

the date of enactment of Pub. L. 103-465, which was approved Dec. 8, 1994.

#### AMENDMENTS

2002—Subsec. (b)(4)(A). Pub. L. 107-273, §13206(a)(8), struck out “, United States Code,” after “title 5”.

Subsec. (d)(4)(A). Pub. L. 107-273, §13204, amended subsec. (d)(4)(A) as in effect on Nov. 29, 2000, by substituting “the date of” for “the date on which the Patent and Trademark Office receives a copy of the” and “publication in the English language” for “international application in the English language”.

1999—Pub. L. 106-113, §1000(a)(9) [title IV, §4504(1)], inserted “; provisional rights” after “patent” in section catchline.

Subsec. (b). Pub. L. 106-113, §1000(a)(9) [title IV, §4402(a)], amended heading and text of subsec. (b) generally. Prior to amendment, text provided for interference delay or secrecy orders, extensions for appellate review, a limitations period, and a maximum period of 5 years duration for all extensions.

Subsec. (d). Pub. L. 106-113, §1000(a)(9) [title IV, §4504(2)], added subsec. (d).

1996—Subsec. (c)(2). Pub. L. 104-295 substituted “acts” for “Acts” in introductory provisions.

1994—Pub. L. 103-465 amended section catchline and text generally. Prior to amendment, text read as follows: “Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, for the term of seventeen years, subject to the payment of fees as provided for in this title, of the right to exclude others from making, using, or selling the invention throughout the United States and, if the invention is a process, of the right to exclude others from using or selling throughout the United States, or importing into the United States, products made by that process., referring to the specification for the particulars thereof. A copy of the specification and drawings shall be annexed to the patent and be a part thereof.”

1988—Pub. L. 100-418 inserted “and, if the invention is a process, of the right to exclude others from using or selling throughout the United States, or importing into the United States, products made by that process,” after “United States”.

1980—Pub. L. 96-517 substituted “payment of fees” for “payment of issue fees”.

1965—Pub. L. 89-83 added “subject to the payment of issue fees as provided for in this title”.

#### EFFECTIVE DATE OF 1999 AMENDMENT

Pub. L. 106-113, div. B, §1000(a)(9) [title IV, §4405(a)], Nov. 29, 1999, 113 Stat. 1536, 1501A-560, provided that: “The amendments made by sections 4402 and 4404 [amending this section, sections 156 and 282 of this title, and section 1295 of Title 28, Judiciary and Judicial Procedure] shall take effect on the date that is 6 months after the date of the enactment of this Act [Nov. 29, 1999] and, except for a design patent application filed under chapter 16 of title 35, United States Code, shall apply to any application filed on or after the date that is 6 months after the date of the enactment of this Act.”

Amendment by section 1000(a)(9) [title IV, §4504] of Pub. L. 106-113 effective Nov. 29, 2000, applicable only to applications (including international applications designating the United States) filed on or after that date, and additionally applicable to any pending application filed before Nov. 29, 2000, if such pending application is published pursuant to a request of the applicant under such procedures as may be established by the Director, see section 1000(a)(9) [title IV, §4508] of Pub. L. 106-113, as amended, set out as a note under section 10 of this title.

#### EFFECTIVE DATE OF 1994 AMENDMENT

Section 534 of title V of Pub. L. 103-465 provided that: “(a) IN GENERAL.—Subject to subsection (b), the amendments made by this subtitle [subtitle C

(§§531-534) of title V of Pub. L. 103-465, amending this section and sections 41, 104, 111, 119, 156, 172, 173, 252, 262, 271, 272, 287, 292, 295, 307, 365, and 373 of this title] take effect on the date that is one year after the date on which the WTO Agreement enters into force with respect to the United States [Jan. 1, 1995].

#### “(b) PATENT APPLICATIONS.—

“(1) IN GENERAL.—Subject to paragraph (2), the amendments made by section 532 [amending this section and sections 41, 111, 119, 156, 172, 173, 365, and 373 of this title] take effect on the date that is 6 months after the date of the enactment of this Act [Dec. 8, 1994] and shall apply to all patent applications filed in the United States on or after the effective date.

