

**§ 1.765 Duty of disclosure in patent term extension proceedings.**

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

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

(c) No patent will be determined eligible for extension and no extension will be issued if it is determined that

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

(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]