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

MEMORANDUM IN SUPPORT OF 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).

Introduction

As set forth in greater detail below and in the 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, confidential Biologics License Application ("BLA") summarizing Roche's key communications with the FDA surrounding its submission of its BLA. This exhibit shouldn't be accepted for filing at all because it is offered on a narrow issue that Roche does not dispute, and is merely cumulative of publicly available evidence that is also submitted by Amgen, and thus Exhibit 2 is not necessary for the Court's decision on Amgen's motion. If the Court does deem it necessary for its ruling, however, Roche requests that Exhibit 2 be filed under seal to protect Roche's highly confidential trade secrets contained within.

I. The Document At Issue Is Not Necessary And Should Not Be Accepted For Filing

The Court's review of Exhibit 2 is not necessary, and thus should not be accepted for filing in the public record or otherwise, because it is offered as evidence on a narrow issue that Roche does not dispute. Amgen only relies on Exhibit 2 for the limited purpose of showing that Roche planned to submit additional data to the FDA four months after the filing of its BLA in April 2006. Roche does not dispute this point, nor does it dispute that it has had communications with the FDA, both oral and written, since the filing of the BLA in April 2006, so this document is not necessary for the Court's consideration of this issue.

Furthermore, Exhibit 2 is merely cumulative of other evidence provided by Amgen and thus it is not necessary for the Court's decision on Amgen's motion. Amgen also provides two other sources, both of which are publicly available, to support its point that Roche has submitted data to the FDA after it filed the BLA. *See* Amgen's Memorandum in Support of its Motion

(Docket No. 282) at n.3 (listing two sources in addition to Exhibit 2 to show Roche's supplemental filings). The Court should not be burdened by reviewing a highly confidential document for trade secrets when its is cumulative of publicly available documents that will serve the same purpose.

To the extent that the information contained in Exhibit 2 is relevant to Amgen's motion at all, Amgen has aptly summarized the relevant content of the document in the text of its Memorandum. Of the 13 pages of Roche's highly confidential excerpt from the BLA that were submitted for *in camera* review, only one sentence is even arguably relevant,[2] and Amgen has summarized that sentence in its publicly filed memorandum at pages 1 (note 3), 3 (note 7), and 6 (note 14). The Court need not examine all 13 pages of Exhibit 2 in order to accept Amgen's summary of the contents of one sentence. Roche urges the Court to not accept this document for filing at all, but if the Court so requires, to file this document under seal.

II. Exhibit 2 Contains Information Which Is Not Publicly Known and Which Would Cause Irreparable Harm To Roche If Revealed

Exhibit 2 contains detailed information regarding the private, highly confidential communications between Roche and the BLA sponsors at the FDA and the agreement reached through such communications. This document reflects a summary of agreements with FDA on the preclinical, manufacturing, and clinical studies the FDA required of Roche to file the BLA. As is customary during the FDA approval process, Roche met with the FDA at key milestones in its drug development in order to assess the status of preclinical and clinical trials required to support the BLA and eventually obtain approval. This document contains technical information regarding Roche's drug development at these milestones, including details as to the agreements

[2] Amgen only relies upon the first sentence of bullet-point two on page 10 of the document submitted for *in camera* review.

made with FDA on the content of the BLA, the necessary studies for Roche to conduct, and the manufacturing program, particularly regarding the comparability of Roche's commercial production of MIRCERA™ to the smaller test-production scales. *See* Viswanadhan Declaration at ¶ 6.

The continued secrecy of the highly confidential, proprietary information contained in Exhibit 2 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 Roche's and its own drug development process. Such valuable information in the hands of a competitor would serve as a valuable roadmap of what the FDA is likely to require, and thus would provide an unwarranted advantage in its development of a competing product. *See* Viswanadhan Declaration at ¶ 7.

As Mr. Viswanadhan attests, pursuant to FDA policy and Roche company policy, the BLA and communications with the FDA regarding it are maintained in confidence and secrecy throughout the FDA approval process, and continue to be held in confidence even after approval (if any) is granted. 21 C.F.R. § 601.51(d)(1). Even after approval is granted, an applicant's communications with the FDA would typically not be publicly disclosed in this level of detail. *See* Viswanadhan Declaration at ¶ 5, 8. Therefore, it is imperative that Exhibit 2 be filed under seal.

