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'S MOTION TO PRECLUDE FURTHER INTERFERENCE WITH THIRD-PARTY DISCOVERY

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 Local Rule 7.2 and to the protective order, for leave to file under seal certain documents which contain Roche's confidential and trade secret materials, if the Court deems them necessary for its ruling on Amgen's Motion to Preclude Further Interference with Third-Party Discovery and Compel Production of Documents and Deposition Testimony, or in the Alternative, Motion to Strike Defendants' Defense Under 35 U.S.C. § 271(e)(1) (Docket No. 377).[1] The present motion relates solely to the confidentiality of

[1] The documents Amgen seeks to file in the public record were submitted for *in camera* review on April 13 and 16, 2007 and correspond to Exhibits 4-6, 10-12, 14-15, and 17-18 of the Declaration of Mario Moore in Support of Plaintiff Amgen Inc.'s Motion to Preclude Further Interference with Third-Party Discovery and Compel Production of Documents and Deposition Testimony, or in the Alternative, Motion to Strike Defendants' Defense Under 35 U.S.C. § 271(e)(1) (Docket No. 379) (the Moore declaration). Amgen first submitted only 5 of the 19 confidential documents on April 13, 2007 and erroneously filed 14 of Roche's confidential documents in the public record. Upon request by Roche, Amgen removed those documents from the public record and submitted them for *in camera* review on April 16, 2007. The present motion seeks leave to file under seal all of the documents containing trade secrets submitted in connection with the Moore declaration.

documents submitted in connection with Amgen's motion papers; as to the substantive issues, Roche will file its opposition to Amgen's motion on or before the deadline of April 27, 2007.

Introduction

For the reasons given below, none of the exhibits that Amgen seeks to file should be accepted for filing at all, in the public record or otherwise, because they are unnecessary to the Court's disposition of Amgen's motion. Indeed, Amgen has repeatedly attempted to file Roche's confidential and trade secret documents in connection with its discovery motions, and the Court has in turn decided each motion without need to reference these documents. The Court has also noted that Amgen is seeking to harass Roche with this tactic.[2] The documents at issue here are similarly unnecessary to the Court's disposition and should not be accepted for filing at all. If the Court determines that some or all of these exhibits are necessary for its decision, however, Roche requests that Exhibits 4-6, 10-12, 14-15, and 17-18 be filed under seal to protect Roche trade secrets contained in these documents.[3]

As set forth in greater detail below and in the accompanying declaration of Richard Beswick, Associate Medical Director at Hoffmann-La Roche ("Beswick Declaration"), the Roche documents which Amgen seeks to file in the public record ("the Trade Secret Materials") include technical internal Roche documents regarding, *inter alia*, confidential information concerning (1) the details as to time frame, size and dosing used in individual ongoing and future clinical trials conducted in furtherance of Roche's Biologics License Application ("BLA") and Investigational Drug Applications ("IND") submitted to the Food and Drug Administration (the

[2] In its February 28, 2007 Order, the Court held: "This Ruling Has Been Made Without Any Reference to the So-Called Confidential Documents, A Procedure Which - It Is Becoming Increasingly Apparent - Is Being Employed Solely to Harass and Embarrass An Opposing Litigant and Cause Waste of Resources. This Court Will Not Continue to Tolerate Such Litigation Conduct."

[3] While Roche maintains that all of the exhibits submitted for *in camera* review are highly confidential documents, in light of the Court's requirement that only trade secrets be filed under seal, Roche will not object to Exhibits 7-9, 13-14, 16, 23-24, 28, and 29 being filed in the public record if the Court determines that they are necessary to decide Amgen's motion.

"FDA"), (2) Roche's manufacturing processes and scale-up of its product, (3) confidential Roche marketing strategy and budgeting information, and (4) Roche's internal forward-looking statements regarding the potential success of its product. Thus, the materials which Roche is requesting to be filed under seal are Exhibits 4-6, 10-12, 14-15, and 17-18. These documents represent the core of Roche's drug development and business strategy, and, for that reason, Roche considers them to be trade secretes and has consistently and vigilantly guarded their secrecy.

