to patent term adjustment.

Comment 21: One comment stated that making the period of reduction in § 1.704(c)(2) equal to the time between the date a request for deferral from issuance is filed to the date of issue of the patent was unfair because it includes the time in which the patent is printed. Another comment argued that the period should only be used to reduce a period of adjustment under § 1.703(a)(6) and (b) (failure to issue a patent within four months of the issue fee and compliance with all formal requirements, and failure to issue a patent within three years of the filing date of the application).

Response: An applicant can avoid any reduction of patent term adjustment under § 1.703(c)(2) by refraining from requesting that the Office suspend or defer action in the application. An applicant who affirmatively seeks a

deferral of action by the Office should not complain that such a request has resulted in a reduction of any patent term adjustment due to administrative delays by the Office.

Comment 22: One comment stated that the proposal to make the period of reduction in § 1.704(c)(3) run from the date of abandonment to the date a favorable decision is mailed was unfair. The comment suggested that the applicant should not be charged with periods beyond four months from the date a petition is filed (as provided in proposed § 1.704(c)(15)).

Response: The suggestion is adopted to the extent described below. In many applications, the first-filed petitions to revive an application or to accept late payment is not grantable and further evidence, a terminal disclaimer or a fee is required before it can be granted. The Office of Petitions may call the applicant and request the necessary item, have the applicant send it by facsimile transmission, and then grant the petition on the same day. Section 1.704(c)(3) has been revised to state that the period of reduction will be 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: (1) the date of mailing of the decision reviving the application or accepting late payment of the issue fee § 1.703; 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.

Comment 23: One comment argued that the periods of reduction in § 1.704(c)(3) and (c)(4) should be combined and that the period should be reinstated if the abandonment was not the fault of applicant. Another comment argued that a reduction should apply only if the abandonment was unintentional (not unavoidable).

Response: The suggestions are not adopted. The provisions of § 1.704(c)(3) relate to situations in which the application was in fact abandoned, but the abandonment was either unavoidable or unintentional (permitting revival of the application). If an application is not properly held abandoned (is not in fact abandoned), the applicant should not petition to revive under § 1.137, but should petition to have the (improper) holding of abandonment withdrawn. The provisions of § 1.704(c)(4) relate to where the holding of abandonment is withdrawn because applicant has shown, for example, that the application became abandoned because the Office mailed a communication to the incorrect address, or applicant did not

receive the communication. When a petition to withdraw the holding of abandonment is granted, the application is treated as never having been abandoned, but where an application is revived the period in which the application was abandoned is a failure to engage in reasonable efforts to conclude prosecution. Since the two concepts are different, they have been separated into separate paragraphs of § 1.704.

Section 1.704(c)(3) applies regardless of whether the abandonment was unavoidable or just unintentional (but not unavoidable). The abandonment of an application as a result of actions or inactions within the control of applicant (and outside the control of the Office) does not preclude a finding of unavoidable delay. *See, e.g., In re Lonardo*, 17 USPQ2d 1455 (Comm'r Pat. 1990)(delay caused by deception of applicant by applicant's representative); *Ex parte Pratt*, 1887 Dec. Comm'r Pat. 31 (1887)(delay caused by error by representative's clerical staff); *In re Katrapat, A.G.*, 6 USPQ2d 1863 (Comm'r Pat. 1988)(same). Such action, however, is still considered a failure to engage in reasonable efforts to conclude prosecution of the application.

Comment 24: Another comment argued that the reduction in § 1.704(c)(4) was unfair because it will generate a need for applicant to file a petition under § 1.705.

Response: The Office is mindful that 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. As discussed above, applicants may check the Office's PALM system records for their applications through PAIR at <http://pair.uspto.gov> (and are encouraged to do so). For example, if applicant shows 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. An applicant who receives a Notice of Abandonment and does not request that the holding be withdrawn within two months of the mailing date of the notice, however, is considered to have failed to engage in reasonable efforts to conclude prosecution and it is appropriate to use this period under § 1.704(c)(3) as a reduction.

Comment 25: One comment generally agreed with § 1.704(c)(4), but objected to a "blameless applicant" who never received a Notice of Abandonment experiencing a reduction in term

adjustment because they did not reply to the Notice within two months.

Response: The Office currently issues over 160,000 patents each year. The only practical way to perform the calculations required by the patent term adjustment provisions of 35 U.S.C. 154 (and its implementation regulations) is by a program using the information contained in the PALM system. If the patent term adjustment were to be manually calculated for each application, the time required for the term adjustment calculation could exceed the time required to otherwise process the application. In order to minimize the cost of the patent term adjustment determination and conserve resources for examination of the application (e.g., the prior art search and a decision of whether the claims are patentable), it is imperative that as much of the computation be done using the Office's automated information systems. The computer program must rely upon the information in the Office's PALM system records for the dates of receipt of applicant correspondence and the dates of mailing of Office actions or notices and of the nature of such applicant correspondence and Office actions or notices. As discussed above, applicants may check the Office's PALM system records for their applications through the PAIR system at <http://pair.uspto.gov> (and are encouraged to do so).

Comment 26: Two comments argued that in § 1.704(c)(5), the reduction for conversion of a provisional application to a non-provisional application should only offset periods of adjustment in § 1.703(a)(1) and (b) (the fourteen-month and three-year provisions).

Response: 35 U.S.C. 154(b)(2)(C)(i) provides 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 of the application." In any event, requesting conversion of a provisional application into a nonprovisional application is a poor choice for any applicant interested in maximizing patent term. See *Changes to Application Examination and Provisional Application Practice*, Interim Rule, 65 FR 14865, 14866 (Mar. 20, 2000), 1233 *Off. Gaz. Pat. Office* 47, 47 (Apr. 11, 2000). In addition, converting a provisional application into a nonprovisional application (rather than simply processing a nonprovisional application that claims the benefit of the provisional application's filing date) requires exception processing by the Office. As discussed above, applicants who prosecute applications in a manner that

requires exception handling by the Office have no complaint concerning the negative patent term impacts that result from their poor choices.

Comment 27: Several comments argued that the provisions of § 1.704(c)(6) reducing patent term adjustment for all the time taken by an applicant to complete the requirements of a patent application were an unfair penalty. The comments argued that there should be a relationship between the reduction and an adjustment, that the Office should be able to demonstrate that the actions of the applicant resulted in delays in examination of that application, and that it was not unreasonable to file an application as soon as possible and to file an executed oath or declaration, formal drawings or a translation of the application at a later date. Another comment argued that the provisions of § 1.704(c)(6) penalized an applicant for the Office's delay in assigning an application number. Another comment argued that it is better for the Office for the applicant to wait until a Notice to File Missing Parts of Application is received than for the applicant to file the missing parts after filing the application and without a copy of a Notice to File Missing Parts of Application, and that the reduction should be measured from the mailing date of the notice.

Response: The Office has revised § 1.704 to eliminate proposed § 1.704(c)(6), such that missing parts (missing filing fee, oath or declaration, and missing English language translation of a non-English language application) and application formalities (specification on papers in compliance with § 1.52, title and abstract in compliance with § 1.72, drawings in compliance with § 1.84, and sequence listings in compliance with § 1.821 *et seq.*) are treated under § 1.704(b). Thus, any patent term adjustment will be reduced if an applicant does not supply the missing part or correct the informality within three months of the Office action or notice requiring the missing part or correction of the informality.

Comment 28: One comment argued that 35 U.S.C. 154(b)(2)(C)(ii) provides that a reply filed within three months of the date of an Office action or notice setting forth a requirement should not result in any patent term adjustment penalty. The comment also argued that since the eighteen-month publication rules permit a redacted application to be filed up to sixteen months from the priority date, the requirement for papers to be filed for purposes any earlier than this date was not justified. Another comment argued that the provisions of

proposed § 1.704(c)(6) were too strict and that applicants should be given three months to complete formal requirements after receiving notice of the necessary formal requirements. The comment argues that a period of three months after the Office makes any rejection, objection or other request should be considered *prima facie* reasonable. Another comment argued that the period in which an applicant is considered to have "failed to engage in reasonable efforts" should begin with the date on which applicant is given notice of the defect.

