

APR 21 1999



UNITED STATES DEPARTMENT OF COMMERCE
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Washington, D.C. 20231

William H. Drummond
DRUMMOND & DUCKWORTH
4590 MacArthur Blvd., Suite 500
Newport Beach CA 92660

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,321,251

NOTICE OF FINAL DETERMINATION

An application for interim extension of the patent term of U.S. Patent No. 4,321,251 under 35 U.S.C. § 156 (d)(5) was filed in the United States Patent and Trademark Office on March 1, 1999. Interim extension is sought based upon the premarket review under § 505 of the Federal Food, Drug, and Cosmetic Act (FFDCA) of a product known by the tradename ORATEST™ (tolonium chloride or toluidine blue). A determination has been made that U.S. Patent No. 4,321,251 is NOT eligible for interim patent term extension under 35 U.S.C. § 156 based upon the regulatory review period of ORATEST™.

A single request for reconsideration of this final determination of eligibility may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are applicable to this time period. See 37 CFR 1.750.

U.S. Patent No. 4,321,251 issued on March 23, 1982 from an application filed on December 19, 1979. In view of 35 U.S.C. § 154(c)(1) the patent will expire on December 19, 1999, not March 23, 1999 as stated in the application for interim extension. An application for interim extension may only be filed in the period beginning six months and ending fifteen days before patent expiration. An application for interim extension for U.S. Patent No. 4,321,251 may only be filed between June 19, 1999 and December 4, 1999. The application, filed March 1, 1999, was premature and must be dismissed without prejudice.

Applicant may request that the filing fee for the application for interim extension prescribed by 37 CFR 1.20(j), which was paid by mistake, be refunded or applied to a subsequent application for interim extension.

DECISION

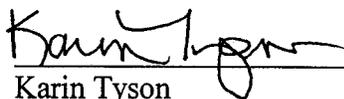
Under the circumstances of this application, for the reasons set forth above, it is held that U.S. Patent No. 4,321,251 is not eligible for interim extension of the patent term under 35 U.S.C. § 156(d)(5) at this time. Accordingly, the application for extension of the patent term is dismissed.

Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.



Karin Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects