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 KRISHNAN VISWANADHAN IN SUPPORT OF ROCHE'S 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 AND ROCHE'S OPPOSITION TO AMGEN'S MOTION FOR SUMMARY JUDGMENT ON ROCHE'S ANTITRUST AND STATE LAW COUNTERCLAIMS

I, Krishnan Viswanadhan, declare as follows:

1. I am the Associate Director of Drug Regulatory Affairs at Hoffmann-La Roche Inc. ("Roche"). I have been an employee of Roche since 2002. My educational background includes a B.S. in pharmacy from Rutgers University, and a Pharm.D. from Rutgers University. My duties include acting as a contact with the Food and Drug Administration (the "FDA") regarding the review of Roche's Biologics License Application ("BLA") for and the Investigational New Drug Applications ("IND") in Renal Anemia.

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 1, 2, 7, 20-23, 28, 41, 53, 59, 61, and 62 ("the Exhibits") to 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, and 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 based upon my work at Roche.

4. I have also been asked to examine documents which correspond to Exhibits 6, 7, 166, and 223 ("the Roche Exhibits") to Roche's Opposition to Amgen's Motion for Summary Judgment on Roche's Antitrust and State Law Counterclaims.

5. The Exhibits and Roche Exhibits contain highly sensitive, confidential trade secret information belonging to Roche, including information from confidential internal Roche documents regarding both the preclinical and clinical testing for Roche's MIRCERA®, and highly confidential Roche communications with the FDA. This includes documents that have been submitted to the FDA as part of 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 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). Furthermore, pursuant to Roche company policy, all the Exhibits, the information contained in the Exhibits, and any communications involving the Exhibits and their information are maintained in confidence and secrecy. 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.

6. In general, the Exhibits which I reviewed contain four categories of highly sensitive and confidential information that are considered trade secrets by Roche. The categories are: (1) the data generated by preclinical and clinical studies and Roche's proprietary analysis of

that data, (2) the methodology and design of Roche's preclinical and clinical studies, (3) detailed technical information drawn from the Chemistry, Manufacturing, and Controls ("CMC") section fo the BLA, and (4) confidential communications with the FDA, including those regarding non-final, unapproved documentation for MIRCERA®.

7. Roche would be harmed if the data from its preclinical and clinical 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 and clinical studies, and Roche's analysis of those results, reveal critical information regarding MIRCERA®, including specific information regarding its effectiveness, potency, biological activity, and toxicity. 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 and clinical testing regimes to gather the necessary data, which are expenditures a competitor could forego if they have direct access to Roche's data and analysis. Thus, Roche could be harmed in the highly competitive pharmaceutical market were this information to be disclosed.

8. Roche could also be harmed by the disclosure of the methodology and results of the preclinical and clinical studies that it has conducted on MIRCERA®. In addition to the expense of conducting the experiments, Roche expends significant resources designing the specific parameters its proprietary preclinical and clinical studies to maximize the efficiency of the studies and the reliability of the results. Roche also expends significant resources in designing its overall clinical and preclinical regimens to maximize the efficiency and speed of its drug development process. 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 and clinical protocols.

9. Many of the Exhibits also contain detailed summaries of information drawn from the CMC section of the BLA. As my colleague Susan Batcha explains in greater detail in Paragraphs 5-9 of her declaration, the CMC section contains critical and highly sensitive information regarding the formulation and manufacture of MIRCERA®. The public disclosure of such this information would help Roche's competitors, including generic drug manufacturers in jurisdictions without adequate patent protection, duplicate MIRCERA® and replicate Roche's proprietary manufacturing methods.

10. In addition, many of the Exhibits and the Roche Exhibits contain Roche's confidential communications with the FDA regarding non-final, unapproved documentation for MIRCERA®. It is Roche's company policy to keep this non-final, unapproved documentation strictly confidential due to the possible risks of public confusion if the non-final documentation differs from the finalized, FDA approved documentation.

EXHIBITS TO AMGEN'S MOTION FOR SUMMARY JUDGMENT OF INFRINGEMENT OF '422 CLAIM 1, '933 CLAIM 3, AND '698 CLAIM 4

11. In the paragraphs below I set forth a detailed description of the information contained in the Exhibits and the reasons the Exhibits should not be disclosed publicly.

12. Exhibit 1 is a copy of the April 18, 2006 cover letter from Roche to the FDA submitting Roche's BLA. This document contains a descriptions of Roche's clinical trials, including the number of patients studied, as well as a description of the preclinical studies conducted by Roche. This information has not been released by Roche to the general public, and Roche specifically noted the confidentiality of this information on the last page of the letter. The

release of this information to Roche's competitors, such as generic drug companies, would harm Roche for the reasons given in Paragraph 8, and would further advantage competitors by providing a roadmap as to Roche's preclinical and clinical protocols, thereby potentially accelerating a competitors' approval for a similar drug.

