IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	MARAGANORE *et al.*	Confirmation No.:	9190
Patent No.:	5,196,404	Issue:	March 23, 1993
Application No.:	07/549,388	Filed:	July 6, 1990
Title:	INHIBITORS OF THROMBIN		

Mail Stop Patent Ext.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR INTERIM EXTENSION OF PATENT TERM

Dear Sir:

The Medicines Company ("MDCO") requests a one-year interim extension of the term of U.S. Patent No. 5,196,404 ("the '404 patent").

On March 16, 2010, the United States District Court for the Eastern District of Virginia vacated the PTO's denial of MDCO's application under 35 U.S.C.§ 156 to restore the term of the '404 patent, and remanded the matter to the PTO for reconsideration. *See The Medicines Co. v. Kappos*, No. 1:10-cv-81, slip op. at 18 (E.D. Va. Mar. 16, 2010) (slip op. & order attached as Exhibit A). In its decision, the Court observed that "there is no dispute that MDCO satisfied all of the substantive requirements of 35 U.S.C. § 156," *id.* at 4-5, and it directed the PTO "to take such actions as necessary to ensure that the '404 patent does not expire pending further resolution of these proceedings," *id.* at 18; *see* Order at 1.

The '404 patent is set to expire on March 23, 2010—just five days from now. Resolving these proceedings will require substantially more than five days. For example, even if the PTO were to conclude within the next five days that, based on the Court's guidance, the present § 156

application was timely filed under § 156(d)(1), the PTO could not grant the requested extension until after the Food and Drug Administration ("FDA") had determined the length of the regulatory review period, published that determination, and allowed a period for public comment. Conversely, if the PTO were to conclude, despite the Court's guidance, that the application were not timely filed, MDCO would be entitled to seek reconsideration of that determination, as well as judicial review of any final PTO determination. Any such review would necessarily require substantially more than five days. In other words, any final resolution of these proceedings will not occur before the expiration of the patent on March 23, 2010.

Accordingly, an interim extension is necessary to comply with the express terms of the district court's order and is required under 35 U.S.C. § 156(e)(2).[1] As instructed by the district court, an extension should continue through the final resolution of the proceedings in this matter—including the PTO's decision on remand and further judicial review, if any. Because resolution of these proceedings will require a substantial amount of time—due to the involvement of the FDA and potentially the court—the PTO should immediately grant a one-year interim extension, without prejudice to the grant of additional interim extensions, if needed to comply with the Court's order.

In light of the impending March 23, 2010 expiration of the patent, MDCO respectfully requests that the PTO act on this request on or before March 19, 2010.

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[1] The mandate from the district court requires grant of the interim extension in this case. Even without that mandate, an interim extension would be required under § 156(e)(2). *See In re Reckitt & Colman Prods. Ltd.*, 230 U.S.P.Q. 369, 372 (Comm'r Pat. & Trademarks 1986) (granting an interim extension based on a district court judgment that cast doubt on the PTO's decision rejecting a patent term extension application as untimely); *see also, e.g.*, *In re Patent No. 4,600,706* (Comm'r Pat. Oct. 30, 2006) (granting an interim extension to allow the PTO to consider a good-faith request for reconsideration of its decision denying a patent term extension).

Any fee required for consideration of this request should be debited from our Deposit Account No. 08-0219.

Respectfully submitted,

/donald r. steinberg/

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Date: March 18, 2010

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