exhibits identified by the witness during the deposition. The pages of deposition transcripts and exhibits served under this paragraph shall be sequentially numbered by the party in the manner set forth in § 1.672(d). The deposition transcripts shall be accompanied by an index of the names of the witnesses, giving the number of the page where cross-examination, redirect and recross of each witness begins, and an index of exhibits of the type specified in § 1.672(b).

[49 FR 48470, Dec. 12, 1984, added effective Feb. 11, 1985; revised, 60 FR 14488, Mar 17, 1995, effective Apr. 21, 1995]

37 CFR 1.684 [Reserved]

37 CFR 1.685 Errors and irregularities in depositions.

(a) An error in a notice for taking a deposition is waived unless a motion (§ 1.635) to quash the notice is filed as soon as the error is, or could have been, discovered.

(b) An objection to a qualification of an officer taking a deposition is waived unless:

(1) The objection is made on the record of the deposition before a witness begins to testify.

(2) If discovered after the deposition, a motion(§ 1.635) to suppress the deposition is filed as soon as the objection is, or could have been, discovered.

(c) An error or irregularity in the manner in which testimony is transcribed, a certified transcript is signed by a witness, or a certified transcript is prepared, signed, certified, sealed, endorsed, forwarded, filed, or otherwise handled by the officer is waived unless a motion(§ 1.635) to suppress the deposition is filed as soon as the error of irregularity is, or could have been, discovered.

(d) An objection to the deposition on any grounds, such as the competency of a witness, admissibility of evidence, manner of taking the deposition, the form of questions and answers, any oath or affirmation, or conduct of any party at the deposition, is waived unless an objection is made on the record at the deposition stating the specific ground of objection. Any objection which a party wishes considered by the Board at final hearing shall be included in a motion to suppress under § 1.656(h).

(e) Nothing in this section precludes taking notice of plain errors affecting substantial rights although they were not brought to the attention of an administrative patent judge or the Board.

[49FR 48471, Dec. 12, 1984, added effective Feb. 11, 1985; 50 FR 23124, May 31, 1985; amended 60 FR 14488-536, Mar 17, 1995]

37 CFR 1.687 Additional discovery.

(a) A party is not entitled to discovery except as authorized in this subpart.

(b) Where appropriate, a party may obtain production of documents and things during cross-examination of an opponent's witness or during the testimony period of the party's case-in-rebuttal.

(c) Upon a motion (§ 1.635) brought by a party within the time set by an administrative patent judge under § 1.651 or thereafter as authorized by § 1.645 and upon a showing that the interest of justice so requires, an administrative patent judge may order additional discovery, as to matters under the control of a party within the scope of the Federal Rules of Civil Procedure, specifying the terms and conditions of such additional discovery. See § 1.647 concerning translations of documents in a foreign language.

(d) The parties may agree to discovery among themselves at any time. In the absence of an agreement, a motion for additional discovery shall not be filed except as authorized by this subpart.

[49 FR 48471, Dec. 12, 1984, added effective Feb. 11, 1985; paras. (d) & (e) revised, 60 FR 14488, Mar 17, 1995, effective Apr. 21, 1995]

37 CFR 1.688 Use of discovery.

(a) If otherwise admissible, a party may introduce into evidence, an answer to a written request for an admission or an answer to a written interrogatory obtained by discovery under § 1.687

by filing a copy of the request for admission or the written interrogatory and the answer. If the answer relates to a party's case-in-chief, the answer shall be served together with any affidavits served by the party under § 1.672(b) for its case-in-chief or, if the party does not serve any affidavits under § 1.672(b) for its case-in-chief, no later than the date set by an administrative patent judge for the party to serve affidavits under § 1.672(b) for its case-in-chief. If the answer relates to the party's rebuttal, the answer shall be served together with any affidavits served by the party under § 1.672(b) for the its case-in-rebuttal or, if the party does not serve any affidavits under § 1.672(b) for its case-in-rebuttal, no later than the date set by an administrative patent judge for the party to serve affidavits under § 1.672(b) for its case-in-rebuttal.