13. Exhibit 1 also contains sensitive information concerning the details taken from the CMC section of Roche's highly confidential BLA. This information is maintained in confidence and secrecy by Roche. Such details, if they were made public, would give competitors to Roche an advantage by revealing Roche's approach to the formulation of MIRCERA®.

14. Exhibit 2 is a copy of the proposed package insert for MIRCERA® that was submitted to the FDA as part of Roche's BLA for MIRCERA®. This document, which has not yet been approved by the FDA or disclosed to the public, contains a summary of important information as to efficacy and potential adverse effects of MIRCERA®. It is Roche's company policy to keep this non-final, unapproved documentation strictly confidential due to the possible risks of public confusion if the non-final documentation differs from the finalized, FDA approved documentation.

15. Exhibit 3 is an excerpt from Roche's highly confidential BLA entitled *Application Summary for MIRCERA.* It contains a draft of the package insert for, MIRCERA® which has not been approved by the FDA or disclosed to the public. It is Roche's company policy to keep this non-final, unapproved documentation strictly confidential due to the possible risks of public confusion if the non-final documentation differs from the finalized, FDA approved documentation.

16. Exhibit 20 is an excerpt from Roche's BLA detailing clinical study Nos. BP16198 and BP16239. This excerpt reveals results from two healthy volunteer studies of MIRCERA®. Specifically, it states results for tolerance of MIRCERA® at different dosage levels, and the dosage dependence of erythropoietic effects observed with administration of MIRCERA®. The excerpt also contains specific details on the effects observed after multiple dosages of MIRCERA®. This information has not been publicly disclosed in this level of detail by Roche, and is maintained in confidence and secrecy by Roche. As is detailed in Paragraphs 7 and 8, if this information became public, it could confer an advantage to competitors of Roche, such as generic manufacturers, by providing specific information as to Roche's study design and the specific biological activity of MIRCERA®.

17. Exhibit 21 is an excerpt from the Clinical Overview of Roche's clinical studies it submitted with its BLA. Exhibit 21 contains Roche's safety and benefit/risk conclusions of MIRCERA® as compared to EPO, which is maintained in confidence and secrecy by Roche company policy and FDA policy, and also contains an overview of the information arising from its clinical studies. This information has not previously been disclosed by Roche at the level of detail, and it is Roche's company policy to keep this non-final, unapproved conclusions and analysis strictly confidential due to the possible risks of public confusion if the non-final conclusions differs from the finalized, FDA approved documentation.

18. Exhibit 22 is an excerpt from Roche's clinical study report from BA16736, submitted to the FDA with Roche's BLA for MIRCERA® and which details clinical information as to one patient in this study. This information is maintained in confidence and secrecy by Roche company policy. Because this document contains data regarding an individual patient, its

public disclosure would be inconsistent with Roche's obligations under federal and state privacy laws.

19. Exhibit 23 is a true and correct copy of an excerpt from Roche's highly confidential IND for the use of MIRCERA® in treating anemia in cancer patients receiving anti-neoplastic therapy in subcutaneous administration. This excerpt contains an overview of the scope of the toxicology program undertaken by Roche prior to submitting the IND, with details as to the methodology of each, such as the testing for local tolerability at the injection site. The document also reveals Roche's analysis of this toxicity data in compared with data for epoetin beta. The specific toxicity testing methodology for MIRCERA® is maintained in confidence and secrecy by Roche. If Exhibit 23 were made public, it would confer a competitive advantage on Roche's competitors for the reasons detailed in paragraphs 7 and 8 above.

20. Exhibit 28 is an excerpt of Roche's overview of preclinical testing strategy for MIRCERA® that it submitted with the BLA. This excerpt contains detailed information concerning the strategy for Roche's preclinical development phase for MIRCERA®. These include descriptions of Roche's pharmacological activity studies, dose-effect relationship studies, pharmacokinetic studies, and toxicological studies. This excerpt includes descriptions of the methodology of these studies, including information as to the testing subjects, the frequency of dosing, and the hematological parameters studied. To my knowledge, Roche has not disclosed this information publicly at this level of detail and would be harmed by such a disclosure for the reasons given in Paragraphs 8 above in that it would provide a roadmap on Roche's proprietary preclinical testing strategy.

