

(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 date.

[52 FR 9394, Mar. 24, 1987, as amended at 54 FR 30381, July 20, 1989]

§ 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) The length of the regulatory review period for a food additive or color additive will be determined by the Secretary of Health and Human Services. Under 35 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

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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

(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.

§ 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 Serv-

ices, 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