

stituted “An interest that constitutes an assignment” for “An assignment” in fourth par.

1982—Pub. L. 97-247 inserted “, or apostille of an official designated by a foreign country which, by treaty or convention, accords like effect to apostilles of designated officials in the United States”.

1975—Pub. L. 93-596 substituted “Patent and Trademark Office” for “Patent Office”.

EFFECTIVE DATE OF 2012 AMENDMENT

Amendment by Pub. L. 112-211 effective on the date that is 1 year after Dec. 18, 2012, applicable to patents issued before, on, or after that effective date and patent applications pending on or filed after that effective date, and not effective with respect to patents in litigation commenced before that effective date, see section 203 of Pub. L. 112-211, set out as an Effective Date note under section 27 of this title.

EFFECTIVE DATE OF 1982 AMENDMENT

Amendment by Pub. L. 97-247 effective Aug. 27, 1982, see section 17(a) of Pub. L. 97-247, set out as a note under section 41 of this title.

EFFECTIVE DATE OF 1975 AMENDMENT

Amendment by Pub. L. 93-596 effective Jan. 2, 1975, see section 4 of Pub. L. 93-596, set out as a note under section 1111 of Title 15, Commerce and Trade.

§ 262. Joint owners

In the absence of any agreement to the contrary, each of the joint owners of a patent may make, use, offer to sell, or sell the patented invention within the United States, or import the patented invention into the United States, without the consent of and without accounting to the other owners.

(July 19, 1952, ch. 950, 66 Stat. 810; Pub. L. 103-465, title V, §533(b)(3), Dec. 8, 1994, 108 Stat. 4989.)

HISTORICAL AND REVISION NOTES

This section states a condition in existing law not expressed in the existing statutes.

AMENDMENTS

1994—Pub. L. 103-465 substituted “use, offer to sell, or sell” for “use or sell” and inserted “within the United States, or import the patented invention into the United States,” after “invention”.

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.

CHAPTER 27—GOVERNMENT INTERESTS IN PATENTS

Sec.	
[266.]	Repealed.]
267.	Time for taking action in Government applications.

AMENDMENTS

1965—Pub. L. 89-83, § 8, July 24, 1965, 79 Stat. 261, struck out item 266 “Issue of patents without fees to Government employees”.

[§ 266. Repealed. Pub. L. 89-83, § 8, July 24, 1965, 79 Stat. 261]

Section, act July 19, 1952, ch. 950, § 1, 66 Stat. 811, provided for issuance of patents to government employees without fees.

EFFECTIVE DATE OF REPEAL

Repeal effective three months after July 24, 1965, see section 7(a) of Pub. L. 89-83, set out as an Effective Date of 1965 Amendment note under section 41 of this title.

§ 267. Time for taking action in Government applications

Notwithstanding the provisions of sections 133 and 151, the Director may extend the time for taking any action to three years, when an application has become the property of the United States and the head of the appropriate department or agency of the Government has certified to the Director that the invention disclosed therein is important to the armament or defense of the United States.

(July 19, 1952, ch. 950, 66 Stat. 811; Pub. L. 106-113, div. B, §1000(a)(9) [title IV, §4732(a)(10)(A)], Nov. 29, 1999, 113 Stat. 1536, 1501A-582; 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.)

HISTORICAL AND REVISION NOTES

Based on Title 35, U.S.C., 1946 ed., §37 (R.S. 4894, amended (1) Mar. 3, 1897, ch. 391, §4, 29 Stat. 692, 693, (2) July 6, 1916, ch. 225, §1, 39 Stat. 345, 347-8, (3) Mar. 2, 1927, ch. 273, §1, 44 Stat. 1335, (4) Aug. 7, 1939, ch. 568, 53 Stat. 1264).

This provision, which appears as the last two sentences of the corresponding section of the present statute (see note to section 133) is made a separate section and rewritten in simpler form.

AMENDMENTS

2011—Pub. L. 112-29 struck out “of this title” after “151”.

2002—Pub. L. 107-273 made technical correction to directory language of Pub. L. 106-113. See 1999 Amendment note below.

1999—Pub. L. 106-113, as amended by Pub. L. 107-273, substituted “Director” for “Commissioner” in two places.

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.

CHAPTER 28—INFRINGEMENT OF PATENTS

Sec.	
271.	Infringement of patent.
272.	Temporary presence in the United States.
273.	Defense to infringement based on prior commercial use.

AMENDMENTS

2011—Pub. L. 112-29, §5(b), Sept. 16, 2011, 125 Stat. 299, amended item 273 generally, substituting “Defense to infringement based on prior commercial use” for “Defense to infringement based on earlier inventor”.

1999—Pub. L. 106-113, div. B, §1000(a)(9) [title IV, §4302(b)], Nov. 29, 1999, 113 Stat. 1536, 1501A-557, added item 273.