21. Exhibit 41 is a copy of the second version of Roche's Investigator's Brochure for MIRCERA® product, issued in July 2000, which is prepared to give Roche's clinical investigators a detailed overview of the characteristics of MIRCERA® and of the preclinical and clinical studies already complete. This document is only shared with clinical investigators for MIRCERA® under the express condition that it is to be maintained in strict confidence and secrecy. Indeed, the confidentiality of this document is manifested in a legend on the first page, which requires that those persons having access to this document will not disclose the information to others.

22. Exhibit 41 contains highly confidential trade secret information regarding the methodology and results of the preclinical studies that Roche carried out on, MIRCERA® including pharmacodynamic studies, pharmacokinetic studies, and toxicological studies on animals as of May 2000. These include detailed description and analysis of studies comparing the pharmacodynamic, pharmacokinetic, and toxicity properties of MIRCERA® with EPO. For each study, this document details the target animal population, the dosage and schedule, and the pharmacokinetic (such as clearance or half-life), pharmacodynamic (such as stimulation of reticulocytes), or toxicity (such as urinalysis) parameters measured in evaluating the study. The study contains conclusions outlining the comparative advantages and disadvantages that MIRCERA® has with respect to EPO in these areas. This document also contains information regarding the dosages and formulations of MIRCERA® that were to be used during the clinical studies. Roche has not made either the methodology or results of these studies available to the public at this level of detail – and would not disclose this information to its investigators absent an express promise of secrecy – because disclosure of this information to Roche's competitors

would harm Roche for the reasons detailed in Paragraphs 7 and 8 above. Competitors could use these trade secrets of Roche in guiding the development of competing drugs, especially since these documents reveal detailed data regarding the properties of MIRCERA®.

23. Exhibit 41 also contains trade secret information drawn from Roche's highly confidential CMC section of the BLA relating to Roche's proprietary methods of synthesizing and purifying MIRCERA®, the public release of which would harm Roche for the reasons given in Paragraph 9 above.

24. Exhibit 41 also contains non-final information regarding the stability and potential side effects and warnings for MIRCERA® which has not yet been approved by the FDA. It is Roche's company policy to keep this non-final, unapproved documentation strictly confidential due to the possible risks of public confusion if the non-final documentation differs from the finalized, FDA approved documentation.

25. Exhibit 59 is a copy of the sixth version of Roche's Investigator's Brochure for MIRCERA®, issued in September 2003. Exhibit 59 is an updated version of Exhibit 41, which contains new information regarding the progress of Roche's clinical and preclinical testing program for MIRCERA®. Exhibit 59, like Exhibit 41, is only shared with clinical investigators for MIRCERA®under the express condition that it is to be maintained in strict confidence and secrecy. Indeed, the confidentiality of this document is manifested in a legend on the first page, which requires that those persons having access to this document will not disclose the information to others.

26. In addition, to the trade secret information contained in Exhibit 41, Exhibit 59 contains detailed information concerning Roche's clinical trials of MIRCERA®. This

information includes details of the methods and results of Phase I studies determining the pharmacokinetics and pharmacodynamics of MIRCERA® in humans. These document details the dosing schedules, the pool of volunteers, and the pharmacokinetic and pharmacodynamic property measured for Phase I studies, and Roche's detailed analysis and conclusions (such as tolerability and formation of antibodies) that are drawn from the Phase I studies that had been performed to that date. To my knowledge, Roche has not revealed the methodology or results of its Phase I studies publicly at this level of detail, and such a disclosure would harm Roche for the reasons detailed in Paragraphs 7 and 8 above.

27. Exhibit 59 also contains detailed data concerning Phase II studies BA16260, BA16285, and BA16286, which were carried out by Roche in dialysis patients in order to determine safety and efficacy of MIRCERA®, as well as to develop useful dosing regimens. Exhibit 59 reveals the target populations of each study, the dosing regimens used, the parameters measured for each group, and the analysis of the data collected from each group. To my knowledge, Roche has not revealed the methodology or results of its Phase II studies publicly at this level of detail, and such a disclosure would harm Roche for the reasons detailed in Paragraphs 7 and 8 above.

28. If the information in Exhibit 59 were publicly disclosed, Roche would be harmed, because competitors, such as generic drug developers, could use this information regarding a Roche's confidential methodologies in testing MIRCERA® in order to speed their own competing drugs to FDA approval and thus could their own generic drugs to the market. Competitors could also be able to follow Roche's Phase I and Phase II studies to quickly narrow the dosing regimens of their own competing drugs targeting similar illnesses. As a consequence,

public disclosure of this material could destroy Roche's competitive advantages it has developed through its drug development programs.