(b) Unless otherwise ordered by an administrative patent judge, any written objection to the admissibility of an answer shall be filed no later than the date set by the administrative patent judge for the opponent to file any objections under § 1.672(c) to affidavits submitted by the party under § 1.672(b). An opponent who fails to challenge the admissibility of an answer on a ground that could have been raised in a timely objection under this paragraph will not be entitled to move under § 1.656(h) to suppress the evidence on that ground. If an opponent timely files an objection, the party may respond with one or more supplemental affidavits, which must be filed together with any supplemental evidence filed by the party under § 1.672(c) or, if the party does not file any supplemental evidence under § 1.672(c), no later than the date set by an administrative patent judge for the party to file supplemental affidavits under § 1.672(c). No objection to the admissibility of the evidence contained in or submitted with a supplemental affidavit shall be made, except as provided by § 1.656(h). The pages of supplemental affidavits and the exhibits filed under this section shall be sequentially numbered by the party in the manner set forth in § 1.672(c). The supplemental affidavits and exhibits shall be accompanied by an index of witnesses and an index of exhibits of the type required by § 1.672(b).

(c) Any request by an opponent to cross-examine on oral deposition the affiant of a supplemental affidavit submitted under paragraph (b) of this section shall be filed no later than the date set by the administrative patent judge for the opponent to file a request to cross-examine an affiant with respect to an affidavit filed by the party under § 1.672(b) or (c). If any opponent requests cross-examination of an affiant, the party shall file a notice of deposition for a reasonable location within the United States under § 1.673(e) for the purpose of cross-examination by any opponent. Any redirect and recross shall take place at the deposition. At any deposition for the purpose of cross-examination of a witness, the party shall not be entitled to rely on any document or thing not mentioned in one or more of the affidavits filed under this paragraph, except to the extent necessary to conduct proper redirect. The party who gives notice of a deposition shall be responsible for providing a translator if the witness does not testify in English, for obtaining a court reporter, and for filing a certified transcript of the deposition as required by § 1.676. Within 45 days of the close of the period for taking cross-examination, the party shall serve (but not file) a copy of each deposition transcript on each opponent together with copies of any additional documentary exhibits identified by the witness during the deposition. The pages of deposition transcripts and exhibits served under this paragraph shall be sequentially numbered by the party in the manner set forth in § 1.672(d). The deposition transcripts shall be accompanied by an index of the names of the witnesses, giving the number of the page where cross-examination, redirect and recross of each witness begins, and an index of exhibits of the type specified in § 1.672(b).

(d) A party may not rely upon any other matter obtained by discovery unless it is introduced into evidence under this subpart.

[49 FR 48471, Dec. 12, 1984, added effective Feb.11, 1985; revised, 60 FR 14488, Mar 17, 1995, effective Apr. 21, 1995]

37 CFR 1.690 Arbitration of interferences.

(a) Parties to a patent interference may determine the interference or any aspect thereof by arbitration. Such arbitration shall be governed by the provisions of Title 9, United States Code. The parties must notify the Board in writing of their intention to arbitrate. An agreement to arbitrate must be in writing, specify the issues to be arbitrated, the name of the arbitrator or a date not more than thirty (30) days after the execution of the agreement for the selection of the arbitrator, and provide that the arbitrator's award shall be binding on the parties and that judgment thereon can be entered by the Board. A copy of the agreement must be filed within twenty (20) days after its

execution. The parties shall be solely responsible for the selection of the arbitrator and the rules for conducting proceedings before the arbitrator. Issues not disposed of by the arbitration will be resolved in accordance with the procedures established in this subpart, as determined by the administrative patent judge.

(b) An arbitration proceeding under this section shall be conducted within such time as may be authorized on a case-by-case basis by an administrative patent judge.

(c) An arbitration award will be given no consideration unless it is binding on the parties, is in writing and states in a clear and definite manner the issue or issues arbitrated and the disposition of each issue The award may include a statement of the grounds and reasoning in support thereof. Unless otherwise ordered by an administrative patent judge, the parties shall give notice to the Board of an arbitration award by filing within twenty (20) days from the date of the award a copy of the award signed by the arbitrator or arbitrators. When an award is timely filed, the award shall, as to the parties to the arbitration, be dispositive of the issue or issues to which it relates.

(d) An arbitration award shall not preclude the Office from determining patentability of any invention involved in the interference.

(b) Proof may be in the form of patents, printed publications, and affidavits.

[Added 52 FR 13838, Apr. 27, 1987; paras. (a)-(c) revised, 60 FR 14488, Mar 17, 1995, effective Apr. 21, 1995]

SUBPART F–EXTENSION OF PATENT TERM

37 CFR 1.701 Extension of patent term due to prosecution delay.

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

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

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

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

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

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

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

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

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

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

(ii) the number of days, if any, in the period beginning on the date of mailing

of an examiner's answer under § 1.193 in the application under secrecy order and ending on the date the secrecy order and any renewal thereof was removed;

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

(iv) the number of days, if any, in the period beginning on the date of notification under w5.3(c) and ending on the date of mailing of the notice of allowance under § 1.311.

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

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

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

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

[Added, 60 FR 20195, Apr. 25, 1995, effective June 8, 1995]

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

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

(b) The term "product" referred to in paragraph (a) of this section means --

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

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

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

[Added 52 FR 9394, Mar. 24, 1987, effective May 26, 1987; amended, July 20, 1989, 54 FR 30375, effective Aug. 22, 1989]

Patent Laws and Regulations

37 CFR 1.720 Conditions for extension of patent term.

The term of a patent may be extended if:

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

(b) the term of the patent has never been previously extended except for any interim extension issued pursuant to § 1.760;

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

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

(e) the product has received permission for commercial marketing or use and --

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

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

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

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

(g) The term of the patent has not expired before the submission of an application in compliance with § 1.741; and

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

[Added 52 FR 9395, Mar. 24, 1987, effective May 26, 1987; paras. (e) & (f) amended, July 20, 1989, 54 FR 30375, effective Aug. 22, 1989]

37 CFR 1.730 Applicant for extension of patent term.

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

[Added 52 FR 9395, Mar. 24, 1987, effective May 26, 1987]

37 CFR 1.740 Application for extension of patent term.

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

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

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

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

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

(5) A statement that the application is being submitted within the sixty day period permitted for submission pursuant to § 1.720(f) and an identification of the date of the last day on which the application could be submitted;

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

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

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

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

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

(i) For a patent claiming a human drug, antibiotic, or human biological product, the effective date of the investigational new drug (IND) application and the IND number; the date on which a new drug application (NDA) or a Product License Application (PLA) was initially submitted and the NDA or PLA number and the date on which the NDA was approved or the Product License issued;

(ii) For a patent claiming a new animal drug, the date a major health or environmental effects test on the drug was initiated and any available substantiation of the date or the date of an exemption under subsection (j) of section 512 of the Federal Food, Drug, and Cosmetic Act became effective for such animal drug; the date on which a new animal drug application (NADA) was initially submitted and the NADA number; and the date on which the NADA was approved;

(iii) For a patent claiming a veterinary biological product, the date the authority to prepare an experimental biological product under the Virus-Serum-Toxin Act became effective; the date an application for a license was submitted under the Virus-Serum-Toxin Act; and the date the license issued;

(iv) For a patent claiming a food or color additive, the date a major health or environmental effects test on the additive was initiated and any available substantiation of that date; the date on which a petition for product approval under the Federal Food, Drug and Cosmetic Act was initially submitted and the petition number; and the date on which the FDA published a Federal Register notice listing the additive for use;

(v) For a patent claiming a medical device, the effective date of the investigational device exemption (IDE) and the IDE number, if applicable, or the date on which the applicant began the first clinical investigation involving the device if no IDE was submitted and any available substantiation of that date; the date on which the application for product approval or notice of completion of a product development protocol under section 515 of the Federal Food, Drug and Cosmetic Act was initially submitted and the number of the application; and the date on which the application was approved or the protocol declared to be completed.

