the patent and approved for the approved product before the expiration of the term of the patent under the provision of law under which the applicable regulatory review occurred; and

''(3) in the case of a patent which claims a method of manufacturing a product, be limited to the method of manufacturing as used to make the approved product.''

Subsec. (c)(2). Pub. L. 100–670, §201(c), substituted ''(3)(B)(i), (4)(B)(i), and (5)(B)(i)'' for ''and (3)(B)(i)''.

Subsec. (d)(1)(C). Pub. L. 100–670, §201(d), inserted ''or the Secretary of Agriculture'' after ''and Human Services''.

Subsec. (d)(2)(A). Pub. L. 100–670, §201(e), amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: ''Within sixty days of the submittal of an application for extension of the term of a patent under paragraph (1), the Commissioner shall notify the Secretary of Health and Human Services if the patent claims any human drug product, a medical device, or a food additive or color additive or a method of using or manufacturing such a product, device, or additive and if the product, device, and additive are subject to the Federal Food, Drug, and Cosmetic Act, of the extension application and shall submit to the Secretary a copy of the application. Not later than thirty days after the receipt of an application from the Commissioner, the Secretary shall review the dates contained in the application pursuant to paragraph (1)(C) and determine the applicable regulatory review period, shall notify the Commissioner of the determination, and shall publish in the Federal Register a notice of such determination.''

Subsec. (d)(2)(B). Pub. L. 100–670, §201(f), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows:

''(i) If a petition is submitted to the Secretary under subparagraph (A), not later than one hundred and eighty days after the publication of the determination under subparagraph (A), upon which it may reasonably be determined that the applicant did not act with due diligence during the applicable regulatory review period, the Secretary shall, in accordance with regulations promulgated by the Secretary determine if the applicant acted with due diligence during the applicable regulatory review period. The Secretary shall make such determination not later than ninety days after the receipt of such a petition. The Secretary may not delegate the authority to make the determination prescribed by this subparagraph to an office below the Office of the Commissioner of Food and Drugs.

''(ii) The Secretary shall notify the Commissioner of the determination and shall publish in the Federal Register a notice of such determination together with the factual and legal basis for such determination. Any interested person may request, within the sixty-day period beginning on the publication of a determination, the Secretary to hold an informal hearing on the determination. If such a request is made within such period, the Secretary shall hold such hearing not later than thirty days after the date of the request, or at the request of the person making the request, not later than sixty days after such date. The Secretary shall provide notice of the hearing to the owner of the patent involved and to any interested person and provide the owner and any interested person an opportunity to participate in the hearing. Within thirty days after the completion of the hearing, the Secretary shall affirm or revise the determination which was the subject of the hearing and notify the Commissioner of any revision of the determination and shall publish any such revision in the Federal Register.''

Subsec. (f)(1)(A). Pub. L. 100–670, §201(g)(1), struck out ''human'' before ''drug product''.

Subsec. (f)(2). Pub. L. 100–670, §201(g)(1), amended par. (2) generally. Prior to amendment, par. (2) read as follows: ''The term 'human drug product' means the active ingredient of a new 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.''

Subsec. (f)(4)(B), (C). Pub. L. 100–670, §201(g)(2), which directed general amendment of subpars. (B) and (C) of par. (4), was executed by amending subpar. (B) generally, and adding subpar. (C) as probable intent of Congress in light of absence of subpar. (C) in par. (4). Prior to amendment, subpar. (B) read as follows: ''Any reference to section 503, 505, 507, or 515 is a reference to section 503, 505, 507, or 515 of the Federal Food, Drug, and Cosmetic Act.''

Subsec. (f)(7), (8). Pub. L. 100–670, §201(g)(3), added pars. (7) and (8).

Subsec. (g)(1)(A). Pub. L. 100–670, §201(h)(1)(A), (2), substituted ''new drug, antibiotic drug, or human biological product'' for ''human drug product'' and ''paragraph (6)'' for ''paragraph (4)''.

Subsec. (g)(1)(B). Pub. L. 100–670, §201(h)(1)(B), substituted ''new drug, antibiotic drug, or human biological product'' for ''human drug product'' in introductory provisions and ''product'' for ''human drug product'' in cls. (i) and (ii).

