

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 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 matter 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 Edu-