Each of the documents 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 pharmaceutical industry. If placed in the public record, this information would facilitate Roche's competitors in developing and introducing competing drugs by reducing the amount of time necessary to evaluate product opportunity, develop clinical trials, and achieve quicker market penetration, enhanced competitive strategies, and reduced development time and opportunity cost. Moreover, pursuant to FDA policy and Roche company policy, the BLA and the IND applications and those communications involving these applications 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). The disclosure of these documents in the public record would reveal Roche's invaluable trade secrets and cause irreparable damage to Roche. Thus, Roche respectfully requests that the Court grant Roche's motion to file the Trade Secret Materials under seal.

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

Exhibits 4-6, 10-12, 14-15, and 17-18 are not necessary 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. The motion to which these documents relate, Amgen's Motion to Preclude Further Interference with Third-Party Discovery and Compel Production of Documents and Deposition Testimony, or in the Alternative, Motion to Strike Defendants' Defense Under 35 U.S.C. § 271(e)(1) (Docket No. 377) is nothing more than a fourth attempt to compel Roche to produce certain information about its ongoing clinical studies, which this Court has repeatedly ruled is not discoverable (noting in its final Order that "Hoffman-La Roche's Position is Correct"). *See* Orders dated December 29, 2006, January 22, 2007, and March 2, 2007. Amgen's fourth motion, although styled as a motion to prevent interference with third party discovery, is in reality another version of Amgen's prior motions to compel and was filed after the court-ordered deadline of April 2, 2007 for filing motions to compel relating to fact discovery. Thus, consideration of these documents is not necessary given the untimely nature of the underlying motion.

Moreover, Amgen has aptly summarized the content of these documents in specific detail 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 the disposition of Amgen's motion.

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

A. Exhibit 4 to the Moore Declaration

Exhibit 4 is an internal Roche slide presentation containing highly confidential, trade secret information including detailed analysis of Roche's drug development activities and strategy, including test result data, comparative study plans and outcomes, development and marketing timelines, budget data, and related information at the core of Roche's drug

development and marketing business. This information is maintained in strict confidence as a trade secret in the highly competitive worldwide pharmaceutical industry. This trade secret information is basic to Roche's ability to compete and succeed in its business and gives it an advantage in the marketplace. A person with skill in the art could use information in this document to determine critical aspects of the production of Roche's proprietary product. Roche has never, and would never, disclose such detailed information to the public. This product is the result of years of testing and development. Public disclosure of this information to Roche's competitors on the public record 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 the drugs and marketing strategies set forth in this document. *See* Beswick Decl. at ¶8.

Further, Exhibit 4 contains many details regarding Roche's dialysis program which have never been made public, and would be extremely damaging if they were to be made public at this time. For example, the document contains information regarding mean dosing, inclusion criteria such as how many patients participated in each study, how many patients were planned for each study, how the patients were randomized, how many patients were in the United States, and final endpoints. All of this information would be highly instructive to a competitor because it would provide an insider's perspective on Roche's clinical trials. It is critical to Roche's business strategy that this information not be released in the public record. *See* Beswick Decl. at ¶9.

Also, Exhibit 4 contains a "competitive profile," which essentially represents Roche's analysis of its strengths and weaknesses with respect to its competitors regarding chronic kidney disease ("CKD") studies. This information would allow a competitor of Roche to critique and assess Roche's weaknesses in great detail. This would give the competitor the advantage of

benefiting both from applying the knowledge of Roche's vulnerabilities to its own drug development, and from the ability to use this information against Roche in the market. *See* Beswick Decl. at ¶10.

Finally, Exhibit 4 includes a description of Roche's speculative and forward-looking predictions as to the potential results of various studies. For example, pages 17-20 of Exhibit 4 detail what the presenter believes Roche's CKD program will deliver and what it will not deliver, while pages 24-27 do the same for Roche's dialysis program. These predictions are highly sensitive, confidential business strategy which could, if revealed in the public record, be extremely harmful to Roche. This document was created and presented as a confidential internal Roche document not intended to be seen by the public at large, or by potential investors. Indeed, Roche has strict obligations regarding forward-looking statements and speculation as to the success of its product. Absent additional cautionary language, a forward-looking statement may become the basis of liability. Exhibit 4 was created and presented as a confidential internal Roche document, not intended to be seen by the public at large, or by potential investors. *See* Beswick Decl. at ¶ 11. The information contained in Exhibit 4 could potentially qualify as a forward-looking statement in that the document reflects discussions of the CERA medical team and is a statement about the future plans and objectives of Roche with respect to CERA. Disclosure of this information in the public record would potentially be inconsistent with Roche's legal obligations regarding public, forward-looking predictions of its products.