III. Exhibit 2 Contains Trade Secrets Under Massachusetts Law

A. Exhibit 2 Contains Trade Secrets Under The Massachusetts Standard

Under Massachusetts law, a trade secret is defined as "anything tangible or intangible or electronically kept or stored, which constitutes, represents, evidences, or records a secret

scientific, technical, merchandising, production, management information, design, process, procedure, formula, invention or improvement." M.G.L. ch. 266 § 30(4).[3] *See Trent Partners and Associates, Inc. v. Digital Equipment Corp.*, 120 F. Supp. 2d 84 (D. Mass. 1999) (Woodlock, J.). As asserted by Mr. Viswanadhan, Exhibit 2 concern secret scientific, technical, production, design, process, procedure, formula, invention and improvement information belonging to Roche which, if revealed, would harm Roche. *See* Viswanadhan Declaration at ¶ 5, 7. Trade secret status requires that reasonable steps be taken to keep the information confidential. Here, Roche has never allowed these communications with the FDA to enter the public domain and has taken all possible measures to ensure that the information contained therein remains confidential. *See* Viswanadhan Declaration at ¶ 6.

Further, the FDA itself regards BLAs and the communications regarding the BLA between the FDA and an applicant as highly confidential. Pursuant to FDA policy, the BLA is maintained in confidence and secrecy throughout the FDA approval process and continues to be held in confidence even after approval is granted. 21 C.F.R. § 601.51(d)(1). Thus, Roche seeks to enjoy the same confidential and efficient process that is available to all other applicants for FDA approval, by keeping the highly sensitive portions of its BLA and other information relating to its FDA approval process confidential. Roche would suffer irreparable harm if Exhibit 2 were to be filed in the public record.

Additionally, Roche and Amgen entered into an express agreement – the Protective Order – restricting the disclosure of the BLA. This Protective Order is extremely rigorous for the very reason that Roche, Amgen and this Court all recognize the great degree of sensitivity of

[3] M.G.L. ch. 93 § 42 incorporates by reference the definition of trade secrets found in M.G.L. ch. 266 § 30. Additionally, a similar definition is found at M.G.L. c. 93 § 2.

documents such as the BLA and the trade secret information contained therein. In fact, the Protective Order restricts access to the BLA to the parties' outside counsel, and designated in-house counsel are only permitted access to the actual documents (whether in hard copy or electronic form) in a locked room, or in certain circumstances, under lock and key. *See* Protective Order at ¶ 4 (Docket No. 274). Thus, Roche requests that the Court treat Exhibit 2 with the same level of confidentiality that the parties confer upon it in the Protective Order, and grant Roche's motion to file the document under seal.

B. If Exhibit 2 Were Revealed, Competitors Could Replicate Roche's Drug And Misappropriate Its Trade Secrets

Exhibit 2 relates the communications between Roche and the FDA concerning the clinical trials of Roche's new drug MICERA, which can treat anemia differently from Amgen's drug, and has significant value in the market upon FDA approval. In these circumstances, disclosing Exhibit 2 in the public record would harm the economic advantage that Roche has invested in and worked for as a company in the position of creating a new drug. *See Webb v. Dep't of Health & Human Servs.*, 696 F.2d 101, 103 (D.C.Cir. 1982) ("If a [drug] manufacturer's competitor could obtain all the data in the manufacturer's NDA [the chemical equivalent of a BLA], it could utilize them in its own NDA without incurring the time, labor, risk and expense involved in developing them independently. Premature disclosure of NDA data is . . . discouraged by the existence of criminal sanctions . . . contained in both the Food, Drug, and Cosmetic Act and the Trade Secrets Act."); *see also Campaign for Responsible Transplantation v. United States Food and Drug Administration,* 219 F. Supp. 2d 106, n.10 (D.D.C. 2002) (stating that the release of confidential commercial information could "cause substantial competitive harm to the sponsor of the IND because a competitor could appropriate the information for use in its own IND or INDs . . . [Center for Biologics Evaluation and Research]

regulations protect the confidentiality of IND submissions."). Thus, it is crucial that Exhibit 2 be filed under seal, if at all.

VI. Conclusion

For all the foregoing reasons, Roche respectfully requests that Exhibit 2 not be accepted for filing because it is 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.

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

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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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