Response: While the Office has revised § 1.704 such that missing parts and application formalities are treated under § 1.704(b) (as discussed above), this revision to § 1.704 is not required by the provisions of 35 U.S.C. 154(b)(2)(C). Since 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, 35 U.S.C. 154(b)(2)(C)(ii) cannot be considered exhaustive of the circumstances for which an applicant may be determined to have failed to engage in reasonable efforts to conclude processing or examination of an application. If the Office determines that treating missing parts and application formalities under § 1.704(b) is causing the Office to miss the time periods set forth in 35 U.S.C. 154(b)(1), the Office will need to reconsider its original proposal to treat missing parts and application formalities as a failure to engage in reasonable efforts to conclude processing or examination without regard to whether the applicant has been given a prior reminder or notice to supply the missing part or correct the informality.

As to the provisions for a redacted application to be filed up to sixteen months from the earliest priority date or filing date of the application, these provisions are not relevant to whether filing components of an application after the filing date of the application is a failure to engage in reasonable efforts to conclude processing or examination of an application. The timing of when a redacted application is filed is irrelevant to the prosecution of an application because the filing of a redacted copy of an application is completely unrelated to prosecution of the application.

Comment 29: One comment suggested that the missing parts practice in the Office of Initial Patent Examination (OIPE) be expanded to include examination of components required for

eighteen-month publication so as to minimize any term adjustment reductions.

Response: The Office plans to modify the review in OIPE to include items necessary for publication of applications.

Comment 30: Another comment argued that proposed § 1.704(c)(6) was in conflict with the diligence requirements of § 1.47 and frustrates a fundamental objective of patent law (*i.e.*, encouraging an applicant to file a patent application as soon as possible). The comment argues that because inventorship is not determined until the claims are finalized and because of the requirement for diligence under § 1.47, it is not possible to file a petition under § 1.47 for months after an application is filed.

Response: As discussed above, the Office has revised § 1.704 to eliminate proposed § 1.704(c)(6), such that missing parts (missing filing fee, oath or declaration, and missing English language translation) are treated under § 1.704(b), in that any patent term adjustment will be reduced if an applicant does not supply a missing filing fee, oath or declaration, or English-language translation within three months of the Office notice requiring the filing fee, oath or declaration, or English-language translation.

In the event that one or all of the inventors refuse to execute the oath or declaration, the Office cannot process the application for publication or examine the application until the party filing the application on behalf of the inventor(s) establishes that he or she is the appropriate applicant and that the requirements of 35 U.S.C. 116 and 118 have been met. Thus, if one or all of the inventors refuse to execute the oath or declaration, a grantable petition under § 1.47 must be filed within three months of the Office notice requiring an executed oath or declaration (*e.g.*, a Notice to File Missing Parts of Application (PTO-1533)) to avoid a reduction of any patent term adjustment under § 1.704(b). While the patent law does encourage the filing of a patent application as soon as possible (*e.g.*, to avoid a bar under 35 U.S.C. 102(b)), § 1.47 (35 U.S.C. 116 and 118) was not intended to give applicants a longer time to prepare an application for filing. *See Ex parte Sassin*, 1906 Dec. Comm'r Pat 205, 206 (1906).

Comment 31: Several comments argued that the provisions of proposed § 1.704(c)(7) unfairly discriminated against PCT applicants and ignored the legislative history of the Act. These comments suggested that the Office

should define, for purposes of patent term adjustment, the "actual filing date" as the date that all requirements for entry into the national stage are met. Another comment argued that the provisions of proposed § 1.704(c)(7) and (c)(8) undermine the benefits provided by the international phase procedure under the PCT. This comment also: (1) suggested that any period of patent term adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B) be reduced by the number of days (if any) beginning on the date on which the national phase commences under 35 U.S.C. 371(b) or (f) and ending on the day the applicant completes the requirements for entry into the national phase; (2) observed that events that occur in the international phase advance prosecution because formalities are resolved, a search is conducted, and preliminary examination is begun; (3) argued that proposed § 1.704(c)(7) will force applicants to forgo their entitlements under the treaty or risk a reduction in a term adjustment, and that applicants under the PCT will be in a worse position than regular national applicants; and (4) noted that someone who files a "bypass" application (an application under 35 U.S.C. 111 claiming the benefit of the international application under 35 U.S.C. 120) instead of entering the national phase under 35 U.S.C. 371 will not have the international phase used as a reduction to any term adjustment. The comments also argued that the provisions of proposed § 1.704(c)(8) were unfair for the same reasons as stated for proposed § 1.704(c)(7). Finally, several comments requested clarification of, or made suggestions, for the language of proposed § 1.704(c)(7) and proposed § 1.704(c)(8).

Response: The Office is interpreting the phrase "actual filing date of the application in the United States" in 35 U.S.C. 154(b)(1)(B) to mean the date the national stage commenced under 35 U.S.C. 371(b) or (f) in the case of an international application. The Office originally interpreted the phrase "actual filing date of the application in the United States" in 35 U.S.C. 154(b)(1)(B) to mean the international filing date of the application under PCT Article 11(3) and 35 U.S.C. 363 in the case of an international application. *See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term*, 65 FR at 17220, 1233 *Off. Gaz. Pat. Office* at 113. Further consideration of this position, however, leads to the conclusion that: (1) the interpretation of the phrase "actual filing date of the application in the United States" in 35

U.S.C. 154(b)(1)(B) to be the filing date of the international application under PCT Article 11(3) and 35 U.S.C. 363 in the case of an international application is inconsistent with the legislative history of 35 U.S.C. 154(b)(1)(B) and is incongruous with the provisions of 35 U.S.C. 154(b)(1)(A)(i)(II) and (B)(iii); and (2) the phrase "actual filing date of the application in the United States" in 35 U.S.C. 154(b)(1)(B) must mean the date the national stage commenced under 35 U.S.C. 371(b) or (f) in the case of an international application.

Without resort to guides to interpretation (*e.g.*, legislative history, other provisions of title 35, U.S.C., or the PCT), the phrase "actual filing date of the application in the United States" appears to mean that the three-year period specified in 35 U.S.C. 154(b)(1)(B) is measured from the date the application is actually filed (*i.e.*, physically received) in the United States Patent and Trademark Office. That is, the phrase "actual filing date of the application in the United States" appears to mean the date that the application itself is physically received in the United States Patent and Trademark Office, regardless of whether it is an application filed under 35 U.S.C. 111(a) or an international application filed under PCT Article 11.

As discussed above, the American Inventors Protection Act of 1999 was enacted into law as part of Pub. L. 106-113. The Conference Report for H.R. 3194 (which resulted in Pub. L. 106-113) does not contain any discussion (other than the incorporated language) of the American Inventors Protection Act of 1999 (title IV of S. 1948). *See H.R. Conf. Rep. No. 106-497*, at 37 and 1089-174 (1999). A section-by-section analysis of S. 1948, however, was printed in the Congressional Record at the request of Senator Lott. *See 145 Cong. Rec. S14,708-26* (1999)(daily ed. Nov. 17, 1999). The section-by-section analysis explained that:

day-for-day restoration of term is granted if the [Office] has not issued a patent within three years after "the actual date of the application in the United States." This language was intentionally selected to exclude the filing date of an application under the Patent Cooperation Treaty (PCT). Otherwise, an applicant could obtain up to a 30-month extension of a U.S. patent merely by filing under PCT, rather than directly in the [Office], gaining an unfair advantage in contrast to strictly domestic applicants.

See 145 Cong. Rec. at S14,718.

The legislative history of 35 U.S.C. 154(b)(1)(B) is clear that the phrase "actual filing date of the application in the United States" in 35 U.S.C. 154(b)(1)(B) does not mean (but was

intentionally selected to exclude) the date on which the international application was filed under the PCT. The interpretation of the phrase "actual filing date of the application in the United States" in 35 U.S.C. 154(b)(1)(B) as meaning the filing date of the application under the PCT (PCT Article 11(3)) would defeat the plain intent of Congress to "exclude the filing date of an application under the [PCT]" and would permit (rather than avoid) the use of the PCT to give an applicant an advantage in obtaining a longer patent term adjustment compared to a similarly processed and examined application filed under 35 U.S.C. 111(a). Therefore, the interpretation of the phrase "actual filing date of the application in the United States" in 35 U.S.C. 154(b)(1)(B) as not meaning the filing date of the application under the PCT (PCT Article 11(3)) is consistent with the legislative history of 35 U.S.C. 154(b)(1)(B).

