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 DOCUMENTS CONTAINING DEFENDANTS' CONFIDENTIAL AND TRADE SECRET MATERIALS

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively "Roche") respectfully move, pursuant to the Protective Order, to file under seal documents which contain Roche's confidential and trade secret materials submitted for *in camera* review by Amgen if the Court deems them necessary for its ruling on Amgen's Motion To Determine The Sufficiency Of Roche's Responses To Amgen's Requests For Admission (Docket No. 275).[1] The present motion relates solely to the confidentiality of Amgen's motion papers; as to the substantive issues, Roche will file its opposition to Amgen's motion on or before the deadline of February 27, 2007.

[1] The documents Amgen seeks to file were submitted to the Court in a sealed envelope for *in camera* review on February 13, 2007, and correspond to Exhibits 2, 9, 10 and 11 of Amgen's Declaration Of Krista M. Carter In Support Of Plaintiff's Motion To Determine The Sufficiency Of Roche's Responses To Amgen's Requests For Admission (Docket No. 277) and to excerpts thereof in Amgen's Memorandum in Support of Plaintiff's Motion To Determine The Sufficiency Of Roche's Responses To Amgen's Requests For Admission (Docket No. 276) on pages 15 and 18, and in Attachment A pages 2, 8-10, 11 (at fn 54) and 12 (at fn 56).

Introduction

For the reasons given below, none of the four exhibits that Amgen seeks to file should be accepted for filing at all, in the public record or otherwise, because they are irrelevant and/or unnecessary to the Court's disposition of Amgen's motion. If the Court determines that some or all of these exhibits are necessary for its decision, however, Roche requests that Exhibits 2, 9, and 10 be filed under seal to protect Roche trade secrets contained in these documents.[2]

I. The Documents At Issue Are Not Necessary And/Or Relevant And Should Not Be Accepted For Filing In The Public Record or Otherwise

Exhibits 9, 10, and 11 are not relevant to the Court's decision on the issues in Amgen's motion, and, for this reason, Roche requests that the documents not be accepted for filing in public record or otherwise. As a matter of law, Exhibits 9, 10, and 11 (which are Roche business documents and interrogatory answers) are irrelevant because they are documents that Amgen contends to be inconsistent with certain requests for admission that Roche has denied. It is axiomatic, however, that Amgen may not litigate the accuracy or truthfulness of Roche's denials at this stage of the litigation. As a leading treatise states, "[a] motion to determine the sufficiency of a response to a request for admission is not to be used as an attempt to litigate the accuracy of a response. Rule 36 does not authorize the court to make determinations on the accuracy of responses before trial. Nor may a court order that the subject matter of a request be admitted because the opposing party's denial is unsupported by evidence." *Moore's Federal Practice*, Sec. 36.12[1] at 36-41 and cases cited; *see also Foretich v. Chung*, 151 F.F.D. 3, 4 (D.D.C. 1993) (Greene, J.) ("In this case, the plaintiff clearly stated that he was denying the defendants' request for an admission.... Regardless of its accuracy, this response was appropriate

[2] While Roche maintains that all four exhibits are highly confidential documents, in light of the Court's requirement that only trade secrets be filed under seal, Roche will not object to Exhibit 11 being filed in the public record if the Court determines that it is necessary to decide Amgen's motion.

under Rule 36 and the Federal Rules do not allow the defendants to litigate, at this time, whether the plaintiff was justified in denying their request."); *A&V Fishing, Inc. v. Home Ins. Co.*, 145 F.R.D. 285, 287 (D. Mass. 1993) (Collings, M.J.) (stating that denial of facts allegedly known to be true is "not a proper ground for a motion to determine the sufficiency of the answers under Rule 36(a)"). Thus, because the only purpose for these exhibits is to contest the accuracy of Roche's responses, these documents serve no relevant function in relation to Amgen's present motion.

Moreover, to the extent that the information contained in Exhibits 9, 10, and 11 is relevant to Amgen's motion at all, Amgen has aptly summarized the content of these documents in the text of its memorandum, and the Court does not need to examine any of these documents themselves to accept Amgen's summary of their contents. The Court should not be burdened by deciding the trade secret status of these exhibits or the information contained therein where the exhibits are unnecessary for Amgen's motion.

Likewise, Exhibit 2, which is Roche's Responses to the Requests for Admission, should not be accepted for filing in the public record or under seal because it is clear from the excerpts that Amgen included in its publicly filed memorandum that Roche has made a full response to the RFAs or stated sufficient reasons for its objections. Thus, there is no reason for the Court to examine the source document contained in Exhibit 2 in order to dispose of Amgen's motion.

II. Each Of The Excerpts At Issue In Exhibit 2 and Exhibit 9, And All Of Exhibit 10, Contains Information Which Is Not Publicly Known and Which Would Cause Irreparable Harm To Roche If Revealed

If the Court deems Exhibits 2, 9, 10, and 11 necessary to decide Amgen's motion, then Roche requests that Exhibit 10 and all of Exhibits 2 and 9 be filed under seal, but if not the entire document for Exhibits 2 and 9, then at least the portions contained in Exhibit 2 at pages 22-27

and 29-35 (RFA Nos. 15-17 and 19-22), and Exhibit 9 at pages 32-35 (Interrogatory Response No. 4), all of which contain excerpts of trade secret information from Roche's BLA. While Roche considers all of the RFAs and Interrogatory Responses 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.

Exhibits 2, 9, and 10 contain 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. *See* Franze Declaration at ¶ 6, 15, 18.

Moreover, the invaluable economic benefit that these exhibit 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 and millions of dollars to develop. 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 invest none of the intense labor or resources which Roche has invested in its drug development, yet would 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 2 and 9, or at least these most important pages of Exhibit 2 and 9, and the entirety of Exhibit 10 should be filed under seal.

