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

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION FOR LEAVE TO FILE UNDER SEAL DOCUMENTS CONTAINING DEFENDANTS' TRADE SECRETS AND SUBMITTED IN CONNECTION WITH AMGEN INC.'S MOTION FOR SUMMARY JUDGMENT OF INFRINGEMENT OF '422 CLAIM 1, '933 CLAIM 3 AND '698 CLAIM 6

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively "Roche") submit this memorandum and accompanying declarations in support of their motion, pursuant to Local Rule 7.2 and the protective order, to file under seal documents which contain Roche's confidential and trade secret materials submitted for *in camera* review by Amgen Inc. ("Amgen") if the Court deems them necessary for its ruling on Amgen Inc.'s Motion for Summary Judgment of Infringement of '422 Claim 1, '933 Claim 3, and '698 Claim 6 (Docket No. 509).[1]

As set forth in greater detail below and in the accompanying declarations of Dr. Michael Jarsch ("Jarsch Decl."), Dr. Krishnan Viswanidhan ("Viswanidhan Decl."), and Susan Batcha

[1] The documents Amgen seeks to file in the public record were submitted for *in camera* review on June 15, 2007 and correspond to Exhibits of the Declaration of Katie J.L. Scott in Support of Amgen Inc.'s Motion for Summary Judgment of Infringement of '422 Claim 1, '933 Claim 3, and '698 Claim 6 (Docket No. 514), and the confidential versions of Amgen's memorandum of law (Docket No. 510), Statement of Facts Pursuant to Local Rule 56.1, (Docket No. 512), and Declaration of Harvey Lodish (Docket No. 513).

("Batcha Decl."), Roche's exhibits 1-11, 14-16, 18-25, 28, 34-38, 41-45, 50-56, 59, 61-63, 65-68 ("the Exhibits"), which were submitted by Amgen for *in camera* review, contain sensitive and highly confidential trade secret information, the public disclosure of which would irreparably harm Roche's position in the highly competitive pharmaceutical industry.[2] Thus, Roche requests that the Exhibits — and the trade secret information from the Exhibits contained in Amgen's accompanying memorandum of law, statement of fact, and declaration of Harvey Lodish — be filed under seal if the Court determines that they are necessary for its determination of the underlying motion.

While Roche maintains all of the documents submitted for *in camera* review are confidential, in light of the Court's requirement that only trade secrets be filed under seal, it has limited the present motion to the Exhibits listed above. To the extent that the Court finds any exhibit (or portion of an exhibit) to be unnecessary in its determination of the underlying motion, Roche respectfully requests that it not be filed at all, whether in the public record or under seal.

INTRODUCTION

As testified to by Dr. Jarsch, Dr. Viswanidhan, and Ms. Batcha, the Exhibits that Roche is requesting to have filed under seal contain invaluable trade secrets regarding (1) Roche's proprietary manufacturing method, formulation, and technical characteristics for Mircera®, (2) Roche's proprietary methodology and results of its clinical and preclinical studies, (3) Roche's early development and feasibility studies, and (4) non-final, non-approved data and FDA submissions, (5) confidential patient or third party information. Each of the Exhibits at issue contains extremely confidential, proprietary information, the continued secrecy of which is critical to the maintenance of Roche's hard won competitive advantage in the highly competitive

[2] In the accompanying declarations, Dr. Jarsch, Dr. Viswanidhan, and Ms. Batcha offer particularized testimony regarding the trade secret status of each Exhibit. Attached as Appendix A is an index of which declarants speak to which Exhibits.

pharmaceutical industry. For this reason, Roche considers the Exhibits to be its trade secrets and has consistently and vigilantly guarded their secrecy.

I. The Documents At Issue Are Trade Secrets Under Massachusetts Law

Under Massachusetts law, a trade secret is defined as "anything tangible or intangible or electronically kept or stored, which constitutes, represents, evidences, or records a secret scientific, technical, merchandising, production, management information, design, process, procedure, formula, invention or improvement." M.G.L. ch. 266 § 30(4);[3] *see Trent Partners and Associates, Inc. v. Digital Equipment Corp.*, 120 F. Supp. 2d 84 (D. Mass. 1999) (Woodlock, J.); *In re Gabapentin Patent Litigation*, 312 F. Supp. 2d 653, 659 and 667 (D.N.J. 2004) (affirming magistrate judge's holding that "the parties' products, research and development, processes secret chemical formulas, the parties' suppliers" constituted "clearly protectable and highly confidential trade secrets" in pharmaceutical patent case). As asserted by Dr. Jarsch, Dr. Viswanidhan, and Ms. Batcha, the Exhibits concern secret scientific information belonging to Roche which, if revealed, would cause irreparable harm to Roche. *See* Jarsch Decl. at ¶¶ 5, 29; Viswanidhan Decl. at ¶¶ 5, 37; Batcha Decl. at ¶¶ 4, 32.

II. The Trade Secret Information In The Exhibits Remains Confidential

Trade secret status requires that reasonable steps be taken to keep the information confidential. Here, Roche has never allowed the Exhibits or their contents to enter the public domain and has taken all possible measures to ensure that the information contained therein remains confidential. *See* Jarsch Decl. at ¶¶ 11-27; Viswanidhan Decl. at ¶¶ 12-31; Batcha Decl. at ¶¶ 10-68.