In addition, the interpretation of the phrase "actual filing date of the application in the United States" in 35 U.S.C. 154(b)(1)(B) as meaning the filing date of the application under the PCT is incongruous with the provision in 35 U.S.C. 154(b)(1)(B)(iii). 35 U.S.C. 154(b)(1)(B) provides that if the pendency of an application is more than three years from the actual filing date of the application, the term of the patent issuing from the application shall be extended one day for each day after the end of the three-year period, but that certain time periods are excluded from the three-year period. 35 U.S.C. 154(b)(1)(B)(iii) specifically provides that time consumed by delays in the processing of the application by the Office requested by applicant are excluded from this three-year period. The interpretation of the phrase "actual filing date of the application in the United States" in 35 U.S.C. 154(b)(1)(B) as meaning the "international filing date" under PCT Article 11(3) leads to the result that an applicant is able to obtain a delay in paying fees and filing papers and in the processing of the application by using the PCT (*MPEP* 1893), and obtain term adjustment based upon the three-year period being measured from the international filing date (*i.e.*, without the delay being excluded from the three-year period as with other applicant-elected delays). This result is incongruous with the provisions in 35 U.S.C. 154(b)(1)(B)(iii) that time consumed by delays in the processing of the application by the Office requested by applicant are excluded from this three-year period.

The interpretation of the phrase "actual filing date of the application in the United States" in 35 U.S.C.

154(b)(1)(B) as meaning the filing date of the application under the PCT is also incongruous with the provision in 35 U.S.C. 154(b)(1)(A)(i)(II) where a date later than the filing date of the application under the PCT is used. Each of 35 U.S.C. 154(b)(1)(A)(i) and 154(b)(1)(B) provide that an applicant may be entitled to patent term adjustment if the Office fails to take certain action within a specified time period: (1) provide at least one of an Office action under 35 U.S.C. 132 or notice of allowance under 35 U.S.C. 151 within fourteen months (35 U.S.C. 154(b)(1)(A)(i)); or (2) issue a patent within three years (35 U.S.C. 154(b)(1)(B)). For applications filed under 35 U.S.C. 111(a), the fourteen-month period begins with the filing date of the application (35 U.S.C. 154(b)(1)(A)(i)(I)), but for applications that enter the national stage under 35 U.S.C. 371, the fourteen-month period begins with the date on which the international application fulfilled the requirements of 35 U.S.C. 371 (35 U.S.C. 154(b)(1)(A)(i)(II)), which can be more than thirty months after the international filing date of the application.

As discussed above, Congress recognized that national processing of an international application is delayed by up to thirty months under the PCT filing system. Interpreting the phrase "actual filing date of the application in the United States" in 35 U.S.C. 154(b)(1)(B) as meaning the filing date of the application under the PCT would require the conclusion that Congress considered the Office's failure to issue a patent within thirty-six months of the filing date of an international application under 35 U.S.C. 363 to constitute an unusual administrative delay (35 U.S.C. 154(b)(1)(B)), but did not consider the Office's failure to initially act on the application to be an unusual administrative delay unless the Office did not issue either an Office action under 35 U.S.C. 132 or notice of allowance under 35 U.S.C. 151 within forty-four (thirty plus fourteen) months of the filing date of an international application under 35 U.S.C. 363 (35 U.S.C. 154(b)(1)(A)(i)(II)). 35 U.S.C. 131 and 151, however, require the Office to examine an application and issue a notice of allowance under 35 U.S.C. 151 before issuing a patent on the application. Thus, the interpretation of the "actual filing date of the application in the United States" to mean the filing date under 35 U.S.C. 363 requires the conclusion that Congress intended an odd if not absurd result: that the Office is expected to be able to issue a patent

quicker (within thirty-six months of the filing date under 35 U.S.C. 363) than it is expected to be able to initially act on the application (within forty-four months of the filing date under 35 U.S.C. 363).

The legislative history of 35 U.S.C. 154(b)(1)(B) specifically indicates that Congress wanted to avoid the situation in which an applicant could gain an extension of "up to" thirty months merely by filing the application under the PCT system. *See* 145 Cong. Rec. at S14,718 ([o]therwise, an applicant could obtain up to a 30-month extension of a U.S. patent merely by filing under PCT, rather than directly in the [Office], gaining an unfair advantage in contrast to strictly domestic applicants). While 35 U.S.C. 154(b)(1)(A)(i)(II) ties its fourteen-month period to fulfillment of the requirements of 35 U.S.C. 371 in the case of an international application, the PCT and 35 U.S.C. 371 permit applicants to delay fulfillment of the requirements of 35 U.S.C. 371 beyond thirty months (rather than "up to" thirty months). The PCT (PCT Article 39(1)(a)), however, allows an applicant to obtain a delay of up to thirty months in commencement of the national stage (35 U.S.C. 371(b)) by the timely filing of a demand for international preliminary examination. Therefore, the legislative history of 35 U.S.C. 154(b)(1)(B) indicates that the phrase "actual filing date of the application in the United States" as used in 35 U.S.C. 154(b)(1)(B) means the date the national stage commenced under 35 U.S.C. 371(b) or (f) in the case of an international application.

In addition, while the international phase of an international application is not entirely devoid of activity, the Office does not (and cannot) begin examination of the application as provided for in 35 U.S.C. 131 and 132 until after it has entered that national stage of processing under 35 U.S.C. 371(b) or (f). *See* PCT Articles 23 and 40. Therefore, it is consistent with the legislative history of 35 U.S.C. 154(b) to not take the period prior to commencement of the national stage into account in determining whether the Office is meeting any of the time frames for examination of the application provided for in 35 U.S.C. 154(b)(1).

35 U.S.C. 363 does provide, in relevant part, that "[a]n international application designating the United States shall have the effect, from its international filing date under [PCT Article 11], of a national application for patent regularly filed in the [Office]." The legislative history of 35 U.S.C. 363 indicates that an international application designating the United

States, regardless of whether it was filed in this or any other contracting country, has the effect, from its international filing date, of a regular national application for patent filed in the United States Patent and Trademark Office, and that the international filing date of an international application would be considered as the actual filing date in the United States Patent and Trademark Office (except as provided in 35 U.S.C. 102(e)). See H.R. Rep. No. 94-592, at 9 (1975), reprinted in 1975 U.S.C.C.A.N. 1220, 1228. Nevertheless, the phrase "shall have the effect" of having an earlier filing date (the international filing date) as used in the patent statute does not necessarily mean that the actual filing date of the application is the earlier filing date (the international filing date). See *In re Hilmer*, 359 F.2d 859, 149 USPQ 480 (CCPA 1966) (discusses distinction in the patent statute between an actual filing date having the same effect of such a filing date).

In addition, PCT Article 11(3) provides, in relevant part, that "any international application fulfilling the requirements listed in [PCT Article 11(1)(i) through (iii)] and accorded an international filing date shall have the effect of a regular national application in each designated State as of the international filing date, which date shall be considered to be the actual filing date in each designated State." Read in conjunction with the provisions of PCT Article 11(3), the phrase "actual filing date of the application in the United States" in 35 U.S.C. 154(b)(1)(B) might appear to mean the filing date of the international application under PCT Article 11(3) and 35 U.S.C. 363 in the case of an international application. Nevertheless, it is not appropriate to mechanically interpret the phrase "actual filing date of the application in the United States" in 35 U.S.C. 154(b) in light of PCT Article 11(3) when that interpretation is at odds with the legislative history of this provision of 35 U.S.C. 154(b)(1)(B) and the provisions of 35 U.S.C. 154(b)(1)(A)(i)(II) and (B)(iii).

The Office will continue to interpret the phrase "from the date on which the application for the patent was filed in the United States" in 35 U.S.C. 154(a)(2) (and former 35 U.S.C. 154(b)(3)(B)) as meaning the international filing date under PCT Article 11(3) and 35 U.S.C. 363 in the case of an international application.

