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 TO FILE UNDER SEAL A DOCUMENT CONTAINING DEFENDANTS' CONFIDENTIAL AND TRADE SECRET MATERIALS

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively "Roche") submit this memorandum and accompanying declaration in support of their motion, pursuant to the Protective Order, to file under seal a document which contains Roche's confidential and trade secret materials and which Amgen seeks to file in the public record.[1]

Introduction

As set forth in greater detail below and in the accompanying declaration of Dr. Reinhard Franz, Head of Pharmaceutical Biotech Technical Development Fermentation within the Pharmaceutical Biotech Production at Roche Diagnostics GmbH ("the Franz Declaration"), the Roche document which Amgen seeks to file in the public record corresponds to Exhibit 5 of the

[1] The document Amgen seeks to file was submitted to the Court in a sealed envelope for *in camera* review on January 10, 2007, and was returned to counsel for Amgen on January 17, 2007, and corresponds to Exhibit 5 of Amgen's Declaration of Deborah E. Fishman in Support of Plaintiff's Memorandum in Support of its Motion to Compel Production of Roche's Cell Line (Docket No. 224). Roche would be pleased to resubmit this document for *in camera* inspection if the Court so requires.

Declaration of Deborah E. Fishman in Support of Plaintiff's Memorandum in Support of its Motion to Compel Production of Roche's Cell Line ("Exhibit 5"), which is a copy of Defendants' Supplemental Responses to Amgen Inc.'s First Set of Requests for Admission (Nos. 1-22) ("RFAs"). This document includes excerpts from Roche's highly sensitive, confidential Biologics License Application ("BLA") regarding the particular chemical synthesis of Roche's unique product and the recombinant CHO cell line which produces EPO. Specifically, the information contained in the Exhibit reveals the type of cell and the identity of the cell line used in the production of the EPO starting material used to synthesize MIRCERA, detailed cell culture methods and proprietary procedures employed in the production processes to synthesize MIRCERA, the composition and structure of Roche's unique DNA clone used in the production of the EPO starting material used to synthesize MIRCERA, and the periods for the fermentation phases and the product yield for cell growth for production of the EPO starting material.

I. Exhibit 5 Is Not Relevant.

Exhibit 5 is not necessary for the Court to decide the issues in Amgen's motion and for this reason, Roche requests that the document not be accepted for filing. Importantly, Amgen's motion is not intended to compel Roche to amend or supplement its RFA responses, but instead is seeking to compel Roche to produce cells and documents. In describing the background of this dispute, Amgen makes a fleeting reference to Roche's original responses (on page 4) and supplemental responses (on page 5) to Amgen's RFAs. *See* Amgen Inc.'s Memorandum In Support Of Its Motion To Compel Production Of Roche's Cell Line And Related Documents at 4, 5 (Docket No. 223). Essentially, Amgen argues that in its RFA responses, Roche "denied basic characteristics about its cell line, including the amount of EPO made by its cell line." *See id*. at 4. Thus, to the extent that Roche's denial of these characteristics in its RFA response is

relevant at all, Amgen has aptly summarized the relevant portion in its memorandum. *See id.* at fn 5. The content of Roche's RFA admissions and denials does not shed any additional light on whether the cells or documents should be produced. Moreover, Amgen only cites RFAs Nos. 18-21 in the footnote citing to Exhibit 5, which is further evidence that Amgen itself agrees that only 4 RFAs out of the 22 RFAs in the document are actually relevant. *See id.* The Court should not be burdened by deciding the trade secret status of Exhibit 5 or the information contained therein where the Exhibit is completely irrelevant to Amgen's motion.

If the Court deems this document is relevant, however, then Roche requests that the entire Exhibit 5 be filed under seal, but if not the entire document, then at least the portions contained at pages 22-27 and 29-35 (RFA Nos. 15-17 and 19-22), all of which contain excerpts of trade secret information from Roche's BLA. While Roche considers all of the RFAs to be highly confidential, in light of this Court's order that only trade secret material may be filed under seal, Roche directs the Court's attention to the particular pages which contain the most sensitive information and which would harm Roche the most if revealed. These pages represent the core of Roche's drug development, and, for that reason, Roche considers them to be trade secrets of the utmost value and has consistently and vigilantly guarded their secrecy.

II. Each Of The Excerpts At Issue in Exhibit 5 Contains Information Which Is Not Publicly Known and Which Would Cause Irreparable Harm To Roche If Revealed.

