UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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| AMGEN INC.,<br><br>Plaintiff,<br><br>v.<br><br>F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GMBH, and HOFFMANN-LA ROCHE INC.,<br><br>Defendants. | CIVIL ACTION No.: 05-CV-12237WGY |

**MEMORANDUM IN SUPPORT OF DEFENDANTS' UNOPPOSED 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 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 declaration of Richard Beswick, Associate Medical Director at Hoffmann-La Roche ("Beswick Declaration"),[2] the Exhibit which Amgen seeks to file in the public record ("Exhibit 1") is a technical internal Roche document regarding, *inter alia*, confidential information concerning Roche's drug development, budgeting,

[1] The document Amgen seeks to file was submitted to the Court in a sealed envelope for *in camera* review on January 12, 2007 and corresponds to Exhibit 1 of Amgen's Declaration of Deborah E. Fishman in Support of Plaintiff's Memorandum in Support of its Motion for Clarification of the Court's December 29, 2006 Order (Docket No. 237).

[2] The Beswick Declaration was filed by Roche on December 22, 2006 (Docket No. 193), in connection with another motion to seal the same document. Pursuant to CM/ECF Administrative Procedures Rule L(3), Roche is not re-filing this Declaration but instead refers herein to the previously filed Declaration.

manufacturing, scale-up of its product, and supply. This document represents the core of Roche's drug development and business strategy, and, for that reason, Roche considers this information to be trade secret and has consistently protected its confidentiality.

As an initial matter, this document should not be accepted for filing at all because it is irrelevant. Amgen seeks to file this document in connection with its Motion for Clarification of its previously filed Motion to Compel, and had sought to file this same document in connection with that original motion.[3] However, in its Order of December 29, 2006, the Court stated that it "made this [ruling] without the need for reference" to this document (or any of the others submitted with Amgen's original motion) and ordered this document, along with the others, returned to Roche. Indeed, it is neither necessary nor appropriate for the Court to rely on additional evidence in deciding Amgen's Motion for Clarification that it did not reference in its disposition of the original motion. As such, the Court should decide the present motion without reference to Exhibit 1 and should not accept this document for filing.

Exhibit 1 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 competitor in the industry to take advantage of Roche's confidential business strategy, including budgeting, resource allocation and project management for the clinical trials for the product for which Roche is seeking FDA approval. As explained in detail below, this information would be invaluable in the hands of a competitor, and for this reason Roche has consistently protected the secrecy of its medical affairs and business strategy. Thus, Roche respectfully requests that the Court grant Roche's motion to file this document under seal.

[3] Amgen sought to attach this document as Exhibit 7 to its Declaration of Krista M. Carter In Support Of Plaintiff Amgen Inc.'s Memorandum In Support Of Its Motion To Compel, filed on 12/15/06 (Docket No. 177).

## I. Exhibit 1 Contains Information Which Is Not Publicly Known and Which Would Cause Irreparable Harm To Roche If Revealed.

According to Dr. Beswick in his Declaration, Exhibit 1 is an internal Roche slide presentation containing highly confidential, trade secret information regarding planning, resource allocation, and project management for Roche's new product, including details concerning Roche's clinical studies. Although results of clinical studies are sometimes released to the public, details concerning the studies are routinely kept in confidence. The planning, resource allocation and project management information is central to Roche's business and marketing strategy, and is maintained in the strictest confidence in the ordinary course of business. Dr. Beswick further testified that disclosure of this information to a competitor who would learn Roche's plans and timing for its product's development and submission for approval would confer an unfair advantage. As such, this trade secret information is invaluable to Roche, and placing it in the public record would harm Roche's competitive advantage. *See* Beswick Decl. at ¶ 12.

In particular, Dr. Beswick expressed concern about page 8 and the preceding page, which contains Roche's confidential CERA CKD budget for 2005 and 2006, broken down by general line item expenditures. This information is never made public and it would be very harmful to Roche to have this information in the public record for competitors to use. This information would be extremely harmful to Roche in the hands of competitors because it reveals where Roche is spending its resources, and in what areas competitors could gain an advantage by outspending Roche. For example, as Dr. Beswick testified, if a competitor were aware of Roche's plans for future clinical trials based on its budget, it could plan its own clinical trial for the same time period in order to "lock up" available participants and thereby impede Roche from executing its planned trial. This type of information is crucial to Roche's competitive advantage

and its public record disclosure would be extremely destructive to Roche's success in the market. *See* Beswick Decl. at ¶ 13.

Finally, Dr. Beswick asserted that pages 4, 5 and 7 of Exhibit 1 contain Roche's comparison studies, Roche's "extension data" which follows the dosing of patients for one year after participation in clinical trials, and information regarding phase IIIb/IV studies which are still in development. All of this information is central to Roche's development of its CERA product and its confidentiality gives Roche a competitive advantage. *See* Beswick Decl. at ¶ 14.

## II. The Information Contained In Exhibit 1 Constitutes A Trade Secret Under Massachusetts Law.

### A. Exhibit 1 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).[4] *See Trent Partners and Associates, Inc. v. Digital Equipment Corp.*, 120 F. Supp. 2d 84 (D. Mass. 1999) (Woodlock, J.). As asserted by Roche Medical Affairs Director, Richard Beswick, Exhibit 1 concerns 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* Beswick Declaration at ¶ ¶ 5, 7, 16-19.

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).

[4] 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.

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.

**B. The Information Contained In Exhibit 1 Remains Confidential**

Trade secret status requires that reasonable steps be taken to keep the information confidential. Here, Roche has never allowed the information contained in Exhibit 1 to enter the public domain and has taken all possible measures to ensure that it remains confidential. *See* Beswick Declaration at ¶ ¶ 5, 16-19.

Additionally, Roche and Amgen entered into an express agreement – the Protective Order – restricting the disclosure of the type of information contained in Exhibit 1.[5] The Protective Order is extremely rigorous for the very reason that Roche, Amgen and this Court all recognize the great degree of sensitivity of this sort of information. In fact, the Protective Order restricts access to much of this type of information to the parties' outside counsel, and certain designated in-house counsel. *See* Protective Order at ¶ 10 (Docket No. 189). Thus, Roche requests that the Court treat Exhibit 1 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.

**C. If The Information Contained In Exhibit 1 Were Revealed, Competitors Misappropriate Roche's Trade Secrets**

The information contained in Exhibit 1 relates to the business strategy of developing a drug that can treat anemia differently from any other drug in the market, including Amgen's

[5] The Protective Order provides that "Confidential Material may include information which has not been made public and which concerns or relates to the trade secrets, processes, operations, style of work, communications or apparatus, or to the production, sales, shipments, purchases, transfers, identification of customers, inventories, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or other organization, the disclosure of which information is likely to have the effect of causing harm to the Supplier." *See* Protective Order at ¶ 2.

drug, and has significant value in the market upon FDA approval. Disclosing Exhibit 1 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, Roche seeks to enjoy the same confidential and efficient process that is available to all other applicants for FDA approval, by keeping its highly sensitive business strategy information relating to its FDA approval process confidential.

## III. Conclusion

For all the foregoing reasons, Roche respectfully requests that Exhibit 1 not be accepted for filing. However, if the Court does accept the document for filing, Roche respectfully requests that the Court grant Roche's Motion to file Exhibit 1 under seal.

DATED: Boston, Massachusetts
January 19, 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
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