If the phrase "actual filing date of the application in the United States" as used in 35 U.S.C. 154(b)(1)(B) were to be interpreted to mean any date other than the date the national stage commenced under 35 U.S.C. 371(b) or (f) in the case

of an international application, the Office would have to consider the failure to fulfill the requirements of 35 U.S.C. 371 to be a circumstance constituting a failure to engage in reasonable efforts to conclude prosecution (or processing or examination) of an application in an international application and reduce the period of any patent term adjustment by the period beginning on the "actual filing date of the application in the United States" of the application and ending on the date the application fulfilled the requirements of 35 U.S.C. 371. The interpretation of the phrase "actual filing date of the application in the United States" as used in 35 U.S.C. 154(b)(1)(B) to mean the date the national stage commenced under 35 U.S.C. 371(b) or (f) in the case of an international application, however, renders it unnecessary to provide that any period of patent term adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B) be reduced by the number of days (if any) beginning on the date on which the national phase commences under 35 U.S.C. 371(b) and ending on the day the applicant completes the requirements for entry into the national phase. After commencement of national stage processing, delays in fulfilling the requirements of 35 U.S.C. 371 will be treated under § 1.704(b).

Finally, the interpretation of the phrase "actual filing date of the application in the United States" as used in 35 U.S.C. 154(b)(1)(B) to mean the date the national stage commenced under 35 U.S.C. 371(b) or (f) in the case of an international application, rather than establishing the failure to fulfill the requirements of 35 U.S.C. 371 as a circumstance constituting a failure to engage in reasonable efforts to conclude prosecution (or processing or examination) of an application, will not force applicants to forgo their entitlements under the treaty or risk a reduction in a term adjustment, and will place PCT applicants in a similar position to "regular" national applicants or applicants who chose to file a "bypass" application (an application under 35 U.S.C. 111 claiming priority under 35 U.S.C. 120 to the international application) instead of entering the national phase under 35 U.S.C. 371.

Comment 32: Several comments argued that the formalities covered by proposed § 1.704(c)(9) (which subjects an applicant to reduction of any term adjustment if, for example, the application papers cannot be scanned, an abstract is not submitted or does not comply with the rules, printable drawings are not filed or a sequence

listing is not filed in appropriate computer readable form) usually do not delay examination. The comments also expressed concern that the defect would not be objected to in initial examination, and only later by the patent examiner. The comments argue that there should be no failure to engage reduction if the defect is not noted during initial examination, especially if the defect only arises after a restriction requirement which makes a revision to the title, for example, necessary. Several comments alleged that the proposed § 1.704(c)(9) required formal drawings to be included on filing.

Response: The Office has revised § 1.704 such that application formalities (specification on papers in compliance with § 1.52, title and abstract in compliance with § 1.72, drawings in compliance with § 1.84, and sequence listings in compliance with § 1.821 *et seq.*) are treated under § 1.704(b). Thus, any patent term adjustment will be reduced if an applicant does not correct the informality within three months of the Office action or notice requiring the missing part or correction of the informality.

Comment 33: One comment argued that the reduction in proposed § 1.704(c)(10) (§ 1.704(c)(6) as adopted) was excessive because there was no requirement for the Office to treat the preliminary paper within a set time. The comment argues that any time beyond one month from the filing of the preliminary amendment for the Office to issue a supplemental action should not be considered a failure to engage in reasonable efforts to conclude processing of an application. One comment argued that the proposal left an "immense loophole for unlimited PTO delay" and suggested that any reduction be limited to the lesser of (a) the proposed period or (b) the sum of (i) the time between the original Office action and the request for a supplemental action plus (ii) the lesser of four months and the time between the filing of the request and the issuance of the supplemental action. Another comment argued that the reduction should be limited to four months.

Response: Section 1.704(c)(6) as adopted provides that the period of adjustment set forth in § 1.703 shall be reduced by the lesser of the number of days, if any, beginning on 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** (emphasis added). An applicant filing a preliminary amendment or other paper at a time close to when a first Office action is

expected is encouraged to check with the Office (*e.g.*, through PAIR at <http://pair.uspto.gov>) before mailing in the paper. If the application is charged to a patent examiner, the examiner should be informed of the paper and the paper should be submitted to the examiner by facsimile transmission in order to reduce the likelihood of the examiner having to issue a supplemental Office action.

Applicants do not generally ask the Office to issue a supplemental Office action and § 1.704(c)(6) is not directed to this situation. Instead, § 1.704(c)(6) is directed to the situation, for example, in which an amendment is filed in February and then a supplemental amendment is filed in March, but is not in the file when the examiner prepares a reply in April. If the examiner then prepares another Office action in May to treat the March amendment, the reduction under § 1.704(c)(6) would be one month, the time between the April Office action and the May Office action.

Comment 34: As to proposed § 1.704(c)(11) (§ 1.704(c)(7) as adopted), the proposal that patent term adjustment will be reduced for the time period between submission of an initial reply and a reply in compliance with § 1.135(c) was criticized as creating an incentive for the examiner to find a reply non-responsive when a four-month deadline is not met. The comment suggests that other options be considered, including setting an upper limit of four months for this situation.

Response: Patent examiner performance plans hold examiners responsible for acting on applications within specified time frames. Patent examiner performance plans, however, do not hold examiners responsible for the patent term adjustment that may result in their applications. Thus, an examiner should not be overly mindful of the patent term adjustment implications of their actions. If a reply is filed that does not address each and every objection, rejection or other requirement made by the examiner, then the reply is not responsive to the Office action and the time between the filing of the incomplete reply and the date the omission was supplied is the period of time in which applicant's actions resulted in the Office not being able to complete processing or examination of the application.

While Office practice is to treat a *bona fide* but non-responsive reply by issuing a notice setting a one-month (or thirty-day) period for reply and permitting applicants to obtain up to five additional months under § 1.136(a), the Office could have changed this practice (as part of implementing the patent term

adjustment provisions of the American Inventors Protection Act of 1999) to set a one-month (or thirty-day) non-extendable period for supplying omissions in a reply. The Office elected to retain the relatively liberal practice for treating such non-responsive replies. To provide applicants with this extended period within which to supply an omission, however, the Office must provide that any patent term adjustment will be reduced by the period of time between the date the incomplete reply was filed and the date the omission was supplied. Since both the filing of a reply that is complete and the filing of any supplement necessary to a reply having an omission are within the control of the applicant, there is no need for a four-month upper limit.

Comment 35: As to proposed § 1.704(c)(12) (§ 1.704(c)(8) as adopted), one comment argued that the submission of supplemental replies should not be construed as a failure to engage in reasonable efforts because sometimes the supplemental reply expedites resolution of the issues.

Response: Section 1.704(c)(8) as adopted contains an exclusion for "a supplemental reply or other paper expressly requested by the examiner." Thus, a supplemental reply or other paper expressly requested by the examiner (*e.g.*, a supplemental amendment carrying into effect agreements reached between the applicant and the examiner) will not be considered a failure to engage in reasonable efforts to conclude processing or examination of an application, where the filing of a supplemental reply or other paper that was not expressly requested by the examiner will be considered a failure to engage in reasonable efforts to conclude processing or examination of an application.

Comment 36: Several other comments addressed proposed § 1.704(c)(12), arguing that an information disclosure statement filed within three months of applicant learning of the prior art should not be construed as a failure to engage in reasonable efforts because this event is beyond the control of the applicant.

Response: The filing of an information disclosure statement (or supplemental reply) after the filing of a reply will significantly interfere with the Office's ability to meet the time frame set forth in 35 U.S.C. 154(b)(1)(A)(ii) and 154(b)(1)(B) and § 1.702(a)(2) and (b). Nevertheless, the Office considers it appropriate to permit applicants to submit information cited in a communication from a foreign patent office 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 communication from the foreign patent office was received by an individual designated in § 1.56(c). While this time period is considerably shorter than the three-month period provided in § 1.97(e), a non-extendable thirty-day time period is necessary to avoid substantial interference with the time frame imposed on the Office by 35 U.S.C. 154(b)(1)(A)(ii).

Comment 37: One comment argued that proposed § 1.704(c)(12) would result in a request for filing an assignment being used to reduce the period of adjustment.

Response: Assignment papers should be mailed to BOX ASSIGNMENT and should not be placed into an application file. *See MPEP* 303. As a result, the filing of a cover sheet for an assignment and an assignment would not be used in the patent term adjustment determination. Furthermore, a Notice of Non-Recordation (*MPEP* 302.09) is not a notice related to the processing or examination of a patent application and will not be used in the patent term adjustment determination.

