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 RICHARD BESWICK IN SUPPORT OF DEFENDANTS' MOTION FOR LEAVE TO FILE UNDER SEAL DOCUMENTS CONTAINING DEFENDANTS' TRADE SECRETS AND SUBMITTED IN CONNECTION WITH AMGEN'S MOTION TO PRECLUDE FURTHER INTERFERENCE WITH THIRD-PARTY DISCOVERY

I, Richard Beswick, declare as follows:

1. I am an Associate Medical Director at Hoffmann-La Roche Inc. ("Roche"). I have been an employee of Roche since 2005 and I have worked in the pharmaceutical industry at other companies, in a similar position, since 2002. My educational background includes a B.S. in Biology from Morehouse College, an M.A. in Cardiovascular Physiology from Central Michigan University, an M.B.A. from Rollins Crummer Graduate School of Business, and a Ph.D in Molecular Renal Physiology from the University of Michigan School of Medicine.

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

3. My duties include directing and developing medical initiatives for the development of CERA.

4. I have been asked to examine certain Exhibits submitted for *in camera* review on April 13 and 16, 2007 in connection with the Declaration of Mario Moore in Support of Plaintiff Amgen Inc.'s Motion to Preclude Further Interference with Third-Party Discovery and Compel Production of Documents And Deposition Testimony, or in the Alternative, Motion To Strike Defendants' Defense Under 35 U.S.C. § 271(e)(1) (Docket No. 379). Specifically, I have been asked to examine Exhibits 4-6, 10-12, 14-15, and 17-18 (collectively, the "Exhibits"), all of which have been identified as confidential or 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 contain highly sensitive, confidential trade secret information belonging to Roche, including information from confidential internal Roche documents regarding clinical trials conducted in furtherance of Roche's Biologics License Application ("BLA") and Investigational Drug Applications ("IND") submitted to the Food and Drug Administration (the "FDA"). Pursuant to FDA policy and Roche company policy, the BLA and the IND applications and those communications involving these 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. Disclosure of the Exhibits in the public record would destroy the trade secret status of the information contained therein.

7. In general, the Exhibits contain four categories of highly sensitive and confidential information, concerning: (1) confidential information concerning the details as to time frame, size and dosing used in individual ongoing and future clinical trials, (2) Roche's manufacturing processes and scale-up of its product, (3) confidential Roche marketing strategy and budgeting information, and (4) Roche's internal forward-looking statements regarding the potential success of its product. 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 allow them to bypass the extensive time, effort and expense incurred by Roche in developing this pharmaceutical technology, or in conducting analysis of the market for this product. 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 4 is an internal Roche slide presentation containing highly confidential, trade secret information including detailed analysis of Roche's drug development activities and strategy, including test result data, comparative study plans and outcomes, development and marketing timelines, budget data, and related information at the core of Roche's drug development and marketing business. I am very familiar with this Exhibit because it originated in my department, Medical Affairs. This information is

maintained in strict confidence as a trade secret in the highly competitive worldwide pharmaceutical industry. This trade secret information is basic to Roche's ability to compete and succeed in its business and gives it an advantage in the marketplace. 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. Roche has never, and would never, disclose such detailed information to the public. This product is the result of years of testing and development. Public disclosure of this information to Roche's competitors on the public record would destroy its trade secret status and unfairly benefit Roche's competitors, allowing them to gain this knowledge and information without incurring the substantial effort and expense undertaken by Roche to develop the drugs and marketing strategies set forth in this document.

9. Exhibit 4 contains many details regarding Roche's dialysis program which have never been made public, and would be extremely damaging if they were to be made public at this time. For example, the document contains information regarding mean dosing, inclusion criteria such as how many patients participated in each study, how many patients were planned for each study, how the patients were randomized, how many patients were in the United States, and final endpoints. All of this information would be highly instructive to a competitor because it would provide an insider's perspective on Roche's clinical trials. It is critical to Roche's business strategy that this information not be released in the public record.

10. Exhibit 4 contains a "competitive profile," which essentially represents Roche's analysis of its strengths and weaknesses with respect to its competitors regarding chronic kidney disease ("CKD") studies. Because I have previously worked for other

pharmaceutical companies, I understand the perspective of a competitor viewing this information. This information would allow a competitor of Roche to critique and assess Roche's weaknesses in great detail. This would give the competitor the advantage of benefiting both from applying the knowledge of Roche's vulnerabilities to its own drug development, and from the ability to use this information against Roche in the market.

