

Section 351 of the Public Health Service Act, referred to in subsec. (e)(2)(C), (4)(D), (6)(A), (C), is classified to section 262 of Title 42, The Public Health and Welfare.

AMENDMENTS

2010—Subsec. (e)(2). Pub. L. 111-148, §7002(c)(1)(A)(iv), substituted “, veterinary biological product, or biological product” for “or veterinary biological product” in concluding provisions.

Subsec. (e)(2)(C). Pub. L. 111-148, §7002(c)(1)(A)(i)–(iii), added subpar. (C).

Subsec. (e)(4). Pub. L. 111-148, §7002(c)(1)(B)(iv), substituted “(C), and (D)” for “and (C)” in concluding provisions.

Subsec. (e)(4)(B). Pub. L. 111-148, §7002(c)(1)(B)(i), substituted “, veterinary biological product, or biological product” for “or veterinary biological product” and struck out “and” at end.

Subsec. (e)(4)(C). Pub. L. 111-148, §7002(c)(1)(B)(ii), substituted “, veterinary biological product, or biological product” for “or veterinary biological product” and “, and” for period at end.

Subsec. (e)(4)(D). Pub. L. 111-148, §7002(c)(1)(B)(iii), added subpar. (D).

Subsec. (e)(6). Pub. L. 111-148, §7002(c)(1)(C), added par. (6).

2003—Subsec. (e)(5). Pub. L. 108-173 added par. (5).

1994—Subsec. (a). Pub. L. 103-465, §533(a)(1), inserted “, offers to sell,” after “uses” and “or imports into the United States any patented invention” after “the United States”.

Subsec. (c). Pub. L. 103-465, §533(a)(2), substituted “offers to sell or sells within the United States or imports into the United States” for “sells”.

Subsec. (e)(1). Pub. L. 103-465, §533(a)(3)(A), substituted “offer to sell, or sell within the United States or import into the United States” for “or sell”.

Subsec. (e)(3). Pub. L. 103-465, §533(a)(3)(B), substituted “offering to sell, or selling within the United States or importing into the United States” for “or selling”.

Subsec. (e)(4)(B), (C). Pub. L. 103-465, §533(a)(3)(C), (D), substituted “offer to sell, or sale within the United States or importation into the United States” for “or sale”.

Subsec. (g). Pub. L. 103-465, §533(a)(4), substituted “offers to sell, sells,” for “sells”, “importation, offer to sell, sale,” for “importation, sale,” and “other use, offer to sell, or” for “other use or”.

Subsec. (i). Pub. L. 103-465, §533(a)(5), added subsec. (i).

1992—Subsec. (h). Pub. L. 102-560 added subsec. (h).

1988—Subsec. (d). Pub. L. 100-703 added cls. (4) and (5).

Subsec. (e)(1). Pub. L. 100-670, §201(i)(1), inserted “which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques” after “March 4, 1913” and “or veterinary biological products” after “sale of drugs”.

Subsec. (e)(2). Pub. L. 100-670, §201(i)(2), amended par. (2) generally. Prior to amendment, par. (2) read as follows: “It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.”

Subsec. (e)(4). Pub. L. 100-670, §201(i)(3), inserted “or veterinary biological product” after “drug” in subpars. (A) to (C).

Subsec. (g). Pub. L. 100-418 added subsec. (g).

1984—Subsec. (e). Pub. L. 98-417 added subsec. (e).

Subsec. (f). Pub. L. 98-622 added subsec. (f).

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103-465 effective on date that is one year after date on which the WTO Agreement en-

ters into force with respect to the United States [Jan. 1, 1995], with provisions relating to earliest filed patent application, see section 534(a), (b)(3) of Pub. L. 103-465, set out as a note under section 154 of this title.

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102-560 effective with respect to violations that occur on or after Oct. 28, 1992, see section 4 of Pub. L. 102-560, set out as a note under section 2541 of Title 7, Agriculture.

EFFECTIVE DATE OF 1988 AMENDMENTS

Section 202 of title II of Pub. L. 100-703 provided that: “The amendment made by this title [amending this section] shall apply only to cases filed on or after the date of the enactment of this Act [Nov. 19, 1988].”

Section 9006 of Pub. L. 100-418 provided that:

“(a) IN GENERAL.—The amendments made by this subtitle [subtitle A (§§9001-9007) of title IX of Pub. L. 100-418, enacting section 295 of this title and amending this section and sections 154 and 287 of this title] take effect 6 months after the date of enactment of this Act [Aug. 23, 1988] and, subject to subsections (b) and (c), shall apply only with respect to products made or imported after the effective date of the amendments made by this subtitle.

“(b) EXCEPTIONS.—The amendments made by this subtitle shall not abridge or affect the right of any person or any successor in business of such person to continue to use, sell, or import any specific product already in substantial and continuous sale or use by such person in the United States on January 1, 1988, or for which substantial preparation by such person for such sale or use was made before such date, to the extent equitable for the protection of commercial investments made or business commenced in the United States before such date. This subsection shall not apply to any person or any successor in business of such person using, selling, or importing a product produced by a patented process that is the subject of a process patent enforcement action commenced before January 1, 1987, before the International Trade Commission, that is pending or in which an order has been entered.

“(c) RETENTION OF OTHER REMEDIES.—The amendments made by this subtitle shall not deprive a patent owner of any remedies available under subsections (a) through (f) of section 271 of title 35, United States Code, under section 337 of the Tariff Act of 1930 [19 U.S.C. 1337], or under any other provision of law.”

EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by Pub. L. 98-622 applicable only to the supplying, or causing to be supplied, of any component or components of a patented invention after Nov. 8, 1984, see section 106(c) of Pub. L. 98-622, set out as a note under section 103 of this title.

REPORTS TO CONGRESS; EFFECT ON DOMESTIC INDUSTRIES OF PROCESS PATENT AMENDMENTS ACT OF 1988

Pub. L. 100-418, title IX, §9007, Aug. 23, 1988, 102 Stat. 1567, provided that the Secretary of Commerce was to make annual reports to Congress covering each of the successive five 1-year periods beginning 6 months after Aug. 23, 1988, on the effect of the amendments made by subtitle A (§§9001-9007) of title IX of Pub. L. 100-418, enacting section 295 of this title and amending sections 154, 271, and 287 of this title, on those domestic industries that submit complaints to the Department of Commerce alleging that their legitimate sources of supply have been adversely affected by the amendments.

§ 272. Temporary presence in the United States

The use of any invention in any vessel, aircraft or vehicle of any country which affords similar privileges to vessels, aircraft or vehicles of the United States, entering the United States temporarily or accidentally, shall not constitute

infringement of any patent, if the invention is used exclusively for the needs of the vessel, aircraft or vehicle and is not offered for sale or sold in or used for the manufacture of anything to be sold in or exported from the United States.

(July 19, 1952, ch. 950, 66 Stat. 812; Pub. L. 103-465, title V, §533(b)(4), Dec. 8, 1994, 108 Stat. 4989.)

HISTORICAL AND REVISION NOTES

This section follows the requirement of the International Convention for the Protection of Industrial Property, to which the United States is a party, and also codifies the holding of the Supreme Court that use of a patented invention on board a foreign ship does not infringe a patent.

AMENDMENTS

1994—Pub. L. 103-465 substituted “not offered for sale or sold” for “not sold”.

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103-465 effective on date that is one year after date on which the WTO Agreement enters into force with respect to the United States [Jan. 1, 1995], with provisions relating to earliest filed patent application, see section 534(a), (b)(3) of Pub. L. 103-465, set out as a note under section 154 of this title.

§ 273. Defense to infringement based on earlier inventor

(a) DEFINITIONS.—For purposes of this section—

(1) the terms “commercially used” and “commercial use” mean use of a method in the United States, so long as such use is in connection with an internal commercial use or an actual arm’s-length sale or other arm’s-length commercial transfer of a useful end result, whether or not the subject matter at issue is accessible to or otherwise known to the public, except that the subject matter for which commercial marketing or use is subject to a premarketing regulatory review period during which the safety or efficacy of the subject matter is established, including any period specified in section 156(g), shall be deemed “commercially used” and in “commercial use” during such regulatory review period;

(2) in the case of activities performed by a nonprofit research laboratory, or nonprofit entity such as a university, research center, or hospital, a use for which the public is the intended beneficiary shall be considered to be a use described in paragraph (1), except that the use—

(A) may be asserted as a defense under this section only for continued use by and in the laboratory or nonprofit entity; and

(B) may not be asserted as a defense with respect to any subsequent commercialization or use outside such laboratory or nonprofit entity;

(3) the term “method” means a method of doing or conducting business; and

(4) the “effective filing date” of a patent is the earlier of the actual filing date of the application for the patent or the filing date of any earlier United States, foreign, or international application to which the subject matter at issue is entitled under section 119, 120, or 365 of this title.

(b) DEFENSE TO INFRINGEMENT.—

(1) IN GENERAL.—It shall be a defense to an action for infringement under section 271 of this title with respect to any subject matter that would otherwise infringe one or more claims for a method in the patent being asserted against a person, if such person had, acting in good faith, actually reduced the subject matter to practice at least 1 year before the effective filing date of such patent, and commercially used the subject matter before the effective filing date of such patent.

(2) EXHAUSTION OF RIGHT.—The sale or other disposition of a useful end product produced by a patented method, by a person entitled to assert a defense under this section with respect to that useful end result shall exhaust the patent owner’s rights under the patent to the extent such rights would have been exhausted had such sale or other disposition been made by the patent owner.

(3) LIMITATIONS AND QUALIFICATIONS OF DEFENSE.—The defense to infringement under this section is subject to the following:

(A) PATENT.—A person may not assert the defense under this section unless the invention for which the defense is asserted is for a method.

(B) DERIVATION.—A person may not assert the defense under this section if the subject matter on which the defense is based was derived from the patentee or persons in privity with the patentee.

(C) NOT A GENERAL LICENSE.—The defense asserted by a person under this section is not a general license under all claims of the patent at issue, but extends only to the specific subject matter claimed in the patent with respect to which the person can assert a defense under this chapter, except that the defense shall also extend to variations in the quantity or volume of use of the claimed subject matter, and to improvements in the claimed subject matter that do not infringe additional specifically claimed subject matter of the patent.

(4) BURDEN OF PROOF.—A person asserting the defense under this section shall have the burden of establishing the defense by clear and convincing evidence.

(5) ABANDONMENT OF USE.—A person who has abandoned commercial use of subject matter may not rely on activities performed before the date of such abandonment in establishing a defense under this section with respect to actions taken after the date of such abandonment.

(6) PERSONAL DEFENSE.—The defense under this section may be asserted only by the person who performed the acts necessary to establish the defense and, except for any transfer to the patent owner, the right to assert the defense shall not be licensed or assigned or transferred to another person except as an ancillary and subordinate part of a good faith assignment or transfer for other reasons of the entire enterprise or line of business to which the defense relates.

(7) LIMITATION ON SITES.—A defense under this section, when acquired as part of a good faith assignment or transfer of an entire en-