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Commissioner for Patents
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Donald R. Steinberg
Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,196,404

Dear Mr. Steinberg :

An interim extension is enclosed extending the term of U.S. Patent No. 5,196,404 for a period of 1 year from its previously extended expiration date. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website:
<http://www.fda.gov/opacom/morechoices/fdaforms/default.html>
(<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf>).

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: Angiomax®
FDA Docket No.: 01E-0213

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Biogen Idec MA Inc. : ORDER GRANTING
U.S. Patent No. 5,196,404 : INTERIM EXTENSION

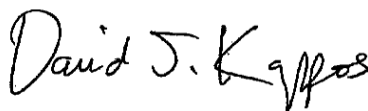
Biogen Idec MA Inc., the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 5,196,404 (the '404 patent), through its authorized agent, The Medicines Company, filed an application for patent term extension under 35 U.S.C. § 156 on February 14, 2001. The '404 patent claims the active ingredient bivalirudin, in the human drug product Angiomax®, which was approved by the Food and Drug Administration for commercial marketing or use on December 15, 2000. An extension of 1,728 days is requested.

The original term of the patent expired on March 23, 2010. On March 18, 2010, the USPTO granted a first interim extension extending the term of the '404 patent through May 23, 2010. On May 21, 2010, the USPTO granted a second interim extension extending the term of the '404 patent through and including the day ten days after the United States District Court for the Eastern District of Virginia, Alexandria Division issued an Order deciding the pending cross motions for summary judgment in *The Medicines Company v. David Kappos et al.*, Civil Action No. 01:10-cv-286. That Order issued on August 3, 2010.

A third interim extension is hereby granted, extending the term of U.S. Patent No. 5,196,404 until August 13, 2011.

August 5, 2010

Date



David J. Kappos
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office