

Mailed: March 4, 2002

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One Cambridge Center
Cambridge MA 02142In Re: Patent Term Extension
Application for
U.S. Patent No. 5,196,404

CORRECTED NOTICE OF FINAL DETERMINATION

This decision replaces the Notice of Final Determination that was mailed in December 2001, without a mailing date. An application for extension of the patent term of U.S. Patent No. 5,196,404 under 35 U.S.C. § 156 was filed in the United States Patent and Trademark Office on February 14, 2001. Extension is sought based upon the premarket review under § 505(b) of the Federal Food, Drug, and Cosmetic Act (FFDCA) of a human drug product known by the tradename ANGIOMAX having the active ingredient bivalirudin. ANGIOMAX was approved for commercial use and sale by the Food and Drug Administration (FDA) on December 15, 2000.

A determination has been made that U.S. Patent No. 5,196,404 is **NOT** eligible for patent term extension under 35 U.S.C. § 156 based upon the regulatory review period of ANGIOMAX.

A single request for reconsideration of this FINAL DETERMINATION OF INELIGIBILITY may be made if filed by the applicant within TWO MONTHS of the mailing date of this letter. The period for response may be extended pursuant to 37 C.F.R. 1.136. See 37 C.F.R. 1.750. A failure to respond to this letter will result in the application papers being placed into the patent file with no further action taken on the application for patent term extension.

The FDA official records indicate that ANGIOMAX was previously approved for commercial marketing or use prior to the approval of ANGIOMAX. In a letter dated September 6, 2001, FDA stated:

The NDA was approved on December 15, 2000, which makes the submission of the patent term extension application on February 14, 2001, untimely within the meaning of 35 U.S.C. 156(d)(1), which requires that the patent term restoration application to be submitted within 60 days of the product's approval.

35 U.S.C. § 156(d) requires that an application for patent term extension be filed "within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use. Sixty days after the approval date, December 15, 2001, is February 13, 2001. Since February 13, 2001 was a regular business day, the application must be dismissed as untimely. See also Manual of Patent Examining Procedure, Section 2754.01, Eighth Edition (August 2001).

In view of the above, the term of U.S. Patent No. 5,196,404 is not eligible for extension under 35 U.S.C. § 156 based upon the approval of the product ANGIOMAX and the application for patent term extension is dismissed.

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

By mail: Commissioner for Patents
Box Patent Ext.

Washington, D.C. 20231

By FAX: (703) 872-9411

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159. E-mail inquiries should be directed to Karin.Tyson@uspto.gov.

/s/

Karin Tyson
Senior Legal Advisor
Office of Patent Legal Administration
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for Patent Policy and Projects

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RE: ANGIOMAX
FDA Docket No.: 01E-0213