Each of the excerpts at issue in Exhibit 5 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 pharmaceutical industry. If placed in the public record, this information would enable any person or company with skill in the art to replicate Roche's processes and end product, thereby misappropriating Roche's invaluable trade secrets and causing irreparable damage to Roche. For example, one or more generic drug manufacturers

in jurisdictions where patent protection is lacking could vault into the market without having to expend the years of effort and millions of dollars that Roche devoted to its CERA product, and seize substantial market share to Roche's irreparable damage. *See* Franz Declaration at ¶ 7. Thus, Roche respectfully requests that the Court grant Roche's motion to file Exhibit 5 under seal.

A. Pages 22-23 of Exhibit 5 (RFA No. 15)

Pages 22-23 (RFA No. 15) contain a highly confidential excerpt from Roche's BLA. As Dr. Franz, Head of Pharmaceutical Biotech Technical Development Fermentation within the Pharmaceutical Biotech Production at Roche attests in his Declaration, this document contains 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. Dr. Franz further testifies that this information constitutes a trade secret in that it has never been publicly disclosed and it would be extremely harmful to Roche if it were to be filed in the public record. *See* Franz Declaration at ¶ 8.

Moreover, the invaluable economic benefit that the excerpts in Exhibit 5 confer would be eviscerated if a generic manufacturer could access these highly sensitive and confidential documents in the public record, and use the information contained therein to replicate Roche's drug CERA which has taken years to develop and millions of dollars of expenditure. Such a scenario is not merely a hypothetical. For example, in Europe, India, and many other parts of the world where patent protection is not as robust as it is in this country, a generic manufacturer based in one of these countries could make swift use of these crucially important trade secrets to enter the market with a replication of Roche's product. Such a company would put in none of the intense labor or resources which Roche has invested in its drug development, yet benefit

from all of Roche's work, due solely to the naked exposure of all of Roche's trade secrets in the public record. Therefore, it is imperative that Exhibit 5, or at least these most important pages of Exhibit 5, should be filed under seal.

B. Page 24 of Exhibit 5 (RFA No. 16)

Page 24 (RFA No. 16) contains a highly confidential excerpt from Roche's BLA. As Dr. Franz describes, this document contains 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. Dr. Franz also testifies that this information constitutes a trade secret in that it has never been publicly disclosed and it would be extremely harmful to Roche if it were to be filed in the public record. *See* Franz Declaration at ¶ 9. As set forth above, Roche would suffer great harm if this information were to be revealed in the public record.

C. Pages 25-27 of Exhibit 5 (RFA No. 17)

Pages 25-27 (RFA No. 17) contain a highly confidential excerpt from Roche's BLA. In Dr. Franz's Declaration, he testifies that this document contains 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. Dr. Franz further testifies that this information constitutes a trade secret in that 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. *See* Franz Declaration at ¶ 10. As set forth above, Roche would suffer great harm if this information were to be revealed in the public record.

D. Pages 29-30 of Exhibit 5 (RFA No. 19)

Pages 29-30 (RFA No. 19) contain a highly confidential excerpt from Roche's BLA. According to Dr. Franz, this document contains 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. Dr. Franz also attests that this information constitutes a trade secret in that it has never been publicly disclosed and it would be extremely harmful to Roche if it were to be filed in the public record. *See* Franz Declaration at ¶ 11. As set forth above, Roche would suffer great harm if this information were to be revealed in the public record.

E. Pages 30-31 of Exhibit 5 (RFA No. 20)

Pages 30-31 (RFA No. 20) contain a highly confidential excerpt from Roche's BLA. As Dr. Franz attests, this document contains 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. Dr. Franz further testifies that this information constitutes a trade secret in that it has never been publicly disclosed and it would be extremely harmful to Roche if it were to be filed in the public record. *See* Franz Declaration at ¶ 12. As set forth above, Roche would suffer great harm if this information were to be revealed in the public record.

F. Pages 31 – 33 of Exhibit 5 (RFA No. 21)

Pages 31-33 (RFA No. 21) contain a highly confidential excerpt from Roche's BLA. As asserted by Dr. Franz, this document contains information regarding 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.[2] Dr. Franz further states that this information

[2] This information is contained in Roche's original response to RFA No. 21, and is not contained in Roche's supplemental response.

constitutes a trade secret in that it has never been publicly disclosed and it would be extremely harmful to Roche if it were to be filed in the public record. *See* Franz Declaration at ¶ 13. As set forth above, Roche would suffer great harm if this information were to be revealed in the public record.