Subsec. (g)(2)(A), (3)(A). Pub. L. 100–670, §201(h)(3), substituted ''paragraph (6)'' for ''paragraph (4)''.

Subsec. (g)(4), (5). Pub. L. 100–670, §201(h)(4), added pars. (4) and (5). Former par. (4) redesignated (6).

Subsec. (g)(6). Pub. L. 100–670, §201(h)(4), redesignated former par. (4) as (6).

Subsec. (g)(6)(B)(i). Pub. L. 100–670, §201(h)(5)(A), substituted ''paragraph (1)(B) or (4)(B) was submitted and no request for the authority described in paragraph (5)(B) was submitted'' for ''paragraph (1)(B) was submitted''.

Subsec. (g)(6)(B)(ii). Pub. L. 100–670, §201(h)(5)(B), substituted ''paragraph (2)(B) or (4)(B)'' for ''paragraph (2)''.

Subsec. (g)(6)(C). Pub. L. 100–670, §201(h)(5)(C), inserted ''or in the case of an approved product which is a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act or the Virus-Serum-Toxin Act), three years'' after ''exceed two years''.

EFFECTIVE DATE OF 2011 AMENDMENT

Pub. L. 112–29, §37(b), Sept. 16, 2011, 125 Stat. 341, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to any application for extension of a patent term under section 156 of title 35, United States Code, that is pending on, that is filed after, or as to which a decision regarding the application is subject to judicial review on, the date of the enactment of this Act [Sept. 16, 2011].''

EFFECTIVE DATE OF 1999 AMENDMENT

Amendment by section 1000(a)(9) [title IV, §4404] of Pub. L. 106–113 effective on date that is 6 months after Nov. 29, 1999, and, except for design patent application filed under chapter 16 of this title, applicable to any application filed on or after such date, see section 1000(a)(9) [title IV, §4405(a)] of Pub. L. 106–113, set out as a note under section 154 of this title.

Amendment by section 1000(a)(9) [title IV, §4732(a)(10)(A)] of 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.

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103–465 effective 6 months after Dec. 8, 1994, and applicable to all patent applications filed in the United States on or after that effective date, with provisions relating to earliest filed patent application, see section 534(b)(1), (3) of Pub. L. 103–465, set out as a note under section 154 of this title.

[§ 157. Repealed. Pub. L. 112–29, § 3(e)(1), Sept. 16, 2011, 125 Stat. 287]

Section, added Pub. L. 98–622, title I, §102(a), Nov. 8, 1984, 98 Stat. 3383; amended Pub. L. 106–113, div. B,

§ 1000(a)(9) [title IV, § 4732(a)(10)(A), (11)], Nov. 29, 1999, 113 Stat. 1536, 1501A–582, 1501A–583; Pub. L. 107–273, div. C, title III, § 13206(b)(1)(B), Nov. 2, 2002, 116 Stat. 1906; Pub. L. 112–29, § 20(j), Sept. 16, 2011, 125 Stat. 335, related to statutory invention registration.

EFFECTIVE DATE OF REPEAL

Repeal effective upon the expiration of the 18-month period beginning on Sept. 16, 2011, and applicable to any request for a statutory invention registration filed on or after that effective date, see section 3(e)(3) of Pub. L. 112–29, set out as an Effective Date of 2011 Amendment note under section 111 of this title.

CHAPTER 15—PLANT PATENTS

§ 161. Patents for plants

Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefor, subject to the conditions and requirements of this title.

The provisions of this title relating to patents for inventions shall apply to patents for plants, except as otherwise provided.

(June 19, 1952, ch. 950, 66 Stat. 804; Sept. 3, 1954, ch. 1259, 68 Stat. 1190.)

HISTORICAL AND REVISION NOTES

Based on Title 35, U.S.C., 1946 ed., § 31, part (R.S. 4886, amended (1) Mar. 3, 1897, ch. 391, § 1, 29 Stat. 692, (2) May 23, 1930, ch. 312, § 1, 46 Stat. 376, (3) Aug. 5, 1939, ch. 450, § 1, 53 Stat. 1212).

The provision relating to plants in the corresponding section of existing statute is made a separate section.