29. Further, the appendices to Exhibit 59 contain detailed descriptions of the adverse events and frequency thereof occurring during the clinical trials to date. This information is never revealed to the public at this level of detail, and it is Roche policy not to reveal any non-final information regarding possible adverse effects until the information has been finalized and approved by the FDA, due to the risk of public confusion that the release of such non-final information may cause.

30. Exhibit 61 is a draft of the Core Data Sheet 1.0 for MIRCERA®, dated December 10, 2004. This document contains highly confidential information regarding Roche's internal assessment of the safety MIRCERA®, including overviews concerning clinical studies of MIRCERA®. For example, this document gives detailed reports of adverse events and reveals the target population and dosing regimens used in each study. If Roche's internal assessment of potential adverse effects were to be publicly disclosed, Roche could suffer harm to its MIRCERA® program. Further, disclosure of this documents prior to FDA approval would allow competitors to access Roche's trade secrets concerning the dosage levels, toxicity levels, and pharmacological activity of MIRCERA®, which they could use to harm Roche's entry into the marketplace.

31. Exhibit 62 is a draft of the Roche's Core Data Sheet for MIRCERA®, version 0.1, dated December 17, 2004. Exhibit 62 is a later draft of the document contained in Exhibit 61, and thus like Exhibit 61, If Roche's internal assessment of potential adverse effects were to be publicly disclosed, Roche could suffer harm to its MIRCERA® program. Further, disclosure of

this documents prior to FDA approval would allow competitors to access Roche's trade secrets concerning the dosage levels, toxicity levels, and pharmacological activity of MIRCERA®, which they could use to harm Roche's entry into the marketplace.

EXHIBITS TO ROCHE'S OPPOSITION TO AMGEN'S MOTION FOR SUMMARY JUDGMENT ON ROCHE'S ANTITRUST AND STATE LAW COUNTERCLAIMS

32. Roche Exhibit 6 is an excerpt from Roche's BLA disclosing detailed information from Roche's Application Summary for its highly confidential BLA, which contains detailed information regarding Roche's Phase II and Phase III clinical studies. This analysis reveals Roche's determinations of the efficacy for MIRCERA® as well as proper dosing regimens. This analysis and dosage information has not been revealed publicly, and is maintained in confidence and secrecy by Roche. This exhibit also reveals detailed information Roche's Phase III maintenance studies, including the population of the studies, the screening/baseline period, the dosing period, and the evaluation period. Also revealed is the method for determining efficacy, as well as detailed analysis of the efficacy and safety of MIRCERA® following these studies, including analysis of potential adverse effects. This information has not been revealed at this level of detail to the public, and Roche maintains this information in confidence and secrecy according to its company policy. Roche would be harmed if this document is revealed publicly, as it reveals Roche's strategy for Phase II and Phase III testing to any and all of its competitors, as well as reveals Roche's method for evaluating the safety and efficacy of its drugs. It is particularly important that Roche be able to protect this information while Roche awaits FDA approval for MIRCERA®.

33. Roche Exhibit 7, Expert Report of Professor Steven Fishbane, M.D. (from which un-cited material has been redacted), is an excerpt of a report that summarizes and comments on the results of Roche's clinical studies and data obtained therefrom. Specifically, paragraph 51 reveals the median time required to meet target hemoglobin levels with MIRCERA® as compared to ARANESP®. This information has not been revealed at this level of detail to the public, and Roche maintains this information in confidence and secrecy according to its company policy.

34. Roche Exhibit 166 is an excerpt of an internal Roche document summarizing communications from the FDA regarding Roche's clinical testing of MIRCERA® which is required for approval by that agency. This document reveals the requirements and standards the FDA will impose upon MIRCERA®. Roche has, consistent with company and FDA policies, not publicly disclosed its communications with the FDA, even in summary, because the public release of such information would be detrimental to Roche. If a competitor or interested third party were to become aware of Roche's dialogue with the FDA, it could intervene in a way so as to damage Roche.

35. Roche Exhibit 223 is an excerpt from the clinical study report of BA16738 from Roche's highly confidential IND and BLA. This excerpt reveals Roche's testing methodology and Roche's internal analysis of the study's results regarding the efficacy of MIRCERA®. This document is considered to be trade secret by Roche, and the information contained within has not been revealed at this level of detail. If this document were to be revealed, Roche would be harmed for the reasons set forth in Paragraphs 7 and 8 above.

36. Roche deems it necessary to maintain the confidentiality of such information, as detailed above, 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.

37. 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. Accordingly, it is of critical importance that the Exhibits and Roche Exhibits, which contain Roche's highly confidential, trade secret information, not be disclosed in the public record.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 28th day of June 2007 at New York, New York.

/s/ Krishnan Viswanadhan
Krishnan Viswanadhan

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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