Comment 38: Several comments stated that it was manifestly unfair for a term adjustment to be reduced by the time between filing a notice of appeal and the appeal brief in proposed § 1.704(c)(13). Several of these comments suggested that the time between two months after the notice of appeal and filing of the appeal brief be used as a failure to engage reduction. One of the comments suggested that applicants be given at least one month between notice of appeal and filing of the appeal brief before further delays begin to be considered a failure to engage. Another comment argued that proposed § 1.704(c)(13) was unfair because a notice of appeal is a desirable means of avoiding paying extension of time fees. The comment further argued that if the appeal is successful, the time taken to file an appeal brief should not be considered a failure to engage in reasonable efforts to conclude processing or examination of the application unless more than a reasonable amount of time is taken to file the appeal brief. Several comments suggested that the taking of an appeal begins with the filing of the appeal brief and not with the filing of a notice of appeal. One of these comments stated that the Office's treating an appeal as having been taken when the notice of appeal is filed but reducing any patent term adjustment by the period between

the filing of the notice of appeal and the filing of an appeal brief will have the effect of having the relevant four-month period run from the filing of the appeal brief and probably reached the result Congress intended, but indicated that such a practice will create client-relation difficulty.

Response: The Office is interpreting the phrase "the date on which" an "appeal was taken" in 35 U.S.C. 154(b)(1)(A)(ii) as the date an appeal brief in compliance with § 1.192 was filed. The Office originally interpreted the phrase "the date on which" an "appeal was taken" in 35 U.S.C. 154(b)(1)(A)(ii) to mean the date a notice of appeal to the Board of Patent Appeals and Interferences under 35 U.S.C. 134 and § 1.191 was filed. See *Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term*, 65 FR at 17217, 1233 *Off. Gaz. Pat. Office* at 111. The Office has reconsidered this interpretation of the phrase "the date on which" an "appeal was taken" in 35 U.S.C. 154(b)(1)(A)(ii).

Neither the patent statute nor the rules of practice provide any definition (or antecedent basis) for the phrase "appeal was taken" so as to signify whether "the date on which" an "appeal was taken" means the date a notice of appeal to the Board of Patent Appeals and Interferences under 35 U.S.C. 134 and § 1.191 was filed, or whether it means the date the documents and fees from applicant (*i.e.*, an appeal brief in compliance with § 1.192) that are necessary for the appeal to go forward (or be "taken") to the Board of Patent Appeals and Interferences was filed. Therefore, it is necessary to resort to the context of this provision within the scheme of 35 U.S.C. 154(b)(1) and legislative history of 35 U.S.C. 154(b) to ascertain the meaning of this phrase.

The interpretation of the phrase "the date on which" an "appeal was taken" as meaning the date a notice of appeal to the Board of Patent Appeals and Interferences under 35 U.S.C. 134 and § 1.191 was filed (rather than the date an appeal brief in compliance with § 1.192 was filed) is not consistent with the scheme of 35 U.S.C. 154(b)(1) (A) and (B). Both 35 U.S.C. 154(b)(1) (A) and (B) set forth an objective time clock system. 35 U.S.C. 154(b)(1)(A) sets forth an objective clock system that measures the time taken by the Office to perform certain acts of examination when such actions are expected in response to actions (*e.g.*, the filing of an application, reply to an Office action, payment of the issue fee) by the applicant, where 35 U.S.C. 154(b)(1)(B) sets forth an objective clock system that measures

overall time taken by the Office to issue the patent.

The Office is not expected to respond to the filing of a notice of appeal to the Board of Patent Appeals and Interferences under 35 U.S.C. 134 and § 1.191 unless and until the applicant files the documents and fees (*i.e.*, an appeal brief in compliance with § 1.192) necessary for the appeal to go forward (or be "taken") to the Board of Patent Appeals and Interferences. Since this provision is included as part of the clock system of 35 U.S.C. 154(b)(1)(A) that measures the time taken by the Office to perform certain acts of examination when such actions are expected in response to actions by the applicant (rather than the overall clock system of 35 U.S.C. 154(b)(1)(B)), it would be inconsistent with the scheme of 35 U.S.C. 154(b)(1) (A) and (B) to have the four-month period in 35 U.S.C. 154(b)(1)(A)(ii) run at a time (between the filing of a notice of appeal to the Board of Patent Appeals and Interferences under 35 U.S.C. 134 and § 1.191 and the filing of an appeal brief in compliance with § 1.192) when the Office is not expected to perform any action in the application.

The interpretation of the phrase "the date on which" an "appeal was taken" as meaning the date a notice of appeal to the Board of Patent Appeals and Interferences under 35 U.S.C. 134 and § 1.191 was filed (rather than the date an appeal brief in compliance with § 1.192 was filed) is also not consistent with the legislative history of 35 U.S.C. 154(b). As discussed above, the provisions in 35 U.S.C. 154(b) (A) and (B) for patent term adjustment on the bases of administrative delays in acting on an application or issuing a patent evolved from legislation introduced in the 104th Congress. See Patent Application Publication Act of 1995, H.R. 1733, 104th Cong. (1995). Section 8 of H.R. 1733 simply provided for patent term adjustment (or extension) for "an unusual administrative delay," and authorized the Office to "prescribe regulations to govern the determination of the period of delay and the particular circumstances deemed to be an unusual administrative delay" (35 U.S.C. 154(b)(1)(D)).

The Office proposed to implement this provision of H.R. 1733 using a three-prong objective time clock for certain actions by the Office to determine whether there was "an unusual administrative delay" by the Office. Specifically, the Office proposed to define "an unusual administrative delay" by the Office as failure to: (1) act on a reply under § 1.111 or appeal brief under § 1.192 within six months of the

date it was filed; (2) act on application with six months of the date of a decision under § 1.196 by the Board of Patent Appeals and Interferences where claims stand allowed in an application or the nature of the decision requires further action by the examiner (§ 1.197); or (3) issue a patent within six months of the date the issue fee was paid or all outstanding requirements were satisfied, whichever is later. See *Changes to Implement 18-Month Publication of Patent Applications*, Notice of Proposed Rulemaking, 60 FR 42352, 42369-70, 42385-86 (Aug. 15, 1995), 1177 *Off. Gaz. Pat. Office* 61, 76-77, 91-91 (Aug. 15, 1995).

The 104th Congress replaced H.R. 1733 with H.R. 3460. See Moorhead-Schroeder Patent Reform Act, H.R. 3460, 104th Cong. (1996). The patent term adjustment provisions of H.R. 3460 were based upon the objective time clock system proposed by the Office in August of 1995, with two modifications: (1) an additional fourth prong (now the first prong) was added to also define "an unusual administrative delay" by the Office as failure to initially act on an application within fourteen months of its filing date; and (2) the six-month time periods were shortened to four months in the remaining three prongs which correspond to the three prongs proposed by the Office. See H.R. Rep. No. 104-784, at 19 and 33 (1996). There is nothing in the Committee Report for H.R. 3460 to indicate that Congress intended the four-month period in the second prong of the objective time clock to run from the date a notice of appeal to the Board of Patent Appeals and Interferences under 35 U.S.C. 134 and § 1.191 was filed, rather than the date an appeal brief under § 1.192 was filed (as proposed by the Office), with regard to measuring whether the time taken by the Office to respond to an appeal constituted "an unusual administrative delay" by the Office.

While 35 U.S.C. 154(b) as ultimately amended by the 106th Congress in Pub. L. 106-113 differs dramatically from 35 U.S.C. 154(b) as it would have been amended by H.R. 3460, the language of 35 U.S.C. 154(b)(1)(A)(ii) as enacted is identical to the language of 35 U.S.C. 154(b)(1)(B)(ii) (the corresponding provision) in H.R. 3460. Since this objective clock system of 35 U.S.C. 154(b)(1)(A) tracks the objective time clock system proposed by the Office in August of 1995, and there is nothing in the legislative history of 35 U.S.C. 154(b) to indicate that Congress meant to alter this prong of the objective time clock (such that the time period would run from the date a notice of appeal to the Board of Patent Appeals and

Interferences under 35 U.S.C. 134 and § 1.191 was filed rather than the date an appeal brief under § 1.192 was filed), it is reasonable to conclude that Congress intended the phrase “the date on which” an “appeal was taken” in 35 U.S.C. 154(b)(1)(A)(ii) to mean the date an appeal brief under § 1.192 was filed.

Comment 39: As to proposed § 1.704(c)(14) (§ 1.704(c)(9) as adopted), several comments argued that the comments raised against proposed § 1.704(c)(10) were also relevant. One comment argued that the period defined by the rule was not within the control of the applicant and that an upper limit for the period of adjustment (e.g., four months) should be set.

