

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 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.

#### 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 AMENDMENT

Pub. L. 100-703, title II, §202, Nov. 19, 1988, 102 Stat. 4676, 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].”

Pub. L. 100-418, title IX, §9006, Aug. 23, 1988, 102 Stat. 1566, 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 prior commercial use

(a) IN GENERAL.—A person shall be entitled to a defense under section 282(b) with respect to subject matter consisting of a process, or consisting of a machine, manufacture, or composition of matter used in a manufacturing or other commercial process, that would otherwise infringe a claimed invention being asserted against the person if—

(1) such person, acting in good faith, commercially used the subject matter in the United States, either 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 of such commercial use; and

(2) such commercial use occurred at least 1 year before the earlier of either—

(A) the effective filing date of the claimed invention; or

(B) the date on which the claimed invention was disclosed to the public in a manner that qualified for the exception from prior art under section 102(b).

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

(c) **ADDITIONAL COMMERCIAL USES.**—

(1) **PREMARKETING REGULATORY REVIEW.**—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 to be commercially used for purposes of subsection (a)(1) during such regulatory review period.

(2) **NONPROFIT LABORATORY USE.**—A use of subject matter by a nonprofit research laboratory or other nonprofit entity, such as a university or hospital, for which the public is the intended beneficiary, shall be deemed to be a commercial use for purposes of subsection (a)(1), except that a defense under this section may be asserted pursuant to this paragraph only for continued and noncommercial use by and in the laboratory or other nonprofit entity.

(d) **EXHAUSTION OF RIGHTS.**—Notwithstanding subsection (e)(1), the sale or other disposition of a useful end result by a person entitled to assert a defense under this section in connection with a patent with respect to that useful end result shall exhaust the patent owner's rights under the patent to the extent that such rights would have been exhausted had such sale or other disposition been made by the patent owner.

(e) **LIMITATIONS AND EXCEPTIONS.**—

(1) **PERSONAL DEFENSE.**—

(A) **IN GENERAL.**—A defense under this section may be asserted only by the person who performed or directed the performance of the commercial use described in subsection (a), or by an entity that controls, is controlled by, or is under common control with such person.

(B) **TRANSFER OF RIGHT.**—Except for any transfer to the patent owner, the right to assert a defense under this section 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.

(C) **RESTRICTION ON SITES.**—A defense under this section, when acquired by a person as part of an assignment or transfer described in subparagraph (B), may only be asserted for uses at sites where the subject matter that would otherwise infringe a claimed invention is in use before the later of the effective filing date of the claimed invention or the date of the assignment or transfer of such enterprise or line of business.

(2) **DERIVATION.**—A person may not assert a defense under this section if the subject mat-

ter on which the defense is based was derived from the patentee or persons in privity with the patentee.

(3) **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 for which it has been established that a commercial use that qualifies under this section occurred, 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) **ABANDONMENT OF USE.**—A person who has abandoned commercial use (that qualifies under this section) 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 on or after the date of such abandonment.

(5) **UNIVERSITY EXCEPTION.**—

(A) **IN GENERAL.**—A person commercially using subject matter to which subsection (a) applies may not assert a defense under this section if the claimed invention with respect to which the defense is asserted was, at the time the invention was made, owned or subject to an obligation of assignment to either an institution of higher education (as defined in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)),<sup>1</sup> or a technology transfer organization whose primary purpose is to facilitate the commercialization of technologies developed by one or more such institutions of higher education.

(B) **EXCEPTION.**—Subparagraph (A) shall not apply if any of the activities required to reduce to practice the subject matter of the claimed invention could not have been undertaken using funds provided by the Federal Government.

(f) **UNREASONABLE ASSERTION OF DEFENSE.**—If the defense under this section is pleaded by a person who is found to infringe the patent and who subsequently fails to demonstrate a reasonable basis for asserting the defense, the court shall find the case exceptional for the purpose of awarding attorney fees under section 285.

(g) **INVALIDITY.**—A patent shall not be deemed to be invalid under section 102 or 103 solely because a defense is raised or established under this section.

(Added Pub. L. 106-113, div. B, §1000(a)(9) [title IV, §4302(a)], Nov. 29, 1999, 113 Stat. 1536, 1501A-555; amended Pub. L. 112-29, §5(a), Sept. 16, 2011, 125 Stat. 297.)

#### AMENDMENTS

2011—Pub. L. 112-29 amended section generally. Prior to amendment, section related to defense to infringement based on earlier inventor.

<sup>1</sup> So in original. Another closing parenthesis probably should precede the comma.