11. Exhibit 4 includes a description of Roche's speculative and forward-looking predictions as to the potential results of various studies. For example, pages 17-20 of Exhibit 4 detail what the presenter believes Roche's CKD program will deliver and what it will not deliver, while pages 24-27 do the same for Roche's dialysis program. These predictions are highly sensitive, confidential business strategy which could, if revealed in the public record, be extremely harmful to Roche. This document was created and presented as a confidential internal Roche document not intended to be seen by the public at large, or by potential investors. Indeed, Roche has strict obligations regarding forward-looking statements and speculation as to the success of its product. Disclosure of this information in the public record would potentially be inconsistent with Roche's legal obligations regarding public, forward-looking predictions of its products.

12. Exhibit 5 is an internal Roche memorandum originating in and circulated amongst the Clinical Operations Group which outlines the budget and objectives for Roche's phase IIIb clinical studies. This document contains Roche's trade secret and highly detailed information regarding the design and implementation of each clinical study, including the number of patients enrolled in the Time & Motion, Home Dialysis and Continuum

of Care studies, and the First Patient, First Visit ("FPFV") and Last Patient, Last Visit ("LPLV") data. Exhibit 5 also contains information on the budget for each trial, broken down by site, which would be helpful to a competitor trying to undermine and interfere with Roche's studies. Most of these trials have not even commenced and none are completed. This information could be used by a competitor to determine Roche's plans for the exact beginning and end dates of the clinical trials, which would be extremely harmful to Roche because it reveals where Roche is spending its resources, and in what areas competitors could gain an advantage by outspending Roche. For example, if a competitor were aware of Roche's plans for future clinical trials based on its budget, it could plan its own clinical trial for the same time period in order to "lock up" available participants and thereby impede Roche from executing its planned trial. It is my experience that it is a common occurrence in the pharmaceutical industry for competitors to attempt to lock out each other's clinical trials by offering studies that are more appealing to potential participants during the same time frame. Thus, this type of information is typically considered to those in the industry as highly confidential and trade secret, and would greatly harm Roche if it were disclosed in the public record. Additionally, because this document discusses the date at which Roche expects to complete its clinical trials and release its first abstract from those trials, its disclosure in the public record would provide investors with information as to when would be the best time to invest in Roche securities. As discussed in paragraph 11 above, disclosure of this information in the public record would potentially have an impact on Roche's investor relations and would be inconsistent with Roche's legal obligations regarding public, forward-looking predictions of its products.

13. Exhibit 6 is an internal Roche email containing a discussion of Roche's confidential budget for the Time & Motion, Home Dialysis and Continuum of Care clinical trials, broken down by per patient cost. The budget also displays line-item expenditures for vendors, drug packaging, sites, statistics and data management and other operating costs. This information is never made public and it would be very harmful to Roche to have this information in the public record for competitors to use. As discussed in paragraph 12 above, this information would be extremely harmful to Roche in the hands of competitors because it reveals where the areas in which competitors could gain an advantage by outspending Roche and planning its own clinical trial for the same time period in order to "lock up" available participants. This type of information is crucial to Roche's competitive advantage and its public record disclosure would be extremely destructive to Roche's success in the market.

14. Exhibit 10 is an internal Roche monthly report, originating in and circulated amongst the Medical Affairs department, which provides a comprehensive and in depth update on all ongoing and planned clinical trials. The report contains detailed information regarding each step in the process for these studies, including the date of submission of the protocols to the FDA, negotiations with vendors regarding budgets for each site, the number of completed and future pre-study visits, and target begin dates for each trial. This report is quite recent, dated January 2007, and as such, it contains information on clinical trials which are still in the planning stages today. It is imperative that this information be kept confidential, as disclosure would publicly reveal Roche's strategy and timing of its future clinical trial design and implementation. As discussed in paragraph 14 above, disclosure of this information would enable competitors to plan

competing clinical trials in order to ambush Roche's strategy. Additionally, Exhibit 10 reveals the dialysis organizations with which Roche is collaborating on these clinical trials, and the confidentiality of this information is integral to Roche's business relationships. Each collaborator is not necessarily aware of the identity of other collaborators, and each company would not want its identity publicly disclosed to potential customers which may be competitors of Roche. Thus, a competitor would use this information to pit these parties against Roche in order to interfere with Roche's contractual and business relationships, thereby impeding Roche's ability to conduct its clinical trials.

