

independent inquiries as desired before a final determination is made on whether a patent is eligible for extension. In an application for extension filed in compliance with § 1.740, a notice will be mailed to applicant containing the determination as to the eligibility of the patent for extension and the period of time of the extension, if any. This notice shall constitute the final determination as to the eligibility and any period of extension of the patent. A single request for reconsideration of a final determination may be made if filed by the applicant within such time as may be set in the notice of final determination or, if no time is set, within one month from the date of the final determination. The time periods set forth herein are subject to the provisions of § 1.136.

[60 FR 25618, May 12, 1995]

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

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

[65 FR 54680, Sept. 8, 2000]

§ 1.765 Duty of disclosure in patent term extension proceedings.

(a) A duty of candor and good faith toward the Patent and Trademark Office and the Secretary of Health and

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

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

(c) No patent will be determined eligible for extension and no extension will be issued if it is determined that fraud on the Office or the Secretary was practiced or attempted or the duty of disclosure was violated through bad faith or gross negligence in connection

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with the patent term extension proceeding. If it is established by clear and convincing evidence that any fraud was practiced or attempted on the Office or the Secretary in connection with the patent term extension proceeding or that there was any violation of the duty of disclosure through bad faith or gross negligence in connection with the patent term extension proceeding, a final determination will be made pursuant to § 1.750 that the patent is not eligible for extension.

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

[24 FR 10332, Dec. 22, 1959, as amended at 54 FR 30381, July 20, 1989; 60 FR 25618, May 12, 1995]

§ 1.770 Express withdrawal of application for extension of patent term.

An application for extension of patent term may be expressly withdrawn before a determination is made pursuant to § 1.750 by filing in the Office, in duplicate, a written declaration of withdrawal signed by the owner of record of the patent or its agent. An application may not be expressly withdrawn after the date permitted for reply to the final determination on the application. An express withdrawal pursuant to this section is effective when acknowledged in writing by the Office. The filing of an express withdrawal pursuant to this section and its acceptance by the Office does not entitle applicant to a refund of the filing fee (§ 1.20(j)) or any portion thereof.

[62 FR 53201, Oct. 10, 1997]

§ 1.775 Calculation of patent term extension for a human drug, antibiotic drug or human biological product.

(a) If a determination is made pursuant to § 1.750 that a patent for a human drug, antibiotic drug or human biological product is eligible for extension, the term shall be extended by the time

as calculated in days in the manner indicated by this section. The patent term extension will run from the original expiration date of the patent or any earlier date set by terminal disclaimer (§ 1.321).

(b) The term of the patent for a human drug, antibiotic drug or human biological product will be extended by the length of the regulatory review period for the product as determined by the Secretary of Health and Human Services, reduced as appropriate pursuant to paragraphs (d)(1) through (d)(6) of this section.

(c) The length of the regulatory review period for a human drug, antibiotic drug or human biological product will be determined by the Secretary of Health and Human Services. Under 35 U.S.C. 156(g)(1)(B), it is the sum of—

(1) The number of days in the period beginning on the date an exemption under subsection (i) of section 505 or subsection (d) of section 507 of the Federal Food, Drug, and Cosmetic Act became effective for the approved product and ending on the date the application was initially submitted for such product under those sections or under section 351 of the Public Health Service Act; and

(2) The number of days in the period beginning on the date the application was initially submitted for the approved product under section 351 of the Public Health Service Act, subsection (b) of section 505 or section 507 of the Federal Food, Drug, and Cosmetic Act and ending on the date such application was approved under such section.

(d) The term of the patent as extended for a human drug, antibiotic drug or human biological product will be determined by—

(1) Subtracting from the number of days determined by the Secretary of Health and Human Services to be in the regulatory review period:

(i) The number of days in the periods of paragraphs (c)(1) and (c)(2) of this section which were on and before the date on which the patent issued;

(ii) The number of days in the periods of paragraphs (c)(1) and (c)(2) of this section during which it is determined under 35 U.S.C. 156(d)(2)(B) by the Secretary of Health and Human Services