## EFFECTIVE DATE OF 2011 AMENDMENT

Pub. L. 112-29, §5(c), Sept. 16, 2011, 125 Stat. 299, provided that: “The amendments made by this section [amending this section] shall apply to any patent issued on or after the date of the enactment of this Act [Sept. 16, 2011].”

## EFFECTIVE DATE

Pub. L. 106-113, div. B, §1000(a)(9) [title IV, subtitle C, §4303], Nov. 29, 1999, 113 Stat. 1536, 1501A-557, provided that: “This subtitle [enacting this section and provisions set out as a note under section 1 of this title] and the amendments made by this subtitle shall take effect on the date of the enactment of this Act [Nov. 29, 1999], but shall not apply to any action for infringement that is pending on such date of enactment or with respect to any subject matter for which an adjudication of infringement, including a consent judgment, has been made before such date of enactment.”

## CHAPTER 29—REMEDIES FOR INFRINGEMENT OF PATENT, AND OTHER ACTIONS

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## AMENDMENTS

2011—Pub. L. 112-29, §19(d)(2), Sept. 16, 2011, 125 Stat. 333, added item 299.

Pub. L. 112-29, §17(b), Sept. 16, 2011, 125 Stat. 329, added item 298.

Pub. L. 112-29, §3(h)(2), Sept. 16, 2011, 125 Stat. 289, amended item 291 generally, substituting “Derived patents” for “Interfering patents”.

1999—Pub. L. 106-113, div. B, §1000(a)(9) [title IV, §4102(b)], Nov. 29, 1999, 113 Stat. 1536, 1501A-554, added item 297.

1992—Pub. L. 102-560, §2(b), Oct. 28, 1992, 106 Stat. 4230, added item 296.

1988—Pub. L. 100-418, title IX, §§9004(b), 9005(b), Aug. 23, 1988, 102 Stat. 1566, inserted “and other remedies” in item 287 and added item 295.

1982—Pub. L. 97-247, §17(b)(2), Aug. 27, 1982, 96 Stat. 323, added item 294.

## § 281. Remedy for infringement of patent

A patentee shall have remedy by civil action for infringement of his patent.

(July 19, 1952, ch. 950, 66 Stat. 812.)

## HISTORICAL AND REVISION NOTES

Based on Title 35, U.S.C., 1946 ed., §§67 and 70, part (R.S. 4919; R.S. 4921, amended (1) Mar. 3, 1897, ch. 391, §6,

<sup>1</sup> So in original. Does not conform to section catchline.

29 Stat. 694, (2) Feb. 18, 1922, ch. 58, §8, 42 Stat. 392, (3) Aug. 1, 1946, ch. 726, §1, 60 Stat. 778).

The corresponding two sections of existing law are divided among sections 281, 283, 284, 285, 286 and 289 with some changes in language. Section 281 serves as an introduction or preamble to the following sections, the modern term civil action is used, there would be, of course, a right to a jury trial when no injunction is sought.

## § 282. Presumption of validity; defenses

(a) IN GENERAL.—A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.

(b) DEFENSES.—The following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded:

(1) Noninfringement, absence of liability for infringement or unenforceability.

(2) Invalidity of the patent or any claim in suit on any ground specified in part II as a condition for patentability.

(3) Invalidity of the patent or any claim in suit for failure to comply with—

(A) any requirement of section 112, except that the failure to disclose the best mode shall not be a basis on which any claim of a patent may be canceled or held invalid or otherwise unenforceable; or

(B) any requirement of section 251.

(4) Any other fact or act made a defense by this title.

(c) NOTICE OF ACTIONS; ACTIONS DURING EXTENSION OF PATENT TERM.—In an action involving the validity or infringement of a patent the party asserting invalidity or noninfringement shall give notice in the pleadings or otherwise in writing to the adverse party at least thirty days before the trial, of the country, number, date, and name of the patentee of any patent, the title, date, and page numbers of any publication to be relied upon as anticipation of the patent in suit or, except in actions in the United States Court of Federal Claims, as showing the state of the art, and the name and address of any person who may be relied upon as the prior inventor or as having prior knowledge of or as having previously used or offered for sale the invention of the patent in suit. In the absence of such notice proof of the said matters may not be made at the trial except on such terms as the court requires. Invalidity of the extension of a patent term or any portion thereof under section 154(b) or 156 because of the material failure—

(1) by the applicant for the extension, or

(2) by the Director,

to comply with the requirements of such section shall be a defense in any action involving the infringement of a patent during the period of the extension of its term and shall be pleaded. A due diligence determination under section 156(d)(2) is not subject to review in such an action.

(July 19, 1952, ch. 950, 66 Stat. 812; Pub. L. 89-83, §10, July 24, 1965, 79 Stat. 261; Pub. L. 94-131, §10,