

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

_____)	
AMGEN INC.,)	
)	
Plaintiff,)	
)	
v.)	
)	CIVIL ACTION No.: 05-CV-12237WGY
F. HOFFMANN-LA ROCHE LTD,)	
ROCHE DIAGNOSTICS GMBH,)	
and HOFFMANN-LA ROCHE INC.,)	
)	
Defendants.)	
_____)	

**DECLARATION OF RICHARD BESWICK
IN SUPPORT OF RECONSIDERATION OF
EMERGENCY MOTION FOR ORDER REQUIRING PLAINTIFF TO FILE UNDER
SEAL DOCUMENTS CONTAINING DEFENDANTS' CONFIDENTIAL AND TRADE
SECRET MATERIALS**

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 PhD 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 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 6 and 7 (collectively, the "Exhibits"), both 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 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 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, are Exhibits 6 and 7. Disclosure of these Exhibits (and the corresponding excerpts) 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) communications with the FDA regarding the design of certain clinical studies, and information regarding compliance with FDA requirements, (2) confidential information concerning 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 6 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 6 also 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 6 also 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 6 also 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 6 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. Specifically, Roche has strict obligations under securities laws regarding forward-looking statements and speculation as to the success of its product. 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. 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 7 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.

13. In particular, Exhibit 7, on page 8 and the preceding page, contains Roche's confidential CERA CKD budget for 2005 and 2006, broken down by general line item expenditures. 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. This information would be extremely harmful to Roche in the hands of competitors 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. 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. Pages 4, 5 and 7 of Exhibit 7 contain Roche's comparison studies, Roche's "extension data" which follows the dosing of patients for one year after participation in clinical trials, and information regarding phase IIIb/IV studies which are still in development. All of this information is central to Roche's development of its CERA product and its confidentiality gives Roche a competitive advantage.

15. 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.

16. 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.

17. 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.

18. 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/ 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

03099/00501 591822.1