Response: Section 1.704(c)(9) as adopted provides that adjustment set forth in § 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 (emphasis added).

Comment 40: Another comment addressed proposed § 1.704(c)(14) (§ 1.704(c)(9) as adopted), stating that the term “designated” in the phrase “[s]ubmission of an amendment or other paper after a decision of the Board of Patent Appeals and Interferences, other than a decision designated as containing a new ground of rejection under § 1.196(b) or a statement under § 1.196(c)” should not be used to arbitrarily deny term adjustment.

Response: The phrase from § 1.704(c)(9) as adopted addressed in this comment explains that a paper filed in reply to a new ground of rejection will not be used to reduce a term adjustment. Applicants will be able to timely reply to a Board of Patent Appeals and Interferences decision containing a new ground of rejection under § 1.196(b) without a reduction of patent term adjustment.

Comment 41: Several comments objected to the reference to “or other paper” in proposed § 1.704(c)(15) (§ 1.704(c)(10) as adopted) because a paper filed to correct an examiner’s amendment or to request a copy of a PTO-1449 should not be construed as a failure to engage in reasonable efforts to conclude prosecution. One comment suggested instead that only an amendment requiring further examination should be listed under this section.

Response: In order to be able to perform the patent term adjustment calculation at the time of mailing the Notice of Allowance, the Office needs to have the calculation performed by a

computer program using the Office’s records of papers mailed and received as recorded in its PALM system. The PALM system is simply not capable of making value judgments concerning papers filed after allowance. In any event (as discussed above), all papers filed after allowance of an application substantially delay the Office’s ability to process an application for a patent because the Office does not wait for payment of the issue fee to begin the process of preparing the application for publication as a patent. Section 1.704(c)(10) as adopted should deter applicants from filing papers after allowance which should have a beneficial impact upon the Office’s ability to publish applications as patents more quickly.

Applicants can avoid this reduction being applied to applicant’s attempts to correct the record by making a telephone request for a missing copy of a PTO-1449 or other document as soon as possible after receipt of the Notice of Allowance. As to information disclosure statements filed after allowance, pursuant to § 1.704(d) an information disclosure statement citing prior art cited in a communication from the foreign patent office in a counterpart application and filed within thirty days of the communication from the foreign patent office will not reduce the term of any adjustment if the required certification is made. In addition, a status inquiry filed after allowance may result in a reduction of the term adjustment. Applicants are encouraged to either call the Office or use the PAIR system (<http://pair.uspto.gov>) to monitor the status of an application rather than submitting written status inquiries.

Comment 42: One comment argued that proposed § 1.704(c)(16) (§ 1.704(c)(11) as adopted) was unnecessary because time periods before the filing date of an application are not relevant to patent term adjustment and do not constitute delays in the prosecution of the application. Another comment asked whether applicant delays in a prior application would reduce the patent term adjustment in a continuation application.

Response: Delays before the filing date of an application are not relevant to whether an application is entitled to patent term adjustment, but the provision is considered necessary to remind applicants of this. Likewise, 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.

Comment 43: Section 1.705(a) states that the notification of any patent term adjustment under 35 U.S.C. 154(b) will be included on the notice of allowance. One comment asked whether a registered practitioner has an ethical duty to disclose to the Office when the term adjustment indicated is longer period than expected. The comment continues to ask whether attorneys have a similar duty to inform the Office when an examiner indicates subject matter as being allowable with a scope broader than it should be. Finally, the comment asks whether the ethical obligation would be any different if the pre-printed Office form is not used to pay the issue fee and an attorney-generated form is used instead.

Response: The Office currently issues a notice of allowance using the Notice of Allowance and Issue Fee Due (PTOL-85). The Notice of Allowance and Issue Fee Due (PTOL-85) is printed in several parts and one part (PTOL-85B) may be returned with the issue fee payment in order to communicate the assignee and attorney data to be printed on the face of the patent. A registered practitioner is under a general obligation of candor and good faith in practice before the Office. Accordingly, if an examiner suggests claims that the attorney knows are not patentable, § 10.18 precludes the attorney from adopting the examiner’s suggestions in an amendment. Similarly, a practitioner signing the PTOL-85B does so pursuant to § 10.18, which means, for example, that if assignee data is provided on the PTOL-85B, the assignee is an assignee of the entire interest in the application, and that the patent term adjustment is correct to the best of his or her knowledge, information and belief, formed after an inquiry reasonable under the circumstances. For example, if a registered practitioner receives determination that the application is eligible for a 1,500 day adjustment and the practitioner is not sure exactly what the adjustment should be, but believes that the adjustment should be 1,000 days, the practitioner does have a duty to disclose the error to the Office, regardless of whether the issue fee is paid using the Office-generated form (PTOL-85B) or an attorney-generated equivalent. In order to comply with this duty and where the correct adjustment is thought to be less than indicated by the Office, an application for term adjustment under § 1.705(b) need not be filed. Instead, a letter could be filed with the issue fee payment, indicating that the term adjustment is thought to be longer than appropriate.

Comment 44: As to § 1.705(a) one comment asked if the patent term adjustment would be printed in the Official Gazette.

Response: The Office has no plans at this time to add the patent term adjustment to the information printed in the Official Gazette.

Comment 45: As to § 1.705(b), one comment noted that the reference to § 1.704(b) should be a reference to § 1.704.

Response: The suggestion has been adopted in part. The reference to § 1.704(b) has been changed to a reference to § 1.704(a). Section 1.704(a) states that a patent term adjustment shall be reduced by the period of time in which applicant has failed to engage in reasonable efforts to conclude prosecution whereas § 1.704(b) and (c) define when an applicant is determined to have failed to act in such a manner.

Comment 46: As to § 1.705(b), one comment stated that the amount of detail of how the patent term adjustment calculation is made was not stated and urged that the Office provide information as to patent term adjustment which applicants can check as an application is prosecuted. One comment asked that a copy of the patent term adjustment worksheet be included with the patent term adjustment determination.

Response: The Office does plan to provide information as to how the patent term adjustment calculation has been made through PAIR at <http://pair.uspto.gov>. This system is now available to all patent applicants who have a customer number. The precise information that will be communicated, and when this information will be available has not yet been determined.

Comment 47: One comment asked that the software algorithm for the patent term adjustment determination be made available to the public before being implemented.

Response: The computer program written to perform the patent term adjustment determinations of 35 U.S.C. 154 as amended will be written for the Office mainframe computer using the PALM records. It is not anticipated that this software will be capable of being used on another computer. Accordingly, the computer codes are unlikely to be understood by someone outside of the Office. Moreover, the Office does not plan to initially launch a computer program that will perform all necessary patent term adjustment determination, but instead plans to add to the program in stages until it is fully functional. For example, the first patents to be eligible for term adjustment will be when the

Office fails to issue a patent within four months of payment of the issue fee and compliance with all formal requirements. This is unlikely to occur before February of 2001. Accordingly, the first stage of the computer program should be running by November of 2000 to generate a report with the Issue Notification if this four-month deadline is missed. On the other hand, the last part of the program (failing to issue a patent within three years of the filing date of the application) cannot take place before May 29, 2003, and this final stage of the program is not anticipated to be operational until after the remainder of the programming has been completed.

Comment 48: One comment argued that applicants should be able to address patent term adjustment with the filing of a reply to an Office action.

Response: Although 35 U.S.C. 154(b)(3)(C) states that a showing that the delay was in spite of all due care may be filed prior to the issuance of the patent, the general framework of the 35 U.S.C. 154(b)(3) has the Office first making a patent term adjustment determination and then applicant filing a request for reconsideration of the Office's determination (*i.e.*, an application for term adjustment). Since the initial patent term adjustment determination will be made by the Office's computer system with the mailing of the Notice of Allowance and Issue Fee Due, applicant should file any showing explaining the reasons for a delay with any request for reconsideration of this determination so that the showing can be considered with the request for reconsideration.