“(2) SECTION 154(a)(1).—Section 154(a)(1) of title 35, United States Code, as amended by section 532(a)(1) of this Act, shall take effect on the effective date described in subsection (a).

“(3) EARLIEST FILING.—The term of a patent granted on an application that is filed on or after the effective date described in subsection (a) and that contains a specific reference to an earlier application filed under the provisions of section 120, 121, or 365(c) of title 35, United States Code, shall be measured from the filing date of the earliest filed application.”

#### EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100-418 effective 6 months after Aug. 23, 1988, and, subject to enumerated exceptions, applicable only with respect to products made or imported after such effective date, see section 9006 of Pub. L. 100-418, set out as a note under section 271 of this title.

#### EFFECTIVE DATE OF 1980 AMENDMENT

Amendment by Pub. L. 96-517 effective Dec. 12, 1980, see section 8(a) of Pub. L. 96-517, set out as a note under section 41 of this title.

#### EFFECTIVE DATE OF 1965 AMENDMENT

Amendment by Pub. L. 89-83 effective three months after July 24, 1965, see section 7(a) of Pub. L. 89-83, set out as a note under section 41 of this title.

#### REGULATIONS

Section 532(a)(2) of Pub. L. 103-465 authorized the Commissioner of Patents and Trademarks to prescribe regulations for further limited reexamination of applications pending 2 years or longer and for examination of more than 1 independent and distinct invention in applications pending 3 years or longer, as of the effective date of section 154(a)(2) of this title, and to establish appropriate related fees.

#### § 155. Patent term extension

Notwithstanding the provisions of section 154, the term of a patent which encompasses within its scope a composition of matter or a process for using such composition shall be extended if such composition or process has been subjected to a regulatory review by the Federal Food and Drug Administration pursuant to the Federal Food, Drug, and Cosmetic Act leading to the publication of regulation permitting the interstate distribution and sale of such composition or process and for which there has thereafter been a stay of regulation of approval imposed pursuant to section 409 of the Federal Food, Drug, and Cosmetic Act which stay was in effect on January 1, 1981, by a length of time to be measured from the date such stay of regulation of approval was imposed until such proceedings are finally resolved and commercial marketing permitted. The patentee, his heirs, successors or assigns shall notify the Director within ninety days of the date of enactment of this section or

the date the stay of regulation of approval has been removed, whichever is later, of the number of the patent to be extended and the date the stay was imposed and the date commercial marketing was permitted. On receipt of such notice, the Director shall promptly issue to the owner of record of the patent a certificate of extension, under seal, stating the fact and length of the extension and identifying the composition of matter or process for using such composition to which such extension is applicable. Such certificate shall be recorded in the official file of each patent extended and such certificate shall be considered as part of the original patent, and an appropriate notice shall be published in the Official Gazette of the Patent and Trademark Office.

(Added Pub. L. 97-414, §11(a), Jan. 4, 1983, 96 Stat. 2065; amended Pub. L. 106-113, div. B, §1000(a)(9) [title IV, §4732(a)(6), (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

The Federal Food, Drug, and Cosmetic Act, referred to in text, is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. Section 409 of the Federal Food, Drug, and Cosmetic Act is classified to section 348 of Title 21. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

Date of enactment of this section, referred to in text, means date of enactment of Pub. L. 97-414, which was approved Jan. 4, 1983.

#### AMENDMENTS

2002—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—Pub. L. 106-113, §1000(a)(9) [title IV, §4732(a)(10)(A)], as amended by Pub. L. 107-273, substituted “Director shall promptly” for “Commissioner shall promptly”.

Pub. L. 106-113, §1000(a)(9) [title IV, §4732(a)(6)], substituted “notify the Director” for “notify the Commissioner of Patents and Trademarks”.

#### 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”.

#### 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.

### § 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;