B. Exhibit 5 to the Moore Declaration

Exhibit 5 is an internal Roche memorandum originating in and circulated amongst the Clinical Operations Group which outlines the budget and objectives for Roche's phase IIIb clinical studies. This document contains Roche's trade secret and highly detailed information

regarding the design and implementation of each clinical study, including the number of patients enrolled in the Time & Motion, Home Dialysis and Continuum of Care studies, and the First Patient, First Visit ("FPFV") and Last Patient, Last Visit ("LPLV") data. Exhibit 5 also contains information on the budget for each trial, broken down by site, which would be helpful to a competitor trying to undermine and interfere with Roche's studies. This information could be used by a competitor to determine Roche's plans for the exact beginning and end dates of the clinical trials, which would be extremely harmful to Roche because it reveals where Roche is spending its resources, and in what areas competitors could gain an advantage by outspending Roche. For example, 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. According to Mr. Beswick, it is a common occurrence in the pharmaceutical industry for competitors to attempt to lock out each other's clinical trials by offering studies that are more appealing to potential participants during the same time frame. *See* Beswick Decl. at ¶ 12. Thus, this type of information is typically considered to those in the industry as highly confidential and trade secret, and would greatly harm Roche if it were disclosed in the public record. *See* Beswick Decl. at ¶ 12.

Additionally, because this document discusses the date at which Roche expects to complete its clinical trials and release its first abstract from those trials, its disclosure in the public record would provide investors with information as to when would be the best time to invest in Roche securities. As discussed above, disclosure of this information in the public record would potentially have an impact on Roche's investor relations and would be inconsistent

with Roche's legal obligations regarding public, forward-looking predictions of its products. *See* Beswick Decl. at ¶ 12.

C. Exhibit 6 to the Moore Declaration

Exhibit 6 is an internal Roche email containing a discussion of Roche's confidential budget for the Time & Motion, Home Dialysis and Continuum of Care clinical trials, broken down by per patient cost. The budget also displays line-item expenditures for vendors, drug packaging, sites, statistics and data management and other operating costs. This level of detailed 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. As discussed above, this information would be extremely harmful to Roche in the hands of competitors because it reveals where the areas in which competitors could gain an advantage by outspending Roche and planning its own clinical trial for the same time period in order to "lock up" available participants. 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.

D. Exhibit 10 to the Moore Declaration

Exhibit 10 is an internal Roche monthly report, originating in and circulated amongst the Medical Affairs department, which provides a comprehensive and in depth update on all ongoing and planned clinical trials. The report contains detailed information regarding each step in the process for these studies, including the date of submission of the protocols to the FDA, negotiations with vendors regarding budgets for each site, the number of completed and future pre-study visits, and target begin dates for each trial. This report is quite recent, dated January 2007, and as such, it contains information on clinical trials which are still in the planning stages today. *See* Beswick Decl. at ¶ 14.

It is imperative that this information be kept confidential, as disclosure would publicly reveal Roche's strategy and timing of its future clinical trial design and implementation. As discussed above, disclosure of this information would enable competitors to plan competing clinical trials in order to ambush Roche's strategy. Additionally, Exhibit 10 reveals the dialysis organizations with which Roche is collaborating on these clinical trials, and the confidentiality of this information is integral to Roche's business relationships. Each collaborator is not necessarily aware of the identity of other collaborators, and each company would not want its identity publicly disclosed to potential customers which may be competitors of Roche. Thus, a competitor would use this information to pit these parties against Roche in order to interfere with Roche's contractual and business relationships, thereby impeding Roche's ability to conduct its clinical trials. *See* Beswick Decl. at ¶ 14.

E. Exhibit 11 to the Moore Declaration

Exhibit 11 is another issue of the internal Roche monthly report identified in section D above, dated December 2006. This report details the data generation process for each of the key ongoing studies, including the Time and Motion, Continuum of Care and Peritoneal Dialysis study, as well as plans for future clinical studies which are still in the planning stages today. Exhibit 11 also contains information on the cost models for these studies and updates on the progress of contractual negotiations with various collaborators for the studies. For the reasons discussed above, this information is highly confidential and would be destructive to Roche's ability to conduct its clinical trials if disclosed. *See* Beswick Decl. at ¶ 15.

