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

ROCHE'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR LEAVE TO FILE UNDER SEAL DOCUMENTS CONTAINING DEFENDANTS' TRADE SECRETS SUBMITTED IN CONNECTION WITH AMGEN'S MOTION *IN LIMINE* NO. 13

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively "Roche") submit this memorandum in support of their motion, pursuant to the Protective Order and Local Rule 7.2, to file under seal documents containing Roche's confidential and trade secret materials submitted for *in camera* review by Amgen, if the Court deems these materials necessary for its ruling on Amgen's Motion *In Limine* No. 13 (Docket No. 856).

Introduction

As set forth in greater detail below and in the accompanying declaration of Krishnan Viswanadhan, Director of Drug Regulatory Affairs at Hoffmann-La Roche Inc. ("the

Viswanadhan Decl."), Fishman Exhibits 1-4 and 7 ("The Exhibits"),[1] contain highly sensitive, confidential trade secret information belonging to Roche, including information drawn from Roche documents regarding the clinical testing for Roche's MIRCERA®. The Exhibits shouldn't be accepted for filing at all, under seal or otherwise, because the confidential information contained in these documents is unnecessary and irrelevant for Amgen's motion. If the Court does deem these documents necessary for its ruling, however, Roche requests that the Exhibits be filed under seal to protect Roche's highly confidential trade secrets contained within.

I. The Exhibits Are Not Necessary and Should Not be Accepted for Filing

It is unnecessary for the Court to review Roche's confidential documents to resolve the issues before it, so the secrecy of Roche's confidential information contained therein should not be destroyed. Amgen only cites Exhibits 1-5 one time, and even then, only for the general proposition that these expert reports rely upon certain documents. *See* Amgen's Brief in Support of Motion *In Limine* No. 13 at 3, n.6. The Court need not review Roche's confidential, trade secret information to accept this bland characterization of these documents, and, indeed, Roche does not dispute this point. Thus, the Court should not be burdened by deciding the trade secret status of these documents and Roche's confidential information should not be revealed when these documents are unnecessary to any disputed issues pending before it.

The trade secret information contained in Exhibit 7 is similarly unnecessary for the Court to review. Roche does not dispute that it submitted an interim status report on ongoing clinical trials entitled the Special Safety Report by September 2006. As Roche will argue in more detail

[1] Declaration of Deborah E. Fishman in Support of Amgen Inc.'s Motion *In Limine* No. 13: Exclude Evidence and Argument Regarding Roche's FDA Filings and Communications that It Withheld Throughout Fact Discovery (Docket No. 858). These Exhibits were submitted to the Court for *in camera* review on August 22, 2007. While Roche maintains that all of the exhibits submitted for *in camera* review are highly confidential documents, in light of the Court's requirement that only trade secrets be filed under seal, Roche will not object to Exhibits 5 being filed in the public record if the Court deems it necessary to decide Amgen's motion.

in its opposition on the merits, the timing of this submission — which is the only proposition that Amgen cites Exhibit 7 for — is undisputed and irrelevant because Roche was not required to produce communications relating to ongoing clinical studies, such as the Special Safety Report. Thus, the Court need not review the confidential, trade secret information contained in Exhibit 7 to decide the issues before it.

II. The Exhibits Contain Information Which Is Not Publicly Known and Which Would Cause Irreparable Harm To Roche If Revealed

As Mr. Viswanadhan, the Director of Drug Regulatory Affairs at Hoffmann-La Roche Inc., attests, the Exhibits contain sensitive, trade secret information regarding Roche's analysis of safety data collected during its clinical trials for MIRCERA®. Accurately determining the safety characteristics of a new product is one of the most sensitive aspects of bringing it to market because there are grave risks to the public and the company in both understating or overstating potential safety concerns. For example, if a company understates potential safety concerns, it potentially jeopardizes patients' health and exposes itself to the risk of massive products liability litigation. Overstating potential safety concerns can also harm patients by driving away patients who would otherwise benefit from a safe and effective new treatment option, which, in turn, harms the company's ability to benefit from its efforts in bringing a safe and effective new product to market. Indeed, the FDA regularly considers the potential harms of both overstating and understating potential safety risks in its evaluation of drug safety claims. *See* Viswanadhan Decl. ¶ 5; *see e.g.*, Food & Drug Admin., Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3,922, 3935 (Jan. 24 2006) ("Exaggeration of risk could discourage appropriate use of a beneficial drug.")

Given these difficulties, Roche does not publicly disclose its internal safety analyses prior to regulatory approval, and would be irreparably harmed if forced to do so. The FDA's purpose

is to act as an independent arbiter to determine the safety and efficacy of prescription products in order to ensure that the public has an accurate description of the risks and benefits of a product. Even FDA approval, however, cannot cure the harm caused by the premature disclosure of safety conclusions that may later be determined to overstate or understate the risks of a new product. Thus, it is Roche's policy not to disclose its safety analysis, especially at the exacting level of detail contained in the Exhibits, prior to final FDA approval. Consequently, Roche would be irreparably harmed by the public disclosure of Roche's preliminary safety analysis for MIRCERA®. *See* Viswanadhan Decl. ¶ 6.

III. The Exhibits Contains Trade Secrets Under Massachusetts Law

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).[2] *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, The Exhibits contain information regarding Roche's internal scientific analysis regarding the safety characteristics of MIRCERA®, which, if revealed, would harm Roche. *See* Viswanadhan Declaration at ¶ 4-12.

Trade secret status also requires that reasonable steps be taken to keep the information confidential. Here, Roche has never allowed its communications with the FDA regarding its analysis of MIRCERA® safety data to enter the public domain and has taken all possible measures to ensure that this information remains confidential. *See* Viswanadhan Declaration

[2] 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.

at ¶ 4, 8-12. The FDA itself regards these communications as highly confidential, and is required by law to guard the secrecy of Roche's trade secrets. 21 C.F.R. § 601.51; 21 C.F.R. § 20.61 ("Data and information submitted or divulged to the Food and Drug Administration which fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure."). Thus, Roche seeks to enjoy the same confidential and efficient process that is available to all other applicants for FDA approval.

VI. Conclusion

For all the foregoing reasons, Roche respectfully requests that the Exhibits not be accepted for filing because they are irrelevant and unnecessary for the disposition of Amgen's motion. However, if the Court deems them relevant, then Roche requests that the Court grant Roche's motion to file these documents under seal.

DATED: Boston, Massachusetts
August 31, 2007

Respectfully submitted,

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

By their Attorneys,

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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
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