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

I, Susan Batcha, hereby declare under penalty of perjury that:

1. I am the Program Director for Chemistry, Manufacturing, and Controls for Hoffmann-La Roche Inc. ("Roche"). I have been an employee of Roche since February 26, 2001. My educational background includes a BS in Medical Technology from Kent State University.

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 3-6, 7-11, 25, 34, 45, 51, 53-56, 63, 66, 68 ("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. In General, the Exhibits all include highly sensitive, confidential trade secret information belonging to Roche, including excerpts from Roche's highly confidential BLA and 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).

5. A majority of the Exhibits I have been asked to review are taken from, or incorporate information from, the *Chemistry, Manufacturing, and Controls* ("CMC") section of Roche's highly confidential BLA for MIRCERA®, which contains specific detail information regarding the proprietary chemical composition and the manufacturing process for MIRCERA®. To obtain FDA approval, the FDA requires that the CMC section describe in exacting detail the step-by-step "recipe" for MIRCERA®, including the steps taken to insure the quality of the finished product, as well as a complete list of the specifications for each component of the process. Thus, the CMC section is required to contain Roche's most closely guarded trade secrets, such as the precise formula and process for creating MIRCERA®, as well as detailed descriptions regarding such things as purification process, process controls, and data regarding the potency, quality, purity, and bioavailability of the drug substance. Indeed, this is one of the principal reasons why the confidentiality of the BLA is insured by law. This highly sensitive, confidential information is the culmination of years of effort in the drug development process. It is the core of Roche's development efforts for MIRCERA®.

6. Roche would be irreparably harmed if the Exhibits were made public because they contain everything Roche's competitors — such as generic manufacturers in jurisdictions without adequate patent protection — require to produce a product identical to MIRCERA®. In the CMC, Roche is effectively required to teach the FDA how to make MIRCERA®, including specific information regarding its chemical structure and biological activity, such as its potency and purity. This, in turn, would teach generic drug manufactures and other competitors everything they need to know to copy MIRCERA®. Public disclosure of this information 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 MIRCERA®.

7. In addition, Roche would also be harmed if the information contained in the Exhibits relating to its proprietary manufacturing process were made public. Roche commits significant resources in optimizing its manufacturing process by experimenting with different ratios and formulations of the reagents used in the various stages of manufacturing, such as fermentation, amplification, and purification. These optimized processes give Roche a significant competitive advantage by increasing the yield and potency of its product. Its disclosure, however, would allow Roche's competitors to use the fruits of Roche's labor to optimize their own manufacturing processes, thereby destroying Roche's competitive advantage.

8. Furthermore, Roche would also be harmed by the disclosure of the methodology and results of its quality control testing that for MIRCERA®. Roche expends significant resources designing the specific parameters of its proprietary assays

and in thoroughly testing its product at various stages of the manufacturing process. Further, the data generated by these tests reveals sensitive information about the potency, purity, and biological activity of Roche's product. If information contained in the Exhibits is made public, however, generic drug manufactures and other competitors can avoid this expense by using the tests that Roche developed, thereby improving their competitive position against Roche.

9. 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.

10. Exhibit 3 is an excerpt from Roche's highly confidential BLA entitled *Application Summary for MIRCERA*, which contains a summary of the CMC section of the BLA, including specific information relating to the biological activity and stability of the drug, as well as Roche's proprietary process for the purification of MIRCERA®. This document also contains summaries of the clinical section, including Roche's conclusions about recommended dosage and overall safety. This information is considered confidential and trade secret to Roche, and its public disclosure would harm Roche for the reasons given in Paragraphs 6 and 8.

11. Exhibit 4 is an excerpt from the CMC section of Roche's highly confidential BLA entitled *Structure of RO0503821*, which contains confidential trade secret information regarding the physicochemical and biological properties of MIRCERA®, and the tests Roche conducted to determine these properties. This information hasn't been made public at this level of detail, and its disclosure would harm Roche for the reasons given in Paragraph 8 above.

12. Exhibit 5 is an excerpt from Roche's highly confidential BLA entitled *Description of Manufacturing Process and Process Controls.* This approximately 200 page document is, in effect, the step-by-step "recipe" for MIRCERA®, and contains highly detailed technical information regarding the full scope of the manufacturing process. For example, this document contains such highly sensitive information such as the precise ratio of the various reagents introduced during the manufacturing process, detailed descriptions of the manufacturing techniques used, and the precise method of harvesting and purifying MIRCERA®. In addition, this document contains detailed and highly sensitive information regarding Roche's control and testing methods that it uses to insure that the finished product meets specifications. This information has not been disclosed to the public in any form, and its disclosure would severely harm Roche for the reasons detailed in Paragraphs 6, 7, and 8 above.

13. In addition, Exhibit 5 contains the highly confidential trade secrets of a third party. I understand that Roche has an confidentiality agreement in place through which Roche was allowed to submit third party trade secret information regarding the PEG reagent to the FDA. Thus, this document must be kept from the public record in order to safeguard the third-party's trade secrets contained within.