F. Exhibit 12 to the Moore Declaration

Exhibit 12 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. 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. 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 ¶ 16.

G. Exhibit 15 to the Moore Declaration

Exhibit 15 is an excerpt from an internal Roche weekly report, originating in and circulated amongst the Medical Affairs department. This report was generated after the first meeting of the Anemia Clinical Trial Task Force in January 2007 in order to provide an update regarding all of the current and future clinical trials. This report is essentially an internal tracking form which contains constantly changing, detailed and highly confidential information, including Mr. Beswick's handwritten notes, regarding how many sites will be active at a specific time, which companies Roche is collaborating with on these clinical trials, the number of confidentiality agreements distributed, executed, and returned, and the number of informed consents Roche is targeting. If this information were publicly disclosed, a competitor would use this information to 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 ¶ 17.

Also, as discussed above, the information regarding the companies with which Roche is collaborating on for its clinical trials is a guarded secret because these entities would not want the existence of a contract with Roche disclosed to other potential customers, which may be competitors of Roche. A competitor would use information on Roche's collaborators to pit these parties against Roche in order to interfere with Roche's contractual and business relationships, thereby impeding Roche's ability to conduct its clinical trials. *See* Beswick Decl. at ¶ 17.

H. Exhibit 17 to the Moore Declaration

Exhibit 17 is an internal presentation given to Roche's North American Operating Committee, which is a group made up of the company's North American presidents and vice-presidents. This document is an outline of the timelines for the Dialysis and CKD studies, and future studies still in the planning stages today, including highly detailed and confidential information such as when the synopses will be approved, the number of patients in each study, the number of minority studies, and the number and date of when each site will be initiated, and the companies with which Roche is collaborating. For the reasons discussed above, this document contains highly confidential, trade secrets which would be extremely harmful to Roche if disclosed. *See* Beswick Decl. at ¶ 18.

I. Exhibit 18 to the Moore Declaration

Exhibit 18 is an internal Roche email discussion between the Medical Affairs department in the U.S. and the drug department in Germany regarding Roche's clinical supply for each of its CERA studies. The document contains a request for a specific number of PreFilled Syringes and discloses the doses and quantities planned for each study, as well as the First Patient, First Visit information for each study. This information is essentially a blueprint of Roche's clinical study design, including the size, begin dates, number of patients and exact dosage quantities. As

discussed above, a competitor seeking to interfere with Roche's clinical trials would use this information to plan its own competing clinical trial which would "lock-up" the potential patients available and prevent Roche from executing its clinical trial. This type of information is key to Roche's competitive advantage and its disclosure would be extremely harmful to Roche's success in the market. *See* Beswick Decl. at ¶ 19.

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

A. The Trade Secret Materials 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).[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's Associate Medical Director, Richard Beswick, the Trade Secret Materials at issue 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* Beswick Declaration at ¶ ¶ 5, 7, 20-23.

B. The Trade Secret Materials Remain Confidential

Trade secret status requires that reasonable steps be taken to keep the information confidential. Here, Roche has never allowed the Trade Secret Materials at issue to enter the public domain and has taken all possible measures to ensure that the information contained therein remains confidential. *See* Beswick Declaration at ¶ ¶ 5, 20-23.

[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.

C. If The Trade Secret Materials Were Revealed, Competitors Could Replicate Roche's Drug And Misappropriate Its Trade Secrets

The Trade Secret Materials relate to an innovative formulation of a drug that can treat anemia differently from Amgen's drug, and has significant value in the market upon FDA approval. Disclosing the Trade Secret Materials would destroy the economic advantage that Roche has 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 information relating to its FDA approval process confidential.

Moreover, the invaluable economic benefit that these Trade Secret Materials 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. Roche respectfully asks that the Court prevent such a situation from occurring by granting Roche's motion to file these Trade Secret Materials under seal.

IV. Conclusion

For all the foregoing reasons, Roche respectfully requests that none of the confidential exhibits be accepted for filing at all. If the Court determines that some or all of the exhibits are necessary for its decision, then Roche requests that Exhibits 4-6, 10-12, 14-15 and 17-18 be filed under seal to protect Roche's trade secrets.

DATED: Boston, Massachusetts
April 19, 2007

Respectfully submitted,

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