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

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

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

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

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

(16) A duplicate of the application papers, certified as such; and

(17) An oath or declaration as set forth in paragraph (b) of this section.

(b) Any oath or declaration submitted in compliance with paragraph (a) of this section must be signed by the owner of record of the patent or its agent, specifically identify the papers and the patent for which an extension is sought and aver that the person signing the oath or declaration:

(1) Is the owner, an official of a corporate owner authorized to obligate the corporation, or a patent attorney or agent authorized to practice before the Patent and Trademark Office and who has general authority from the owner to act on behalf of the owner in patent matters.

(2) Has reviewed and understands the contents of the application being submitted pursuant to this section;

(3) Believes the patent is subject to extension pursuant to § 1.710;

(4) Believes an extension of the length claimed is justified under 35 U.S.C. 156 and the applicable regulations; and

(5) Believes the patent for which the extension is being sought meets the conditions for extension of the term of a patent as set forth in § 1.720.

(c) If any application for extension of patent term submitted pursuant to this section is held to be informal, applicant may seek to have that holding reviewed by filing a petition with the required fee, as necessary, pursuant to §§ 1.181, 1.182 or 1.183, as appropriate, within such time as may be set in the notice that the application has been held to be informal, or if no time is set, within one month of the date on which the application was held informal. The time periods set forth herein are subject to the provisions of 37 CFR 1.136.

[Added 52 FR 9395, Mar. 24, 1987, effective May 26, 1987; para. (a) amended July 20, 1989, 54 FR 30375, effective Aug. 22, 1989; para. (a)(14), 56 FR 65142, Dec. 13, 1991, effective Dec. 16, 1991]

37 CFR 1.741 Filing date of application.

(a) The filing date of an application for extension of patent term is the date on which a complete application is received in the Patent and Trademark Office or filed pursuant to the "Certificate of Mailing or Transmission" provisions of 37 CFR 1.8 or "Express Mail" provisions of 37 CFR 1.10.

A complete application shall include:

(1) An identification of the approved product;

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

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

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

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

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

(b) If any application submitted pursuant to this section is held to be incomplete, applicant may seek to have this holding reviewed under § 1.181.

[Added 52 FR 9396, Mar. 24, 1987, effective May 26, 1987; para. (a) amended 54 FR 30375, July 20, 1989, effective Aug. 22, 1989; para. (a) amended, 58 FR 54494, Oct. 22, 1993, effective Nov. 22, 1993]

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

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

[Added 52 FR 9396, Mar. 24, 1987, effective May 26, 1987; revised, 60 FR 25615, May 12, 1995, effective July 11,

1995]

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

An applicant who has filed a formal application for extension in compliance with § 1.740 may request one or more interim extensions for periods of up to one year each pending a final determination on the application pursuant to § 1.750. Any such request should be filed at least three months prior to the expiration date of the patent. The Commissioner may issue interim extensions, without a request by the applicant, for periods of up to one year each until a final determination is made. The patent owner or agent will be notified when an interim extension is granted and notice of the extension will be published in the Official Gazette of the 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.

[Added 52 FR 9396, Mar. 24, 1987, effective May 26, 1987; heading revised, 60 FR 25615, May 12, 1995, effective July 11, 1995]

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

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

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

(c) No patent will be determined eligible for extension and no extension will be issued if it is determined that fraud on the Office or the Secretary was practiced or attempted or the duty of disclosure was violated through bad faith or gross negligence in connection with the patent term extension proceeding If it is established by clear and convincing evidence that any fraud was practiced or attempted on the Office or the Secretary in connection with the patent term extension proceeding or that there was any violation of the duty of disclosure through bad faith or gross negligence in connection with the patent term extension proceeding, a final determination will be made pursuant to § 1.750 that the patent is not eligible for extension.

