UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

DECLARATION OF MICHAEL JARSCH IN SUPPORT OF MOTION FOR LEAVE TO FILE UNDER SEAL DOCUMENTS CONTAINING DEFENDANTS' TRADE SECRETS AND SUBMITTED IN CONNECTION WITH AMGEN'S MOTION FOR SUMMARY JUDGMENT OF INFRINGEMENT OF '422 CLAIM 1, '933 CLAIM 3, AND '698 CLAIM 4

I, Dr. Michael Jarsch, hereby declare under penalty of perjury that:

1. I am the Program and Portfolio Manager for Roche Diagnostics GmbH ("Roche"). I have been an employee of Roche since 1997. My educational background includes a Dr. rer. nat. in Biology.

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

3. I have been asked to examine documents which correspond to Exhibits 14-16, 18, 19, 24, 35-38, 42-44, 50, 52, 65, and 67 ("the Exhibits") of the Declaration of Katie J.L. Scott in Support of Amgen's Motion for Summary Judgment of Infringement of '422 Claim 1, '933 Claim 3, and '698 Claim 4, which were submitted to the Court for

in camera review on June 15, 2007. I have been asked to review these documents to determine whether they contain information regarded as trade secret by Roche.

4. The Exhibits all include highly sensitive, confidential trade secret information belonging to Roche, including highly confidential information relating to Roche's preclinical, feasibility, and early investigation studies for MIRCERA®. In addition, many of the exhibits are excerpts from Roche's highly confidential BLA or INDs. Pursuant to FDA policy and Roche company policy, the BLA and INDs are maintained in confidence and secrecy throughout he 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). Furthermore, pursuant to Roche company policy, all the Exhibits, the information contained in the Exhibits, and any communications involving the documents and their information are maintained in strict confidence and secrecy.

5. In general, the Exhibits I reviewed contain four categories of highly sensitive and confidential information that is considered trade secrets by Roche. The categories are: (1) the data generated by the studies and Roche's proprietary analysis of that data, (2) the methodology and design of Roche's preclinical studies, (3) information regarding Roche's preclinical strategy, and (4) Roche's early development efforts and feasibility analyses of the various drug candidates.

6. Roche would be harmed if the data from its preclinical studies, and Roche's analysis of that data, were publicly disclosed at the level of detail contained within the Exhibits. The results of Roche's preclinical studies, and Roche's analysis of those results, reveal critical information regarding MIRCERA®, including specific information regarding its effectiveness, potency, and biological activity. Competitors,

including generic drug manufacturers in jurisdictions without adequate patent protection, could use this information in designing and qualifying competing products. Furthermore, Roche invests a great deal of resources during its rigorous preclinical testing regime to gather the necessary data, which are expenditures a competitor with direct access to Roche's data and analysis could forego. Thus, Roche would harmed in the highly competitive pharmaceutical industry were this information to be disclosed.

7. Roche would also be harmed by the disclosure of the methodology and results of the preclinical studies that it has conducted on MIRCERA®. In addition to the expense of conducting the experiments, Roche expends significant resources designing the specific parameters of its proprietary preclinical studies to maximize the efficiency of the study and the reliability of the results. The public disclosure of the information contained in the Exhibits would thus unfairly benefit Roche's competitors, such as generic drug manufactures, who could use it to copy Roche's proprietary studies, thereby avoiding the expense Roche has incurred in developing its own preclinical protocols.

8. Similarly, the disclosure of Roche's overall plans and strategy for its preclinical development would cause great harm to Roche. Roche expends substantial resources planning and developing its preclinical testing regimen for new products to maximize the speed and efficiency of its preclinical program. The public disclosure of Roche's preclinical strategy would thus unfairly benefit Roche's competitors, such as generic drug manufactures, who could use Roche's efforts to enhance the efficiency of their own programs, or entirely avoid the expense Roche has incurred by merely copying Roche's plans.

9. Furthermore, the public disclosure of Roche's feasibility analysis and early development of drug candidates would be greatly harmful to Roche. Roche keeps information relating to the selection and early development of potential drug candidates in the utmost secrecy and confidence because potential competitors could use Roche's early development efforts to speed their own development process. Competitors with access to Roche's information could avoid conducting expensive development studies of their own by excluding candidates based on Roche's internally generated data. Also, they could use Roche's data to select a product from the viable candidates that Roche considered but passed up in favor of more promising prospects. Thus, the public disclosure of Roche's internal feasibility and early development analysis would cause severe harm to Roche in the highly competitive pharmaceutical industry.

10. I have done a detailed review the Exhibits, and in the paragraphs below I have set forth a description of the highly sensitive information that is confidential and trade secret to Roche.