A. Pages 22-23 of Exhibit 2 (RFA No. 15)

Pages 22-23 (RFA No. 15) contain a highly confidential excerpt from Roche's BLA. As Dr. Franze, 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. Franze 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* Franze Declaration at ¶ 7.

B. Page 24 of Exhibit 2 (RFA No. 16)

Page 24 (RFA No. 16) contains a highly confidential excerpt from Roche's BLA. As Dr. Franze 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. Franze 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* Franze Declaration at ¶ 8. 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 2 (RFA No. 17)

Pages 25-27 (RFA No. 17) contain a highly confidential excerpt from Roche's BLA. In Dr. Franze'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. Franze 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* Franze Declaration at ¶ 9. 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 2 (RFA No. 19)

Pages 29-30 (RFA No. 19) contain a highly confidential excerpt from Roche's BLA. According to Dr. Franze, 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. Franze 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* Franze Declaration at ¶ 10. 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 2 (RFA No. 20)

Pages 30-31 (RFA No. 20) contain a highly confidential excerpt from Roche's BLA. As Dr. Franze 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. Franze 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* Franze Declaration at ¶ 11. 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 2 (RFA No. 21)

Pages 31-33 (RFA No. 21) contain a highly confidential excerpt from Roche's BLA. As asserted by Dr. Franze, 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. Dr. Franze further states 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* Franze Declaration at ¶ 12. 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 2 (RFA No. 22)

Pages 34-35 (RFA No. 22) contain a highly confidential excerpt from Roche's BLA. As Dr. Franze attests, this document contains information regarding the exact formula for making the product for which Roche currently seeks approval from the FDA. Dr. Franze 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* Franze Declaration at ¶ 13. As set forth above, Roche would suffer great harm if this information were to be revealed in the public record.

H. Pages 32-35 of Exhibit 9 (Interrogatory Response No. 4)

Similarly, Pages 32-35 (Interrogatory Response No. 4) contains a highly confidential excerpts of the BLA regarding the exact formula for making the product for which Roche currently seeks approval from the FDA. These pages also contain information regarding the manufacturing process, and the genealogy and preparation of Roche's cell line. *See* Franze Declaration at ¶ 8, 13. As set forth above, Roche would suffer great harm if this information were to be revealed in the public record.

I. Exhibit 10

Exhibit 10 is an excerpt from Roche's Investigational New Drug application ("IND") titled "Manufacture of the Starting Material of EPO." Exhibit 10 contains highly sensitive and confidential information concerning the characteristics of Roche's production clone/cell bank for EPO, such as the copy number and genetic stability. As asserted by Dr. Franze, Exhibit 10 describes, particularly in figure 2, how the working cell bank used in Roche's actual production of EPO was derived from the master cell bank. Exhibit 10 contains highly confidential and crucial details regarding the generation cycles/cell doublings that were given during the cell propagation phase up to the point when the actual working cell bank was laid down and stored. Dr. Franze further attests that Exhibit 10 contains the crucial information about which cell bank is presently being used by Roche for EPO production and which cell bank is not – information which would be invaluable in the hands of a competitor. *See* Franze Declaration at ¶ 14.

The information contained in Exhibit 10 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. Such detailed information would cause irreparable harm to Roche if revealed because it

would enable a competitor to copy the generation of such a working cell bank which is a core element of Roche's EPO production. *See* Franze Declaration at ¶ 15.

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

A. The Documents At Issue Contain 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. Franze, the excerpts at issue in Exhibit 2 and 10 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 See* Franze Declaration at ¶ 6, 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 2 and 9, or the excerpt of the IND contained in Exhibit 10 to enter the public domain and has taken all possible measures to ensure that the information contained therein remains confidential. *See* Franze Declaration at ¶ 16-19.

Further, the FDA itself regards BLAs and INDs as highly confidential. Pursuant to FDA policy, the BLA and any IND incorporated therein 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

[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.

efficient process that is available to all other applicants for FDA approval, by keeping the highly sensitive portions of its BLA and IND and other information relating to its FDA approval process confidential. Roche would suffer irreparable harm if Exhibits 2, 9, and 10 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 and IND. 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 IND and the trade secret information contained therein. In fact, the Protective Order restricts access to the BLA and IND 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. 274). Thus, Roche requests that the Court treat Exhibits 2 and 10 with the same level of confidentiality that the parties confer upon them in the Protective Order, and grant Roche's motion to file the documents under seal.

B. If The Documents At Issue Were Revealed, Competitors Could Replicate Roche's Drug And Misappropriate Its Trade Secrets

The excerpts in Exhibits 2, 9, and 10 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 Exhibits 2, 9 and 10 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 Exhibits 2, 9, and 10 be filed under seal, if at all.

VI. Conclusion

For all the foregoing reasons, Roche respectfully requests that Exhibits 2, 9, 10 and 11, and the references thereto in Amgen's Memorandum, not be accepted for filing in the public record or under seal because they are irrelevant to the disposition of Amgen's motion. However, if the Court deems them relevant, then Roche requests that the Court grant Roche's motion to file Exhibits 2, 9, and 10 under seal, or at the very least to file pages 32-35 (Interrogatory Response No. 4) of Exhibit 9, and pages 22-27 and 29-35 (RFA Nos. 15-17 and 19-22) of Exhibit 2 and the references thereto in Amgen's Memorandum, and the entirety of Exhibit 10 under seal.

DATED: Boston, Massachusetts
February 20, 2007

Respectfully submitted,

F. HOFFMANN-LA ROCHE LTD,
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