14. Exhibit 6 is an excerpt from the CMC section of Roche's highly confidential BLA entitled *Elucidation of Structure*. This document contains sensitive trade secret information relating to the biological activity of various formulations and dosages of MIRCERA®. Specifically, it includes the methodology and results of tests Roche conducted regarding the "dose-response relationship," which measures the biological activity of different formulations and doses of the drug. This information has

not been disclosed to the public in any form, and its disclosure would severely harm Roche for the reasons given in Paragraph 8 above.

15. Exhibit 7 is a true and correct copy of an excerpt of Roche's BLA describing the biological properties of Epoetin Beta. This excerpt contains information as to the specific methods used by Roche in assessing the bioactivity of Epoetin Beta reagent, which has not been disclosed at this level of detail. This information, should it become public, would cause harm to Roche for the reasons given in Paragraph 8 above.

16. Exhibit 8 in an excerpt from Roche's highly confidential BLA entitled *Summary of the Fermentation and Harvest Process*, which contains highly detailed technical information regarding the manufacture of the Epoetin Beta starting material. For example, it gives specific information regarding the proprietary chemical formulation of the medium in which the Epoetin Beta-producing cells are cultured. This document also contains sensitive information regarding Roche's proprietary method for purifying the harvested Epoetin Beta. Roche has spent a great deal of time and resources optimizing and perfecting the precise chemical formulations contained in this document. Were this information to be publicly disclosed to generic drug manufactures and other competitors, Roche would be harmed for the reasons detailed above in Paragraphs 6 and 7.

17. Exhibit 9 is an excerpt from Roche's highly confidential BLA entitled *Control of Materials: Raw Materials Use for the Epoetin Beta Fermentation*. This documents contains a highly detailed description of the selection and modification of the cloned cells that make Epoetin Beta. In particular, it contains a complete nucleotide sequence for the Epoetin Beta-producing DNA, and the proprietary methods and vectors

by which that DNA sequence is introduced into the host cell. It also contains highly confidential information regarding Roche's method of amplification of the cloned cells. This information in this document is kept in the utmost secrecy because, in effect, it contains all the necessary information for Roche's competitors or generic drug manufactures to create an Epoetin Beta-producing cell line that is identical to Roche's proprietary cell line. Consequently, the public disclosure of this document would harm Roche for the reasons detailed in Paragraphs 6 and 7 above.

18. Exhibit 10 is an excerpt from the CMC section of Roche's highly confidential BLA entitled *Manufacturing Process Development: Developmental History*, which details the process by which Roche developed its proprietary formulations of the medium in which the Epoetin Beta-producing cells are grown. This document contains sensitive information regarding the Roche's cell line, the steps Roche took to improve its cell line, and the processes by which those improvements were made. This information has not previously been disclosed at this level of detail, and its disclosure would harm Roche for the reasons detailed in Paragraph 7 above.

19. Exhibit 11 is an excerpt from the CMC section of Roche's highly confidential BLA entitled *Elucidation of Structure*, which contains highly confidential trade secret information relating to Roche's analysis of the chemical structure of MIRCERA®. This document contains the methodology and results of tests that Roche conducted on two batches of MIRCERA®. This information has not been disclosed to the public in any form, and its disclosure would severely harm Roche for the reasons given in Paragraph 8 above.

20. Exhibit 25 is an excerpt from the CMC section of Roche's highly confidential IND entitled *Chemistry and Formulation*. This document contains sensitive information about Roche's proprietary processes for synthesizing and purifying MIRCERA®, which is considered highly confidential by Roche and is never made public. The disclosure of this information would harm Roche for the reasons given in Paragraphs 6 and 7 above. This exhibit also contains specific information regarding the formulation and stability of MIRCERA®, which, pursuant to company policy, is not disclosed prior to FDA approval. It is Roche company policy is not disclose non-final unapproved data, such as the stability information, to avoid the risk of public confusion if the non-final data is different from the finalized, FDA approved data.

21. Exhibit 34 is from the expert report of Harvey F. Lodish Ph.D., Regarding Infringement. I understand that this document was prepared by Dr. Lodish for this litigation using confidential information from Roche which he had access to pursuant to the protective order. This document contains sensitive trade secret information regarding the chemical structure an formulation of MIRCERA® that has never been disclosed to the public at this level of detail. If this proprietary information were made public, Roche's competitors could use in their efforts to replicate MIRCERA®, thus harming Roche for the reasons detailed above in Paragraph 6.

22. Exhibit 45 is an excerpt from Roche's highly confidential IND entitled *Description and Characterization of PEG-EPO Drug Substance.* This document contains specific information regarding the synthesis, yield, and purity of the manufacturing process for MIRCERA®, as well as Roche's confidential testing methodology and results relating to the chemical structure and synthesis of MIRCERA®.

To my knowledge, the information contained in this document has never been disclosed at this level of detail to the public, and its disclosure would severely harm Roche for the reasons given in Paragraphs 6 and 7 above.

