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

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

I, Krishnan Viswanadhan, declare as follows:

1. I am the Director of Drug Regulatory Affairs at Hoffmann-La Roche Inc. ("Roche"). I have been an employee of Roche since 2002. My educational background includes a B.S. in pharmacy and a Pharm.D. from Rutgers University. My duties include acting as a contact with the Food and Drug Administration (the "FDA") regarding the review of Roche's Biologics License Application ("BLA") for MIRCERA® and the Investigational New Drug Applications ("IND") in Renal Anemia.

2. I make this declaration based upon my own personal knowledge and company information.

3. I have been asked to examine documents which correspond to Exhibits 1–4 and 7 ("the Exhibits") to the Declaration of Deborah E. Fishman in Support of Amgen's Motion *In Limine* to Exclude Evidence and Argument Regarding Roche's FDA Filings and

Communications that It Withheld Throughout Fact Discovery. I have been asked to review these documents to determine whether they contain information regarded as trade secret based upon my work at Roche.

4. The Exhibits contain highly sensitive, confidential trade secret information belonging to Roche, including information drawn from Roche documents regarding the clinical testing for Roche's MIRCERA®. Pursuant to FDA policy and Roche company policy, these documents are maintained in confidence and secrecy throughout the FDA approval process. 21 C.F.R. § 601.51(d)(1). Furthermore, pursuant to Roche company policy, all the Exhibits, the information contained in the Exhibits, and any communications involving the Exhibits and their information are maintained in confidence and secrecy. Disclosure of the Exhibits in this level of detail prior to approval would destroy the trade secret status of the information contained therein and irreparably harm Roche in the highly competitive pharmaceutical industry.

5. All of the exhibits contain sensitive, trade secret information about Roche's analysis of safety data collected during its clinical trials for MIRCERA®. It has been my experience that 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, it is my

understanding that the FDA regularly considers the potential harms of both overstating and understating potential safety risks in its evaluation of drug safety claims.

6. 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 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®.

7. In the paragraphs below I set forth a detailed description of the information contained in the Exhibits and the reasons the Exhibits should not be disclosed publicly.

8. Exhibits 1 is an excerpt from the expert report of Professor Jeffrey S. Borer, M.D., dated May 11, 2007. This document contains sensitive, trade secret information regarding Roche's analysis and conclusions regarding the safety data drawn from its clinical studies for MIRCERA®. This information, and the steps and procedures Roche undertook in validating its conclusions, is confidential to Roche, and has been disclosed to no one at this level of detail, except for regulatory agencies who are required by law to keep this information confidential during the approval process. As set forth in more detail in Paragraphs 4-6 above, Roche would be irreparably harmed by the premature release of its preliminary safety analysis prior to FDA approval.

9. Exhibit 2 is an excerpt from the Expert Report of Joachim Vollmar, dated May 11, 2007. This document contains sensitive, trade secret information regarding Roche's analysis and conclusions regarding the safety data drawn from its clinical studies for MIRCERA®. This information, and the steps and procedures Roche undertook in validating its conclusions, is confidential to Roche, and has been disclosed to no one at this level of detail, except for regulatory agencies who are required by law to keep this information confidential during the approval process. As set forth in more detail in Paragraphs 4-6 above, Roche would be irreparably harmed by the premature release of its preliminary safety analysis prior to FDA approval.

10. Exhibit 3 is an excerpt from the Expert Report of Professor Kenneth V. Lieberman, M.D., dated May 11, 2007. This document contains sensitive, trade secret information regarding Roche's analysis and conclusions regarding the safety data drawn from its clinical studies for MIRCERA®. This information, and the steps and procedures Roche undertook in validating its conclusions, is confidential to Roche, and has been disclosed to no one at this level of detail, except for regulatory agencies who are required by law to keep this information confidential during the approval process. As set forth in more detail in Paragraphs 4-6 above, Roche would be irreparably harmed by the premature release of its preliminary safety analysis prior to FDA approval.

11. Exhibit 4 is an excerpt from the highly confidential Expert Report of Professor Steven Fishbane, M.D., dated May 11, 2007. This document contains sensitive, trade secret information regarding Roche's analysis and conclusions regarding the safety data drawn from its clinical studies for MIRCERA®. This information, and the steps and procedures Roche

undertook in validating its conclusions, is confidential to Roche, and has been disclosed to no one at this level of detail, except for regulatory agencies who are required by law to keep this information confidential during the approval process. As set forth in more detail in Paragraphs 4-6 above, Roche would be irreparably harmed by the premature release of its preliminary safety analysis prior to FDA approval.

12. Exhibit 7 is an excerpt from the deposition transcript of Dr. Jeffrey S. Borer, which was taken on May 22, 2007. This document contains sensitive, trade secret information regarding Roche's analysis and conclusions regarding the preliminary safety data drawn from its clinical studies for MIRCERA®. This information, and the steps and procedures Roche undertook in validating its conclusions, is confidential to Roche, and has been disclosed to no one at this level of detail, except for regulatory agencies who are required by law to keep this information confidential during the approval process. As set forth in more detail in Paragraphs 4-6 above, Roche would be irreparably harmed by the premature release of its preliminary safety analysis prior to FDA approval.

13. Roche deems it necessary to maintain the confidentiality of such information, as detailed above, and it would be irreparably harmed by the disclosure of this highly confidential, trade secret information in the public record prior to regulatory approval. Accordingly, it is of critical importance that the Exhibits not be disclosed in the public record.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 31th day of August 2007 at Basel, Switzerland.

/s/_ Krishnan Viswanadhan_____
Krishnan Viswanadhan

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 referenced date.

/s/ Keith E. Toms
Keith E. Toms

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