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 RECONSIDERATION OF EMERGENCY MOTION FOR ORDER REQUIRING PLAINTIFF TO FILE UNDER SEAL DOCUMENTS 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 certain exhibits attached to the Declaration of Krista M. Carter in Support of Plaintiff Amgen Inc.'s Memorandum in Support of its

Motion to Compel, filed herein December 15, 2006. Specifically, I have been asked to examine Exhibits 8, 12, 14, 19, 20, and 27 (collectively, the "Exhibits"), all of which have been identified as highly confidential by Roche, to determine whether they contain information regarded as trade secrets based upon my work at Roche. In the paragraphs below I set forth a detailed description of the various kinds of information contained in the Exhibits.

5. The Exhibits and excerpts from the Exhibits contain highly sensitive, confidential trade secret information belonging to Roche, including information from confidential internal Roche documents regarding clinical trials, Roche's BLA and INDs submitted to the FDA. Pursuant to FDA policy and Roche company policy, the BLA and the IND applications 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).

6. The Exhibits of special concern to me, in my position with Roche, are Exhibits 8, 12, 14, 19, 20 and 27. Disclosure of these Exhibits (and the corresponding excerpts) on the public record would destroy the trade secret status of the information contained therein.

7. In general, the Exhibits contain three categories of highly sensitive and confidential information, concerning: (1) the specific chemical synthesis, analysis, purification, and manufacturing of Roche's unique product; (2) detailed information from clinical trials, including specific data collected from individual human subjects with end stage renal disease (dialysis patients) ("ESRD") and chronic kidney disease ("CKD"); and (3) Roche's compliance with FDA requirements concerning public

disclosure of information related to products being considered for approval. This highly sensitive, confidential information is the result of years of effort and millions of dollars of expenditure in the drug development process. It is at the core of Roche's business as a pharmaceutical company. Such valuable information in the hands of a competitor, like a generic manufacturer in jurisdictions without adequate patent protection, would obviate the need for the extensive time, effort and expense incurred by Roche in developing this pharmaceutical technology. In other words, the disclosure of this information would destroy its trade secret status and irreparably harm Roche in the highly competitive pharmaceutical industry.

8. Exhibit 27 is an excerpt from Roche's BLA containing information regarding individual patients' data in clinical trials. This document discloses highly detailed, private information of at least four patients involved in Roche's clinical studies. Roche is responsible for complying with privacy laws in its clinical studies. To the extent that this document reveals information which may be in violation of federal or state privacy laws, Roche would be greatly harmed by its disclosure. Moreover, this information constitutes Roche's highly confidential trade secrets in that, as explained above, the individual patient data underlying a study is routinely held in the strictest confidence and is rarely revealed in the public record, even where the results of a study may be announced. To my knowledge, Roche has never publicly revealed individual patient information or data underlying its clinical studies in such a high level of detail, and to do so could cause irreparable harm, give competitors an unfair advantage, and potentially cause Roche to inadvertently violate privacy laws.

9. Exhibit 8 is a portion of a draft of Roche's IND containing highly sensitive, confidential trade secret information. A person with skill in the art could use information in this document to determine critical aspects of the production of Roche's proprietary product. To my knowledge, Roche has never, and would never, disclose such detailed information to the public. Roche's prize chemical and the methods used to reliably produce it are the result of years of testing and development. Disclosure to Roche's competitors on the public record would permit them to circumvent these efforts in an instant, at essentially no cost, and would deprive Roche of any competitive advantage they are entitled to enjoy for the effort invested in developing their novel product.

10. Exhibit 19 is an excerpt from Roche's BLA, containing specific information about development of the product Roche hopes to market in the United States. The second page of this document contains information about certain purification processes. It is generally accepted in the pharmaceutical industry that purifying molecules of any variety is rarely straightforward, and development of an efficient purification method can be an extremely time-consuming and costly endeavor. This document reveals steps in a purification process that has taken years to develop and perfect. In my opinion, disclosure of this information to the public would destroy its trade secret status, would enable competitors to take advantage of Roche's painstaking efforts without investing the resources that Roche invested in developing the process, and would confer an unfair competitive advantage on these parties, to Roche's detriment.

11. Exhibit 12 is an internal Roche document showing Roche's analysis of production batches and validation of its purification processes. This information is

basic to Roche's manufacturing process. The details of how Roche validates its manufacturing process is highly sensitive, confidential trade secret information which gives Roche a competitive advantage over other entities attempting to create similar compounds. Its disclosure in the public record would destroy its trade secret status.

12. Exhibit 14 is an internal Roche document showing information regarding drug development and manufacturing strategy. More specifically, this document pertains to current, long-term contractual relations between Roche and its vendors. Roche's strategic efforts to manage the adequate supply of goods necessary for manufacturing of all its products are the result of years of careful planning and implementation. Disclosure of internal discussions evaluating Roche's present position and considering alternate options for the future has the potential to harm Roche's existing business and contractual relationships, which, in turn, would severely compromise Roche's business operations.

13. Exhibit 20 is also an excerpt from Roche's BLA, containing information regarding highly detailed information which is a comprehensive summary of Roche's phase II and III clinical trials. This document contains highly detailed information on data populations and analyses which are not, to my knowledge, in the public record in this level of detail. While pharmaceutical companies at times reveal the results of various clinical studies that may be presented in the BLA, the detailed data itself is kept in confidence, especially in the high level of detail supplied in this document. This document, which is part of the inherently confidential BLA, if placed in the public record would reveal all the data and analysis of the study itself, which has never been disclosed in this level of detail in the public record. Disclosure of this information to a

competitor could confer an unfair competitive advantage and cause irreparable harm to Roche, in that a competitor could detect differences between its efficacy and safety data and Roche's, and use this information against Roche in the market. This type of information, especially given that the product has not yet been approved, is exactly the type of information that Roche should have the prerogative to determine its disposition.

14. 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.

15. 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.

16. Roche would be severely 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.

17. Accordingly, it is of critical importance 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 December, 2006.

/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 date.

/s/ Nicole A. Rizzo
Nicole A. Rizzo

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