AMENDMENTS

1954—Act Sept. 3, 1954, provided that plant seedlings, discovered, propagated asexually, and proved to have new characteristics distinct from other known plants are patentable.

§ 162. Description, claim

No plant patent shall be declared invalid for noncompliance with section 112 if the description is as complete as is reasonably possible.

The claim in the specification shall be in formal terms to the plant shown and described.

(July 19, 1952, ch. 950, 66 Stat. 804; Pub. L. 112–29, § 20(j), Sept. 16, 2011, 125 Stat. 335.)

HISTORICAL AND REVISION NOTES

Based on Title 35, U.S.C., 1946 ed., § 33, part (R.S. 4888, amended (1) Mar. 3, 1915, ch. 94, § 1, 38 Stat. 958, (2) May 23, 1930, ch. 312, § 2, 46 Stat. 376).

The first paragraph is the provision in R.S. 4888 (see section 112). The second paragraph is not in the statute but represents the actual practice.

AMENDMENTS

2011—Pub. L. 112–29 struck out ''of this title'' after ''112''.

EFFECTIVE DATE OF 2011 AMENDMENT

Amendment by Pub. L. 112–29 effective upon the expiration of the 1-year period beginning on Sept. 16, 2011, and applicable to proceedings commenced on or after that effective date, see section 20(*l*) of Pub. L. 112–29, set out as a note under section 2 of this title.

§ 163. Grant

In the case of a plant patent, the grant shall include the right to exclude others from asexually reproducing the plant, and from using, offering for sale, or selling the plant so reproduced, or any of its parts, throughout the United States, or from importing the plant so reproduced, or any parts thereof, into the United States.

(July 19, 1952, ch. 950, 66 Stat. 804; Pub. L. 105–289, § 3(a), Oct. 27, 1998, 112 Stat. 2781.)

HISTORICAL AND REVISION NOTES

Based on Title 35, U.S.C., 1946 ed., § 40, part (R.S. 4884, amended May 23, 1930, ch. 312, § 1, 46 Stat. 376).

This provision is from R.S. 4884 (see section 154) amended in language.

AMENDMENTS

1998—Pub. L. 105–289 reenacted section catchline without change and amended text generally. Prior to amendment, text read as follows: ''In the case of a plant patent the grant shall be of the right to exclude others from asexually reproducing the plant or selling or using the plant so reproduced.''

EFFECTIVE DATE OF 1998 AMENDMENT

Pub. L. 105–289, § 3(b), Oct. 27, 1998, 112 Stat. 2781, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to any plant patent issued on or after the date of the enactment of this Act [Oct. 27, 1998].''

FINDINGS AND PURPOSES

Pub. L. 105–289, § 2, Oct. 27, 1998, 112 Stat. 2780, provided that:

''(a) FINDINGS.—The Congress makes the following findings:

''(1) The protection provided by plant patents under title 35, United States Code, dating back to 1930, has historically benefited American agriculture and horticulture and the public by providing an incentive for breeders to develop new plant varieties.

''(2) Domestic and foreign agricultural trade is rapidly expanding and is very different from the trade of the past. An unforeseen ambiguity in the provisions of title 35, United States Code, is undermining the orderly collection of royalties due breeders holding United States plant patents.

''(3) Plant parts produced from plants protected by United States plant patents are being taken from illegally reproduced plants and traded in United States markets to the detriment of plant patent holders.

''(4) Resulting lost royalty income inhibits investment in domestic research and breeding activities associated with a wide variety of crops—an area where the United States has historically enjoyed a strong international position. Such research is the foundation of a strong horticultural industry.

''(5) Infringers producing such plant parts from unauthorized plants enjoy an unfair competitive advantage over producers who pay royalties on varieties protected by United States plant patents.

''(b) PURPOSES.—The purposes of this Act [see section 1 of Pub. L. 105–289, set out as a Short Title of 1998 Amendments note under section 1 of this title] are—

''(1) to clearly and explicitly provide that title 35, United States Code, protects the owner of a plant patent against the unauthorized sale of plant parts taken from plants illegally reproduced;

''(2) to make the protections provided under such title more consistent with those provided breeders of