

EFFECTIVE DATE OF 1999 AMENDMENT

Amendment by Pub. L. 106-113 effective 4 months after Nov. 29, 1999, see section 1000(a)(9) [title IV, §4731] of Pub. L. 106-113, set out as a note under section 1 of this title.

§ 155A. Patent term restoration

(a) Notwithstanding section 154 of this title, the term of each of the following patents shall be extended in accordance with this section:

(1) Any patent which encompasses within its scope a composition of matter which is a new drug product, if during the regulatory review of the product by the Federal Food and Drug Administration—

(A) the Federal Food and Drug Administration notified the patentee, by letter dated February 20, 1976, that such product's new drug application was not approvable under section 505(b)(1) of the Federal Food, Drug and Cosmetic Act;

(B) in 1977 the patentee submitted to the Federal Food and Drug Administration the results of a health effects test to evaluate the carcinogenic potential of such product;

(C) the Federal Food and Drug Administration approved, by letter dated December 18, 1979, the new drug application for such product; and

(D) the Federal Food and Drug Administration approved, by letter dated May 26, 1981, a supplementary application covering the facility for the production of such product.

(2) Any patent which encompasses within its scope a process for using the composition of matter described in paragraph (1).

(b) The term of any patent described in subsection (a) shall be extended for a period equal to the period beginning February 20, 1976, and ending May 26, 1981, and such patent shall have the effect as if originally issued with such extended term.

(c) The patentee of any patent described in subsection (a) of this section shall, within ninety days after the date of enactment of this section, notify the Director of the number of any patent so extended. On receipt of such notice, the Director shall confirm such extension by placing a notice thereof in the official file of such patent and publishing an appropriate notice of such extension in the Official Gazette of the Patent and Trademark Office.

(Added Pub. L. 98-127, §4(a), Oct. 13, 1983, 97 Stat. 832; amended Pub. L. 106-113, div. B, §1000(a)(9) [title IV, §4732(a)(7), (10)(A)], Nov. 29, 1999, 113 Stat. 1536, 1501A-582; Pub. L. 107-273, div. C, title III, §13206(b)(1)(B), Nov. 2, 2002, 116 Stat. 1906.)

REFERENCES IN TEXT

Section 505(b)(1) of the Federal Food, Drug and Cosmetic Act, referred to in subsec. (a)(1)(A), is classified to section 355(b)(1) of Title 21, Food and Drugs.

The date of enactment of this section, referred to in subsec. (c), is the date of enactment of Pub. L. 98-127, which was approved Oct. 13, 1983.

AMENDMENTS

2002—Subsec. (c). Pub. L. 107-273 made technical correction to directory language of Pub. L. 106-113,

§1000(a)(9) [title IV, §4732(a)(10)(A)]. See 1999 Amendment note below.

1999—Subsec. (c). Pub. L. 106-113, §1000(a)(9) [title IV, §4732(a)(10)(A)], as amended by Pub. L. 107-273, substituted "Director shall confirm" for "Commissioner shall confirm".

Pub. L. 106-113, §1000(a)(9) [title IV, §4732(a)(7)], substituted "notify the Director" for "notify the Commissioner of Patents and Trademarks".

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§ 156. Extension of patent term

(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b), if—

(1) the term of the patent has not expired before an application is submitted under subsection (d)(1) for its extension;

(2) the term of the patent has never been extended under subsection (e)(1) of this section;

(3) an application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirements of paragraphs (1) through (4) of subsection (d);

(4) the product has been subject to a regulatory review period before its commercial marketing or use;

(5)(A) except as provided in subparagraph (B) or (C), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred;

(B) in the case of a patent which claims a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent; or

(C) for purposes of subparagraph (A), in the case of a patent which—

(i) claims a new animal drug or a veterinary biological product which (I) is not covered by the claims in any other patent which has been extended, and (II) has received permission for the commercial marketing or use in non-food-producing animals and in food-producing animals, and

(ii) 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.