(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.

[Added 52 FR 9396, Mar. 24 1987, effective May 26, 1987, para. (a) amended 54 FR 30375, July 20, 1989, effective Aug. 22, 1989; para. (a) revised, 60 FR 25615, May 12, 1995, effective July 11, 1995]

Patent Laws and Regulations

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

An application for extension of patent term may be expressly withdrawn before a determination is made pursuant to § 1.750 by filing in the Office, in duplicate, a written declaration of withdrawal signed by the owner of record of the patent or its agent. An application may not be expressly withdrawn after the date permitted for response 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.

[Added 52 FR 9397, Mar. 24 1987, effective May 26, 1987; 56 FR 65142, Dec. 13, 1991, effective Dec. 16, 1991]

37 CFR 1.775 Calculation of patent term extension for a 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 human drug product and ending on the date an 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 that applicant did not act with due diligence;

(iii) One-half the number of days remaining in the period defined by paragraph (c)(1) of this section after that period is reduced in accordance with para- graphs (d)(1)(i) and (ii) of this section; half days will be ignored for purposes of subtraction;

(2) By adding the number of days determined in paragraph (d)(1) of this section to the original term of the patent as shortened by any terminal disclaimer;

(3) By adding 14 years to the date of approval of the application under section 351 of the Public Health Service Act, or subsection (b) of section 505 or section 507 of the

Federal Food, Drug, and Cosmetic Act;

(4) By comparing the dates for the ends of the periods obtained pursuant to paragraphs (d)(2) and (d)(3) of this section with each other and selecting the earlier date;

(5) If the original patent was issued after September 24, 1984,

(i) By adding 5 years to the original expiration date of the patent or any earlier date set by terminal disclaimer; and

(ii) By comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(5)(i) of this section with each other and selecting the earlier date;

(6) If the original patent was issued before September 24, 1984, and

(i) If no request was submitted for an exemption under subsection (i) of section 505 or subsection (d) of section 507 of the Federal Food, Drug and Cosmetic Act before September 24, 1984, by—

(A) Adding 5 years to the original expiration date of the patent or earlier date set by terminal disclaimer; and

(B) By comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(i)(A) of this section with each other and selecting the earlier date; or

(ii) If a request was submitted for an exemption under subsection (i) of section 505 or subsection (d) of section 507 of the Federal Food, Drug, or Cosmetic Act before September 24, 1984 and the commercial marketing or use of the product was not approved before September 24, 1984, by -

(A) Adding 2 years to the original expiration date of the patent or earlier date set by terminal disclaimer, and

(B) By comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(ii)(A) of this section with each other and selecting the earlier filing date.

[Added 52 FR 9397, Mar. 24 1987, effective May 26, 1987]

37 CFR 1.776 Calculation of patent term extension for a food additive or color additive.

(a) If a determination is made pursuant to § 1.750 that a patent for a food additive or color additive 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 earlier date set by terminal disclaimer (§ 1.321).

(b) The term of the patent for a food additive or color additive 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) he length of the regulatory review period for a food additive or color additive will be determined by the Secretary of Health and Human Services. Under35 U.S.C. 156(g)(2)(B), it is the sum of -

(1) The number of days in the period beginning on the date a major health or environmental effects test on the additive was initiated and ending on the date a petition was initially submitted with respect to the approved product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product; and

(2) The number of days in the period beginning on the date a petition was initially submitted with respect to the approved product under the Federal Food, Drug and Cosmetic Act requesting the issuance of a regulation for use of the product, and ending on the date such regulation became effective or, if objections were filed to

such regulation, ending on the date such objections were resolved and commercial marketing was permitted or, if commercial marketing was permitted and later revoked pending further proceedings as a result of such objections, ending on the date such proceedings were finally resolved and commercial marketing was permitted.