G. Pages 34-35 of Exhibit 5 (RFA No. 22)

Pages 34-35 (RFA No. 22) contain a highly confidential excerpt from Roche's BLA. As Dr. Franz attests, this document contains information regarding the exact formula for making the product for which Roche currently seeks approval from the FDA. Dr. Franz further testifies that this information constitutes a trade secret in that 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. *See* Franz Declaration at ¶ 14. As set forth above, Roche would suffer great harm if this information were to be revealed in the public record.

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

A. Exhibit 5 Contains Trade Secrets Under The Massachusetts Standard.

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.). As asserted by Dr. Franz, the excerpts at issue in Exhibit 5 concern secret scientific, technical, production, design, process, procedure, formula, invention and improvement information belonging to Roche which, if revealed, would cause irreparable harm to Roche. *See*

[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.

See Franz Declaration at ¶ 7, 15-18. Trade secret status requires that reasonable steps be taken to keep the information confidential. Here, Roche has never allowed the excerpts of the BLA at issue contained in Exhibit 5 to enter the public domain and has taken all possible measures to ensure that the information contained therein remains confidential. *See* Franz Declaration at ¶ 7.

Further, the FDA itself regards the BLA as highly confidential. Pursuant to FDA policy, the BLA is maintained in confidence and secrecy throughout the FDA approval process and continues to be held in confidence even after approval is granted. 21 C.F.R. § 601.51(d)(1). Thus, Roche seeks to enjoy the same confidential and efficient process that is available to all other applicants for FDA approval, by keeping the highly sensitive portions of its BLA and other information relating to its FDA approval process confidential. Roche would suffer irreparable harm if Exhibit 5 were to be filed in the public record.

Additionally, Roche and Amgen entered into an express agreement – the Protective Order – restricting the disclosure of the BLA. This Protective Order is extremely rigorous for the very reason that Roche, Amgen and this Court all recognize the great degree of sensitivity of documents such as the BLA and the trade secret information contained therein. In fact, the Protective Order restricts access to the BLA to the parties' outside counsel, and designated in-house counsel are only permitted access to the actual documents (whether in hard copy or electronic form) in a locked room, or in certain circumstances, under lock and key. *See* Protective Order at ¶ 4 (Docket No. 189). Thus, Roche requests that the Court treat Exhibit 5 with the same level of confidentiality that the parties confer upon it in the Protective Order, and grant Roche's motion to file the entire document under seal.

B. If The Excerpts in Exhibit 5 Were Revealed, Competitors Could Replicate Roche's Drug And Misappropriate Its Trade Secrets.

The excerpts in Exhibit 5 relate to an innovative cell line for production of a starting material that, when used to synthesize Roche's new drug MICERA can treat anemia differently from Amgen's drug, and has significant value in the market upon FDA approval. In these circumstances, disclosing Exhibit 5 in the public record would destroy the economic advantage that Roche has invested in and worked for as a company in the position of creating a new drug. *See Webb v. Dep't of Health & Human Servs*., 696 F.2d 101, 103 (D.C.Cir. 1982) ("If a [drug] manufacturer's competitor could obtain all the data in the manufacturer's NDA [the chemical equivalent of a BLA], it could utilize them in its own NDA without incurring the time, labor, risk and expense involved in developing them independently. Premature disclosure of NDA data is . . . discouraged by the existence of criminal sanctions . . . contained in both the Food, Drug, and Cosmetic Act and the Trade Secrets Act."); *see also Campaign for Responsible Transplantation v. United States Food and Drug Administration,* 219 F. Supp. 2d 106, n.10 (D.D.C. 2002) (stating that the release of confidential commercial information could "cause substantial competitive harm to the sponsor of the IND because a competitor could appropriate the information for use in its own IND or INDs . . . [Center for Biologics Evaluation and Research] regulations protect the confidentiality of IND submissions."). Thus, it is crucial that Exhibit 5 be filed under seal, if at all.

IV. Conclusion

For all the foregoing reasons, Roche respectfully requests that Exhibit 5 not be accepted for filing because it is irrelevant to the disposition of Amgen's motion. However, if the Court deems it relevant, then Roche requests that the Court grant Roche's motion to file Exhibit 5

under seal, or at the very least to file pages 22-27 and 29-35 (RFA Nos. 15-17 and 19-22) under seal.

DATED: Boston, Massachusetts
January 17, 2007

Respectfully submitted,

F. HOFFMANN-LA ROCHE LTD,
ROCHE DIAGNOSTICS GMBH, and
HOFFMANN-LA ROCHE INC.

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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/ Nicole A. Rizzo
Nicole A. Rizzo

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