

cation 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. Statutory invention registration

(a) Notwithstanding any other provision of this title, the Director is authorized to publish a statutory invention registration containing the specification and drawings of a regularly filed application for a patent without examination if the applicant—

(1) meets the requirements of section 112 of this title;

(2) has complied with the requirements for printing, as set forth in regulations of the Director;

(3) waives the right to receive a patent on the invention within such period as may be prescribed by the Director; and

(4) pays application, publication, and other processing fees established by the Director.

If an interference is declared with respect to such an application, a statutory invention registration may not be published unless the issue of priority of invention is finally determined in favor of the applicant.

(b) The waiver under subsection (a)(3) of this section by an applicant shall take effect upon publication of the statutory invention registration.

(c) A statutory invention registration published pursuant to this section shall have all of

the attributes specified for patents in this title except those specified in section 183 and sections 271 through 289 of this title. A statutory invention registration shall not have any of the attributes specified for patents in any other provision of law other than this title. A statutory invention registration published pursuant to this section shall give appropriate notice to the public, pursuant to regulations which the Director shall issue, of the preceding provisions of this subsection. The invention with respect to which a statutory invention certificate is published is not a patented invention for purposes of section 292 of this title.

(d) The Director shall report to the Congress annually on the use of statutory invention registrations. Such report shall include an assessment of the degree to which agencies of the Federal Government are making use of the statutory invention registration system, the degree to which it aids the management of federally developed technology, and an assessment of the cost savings to the Federal Government of the use of such procedures.

(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.)

AMENDMENT OF SECTION

Pub. L. 112-29, §20(j), (l), Sept. 16, 2011, 125 Stat. 335, provided that, 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, this section is amended by striking "of this title" each place that term appears. See 2011 Amendment notes below.

REPEAL OF SECTION

Pub. L. 112-29, §3(e)(1), (3), Sept. 16, 2011, 125 Stat. 287, 288, provided that, 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, this section is repealed.

AMENDMENTS

2011—Subsec. (a). Pub. L. 112-29, §20(j), struck out "of this title" after "provision" in introductory provisions.

Subsec. (a)(1). Pub. L. 112-29, §20(j), struck out "of this title" after "112".

Subsec. (c). Pub. L. 112-29, §20(j), struck out "of this title" after "289" and after "292".

2002—Subsecs. (a), (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—Subsecs. (a), (c). Pub. L. 106-113, §1000(a)(9) [title IV, §4732(a)(10)(A), as amended by Pub. L. 107-273, substituted "Director" for "Commissioner" wherever appearing.

Subsec. (d). Pub. L. 106-113, §1000(a)(9) [title IV, §4732(a)(11)], substituted "Director" for "Secretary of Commerce".

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. 111-29, set out as an Effective Date of 2011 Amendment note under section 111 of this title.

EFFECTIVE DATE OF 2011 AMENDMENT

Amendment by section 20(j) of 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.

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.

EFFECTIVE DATE

Section 102(c) of Pub. L. 98-622 provided that: "The amendments made by this section [enacting this section and item 157 in the table of sections of this chapter] shall take effect six months after the date of enactment of this Act [Nov. 8, 1984]."

TERMINATION OF REPORTING REQUIREMENTS

For termination, effective May 15, 2000, of provisions in subsec. (d) of this section relating to annual reports to Congress, see section 3003 of Pub. L. 104-66, as amended, set out as a note under section 1113 of Title 31, Money and Finance, and page 51 of House Document No. 103-7.

CHAPTER 15—PLANT PATENTS

Sec.

161.	Patents for plants.
162.	Description, claim.
163.	Grant.
164.	Assistance of Department of Agriculture.

§ 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 of this title 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.