(d) The term of the patent as extended for a food additive or color additive 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 that applicant did not act with due diligence;

(iii) The number of days equal to one-half the number of days remaining in the period defined by paragraph (c)(1) of this section after that period is reduced in accordance with paragraphs (d)(1) (i) and (ii) of this section; half days will be ignored for purposes of subtraction;

(2) By adding the number of days determined in paragraph (d)(1) of this section to the original term of the patent as shortened by any terminal disclaimer;

(3) By adding 14 years to the date a regulation for use of the product became effective or, if objections were filed to such regulation, to the date such objections were resolved and commercial marketing was permitted or, if commercial marketing was permitted and later revoked pending further proceedings as a result of such objections, to the date such proceedings were finally resolved and commercial marketing was permitted;

(4) By comparing the dates for the ends of the periods obtained pursuant to paragraphs (d)(2) and (d)(3) of this section with each other and selecting the earlier date;

(5) If the original patent was issued after September 24, 1984,

(i) By adding 5 years to the original expiration date of the patent or earlier date set by terminal disclaimer; and

(ii) By comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(5)(i) of this section with each other and selecting the earlier date;

(6) If the original patent was issued before September 24, 1984, and

(i) If no major health or environmental effects test was initiated and no petition for a regulation or application for registration was submitted before September 24, 1984, by

(A) Adding 5 years to the original expiration date of the patent or earlier date set by terminal disclaimer, and

(B) By comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(i)(A) of this section with each other and selecting the earlier date; or

(ii) If a major health or environmental effects test was initiated or a petition for a regulation or application for registration was submitted by September 24, 1984, and the commercial marketing or use of the product was not approved before September 24, 1984, by --

(A) Adding 2 years to the original expiration date of the patent or earlier date set by terminal disclaimer, and

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(B) By comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(ii)(A) of this section with each other and selecting the earlier date.

[Added 52 FR 9397, Mar. 24, 1987, effective May 26, 1987]

37 CFR 1.777 Calculation of patent term extension for a medical device.

(a) If a determination is made pursuant to § 1.750 that a patent for a medical device 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 earlier date as set by terminal disclaimer (§ 1.321).

(b) The term of the patent for a medical device 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 medical device will be determined by the Secretary of Health and Human Services. Under 35 U.S.C. 156(g)(3)(B), it is the sum of

(1) The number of days in the period beginning on the date a clinical investigation on humans involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act; and

(2) The number of days in the period beginning on the date the application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act, and ending on the date such application was approved under such Act or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515(f)(5) of the Act and ending on the date the protocol was declared completed under section 515(f)(6) of the Act.

(d) The term of the patent as extended for a medical device 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 pursuant to paragraph (c) of this section:

(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 that applicant did not act with due diligence;

(iii) One-half the number of days remaining in the period defined by paragraph (c)(1) of this section after that period is reduced in accordance with paragraphs (d)(1) (i) and (ii) of this section; half days will be ignored for purposes of subtraction;

(2) By adding the number of days determined in paragraph (d)(1) of this section to the original term of the patent as shortened by any terminal disclaimer;

(3) By adding 14 years to the date of approval of the application under section 515 of the Federal Food, Drug, and Cosmetic Act or the date a product development protocol was declared completed under section 515(f)(6) of the Act;

(4) By comparing the dates for the ends of the periods obtained pursuant to paragraphs (d)(2) and (d)(3) of this section with each other and selecting the earlier date;

(5) If the original patent was issued after September 24, 1984,

(i) By adding 5 years to the original expiration date of the patent or earlier

date set by terminal disclaimer; and

(ii) By comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(5)(i) of this section with each other and selecting the earlier date;