15. Exhibit 11 is another issue of the internal Roche monthly report identified in paragraph 14 above, dated December 2006. This report details the data generation process for each of the key ongoing studies, including the Time and Motion, Continuum of Care and Peritoneal Dialysis study, as well as plans for future clinical studies which are still in the planning stages today. Exhibit 11 also contains information on the cost models for these studies and updates on the progress of contractual negotiations with various collaborators for the studies. For the reasons discussed in paragraph 14 above, this information is highly confidential and would be destructive to Roche's ability to conduct its clinical trials if disclosed.

16. Exhibit 12 is an internal Roche slide presentation containing highly confidential, trade secret information regarding planning, resource allocation, and project management for Roche's new product, including details concerning Roche's clinical studies. Although results of clinical studies are sometimes released to the public, details concerning the studies are routinely kept in confidence. The planning, resource allocation and project

management information is central to Roche's business and marketing strategy, and is maintained in the strictest confidence in the ordinary course of business. Disclosure of this information to a competitor who would learn Roche's plans and timing for its product's development and submission for approval would confer an unfair advantage. This trade secret information is invaluable to Roche, and placing it in the public record would harm Roche's competitive advantage.

17. Exhibit 15 is an excerpt from an internal Roche weekly report, originating in and circulated amongst the Medical Affairs department. This report was generated after the first meeting of the Anemia Clinical Trial Task Force in January 2007 in order to provide an update regarding all of the current and future clinical trials. This report is essentially an internal tracking form which contains constantly changing, detailed and highly confidential information, including my handwritten notes, regarding how many sites will be active at a specific time, which companies Roche is collaborating with on these clinical trials, the number of confidentiality agreements distributed, executed, and returned, and the number of informed consents Roche is targeting. If this information were publicly disclosed, a competitor would use this information to plan its own clinical trial for the same time period in order to "lock up" available participants and thereby impede Roche from executing its planned trial. This type of information is crucial to Roche's competitive advantage and its public record disclosure would be extremely destructive to Roche's success in the market. Also, as discussed in paragraph 14 above, the information regarding the companies with which Roche is collaborating on for its clinical trials is a guarded secret because these entities would not want the existence of a contract with Roche disclosed to other potential customers,

which may be competitors of Roche. A competitor would use information on Roche's collaborators to pit these parties against Roche in order to interfere with Roche's contractual and business relationships, thereby impeding Roche's ability to conduct its clinical trials.

18. Exhibit 17 is an internal presentation given to Roche's North American Operating Committee, which is a group made up of the company's North American presidents and vice-presidents. This document is an outline of the timelines for the Dialysis and CKD studies, and future studies still in the planning stages today, including highly detailed and confidential information such as when the synopses will be approved, the number of patients in each study, the number of minority studies, and the number and date of when each site will be initiated, and the companies with which Roche is collaborating. For the reasons discussed in paragraph 12 above, I regard this document as containing highly confidential, trade secrets which would be extremely harmful to Roche if disclosed.

19. Exhibit 18 is an internal Roche email discussion between the Medical Affairs department in the U.S. and the drug department in Germany regarding Roche's clinical supply for each of its CERA studies. The document contains a request for a specific number of PreFilled Syringes and discloses the doses and quantities planned for each study, as well as the First Patient, First Visit information for each study. This information is essentially a blueprint of Roche's clinical study design, including the size, begin dates, number of patients and exact dosage quantities. As discussed in paragraph 12 above, a competitor seeking to interfere with Roche's clinical trials would use this information to plan its own competing clinical trial which would "lock-up" the

potential patients available and prevent Roche from executing its clinical trial. This type of information is key to Roche's competitive advantage and its disclosure would be extremely harmful to Roche's success in the market.

20. 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.

21. 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.

22. 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.

23. 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 19th day of April, 2007.

/s/ Richard Beswick
Richard Beswick

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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