11. Exhibit 14 is an excerpt from Roche's highly confidential BLA entitled *Characterization of* In Vivo *Erythropoietic Activity in Mice Injected with Pegylated Human Epoetin-Beta: Pharmacodynamics of PEG-EPO in a Normal Mouse Model.* This is a report of a preclinical study conducted by Roche to examine the biological activity of MIRCERA®. Exhibit 14 contains sensitive information relating to the specific methodology and design of the study, as well as specific data regarding MIRCERA's biological activity and Roche's internal analysis of that data. The information contained in this document is considered trade secret by Roche and has never been disclosed at this

level of detail to the public. Were it to be made public, Roche would be harmed for the reasons set forth above in Paragraphs 6 and 7.

12. Exhibit 15 is a excerpt from Roche's highly confidential BLA entitled *Characterization of* In Vivo *Erythropoietic Activity in Mice Injected with Pegylated Human Epoetin-Beta: Multiple Dosing with PEG-EPO in a Normal Mouse Model.* This excerpt reports on a preclinical study conducted by Roche to examine the biological activity of MIRCERA®. This document contains sensitive information relating to the methodology and design of the study, as well as data regarding the biological activity of MIRCERA® and Roche's analysis of that data. The information contained in this document is considered trade secret by Roche and has never been disclosed at this level of detail. Were it to be made public, Roche would be harmed for the reasons set forth above in Paragraphs 6 and 7.

13. Exhibit 16 is a excerpt from Roche's highly confidential BLA entitled *Pharmacokinetic Studies in Rat and Dog After Single Intravenous or Subcutaneous Administration of PEG-EPO*. This exhibit is a complete report of a preclinical study conducted by Roche to examine how the body absorbs MIRCERA®. Exhibit 16 contains sensitive information relating to the specific methodology and design of the study, as well as specific data regarding the rate of absorption of MIRCERA® and Roche's internal analysis of that data. The information contained in this document is considered trade secret by Roche and has never been disclosed at this level of detail to the public. Were it to be made public, Roche would be harmed for the reasons set forth above in Paragraphs 6 and 7.

14. Exhibit 18 is a excerpt from Roche's highly confidential BLA entitled *Ro 50-3821/000: A 13-Week Subcutaneous Injection Toxicity Study with a 4-Week Interim Sacrifice and a 8-Week Recovery Phase in Dogs.* This is an excerpt of a report of a preclinical study conducted by Roche to examine the toxicity of MIRCERA®, which contains sensitive information relating to the methodology and design of the study, as well as Roche's internal analysis of specific data generated by the study. The information contained in this document is considered trade secret by Roche and has never been disclosed at this level of detail to the public. Were it to be made public, Roche would be harmed for the reasons set forth above in Paragraphs 6 and 7.

15. Exhibit 19 is a excerpt from Roche's highly confidential BLA entitled *Ro 50-3821/000 (PEG-EPO): A Single-Dose Acute Intravenous Toxicity Study in Mice).* This is an excerpt of a report on a preclinical study conducted by Roche to examine the toxicity of MIRCERA®, which contains sensitive information relating to the specific methodology and design of the study and Roche's internal analysis of that data. The information contained in this document is considered trade secret by Roche and has never been disclosed at this level of detail to the public. Were it to be made public, Roche would be harmed for the reasons set forth above in Paragraphs 6 and 7.

16. Exhibit 24 is an excerpt from Roche's highly confidential IND entitled *Regulatory Document No. 1005851*, which discusses feasibility studies Roche conducted on various candidate drug substances. This document contains trade secret information relating to the parameters that Roche internally selected in its evaluation of the different drug candidates, as well as Roche's goals for the drug development. The information contained in this document is considered trade secret by Roche and has never been

disclosed at this level of detail to the public. Were it to be made public, Roche would be harmed for the reasons set forth above in Paragraph 9.

17. Exhibit 35 is a document entitled *Preface and Risk Assessment,* which discusses a feasibility study Roche conducted regarding pegylation and various candidate PEG reagents. This document contains sensitive information summarizing the study's results and Roche's confidential analysis thereof. The information contained in this document is considered trade secret by Roche and has never been disclosed at this level of detail to the public. Were it to be made public, Roche would be harmed for the reasons set forth above in Paragraphs 6 and 9.

18. Exhibit 36 is a German-language document entitled *Cangene – Pegyliertes EPO*. This internal letter contains Roche's analysis of different competitors' attempts to create pegylated variants of EPO, and Roche's strategy for responding to the competitive threat, including a discussion of a feasibility study and potential goals of planned programs to generate own molecules including strategies to generate improved formulations. The information contained in this document is considered trade secret by Roche and has never been disclosed to the public. Were it to be made public, Roche's could use it to gain unfair insight into Roche's competitive strategies and the early development of its products.

19. Exhibit 37 is a document I prepared in connection with a confidential presentation I gave to Roche employees attending the IEEM Conference in Glasgow on June 14, 2006. Although some slides from this presentation were subsequently incorporated into a public presentation, pages 7, 10, 12, 13, 27–30, 34, 35 have never been disclosed publicly in this form and thus remain confidential to Roche. These

confidential pages contain highly sensitive information relating to the structure and biological activity of MIRCERA®, including data drawn from Roche's internal preclinical studies regarding the biological activity of the drug. Roche would be harmed by the public release of the trade secret portions of this presentation for the reasons detailed in Paragraph 6 above.