(6) If the original patent was issued before September 24, 1984, and

(i) If no clinical investigation on humans involving the device was begun or no product development protocol was submitted under section 515(f)(5) of the Federal Food, Drug and Cosmetic Act before September 24, 1984, by --

(A) Adding 5 years to the original expiration date of the patent or earlier date set by terminal disclaimer, and

(B) By comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(i)(A) of this section with each other and selecting the earlier date; or

(ii) If a clinical investigation on humans involving the device was begun or a product development protocol was submitted under section 515(f)(5) of the Federal Food, Drug, and Cosmetic Act before September 24, 1984 and the commercial marketing or use of the product was not approved before September 24, 1984, by

(A) Adding 2 years to the original expiration date of the patent or earlier date set by terminal disclaimer, and

(B) By comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(ii)(A) of this section with each other and selecting the earlier date.

[Added 52 FR 9398, Mar. 24 1987, effective May 26, 1987]

37 CFR 1.778 Calculation of patent term extension for an animal drug product.

(a) If a determination is made pursuant to § 1.750 that a patent for an animal drug 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 an animal drug will be extended by the length of the regulatory review period for the drug 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 an animal drug will be determined by the Secretary of Health and Human Services. Under 35 U.S.C. 156(g)(4)(B), it is the sum of --

(1) The number of days in the period beginning on the earlier of the date a major health or environmental effects test on the drug was initiated or the date an exemption under subsection (j) of section 512 of the Federal Food, Drug, and Cosmetic Act became effective for the approved animal drug and ending on the date an application was initially submitted for such animal drug under section 512 of the Federal Food, Drug, and Cosmetic Act; and

(2) The number of days in the period beginning on the date the application was initially submitted for the approved animal drug under subsection (b) of section 512 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 an animal drug 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 that 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 that applicant did not act with due diligence;

(iii) One-half the number of days remaining in the period defined by paragraph (c)(1) of this section after that period is reduced in accordance with paragraphs (d)(1)(i) and (ii) of this section; half days will be ignored for purposes of subtraction;

(2) By adding the number of days determined in paragraph (d)(1) of this section to the original term of the patent as shortened by any terminal disclaimer;

(3) By adding 14 years to the date of approval of the application under section 512 of the Federal Food, Drug, and Cosmetic Act;

(4) By comparing the dates for the ends of the periods obtained pursuant to paragraphs (d)(2) and (d)(3) of this section with each other and selecting the earlier date;

(5) If the original patent was issued after November 16, 1988, by —

(i) Adding 5 years to the original expiration date of the patent or any earlier date set by terminal disclaimer; and

(ii) Comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(5)(i) of this section with each other and selecting the earlier date;

(6) If the original patent was issued before November 16, 1988, and

(i) If no major health or environmental effects test on the drug was initiated and no request was submitted for an exemption under subsection (j) of section 512 of the Federal Food, Drug, and Cosmetic Act before November 16, 1988, by —

(A) Adding 5 years to the original expiration date of the patent or earlier date set by terminal disclaimer; and

(B) Comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(i)(A) of this section with each other and selecting the earlier date; or

(ii) If a major health or environmental effects test was initiated or a request for an exemption under subsection (j) of section 512 of the Federal Food, Drug, and Cosmetic Act was submitted before November 16, 1988, and the application for commercial marketing or use of the animal drug was not approved before November 16, 1988, by —

(A) Adding 3 years to the original expiration date of the patent or earlier date set by terminal disclaimer, and

(B) Comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(ii)(A) of this section with each other and selecting the earlier date.

[Added July 20, 1989, 54 FR 30375, effective Aug. 22, 1989]

37 CFR 1.779 Calculation of patent term extension for a veterinary biological product.

(a) If a determination is made pursuant to § 1.750 that a patent for a veterinary 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 veterinary biological product will be extended by the length of the regulatory review period for the product as determined by the Secretary of Agriculture, reduced as appropriate pursuant to paragraphs (d)(1) through (d)(6) of this section.