In addition, the reinstatement provision of 35 U.S.C. 154(b)(3)(C) applies, by its terms, only to reductions under § 1.704(b) because the reductions under § 1.704 (c)(1) through (c)(11) are not based upon failure to reply to an Office action or notice within three months. Thus, reinstatement of reduced patent term adjustment under 35 U.S.C. 154(b)(3)(C) on the basis of a showing that the delay was in spite of all due care is relevant only if: (1) one of the delays specified in 35 U.S.C. 154(b)(1) (A) through (C) occurred during the application process processing; and (2) patent term adjustment accruing as a result of such delay survives the reductions under § 1.704 (c)(1) through (c)(11). Thus, the Office is requiring that applicants not address patent term adjustment until the Office makes its initial patent term adjustment determination in the notice of allowance to avoid unnecessary expenditures of resources by applicants and the Office

in preparing and handling submissions that turn out to be irrelevant.

Comment 49: As to § 1.705(b), several comments asked how the procedure for a request for reconsideration of the term adjustment due to the patent issuing on a date other than the projected issue date will operate. One comment argued that the thirty-day time period was too short and that a three-month time period would be more suitable.

Response: The Office is restricted by the provisions of 35 U.S.C. 154(b)(4)(A) which provide that an applicant dissatisfied with a patent term adjustment determination has 180 days to file a civil action against the Office. In order for the Office to treat the request for reconsideration in sufficient time for the applicant to determine whether court review of the Office's determination is appropriate, the Office must require that the request for reconsideration be filed within thirty days of patent grant. The Office does, however, mail an Issue Notification about two weeks before the issue date of the patent and plans to revise the Issue Notification to include the patent term adjustment information that will be printed on the face of the patent, so applicants will (in most situations) have about forty-five days from the date of this Notice to prepare a request for reconsideration.

Comment 50: Also as to § 1.705(b), one comment asked if the revised patent term adjustment would be printed on the patent, and asked how a third party would obtain information about any revision to the patent term adjustment.

Response: Any petition requesting reconsideration of a patent term adjustment and a decision thereon would be placed into the patent file wrapper and would therefore be available to the public. In addition, the Office is considering establishing procedures where the Office will issue a certificate of correction to add or correct patent term adjustment information printed on the face of the patent, after a decision on a request for reconsideration of a patent term adjustment determination. After the certificate of correction has issued, the Office is considering publishing an Official Gazette Notice of the revised term adjustment determination for the patent.

Comment 51: As to § 1.705(c), one comment suggested that the Office should issue guidelines on how the "in spite of all due care" provisions of 35 U.S.C. 154(b)(3)(C) will be interpreted. Another comment argued that the term "reasonable efforts" is more liberal than the term "due diligence" under old 35 U.S.C. 154(b) which was abandoned by

Congress. The comment argued that events that should not be treated as a failure to engage in reasonable efforts to conclude prosecution include: (1) filing of responses after three months accompanied by a submission under the procedures of § 1.132 where reasonable efforts to prepare the submission are shown; (2) periods of time when applicant's attorney is engaged in *inter partes* matters relating to pending lawsuits and interferences and other matters on his/her professional calendar which are appropriately given priority; (3) illness, vacations of reasonable length, and other appropriate reasons for non-attention to an application that occur in everyday life of applicants and attorneys, and (4) time consumed in communications between the applicant, the applicant's foreign agent and the applicant's U.S. representative when the applicant does not reside in the United States.

Response: Filing a response 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 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) (emphasis added). 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 *Pratt*, 1887 Dec. Comm'r Pat. at 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 of showings that may establish that the applicant was unable to respond within the three-month period in spite of all due care are as follows: (1) a showing that the original three-month period was insufficient to obtain the test data necessary for an affidavit or declaration under § 1.132 that was submitted with a reply filed outside the original three-month period; (2) a showing that the applicant was unable to reply within the original three-month period due to a natural disaster; or (3) 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. Obviously, the patent term adjustment term reinstated would be limited to the period in which the showing establishes that 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 respond within the three-month period "in spite of all due care" if the response 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: (1) an applicant's or representative's preoccupation with other matters (e.g., an *inter partes* lawsuit or interference) that is given priority over the application; (2) 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); (3) 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; (4) vacation or other non-attention to an application that

results in a failure to reply within the three-month period; (5) 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 § 1.8, rather than by Express Mail under § 1.10 or facsimile (if permitted), and the reply is not received (filed) in the Office until after the three-month period; or (6) 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 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).

As to communications between an applicant and others involved in preparing a reply, the attorney's engagement letter with his or her client should impress the importance of reply within three months of any Office action or notice. The letter should also carefully explain to the client that while extensions of time are generally available to reply to Office actions and notices, not only will applicant have to bear the cost of the extension but is likely to experience a reduction in any patent term adjustment as well.

Comment 52: As to § 1.705(d), one comment stated that there was no provision in the rules for the patent to be printed with the patent term adjustment information thereon. Another comment asked how the public would be notified of a successful request for reconsideration of the term adjustment due to the patent issuing on a day other than a date projected.

Response: Patents filed on or after June 8, 1995, are eligible for term adjustment for certain delays and the patent is printed with the term adjustment information printed thereon in the field below the inventor name. If for some reason the patent is not printed with the term adjustment or is printed with the incorrect adjustment, the Office procedure is to inform the patentee of

the error and to issue a Certificate of Correction if no objection is received. The Office plans to continue to print any term adjustment on the front page of the patent, and to issue a Certificate of Correction if the term adjustment is printed incorrectly.

Comment 53: One general comment was received that with patent term adjustment, applicants will be less motivated to take action to expedite prosecution of an application, and suggested that the term adjustment should be shortened if the applicant does not take action to ensure that the application is examined.

Response: The suggestion raises a valid objection which cannot be addressed with a specific rulemaking. Applicants often file status letters to determine if and when an application will be taken up for action. The time required to process and reply to a status letter takes away from the time that the Office has to process and reply to other papers and the Office does not want to create rules to encourage the filing of such papers.

Comment 54: One comment argued that § 1.705(f) should not exclude a third party from filing a submission or petition of the patent term adjustment. The comment argues that a potential Abbreviated New Drug Application (ANDA) applicant may not have another way of challenging the expiration date of the patent and upon filing a paragraph III certification, be forced to stay off the market for an unnecessary period of time, thereby depriving the public of lower cost drugs.

Response: If the patent claims a drug product approved by the Food and Drug Administration, the patent will be listed in the Prescription and OTC Drug Product, Patent and Exclusivity Data section of the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) as covering the drug product and the patent expiration date will be given. If the expiration date listed in the Orange Book is incorrect, the ANDA applicant could dispute the patent expiration date pursuant to 21 CFR 314.53(f). If the date is not corrected, the ANDA applicant could institute a declaratory judgment action with respect to the patent. Alternatively, the ANDA applicant could address the situation by filing a paragraph IV certification (see Food, Drug and Cosmetic Act, Section 505(j)(2)(A)(vii)(IV), 21 U.S.C. 355(j)(2)(A)(vii)(IV)), arguing that because the term adjustment is incorrect, the patent is unenforceable. See 21 CFR 314.94(a)(12)(i)(A)(4).

Pursuant to 35 U.S.C. 154(b)(4)(B) no third party may challenge or appeal a

patent term adjustment determination prior to the grant of a patent. Moreover, the best time and place for the patent term adjustment determination to be challenged by a third party is thought to be during litigation between two interested parties near the expiration date of the patent, before consideration of the term adjustment.

Classification

Regulatory Flexibility Act

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy, Small Business Administration, that the changes in this final rule will not have a significant impact on a substantial number of small entities (Regulatory Flexibility Act, 5 U.S.C. 605(b)). This final rule implements the provisions of §§ 4401 and 4402 of the American Inventors Protection Act of 1999. The changes in this final rule provide procedures for the Office's patent term adjustment determination and for filing an application to request reconsideration of the Office's patent term adjustment determination.

The Office mails a notice of allowance in roughly 160,000 applications each year. The Office's patent term adjustment determination will be a calculation based upon time periods involving the dates of various actions by the Office and the applicant during the application process. Because of the number of actions by the Office and the applicant during the application process, the Office anticipates that there will be disagreement on at least one of these dates in roughly fifteen percent of applications (24,000). Based upon the percentage of applicants who are small entities (thirty percent), the Office expects that 7,200 small entities will file an application requesting reconsideration of a patent term adjustment determination each year. Since a small entity applicant who exercises reasonable due care or diligence should be able to reply to any Office action or notice within three months, the Office does not anticipate that any small entities will file a request for reinstatement of reduced patent term adjustment (based upon a showing that the applicant was unable to reply to an Office action or notice within three months in spite of all due care).