20. Exhibit 38 is a confidential internal correspondence between my colleague Dr. Buch and me, which contains trade secret information regarding Roche's analysis of trace impurities in the active ingredient for MIRCERA®. The information contained in this document is considered trade secret by Roche and has never been disclosed to the public. Were it to be made public, Roche would be harmed for the reasons set forth above in Paragraph 6.

21. Exhibit 42 is an email correspondence dated December 5, 2000 from Wilhelm Tischer to my immediate superior Anton Haselbeck and others regarding the early development of MIRCERA®. This document contains sensitive, trade secret information regarding Roche's evaluation of different PEG reagents. To the best of my knowledge, the information contained in this document is considered trade secret by Roche and has never been disclosed to the public. Were it to be made public, Roche would be harmed for the reasons set forth above in Paragraph 9.

22. Exhibit 43 is a document entitled *Long-Lasting Forms of Polyethyleneglycol conjugated Erythropoietin (PEG-EPO).* This document is the highly confidential report of Roche's early feasibility study into different PEG reagents, including detailed descriptions of the experiments and the data collected. Exhibit 43 also contains Roche's internal analysis of the raw data and recommendations for further

development. The information contained in this document is considered trade secret by Roche and has never been disclosed to the public at this level of detail. Were it to be made public, Roche would be harmed for the reasons set forth above in Paragraphs 6, 7, and 9.

23. Exhibit 44 is a document entitled *CERA Preclinical Core Data*, which is a draft table of sensitive data regarding the biological activity and dosage for MIRCERA®. Because this is a preliminary draft, the information contained therein is incomplete and may be inaccurate, and thus is strictly retained as confidential and internal to Roche. It is Roche company policy is not disclose non-final unapproved data to avoid the risk of public confusion that may be caused if the non-final data is different from the finalized, FDA approved data.

24. Exhibit 50, entitled *An Investigation into the Signaling Pathways Activated by Continuous Erythropoiesis Receptor Activator (CERA)*, is a confidential interim report for a study conducted on behalf of Roche by Dr. Dwayne Barber of the Ontario Cancer Institute. Dr. Barber conducted this experiment while under a research agreement with Roche, which contains provisions to insure the confidentiality of any trade secret information shared with or generated by Dr. Barber. The study detailed in this document was designed to examine and explore chemically how MIRCERA® works, and his report contains sensitive information relating to the specific methodology and design of the study. The information contained in this document is considered trade secret by Roche and has never been disclosed at this level of detail to the public. Were it to be made public, Roche would be harmed for the reasons set forth above in Paragraphs 6 and 7.

25. Exhibit 52 is a confidential progress report to the study of Dr. Barber in Exhibit 50 above, that contains preliminary results and conclusions regarding the signaling pathway for MIRCERA®, including specific data from tests Dr. Barber conducted. As stated above, Dr. Barber's experiment was conducted under a confidentiality agreement and has never been disclosed at this level of detail to the public. Were it to be made public, Roche would be harmed for the reasons set forth above in Paragraphs 6 and 7.

26. Exhibit 65 is an excerpt from the transcript of the deposition of Anton Haselbeck, which was taken in connection with this litigation on March 1, 2007. This document contains confidential trade secret information relating to the results of preclinical studies conducted by Roche. For example, pages 127–130 contain discussions of two preclinical studies (including Dr. Barber's study which is discussed in more detail in Paragraphs 24 and 25 above), which have not been released to the public and are considered trade secrets by Roche. The public release of the information would harm Roche for the reasons given in Paragraphs 6 and 7 above. In addition, I note that Pages 237–239 contains confidential and proprietary information that belongs to one of Roche's licensors who is not a party to this case. Roche has agreed to keep this information confidential, and thus it, and its licensor, would be harmed by the public disclosure of this information.

27. Exhibit 67 is an excerpt from the transcript of my deposition in the present litigation, which was taken on March 27, 2007. This excerpt contains trade secret information that remains confidential to Roche regarding the structure of MIRCERA®. For example, pages 47–50 contain detailed discussions of the amino acid sequence and

glycosylation of MIRCERA®, including quotations from Roche's highly confidential BLA, which have never been publicly disclosed at this level of detail.

28. Roche deems it necessary to maintain the confidentiality of the information contained in the Exhibits in order to safeguard its trade secrets and competitive business information and to avoid giving a advantage to competitors or other who might use the information to the detriment of Roche's business.

29. Disclosure of the Exhibits in the public record would destroy the trade secret status of the information contained therein and irreparably harm Roche in the highly competitive pharmaceutical industry. Accordingly, it is of critical importance that the Exhibits, which contain Roche's highly confidential trade secret information, not be disclosed.

30. Signed under the pains and penalties of perjury this 28th day of June, 2007.

/s/ Dr. Michael Jarsch
Dr. Michael Jarsch

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 June 28, 2007.

/s/ Keith E. Toms
Keith E. Toms

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