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 DEFENDANTS' MOTION TO SEAL A DOCUMENT CONTAINING DEFENDANTS' CONFIDENTIAL AND TRADE SECRET MATERIALS

I, Krishnan Viswanadhan, declare as follows:

1. I am the Associate 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 from Rutgers University, and a Pharm.D. from Rutgers University.

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

3. 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 CERA and the Investigational Drug Applications ("IND") in Renal Anemia.

4. I have been asked to examine a document which corresponds to Exhibit 2 ("the Exhibit") of Amgen Inc.'s Declaration of Deborah E. Fishman In Support of Plaintiff's Motion to Enforce the Court's December 29, 2006 Order and To Compel the Further Production of Documents (Docket No. 283), and which was submitted to the Court for *in camera* review on

February 15, 2007. I have been asked to review this document to determine whether it contains information regarded as trade secret based upon my work at Roche. In the paragraphs below I set forth a detailed description of the information contained in the Exhibit.

5. The Exhibit is an excerpt from Roche's Biologics License Application ("BLA") entitled "Key Agreements On Clinical Development Program." In general, the Exhibit contains highly sensitive, confidential trade secret information belonging to Roche, including information regarding Roche's communications with the FDA surrounding its submission of its BLA. Pursuant to 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. Disclosure of the Exhibit in the public record would destroy the trade secret status of the information contained therein.

6. The Exhibit 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 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

large-scale production of MIRCERA™ to the smaller scales production used during development.

7. A competitor would view information regarding the guidance the FDA provided to Roche in its approval process as a valuable insight into MIRCERA™'s development, and as a valuable resource for its own drug development efforts. If this document is made public, a competitor could learn from Roche's approval efforts what key agreements the FDA will and will not likely require, which would be a valuable resource during the development process of a competing product. The disclosure of this information would destroy the information's trade secret status and could harm Roche in the highly competitive pharmaceutical industry.

8. In the highly competitive pharmaceutical industry, it is standard company practice to maintain the confidentiality of trade secrets and proprietary information, such as the information revealed in the documents discussed above.

9. Maintenance of the confidentiality of such information is deemed necessary by Roche in order to safeguard its trade secrets and competitive business information and to avoid giving competitive advantage to competitors or others who might use the information to the detriment of Roche's business.

10. Roche could be disadvantaged and harmed by the disclosure of the above-referenced highly confidential, trade secret information in the public record where it would be available to all without restriction or limitation, including its competitors and others.

11. Accordingly, it is import that Roche's highly confidential, trade secret information not be disclosed in the public record.

Signed under the penalties of perjury pursuant to 28 U.S.C. Sec. 1746 this 22nd day of February, 2007.

/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 February 22, 2007.

/s/ Keith E. Toms
Keith E. Toms

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