

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC.,)
)
)
 Plaintiff,)
)
 v.)
)
 F. HOFFMANN-LA ROCHE LTD,)
 ROCHE DIAGNOSTICS GMBH,)
 and HOFFMANN-LA ROCHE INC.,)
)
 Defendants.)

CIVIL ACTION No.: 05-CV-12237WGY

**DEFENDANTS’ MOTION TO FILE UNDER SEAL A DOCUMENT CONTAINING
DEFENDANTS’ CONFIDENTIAL AND TRADE SECRET MATERIALS**

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively “Roche”) submit this memorandum and accompanying declaration in support of their motion, pursuant to the Protective Order, to file under seal a document which contains Roche’s confidential and trade secret materials submitted for *in camera* review by Amgen if the Court deems it necessary for its ruling on Amgen’s Motion To Enforce the Court's December 29, 2006 Order and To Compel the Further Production of Documents (Docket No. 281).¹ The present motion relates solely to the confidentiality of Amgen’s motion papers; Roche will file its substantive opposition to Amgen’s motion on or before the deadline of March 1, 2007.

¹ The document Amgen seeks to file was submitted to the Court in a sealed envelope for *in camera* review on February 15, 2007, and corresponds to Exhibit 2 of Amgen’s Declaration Of Deborah E. Fishman In Support Of Amgen Inc.’s Motion To Enforce The Court’s December 29, 2006 Order And To Compel The Further Production Of Documents (Docket No. 283).

As set forth in greater detail in the supporting memorandum and accompanying declaration of Krishnan Viswanadhan, Associate Director of Drug Regulatory Affairs at Hoffmann-La Roche Inc. (“the Viswanadhan Declaration”), Exhibit 2, entitled “Key Agreements with FDA,” is an excerpt from Roche’s highly sensitive, highly confidential Biologics License Application (“BLA”) that recounts Roche’s communications with the FDA.

As a preliminary matter, Exhibit 2 should not be accepted for filing at all, in the public record or otherwise, because it is merely cumulative of two publicly available documents that were also submitted in support of Amgen’s motion. Amgen offers Exhibit 2 for the limited purpose of showing that Roche has submitted data to the FDA after the filing of its BLA in April 2006. Roche does not dispute that it has had ongoing communications, both oral and written, with the FDA since the BLA was filed, and, indeed, Amgen also offers two other publicly available documents in support of this point. Further, only one sentence of the 13 page document is even arguably relevant to Amgen’s motion, and Amgen has aptly summarized the content of that sentence in the text of its Memorandum. There is no reason why the Court should be burdened by the examination of Exhibit 2 for trade secrets when it is merely cumulative with publicly available evidence before it.

If, however, the Court does require this document in its determination of Amgen’s motion, Roche respectfully requests that it be accepted for filing under seal. Exhibit 2 contains highly confidential information and trade secrets, the continued secrecy of which is important to the maintenance of Roche’s hard won competitive advantage in the highly competitive pharmaceutical industry. A competitor would view information regarding the guidance the FDA provided to Roche in its approval process as valuable insight into MIRCERATM’s development,

and as a valuable resource for its own drug development efforts.

For all the foregoing reasons, Roche respectfully requests that Exhibit 2 not be accepted for filing because it is unnecessary and irrelevant to the disposition of Amgen's motion. However, if the Court deems it relevant, then Roche requests that the Court grant Roche's motion to file this document under seal.

CERTIFICATE PURSUANT TO LOCAL RULE 7.1

I certify that counsel for the parties have conferred in an attempt to resolve or narrow the issues presented by this motion and that no agreement was reached.

DATED: Boston, Massachusetts
February 22, 2007

Respectfully submitted,

F. HOFFMANN-LA ROCHE LTD,
ROCHE DIAGNOSTICS GMBH, and
HOFFMANN-LA ROCHE INC.

By their Attorneys,

/s/ Keith E. Toms
Lee Carl Bromberg (BBO# 058480)
Julia Huston (BBO# 562160)
Keith E. Toms (BBO# 663369)
Nicole A. Rizzo (BBO # 663853)
BROMBERG & SUNSTEIN LLP
125 Summer Street
Boston, MA 02110
Tel: (617) 443-9292
ktoms@bromsun.com

Leora Ben-Ami (*pro hac vice*)
Mark S. Popofsky (*pro hac vice*)
Patricia A. Carson (*pro hac vice*)
Thomas F. Fleming (*pro hac vice*)
Howard S. Suh (*pro hac vice*)
Peter Fratangelo (BBO# 639775)
KAYE SCHOLER LLP
425 Park Avenue
New York, NY 10022
Tel: (212) 836-8000

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non registered participants on the above date.

/s/ Keith E. Toms

Keith E. Toms

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