Filing an application requesting reconsideration of a patent term adjustment determination (as well as a request for reinstatement of reduced patent term adjustment) is optional. To obtain any benefit from an application requesting reconsideration of the Office's patent term adjustment

determination, the applicant must plan to pay the three maintenance fees required by law (35 U.S.C. 41(b)) to maintain a patent in force until the end of the non-adjusted patent term as specified in 35 U.S.C. 154. The current first, second, and third maintenance fees are \$415.00, \$950.00, and \$1,455.00, respectively. Since the fee (\$200) for filing an application requesting reconsideration of the Office's patent term adjustment determination is less than one-tenth of the combined cost of these three maintenance fees (and the fee (\$400) for filing a request for reinstatement of reduced patent term adjustment is less than one-sixth of the combined cost of these three maintenance fees), there will not be a significant economic impact on a substantial number of small entities due to the procedures for requesting reconsideration of the Office's patent term adjustment determination.

Executive Order 13132

This final rule does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (August 4, 1999).

Executive Order 12866

This final rule has been determined to be not significant for purposes of Executive Order 12866 (September 30, 1993).

Paperwork Reduction Act

This final rule involves information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The collection of information involved in this final rule has been reviewed and previously approved by OMB under OMB control number 0651-0020.

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the United States Patent and Trademark Office submitted an information collection package to OMB for its review and approval. The United States Patent and Trademark Office submitted this information collection to OMB for its review and approval because this final rule adds the request for reconsideration of a patent term adjustment determination by the United States Patent and Trademark Office and the request for reinstatement of reduced patent term adjustment (based upon a showing that the applicant was unable to reply to an Office action or notice within three months in spite of all due care) provided for in 35 U.S.C. 154(b)(3) to that collection.

The title, description, and respondent description of the information collection is shown below with an estimate of the annual reporting burdens. Included in this estimate is the time for reviewing instructions, gathering, and maintaining the data needed, and completing and reviewing the collection of information. The principal impact of the changes in this final rule is to implement the changes to Office practice necessitated by § 4402 of the American Inventors Protection Act of 1999 (enacted into law by § 1000(a)(9), Division B, of Pub. L. 106-113).

OMB Number: 0651-0020.

Title: Patent Term Extension.

Form Numbers: None.

Type of Review: Approved through September of 2001.

Affected Public: Individuals or households, businesses or other for-profit, not-for-profit institutions, farms, Federal Government, and state, local, or tribal governments.

Estimated Number of Respondents: 26,857.

Estimated Time Per Response: 1.15 hour.

Estimated Total Annual Burden Hours: 30,902 hours.

Needs and Uses: The information supplied to the United States Patent and Trademark Office by an applicant requesting reconsideration of a patent term adjustment determination under 35 U.S.C. 154(b) (§ 1.702 *et seq.*) is used by the United States Patent and Trademark Office to determine whether its determination of patent term adjustment under 35 U.S.C. 154(b) is correct, and whether the applicant is entitled to reinstatement of reduced patent term adjustment. The information supplied to the United States Patent and Trademark Office by an applicant seeking a patent term extension under 35 U.S.C. 156 (§ 1.710 *et seq.*) is used by the United States Patent and Trademark Office, the Department of Health and Human Services, and the Department of Agriculture to determine the eligibility of a patent for extension and to determine the period of any such extension. The applicant can apply for patent term and interim extensions, petition the Office to review final eligibility decisions, withdraw patent term applications, and declare his or her eligibility to apply for a patent term extension.

Comments are invited on: (1) whether the collection of information is necessary for proper performance of the functions of the agency; (2) the accuracy of the agency's estimate of the burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the

burden of the collection of information to respondents.

Interested persons are requested to send comments regarding these information collections, including suggestions for reducing this burden, to Robert J. Spar, Director, Special Program Law Office, United States Patent and Trademark Office, Washington, DC 20231, or to the Office of Information and Regulatory Affairs of OMB, New Executive Office Building, 725 17th Street, NW., Room 10235, Washington, DC 20503, Attention: Desk Officer for the United States Patent and Trademark Office.

Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB control number.

List of Subjects in 37 CFR Part 1

Administrative practice and procedure, Courts, Freedom of Information, Inventions and patents, Reporting and recordkeeping requirements, Small businesses.

For the reasons set forth in the preamble, 37 CFR part 1 is amended as follows:

PART 1—RULES OF PRACTICE IN PATENT CASES

1. The authority citation for 37 CFR part 1 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2).

2. Section 1.18 is amended by revising its heading and adding paragraphs (d), (e) and (f) to read as follows:

§ 1.18 Patent post allowance (including issue) fees.

* * * * *

(d) [Reserved]

(e) For filing an application for patent term adjustment under § 1.705: \$200.00.

(f) For filing a request for reinstatement of all or part of the term reduced pursuant to § 1.704(b) in an application for patent term adjustment under § 1.705: \$400.00.

3. The heading for Subpart F of part 1 is revised to read as follows:

Subpart F—Adjustment and Extension of Patent Term

4. The authority citation for Subpart F of part 1 is revised to read as follows:

Authority: 35 U.S.C. 2(b)(2), 154, and 156.

5. A new, undesignated center heading is added to Subpart F before § 1.701 to read as follows:

Adjustment of Patent Term Due to Examination Delay

6. Section 1.701 is amended by revising its heading and adding a new paragraph (e) to read as follows:

§ 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).

* * * * *

(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.

7. New §§ 1.702 through 1.705 are added to read as follows:

§ 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).

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

(1) Mail at least one of a notification under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151 not later than fourteen months after the date on which the application was filed under 35 U.S.C. 111(a) or fulfilled the requirements of 35 U.S.C. 371 in an international 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 Board of Patent Appeals and Interferences under 35 U.S.C. 134 or 135 or a decision by a Federal court under 35 U.S.C. 141, 145, or 146 where at least one allowable claim remains in the application; or

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

(b) *Failure to issue a patent within three years of the actual filing date of the application.* Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of

the Office to issue a patent within three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application, but not including:

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

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

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

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

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

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

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

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

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

§ 1.703 Period of adjustment of patent term due to examination delay.

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

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

notice of allowance under 35 U.S.C. 151, whichever occurs first;

(2) The number of days, if any, in the period beginning on the day after the date that is four months after the date a reply under § 1.111 was 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 § 1.192 was filed and ending on the date of mailing of any of an examiner's answer under § 1.193, an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first;

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

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

(b) The period of adjustment under § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was 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 a request for continued examination of the application under 35 U.S.C. 132(b) was filed and ending on the date the patent was issued;

(2)(i) The number of days, if any, in the period beginning on the date an

interference was declared or redeclared to involve the application in the interference and ending on the date that the interference was terminated with respect to the application; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

§ 1.704 Reduction of period of adjustment of patent term.

(a) The period of adjustment of the term of a patent under §§ 1.703(a) through (e) shall be reduced by a period

equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution (processing or examination) of the application.

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

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

(1) Suspension of action under § 1.103 at the applicant's request, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the date a request for suspension of action under § 1.103 was 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 Board of Patent Appeals and Interferences, other than a decision designated as containing a new ground of rejection under § 1.196(b) or statement under § 1.196(c), or a decision by a Federal court, less than one month before the mailing of an Office action under 35 U.S.C. 132 or notice of allowance under 35 U.S.C. 151 that requires the mailing of a supplemental Office action or supplemental notice of allowance, in which case the period of adjustment set forth in § 1.703 shall be reduced by the lesser of:

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

(ii) Four months;

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

(i) The number of days, if any, beginning on the date the amendment under § 1.312 or other paper was 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; and

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

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

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

§ 1.705 Patent term adjustment determination.

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

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

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

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

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

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

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

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

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

(c) Any application for patent term adjustment under this section that requests reinstatement of all or part of the period of adjustment reduced pursuant to § 1.704(b) for failing to reply to a rejection, objection, argument, or

other request within three months of the date of mailing of the Office communication notifying the applicant of the rejection, objection, argument, or other request must also be accompanied by:

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

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

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

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

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

8. A new, undesignated center heading is added to Subpart F before § 1.710 to read as follows:

Extension of Patent Term Due to Regulatory Review

Dated: September 5, 2000.

Q. Todd Dickinson,

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

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