

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 DR. REINHARD FRANZE IN SUPPORT OF DEFENDANTS’
MOTION TO FILE UNDER SEAL DOCUMENTS CONTAINING DEFENDANTS’
CONFIDENTIAL AND TRADE SECRET MATERIALS**

I, Dr. Reinhard Franze, declare as follows:

1. I am the Head of Pharmaceutical Biotechnical Development Fermentation within the Pharmaceutical Biotech Production at Roche Diagnostics GmbH (“Roche”). I have been an employee of Roche and formerly Boehringer Mannheim GmbH since 1986. My educational background includes a Ph.D. in Microbiology from the University of Tübingen, Germany.

2. My duties include supervision of the optimization of cell culture and fermentation process.

3. I have been asked to examine the documents which correspond to Exhibit 2 (“Exhibit 2”) and to Exhibit 10 (“Exhibit 10”) (collectively, “the Exhibits”) of Amgen Inc.’s Declaration of Krista M. Carter in Support of Plaintiff’s Motion to Determine the Sufficiency of Roche’s Responses to Amgen’s Requests for Admission, and which were submitted to the Court for *in camera* review on February 13, 2007. I have been asked to review these documents 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.

4. Exhibit 2 is a copy of Defendants' Supplemental Responses to Amgen Inc.'s First Set of Requests for Admission (Nos. 1-22) ("RFAs") which contains highly sensitive, confidential trade secret information belonging to Roche, including excerpts from Roche's April 2006 Biologics License Application ("BLA"). Pursuant to FDA policy and Roche company policy, the BLA is maintained in confidence and secrecy throughout the FDA approval process, and continues to be held in confidence even after approval (if any) is granted. 21 C.F.R. § 601.51(d)(1).

5. Disclosure of Exhibit 2 in the public record would destroy the trade secret status of the information contained therein. While the entire document contains highly confidential information, I am especially concerned about the references on pages 22-27 and 29-35 (RFA Nos. 15-17 and 19-22), all of which contain trade secret information from Roche's BLA.

6. In general, Exhibit 2 contains highly sensitive and confidential information concerning the specific chemical synthesis, analysis, purification, and manufacturing of Roche's unique product and the recombinant CHO cell line which produces EPO. 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.

7. Pages 22-23 (RFA No. 15) of Exhibit 2 contain an excerpt from Roche's BLA containing information regarding the type of cell and the identity of the cell line used in the production of the product for which Roche currently seeks approval from the FDA. This information constitutes a trade secret in that, to the best of my knowledge, it has never been publicly disclosed and it would be extremely harmful to Roche if it were to be filed in the public record.

8. Page 24 (RFA No. 16) of Exhibit 2 contains an excerpt from Roche's BLA containing information regarding the identity of the cell line, the genealogy of the preparation of the cell banks as described in the BLA, and complete lineage of the cell line used in the production of the product for which Roche currently seeks approval from the FDA. This information constitutes a trade secret in that, to the best of my knowledge, it has never been publicly disclosed and it would be extremely harmful to Roche if it were to be filed in the public record.

9. Pages 25-27 (RFA No. 17) of Exhibit 2 contain an excerpt from Roche's BLA containing information regarding detailed cell culture methods and proprietary procedures employed in the production of the product for which Roche currently seeks approval from the FDA. This information constitutes a trade secret in that, to the best of my knowledge, it has never been publicly disclosed in this level of detail and it would be extremely harmful to Roche if it were to be filed in the public record.

10. Pages 29-30 (RFA No. 19) of Exhibit 2 contain an excerpt from Roche's BLA containing information regarding the particular cell type employed along with details of the cell culture methods and proprietary procedures used in the production of the product for which Roche currently seeks approval from the FDA. This information constitutes a trade secret in

that, to the best of my knowledge, it has never been publicly disclosed and it would be extremely harmful to Roche if it were to be filed in the public record.

11. Pages 30-31 (RFA No. 20) of Exhibit 2 contain an excerpt from Roche's BLA containing information regarding the composition and structure of Roche's unique DNA clone used in the production of the product for which Roche currently seeks approval from the FDA. This information constitutes a trade secret in that, to the best of my knowledge, it has never been publicly disclosed and it would be extremely harmful to Roche if it were to be filed in the public record.

12. Pages 31-33 (RFA No. 21) of Exhibit 2 contain an excerpt from Roche's BLA containing the periods for the fermentation phases and the product yield for cell growth for the product for which Roche currently seeks approval from the FDA. This information constitutes a trade secret in that, to the best of my knowledge, it has never been publicly disclosed and it would be extremely harmful to Roche if it were to be filed in the public record.

13. Pages 34-35 (RFA No. 22) of Exhibit 2 contain an excerpt from Roche's BLA containing information regarding the exact formula for making the product for which Roche currently seeks approval from the FDA. This information constitutes a trade secret in that, to the best of my knowledge, it has never been publicly disclosed and it would be extremely harmful to Roche if it were to be filed in the public record at this time.

14. Exhibit 10 is an excerpt from Roche's Investigational New Drug application ("IND") titled "Manufacture of the Starting Material of EPO." In general, Exhibit 10 contains highly sensitive and confidential information concerning the characteristics of Roche's production clone/cell bank for EPO, such as the copy number and genetic stability. Exhibit 10 further describes, particularly in figure 2, how the working cell bank used in Roche's actual

production of EPO was derived from the master cell bank. Exhibit 10 contains highly confidential and crucial details regarding the generation cycles/cell doublings that were given during the cell propagation phase up to the point when the actual working cell bank was laid down and stored. Exhibit 10 also contains the crucial information about which cell bank is presently being used by Roche for EPO production and which not – information which would be invaluable in the hands of a competitor.

15. The information contained in Exhibit 10 constitutes a trade secret in that, to the best of my knowledge, it has never been publicly disclosed and it would be extremely harmful to Roche if it were to be filed in the public record. Such detailed information would cause irreparable harm to Roche if revealed because it would enable a competitor to copy the generation of such a working cell bank which is a core element of Roche's EPO production.

16. 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.

17. 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.

18. 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.

19. 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 20th day of February, 2007.

/s/ Dr. Reinhard Franze
Dr. Reinhard Franze

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically on the above-referenced date 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 20, 2007.

/s/ Keith E. Toms
Keith E. Toms

03099/00501 619138.1