[3] M.G.L. ch. 93 § 42 incorporates by reference the definition of trade secrets found in M.G.L. ch. 266 § 30. Additionally, a similar definition is found at M.G.L. c. 93 § 2.

III. If The Trade Secret Information In The Exhibits Were Revealed Publicly, Roche Would Be Irreparably Harmed

A. Roche Would be Irreparably Harmed by the Disclosure of Its Trade Secrets Relating to the Manufacture and Formulation of Mircera Were Disclosed

Roche would be irreparably harmed by the public disclosure of confidential Exhibits 1, 3-11, 23, 25, 34, 41, 45, 50-53, 55, 56, 59, 63, 66, 67, and 68, which all relate to Roche's proprietary manufacturing methods, formulation, and technical characteristics for Mircera. The confidential exhibits listed above are excerpts from (or contain information from) Roche's *Chemistry, Manufacturing, and Controls* ("CMC") section of its highly confidential BLA and INDs for Mircera, which contains specific detail information regarding the proprietary chemical composition and the manufacturing process for Mircera. To obtain regulatory 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. *See* 21 C.F.R. 314.50(d) (the CMC sections is required "to contain data and information in sufficient detail to permit the agency to make a knowledgeable judgment about whether to approve the application . . . [including] A full description of the drug substance including its physical and chemical characteristics and stability . . . .") (emphasis added); Batcha Decl. ¶ 5.

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. This highly sensitive, confidential information is the culmination of years of effort in the drug development process, and is the core of Roche's development efforts for Mircera. Indeed, the required disclosure of such sensitive

information is one of the principal reasons why the confidentiality of the BLA is insured by law. *See* Batcha Decl. ¶ 5.

Roche would be irreparably harmed if these 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. *See* Batcha Decl. ¶ 6.

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 to 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. The disclosure of this information, 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. *See* Batcha Decl., ¶ 7.

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. *See* Batcha Decl., ¶ 8.

Given the severe and irreparable harm that would befall Roche if its trade secrets regarding its manufacturing process and product formulation and characteristics were revealed, any documents which contain such information should be filed under seal.

B. Roche Would be Irreparably Harmed If Its Highly Confidential Information Relating to its Preclinical and Clinical Studies Were Disclosed

Roche would be severely harmed if the trade secret information from Exhibits 1, 14-16, 18-23, 28, 37, 41, 44, 50, 52, 55, 59, 61, 62, and 65, which relates to its preclinical and clinical studies, 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 would be harmed in the highly competitive pharmaceutical market were this information to be disclosed. *See* Jarsch Decl. ¶ 6; Viswanidhan Decl. ¶ 7.

Roche would 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 of 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. *See* Jarsch Decl. ¶ 7; Viswanidhan Decl. ¶ 8.

Thus, because Roche would be harmed if its trade secrets regarding its preclinical and clinical programs were revealed, any documents which contain such information should be filed under seal.

C. Roche Would be Irreparably Harmed if its Confidential Information Regarding Its Early Development Efforts Were Made Public

Roche would be irreparably harmed if Exhibits 24, 35, 38, 42, 43, 54, and 65, which contain highly confidential trade secret information regarding Roche's feasibility and early development of Mircera, were disclosed to the public. 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 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 which 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. *See* Jarsch Decl. ¶ 9.

Because Roche would be harmed if the documents which contain its trade secrets regarding the early development of its products, any documents which contain such information should be filed under seal.

D. Roche and the Public Could be Harmed by the Public Release of Non-Final, Non-FDA Approved Information

In addition, many of the Exhibits, including 1, 2, 21, 41, 44, 59, 61, and 62, contain Roche's confidential communications with the FDA regarding non-final, unapproved documentation, data, and conclusions for Mircera. The purpose of FDA approval is to have an independent third party review of the accuracy and thoroughness of important pharmaceutical information such as safety, dosing, and effectiveness, before such information is released to the public. The widespread public release of non-final information that has not yet been approved by the FDA is counter to this purpose, and could have potentially harmful effects to the public and to Roche's reputation.

Thus, 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. *See* Viswanadhan Decl. ¶ 10. Consequently, Roche respectfully requests that the exhibits which contain such information be filed under seal if they are necessary for the Court's decision.

E. Roche, Its Patients, and Its Business Partners Would be Harmed by the Public Disclosure of The Exhibits

Finally, Roche, its patients, and its partners would be harmed by the public release of Exhibits 5, 22, and 65, which contain confidential patient and third party information. Roche has obligations under the federal and state privacy laws to insure the confidentiality of information relating to individual patients who participate in Roche's studies. In addition, Roche has certain business agreements in place which obligate Roche to keep confidential proprietary third party information that is contained in these exhibits. The disclosure of these exhibits would be inconsistent with Roche's obligations to its patients and partners, and thus, Roche respectfully requests that these exhibits be filed under seal.

CONCLUSION

For all the foregoing reasons, Roche respectfully requests that if the Court determines that some or all of the documents submitted to it for *in camera* review are necessary for its decision, then Roche requests that Exhibits 1-11, 14-16, 18-25, 28, 34-38, 41-45, 50-56, 59, 61-63, 65-68 be filed under seal to protect Roche's trade secrets.

DATED: Boston, Massachusetts
June 28, 2007

Respectfully submitted,

F. HOFFMANN-LA ROCHE LTD,
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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/ Keith E. Toms
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