Commissioner of Patents and Trademarks
Patent and Trademark Office (P.T.O.)

IN RE NITINOL MEDICAL TECHNOLOGIES, INC. U.S. PATENT NO. 4,425,908
Docket No. 90E-0219
August 31, 1990

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Charles E. Van Horn

Patent Policy & Programs Administrator, Office of the Assistant Commissioner for Patents

Decision on Request for Patent Term Extension Under 35 U.S.C. § 156

An application for patent term extension has been filed under 35 U.S.C. § 156. The application raises a question of eligibility for patent term extension of a patent claiming a product drawn to a medical device which was subject to a regulatory review by the Food and Drug Administration (FDA) under section 510(k) of the Federal Food, Drug, and Cosmetic Act (FFDCA). The question is whether the regulatory review of the product by the FDA under section 510(k) of the FFDCA qualifies as a "regulatory review" as defined by 35 U.S.C. § 156(g)(3). For the reasons set forth below, the application is denied.

BACKGROUND

An application for patent term extension of U.S. Patent No. 4,425,908 granted January 17, 1984, was filed under 35 U.S.C. § 156 in the Patent and Trademark Office (PTO) on June 15, 1990. The application was filed by the owner of the patent, Nitinol Medical Technologies, Inc.

The approved product, a blood clot filter (the Simon Nitonol Filter), is designed to be inserted into a vein of a patient. Upon insertion, the filter expands into a predetermined form which contacts the inner wall of the vein. FDA records show that the Simon Nitonol Filter received permission for marketing on April 20, 1990, under section 510(k) of the FFDCA.

DISCUSSION

Section 156 of Title 35 permits the term of a patent claiming a medical device which was subject to a "regulatory review period" to be extended for a period of time equal to a calculated portion of the regulatory review period which occurred after the date the patent was issued. Section 156(a) sets forth the requirements for a patent to be eligible for patent term extension. Among those requirements, § 156(a)(4) requires:

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

For purposes of the statute, the term "regulatory review period" is defined in § 156(g). For a medical device, § 156(g)(3)(B) provides:

(3)(B) The regulatory review period for a medical device is the sum of--

(i) the period beginning on the date a clinical investigation on humans involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515, and

(ii) the period beginning on the date an application was initially submitted with respect to the device under section 515 and ending on the date such application was approved under such Act or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515(f)(5) and ending on the date the protocol was declared completed under section 515(f)(6).

***2** The reference to section 515 is a reference to section 515 of the FFDCA. See 35 U.S.C. § 156(f)(4).

The starting point for statutory interpretation is the plain language of the statute. Unless it is ambiguous, the language Congress chose is conclusive of its meaning absent a clearly stated contrary intention. Burlington Northern R.R. v. Oklahoma Tax Comm'n, 481 U.S. 454, 461 (1987).

Under the terms of § § 156(a)(4) and 156(g)(3)(B), the regulatory review of a medical device is limited to a regulatory review which was conducted under section 515 of the FFDCA to the exclusion of regulatory review conducted under section 510(k) of the FFDCA. Accordingly, the regulatory review period for the Simon Nitonol Filter under section 510(k) is not a "regulatory review period" which gives rise to eligibility for patent term extension under 35 U.S.C. § 156.

In addition to the clear and unambiguous language of the statute, the legislative history supports the PTO's view that Congress intended to specifically refer to the sections specified in § 156(g)(3) when it referred to a provision of law under which a regulatory review period occurred for a medical device. A House Report, when addressing proposed § 156(g)(3), states:

Under section 156(g)(3) the regulatory review period for medical devices is the sum of the periods: (1) beginning when human clinical investigations were commenced and ending when an application for approval was initially submitted; and (2) beginning when an application for approval was initially submitted and ending when the application was approved, or beginning when a notice of completion of a product development protocol was initially submitted and ending when the protocol was declared completed.

H.R.Rep. No. 98-857, Part II, 98th Cong., 2d Sess. 26 (1984), reprinted in 1984 U.S.Code Cong. & Admin.News 2686, 2710. The House Report, at page 2709, when addressing the definitions of various terms as defined in § 156(f) states:

Subsection (f)(4)(B) states that any reference to section ... 515 is a reference to section ... 515 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. sections ... 360e (relating to premarketing approval of a class III device).

Thus, Congress clearly intended that the medical device be approved for marketing under a regulatory review having a testing phase and an approval phase under section 515 of the FFDCA to be eligible for patent term extension.

DECISION

Under the circumstances of this application, for the reasons set forth above, it is held that U.S. Patent No.4,425,908 is not eligible for extension of the patent term under 35 U.S.C. § 156. The Simon Nitonol Filter has not been subject to a "regulatory review period" within the meaning of 35 U.S.C. § 156(a)(4) as defined in 35 U.S.C. § 156(g)(3). Accordingly, the application for extension of the term of U.S. Patent No. 4,425,908 is denied.

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