§ 271. Infringement of patent

(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers

to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

(b) Whoever actively induces infringement of a patent shall be liable as an infringer.

(c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: (1) derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent; (2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent; (3) sought to enforce his patent rights against infringement or contributory infringement; (4) refused to license or use any rights to the patent; or (5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.

(e)(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit—

(A) 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,

(B) an application under section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. 151–158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent, or

(C)(i) with respect to a patent that is identified in the list of patents described in section 351(l)(3) of the Public Health Service Act (including as provided under section 351(l)(7) of such Act), an application seeking approval of a biological product, or

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,

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, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under paragraph (1).

(4) For an act of infringement described in paragraph (2)—

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product,

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product, and

(D) the court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), provided the patent is the subject of a final court decision, as defined in section 351(k)(6) of the Public Health Service Act, in an action for infringement of the patent under section 351(l)(6) of such Act, and the biological product has not yet been approved because of section 351(k)(7) of such Act.

The remedies prescribed by subparagraphs (A), (B), (C), and (D) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

(5) Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal

Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

(6)(A) Subparagraph (B) applies, in lieu of paragraph (4), in the case of a patent—

(i) that is identified, as applicable, in the list of patents described in section 351(l)(4) of the Public Health Service Act or the lists of patents described in section 351(l)(5)(B) of such Act with respect to a biological product; and

(ii) for which an action for infringement of the patent with respect to the biological product—

(I) was brought after the expiration of the 30-day period described in subparagraph (A) or (B), as applicable, of section 351(l)(6) of such Act; or

(II) was brought before the expiration of the 30-day period described in subclause (I), but which was dismissed without prejudice or was not prosecuted to judgment in good faith.

(B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.

(C) The owner of a patent that should have been included in the list described in section 351(l)(3)(A) of the Public Health Service Act, including as provided under section 351(l)(7) of such Act for a biological product, but was not timely included in such list, may not bring an action under this section for infringement of the patent with respect to the biological product.

(f)(1) Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(2) Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside

of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(g) Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after—

(1) it is materially changed by subsequent processes; or

(2) it becomes a trivial and nonessential component of another product.

(h) As used in this section, the term “whoever” includes any State, any instrumentality of a State, and any officer or employee of a State or instrumentality of a State acting in his official capacity. Any State, and any such instrumentality, officer, or employee, shall be subject to the provisions of this title in the same manner and to the same extent as any nongovernmental entity.

(i) As used in this section, an “offer for sale” or an “offer to sell” by a person other than the patentee, or any designee of the patentee, is that in which the sale will occur before the expiration of the term of the patent.

(July 19, 1952, ch. 950, 66 Stat. 811; Pub. L. 98-417, title II, §202, Sept. 24, 1984, 98 Stat. 1603; Pub. L. 98-622, title I, §101(a), Nov. 8, 1984, 98 Stat. 3383; Pub. L. 100-418, title IX, §9003, Aug. 23, 1988, 102 Stat. 1563; Pub. L. 100-670, title II, §201(i), Nov. 16, 1988, 102 Stat. 3988; Pub. L. 100-703, title II, §201, Nov. 19, 1988, 102 Stat. 4676; Pub. L. 102-560, §2(a)(1), Oct. 28, 1992, 106 Stat. 4230; Pub. L. 103-465, title V, §533(a), Dec. 8, 1994, 108 Stat. 4988; Pub. L. 108-173, title XI, §1101(d), Dec. 8, 2003, 117 Stat. 2457; Pub. L. 111-148, title VII, §7002(c)(1), Mar. 23, 2010, 124 Stat. 815.)

HISTORICAL AND REVISION NOTES

The first paragraph of this section is declaratory only, defining infringement.

Paragraphs (b) and (c) define and limit contributory infringement of a patent and paragraph (d) is ancillary to these paragraphs, see preliminary general description of bill. One who actively induces infringement as by aiding and abetting the same is liable as an infringer, and so is one who sells a component part of a patented invention or material or apparatus for use therein knowing the same to be especially made or especially adapted for use in the infringement of the patent except in the case of a staple article or commodity of commerce having other uses. A patentee is not deemed to have misused his patent solely by reason of doing anything authorized by the section.

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (e)(1), (2), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9

(§ 301 et seq.) of Title 21, Food and Drugs. Sections 505 and 512 of the Act are classified to sections 355 and 360b, respectively, of Title 21. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

Act of March 4, 1913, referred to in subsec. (e)(1), (2), is act Mar. 4, 1913, ch. 145, 37 Stat. 828. The provisions of such act relating to viruses, etc., applicable to domestic animals, popularly known as the Virus-Serum-Toxin Act, are contained in the eighth paragraph under the heading "Bureau of Animal Industry" of act Mar. 4, 1913, at 37 Stat. 832, and are classified generally to chapter 5 (§ 151 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see Short Title note set out under section 151 of Title 21 and Tables.

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 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