23. Exhibit 51 is an excerpt from the deposition of Daniela Conte, which was taken on June 14, 2006 in connection with the parallel litigation between the parties before the ITC. This document contains confidential Roche information regarding the formulation of MIRCERA®. For example, page 33 contains information regarding potential impurities of MIRCERA®, which is information that is has never been disclosed to the public, and its disclose would harm Roche for the reasons stated above in paragraph 6 and 8.

24. Exhibit 53 is a copy of the Expert Report of Vladimir P. Torchilin, Ph.D., D.Sc., which I understand was prepared for this litigation and is dated April 6, 2007. This expert report contains confidential trade secret information regarding the structure and biological activity of MIRCERA®, which is largely taken from information contained in Roche highly confidential BLA and INDs and from Roche's confidential Investigator's Brochure (which I understand is discussed in detail in Paragraphs 21–29 of the declaration of my colleague, Krishnan Viswanidhan). In particular, pages 15–26, and 28–33 contain a detailed description of the formulation and chemical activity of MIRCERA®, as well as trade secret information regarding clinical and preclinical studies which were conducted by Roche. This information has not previously been disclosed at this level of detail, and its disclosure of which would harm Roche for the reasons detailed in Paragraphs 7, 8, and 9 above. In addition, pages 35–36 contain Roche trade secret information regarding Roche's PEG reagent, which has not previously been made public.

25. Exhibit 54 is an internal Roche document entitled *Certificate of Analysis 07140648*, which contains the results of an analysis Roche conducted to validate the potency and purity of a particular batch of MIRCERA®. This document contains confidential trade secret information relating to the biological activity MIRCERA® as well as the particular assays Roche uses to determine the potency of its product. If made public, generic drug manufacturers and other competitors could use this sensitive information to gain insight into the effectiveness of MIRCERA®, and to set the methods and standards by which they qualify their own competing products.

26. Exhibit 55 is an excerpt from the draft of a document that would eventually be incorporated into Roche's highly confidential IND entitled *Description and Characterization of RO 50-3821 Drug Substance*. This draft document deals with the same subject matter as Exhibit 45, but goes into additional detail regarding the specific tests, and the results of those tests, which Roche conducted to determine the structure of MIRCERA®. In addition, this document contains Roche's highly sensitive analysis of the sites of pegylation, and the results of various tests conducted in relation to these pegylation sites. The information contained in this document has never been disclosed in this level of detail, and its disclosure would severely harm Roche for the reasons detailed in Paragraph 6 above.

27. Exhibit 56 is an excerpt from a document entitled *PR-HPLC: Identity Test; Purity; RO 50-3821; Total Impuities; Assay: RO50-3821*, which documents the methodology and results of a test conducted by Roche to determine the purity of MIRCERA®. This document contains information relating to the purity of MIRCERA®, as well as a detailed description of Roche's assay used to conduct the test. The

information contained in this document has never been disclosed to the public, and its disclosure would severely harm Roche for the reasons detailed in Paragraph 8 above.

28. Exhibit 63 is an excerpt from a document entitled *Comparability Program for RO 50-3821 Drug Substance*, which includes information regarding Roche confidential and proprietary protocol for demonstrating the comparability of different batches of MIRCERA®. Under FDA guidelines, whenever an adjustment to the manufacturing process is made, a comprehensive study must be conducted to insure that the relevant properties of the new product is comparable to the old product. This document contains a detailed description of Roche's comparability protocol, which it has developed for the use of MIRCERA®, including specific data used to compare the results of the new product with the old product. The information contained in this document has never been disclosed to the public in any form, and its disclosure would severely harm Roche for the reasons given in Paragraph 7 and 8 above.

29. Exhibit 66 is an excerpt from the deposition transcript of Anne Stern, Ph.D., which was taken in connection with the present litigation on March 22, 2007. This document contains substantial and detailed information regarding the cell lines which Roche uses to produce MIRCERA. In particular, pages 19–53 contain confidential trade secret information regarding the composition of Roche's proprietary cell line, and Roche's the use of specific vectors and promoters. This Roche considers this sensitive internal information to be trade secret, and it would be harmed by the disclosure of this information for the reasons given in Paragraphs 6 and 7 above.

30. Exhibit 68 is a copy of Roche Responses and Objections to Plaintiff Amgen Inc.'s Fourth Set of Interrogatories (Nos. 27-38), which contain Roche's highly

confidential information relating to the manufacture of MIRCERA®. In particular, Roche's response to Interrogatory No. 34 contains trade secret information regarding Roche's manufacturing capacity. This information has never been disclosed and is considered a trade secret by Roche. Furthermore, Roche's competitors could use this information in crafting strategies that will harm Roche in the highly competitive pharmaceutical industry.

31. 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 competitive advantage to competitors to competitors or other who might use the information to the detriment of Roche's business.

32. 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 important that the Exhibits, which contain Roche's highly confidential trade secret information, not be disclosed.

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

/s/ Susan Batcha
Susan Batcha

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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