

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100-418 effective 6 months after Aug. 23, 1988, and, subject to enumerated exceptions, applicable only with respect to products made or imported after such effective date, see section 9006 of Pub. L. 100-418, set out as a note under section 271 of this title.

EFFECTIVE DATE OF 1980 AMENDMENT

Amendment by Pub. L. 96-517 effective Dec. 12, 1980, see section 8(a) of Pub. L. 96-517, set out as a note under section 41 of this title.

EFFECTIVE DATE OF 1965 AMENDMENT

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

REGULATIONS

Pub. L. 103-465, title V, §532(a)(2), Dec. 8, 1994, 108 Stat. 4985, authorized the Commissioner of Patents and Trademarks to prescribe regulations for further limited reexamination of applications pending 2 years or longer and for examination of more than 1 independent and distinct invention in applications pending 3 years or longer, as of the effective date of section 154(a)(2) of this title, and to establish appropriate related fees.

[[§ 155, 155A. Repealed. Pub. L. 112-29, § 20(k), Sept. 16, 2011, 125 Stat. 335]

Section 155, added Pub. L. 97-414, §11(a), Jan. 4, 1983, 96 Stat. 2065; amended Pub. L. 106-113, div. B, §1000(a)(9) [title IV, §4732(a)(6), (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, related to patent term extension.

Section 155A, added Pub. L. 98-127, §4(a), Oct. 13, 1983, 97 Stat. 832; amended Pub. L. 106-113, div. B, §1000(a)(9) [title IV, §4732(a)(7), (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, related to patent term restoration.

EFFECTIVE DATE OF REPEAL

Repeal 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 an Effective Date of 2011 Amendment note under section 2 of this title.

§ 156. Extension of patent term

(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b), if—

(1) the term of the patent has not expired before an application is submitted under subsection (d)(1) for its extension;

(2) the term of the patent has never been extended under subsection (e)(1) of this section;

(3) an application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirements of paragraphs (1) through (4) of subsection (d);

(4) the product has been subject to a regulatory review period before its commercial marketing or use;

(5)(A) except as provided in subparagraph (B) or (C), the permission for the commercial mar-

keting or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred;

(B) in the case of a patent which claims a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent; or

(C) for purposes of subparagraph (A), in the case of a patent which—

(i) claims a new animal drug or a veterinary biological product which (I) is not covered by the claims in any other patent which has been extended, and (II) has received permission for the commercial marketing or use in non-food-producing animals and in food-producing animals, and

(ii) was not extended on the basis of the regulatory review period for use in non-food-producing animals,

the permission for the commercial marketing or use of the drug or product after the regulatory review period for use in food-producing animals is the first permitted commercial marketing or use of the drug or product for administration to a food-producing animal.

The product referred to in paragraphs (4) and (5) is hereinafter in this section referred to as the “approved product”.

(b) Except as provided in subsection (d)(5)(F), the rights derived from any patent the term of which is extended under this section shall during the period during which the term of the patent is extended—

(1) in the case of a patent which claims a product, be limited to any use approved for the product—

(A) before the expiration of the term of the patent—

(i) under the provision of law under which the applicable regulatory review occurred, or

(ii) under the provision of law under which any regulatory review described in paragraph (1), (4), or (5) of subsection (g) occurred, and

(B) on or after the expiration of the regulatory review period upon which the extension of the patent was based;

(2) in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent and approved for the product—

(A) before the expiration of the term of the patent—

(i) under any provision of law under which an applicable regulatory review occurred, and

(ii) under the provision of law under which any regulatory review described in paragraph (1), (4), or (5) of subsection (g) occurred, and

(B) on or after the expiration of the regulatory review period upon which the extension of the patent was based; and