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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 RECONSIDERATION OF EMERGENCY MOTION FOR ORDER REQUIRING PLAINTIFF 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") submit this memorandum and accompanying declarations in support of their motion, pursuant to Local Rule 7.2, for reconsideration of this Court's December 19, 2006 Order denying Roche's emergency motion for an order requiring Plaintiff Amgen Inc. ("Amgen") to file under seal certain documents which contain 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 declarations of Krishnan Viswanadhan, Associate Director of Drug Regulatory Affairs at Hoffman-La Roche ("Viswanadhan Declaration"), and Richard Beswick, Associate Medical Director at Hoffmann-

[1] The documents and information Amgen seeks to file are incorporated into and attached as exhibits to the unredacted versions of its Memorandum Of Points And Authorities In Support Of Its Motion To Compel Production Of Documents (Redacted Version) (Docket No. 174) (superseding Docket No. 166) (Amgen's "Memorandum") and the Declaration of Krista M. Carter In Support Of Plaintiff Amgen Inc.'s Memorandum In Support Of Its Motion To Compel (Redacted Version) (Docket No. 177) (superseding Docket No. 167) (the "Carter Declaration").

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La Roche ("Beswick Declaration"), the Roche documents which Amgen seeks to file in the public record ("the Trade Secret Materials") include excerpts from Roche's highly sensitive, confidential Biologics License Application ("BLA") and from its two Investigational Drug Applications ("IND") for CERA, as well as technical internal Roche documents regarding, *inter alia*, the specific chemical formula of Roche's unique and valuable Ro 50-3821 molecule, Roche's formulation, purification and validation processes for Ro 50-3821, the underlying data used in clinical trials (including private, individual patient information), confidential information concerning Roche's drug development, budgeting, manufacturing, scale-up of its product, and supply strategy (including detailed information regarding existing business and contractual relationships relating thereto), and 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 6-8, 12-14, 19-20 and 27, as well as references to and excerpts of these documents in the Carter Declaration (pp. 13, 15,[2] 19-20).[3] 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

[2] Pages 13 and 15 of the Carter Declaration contain screenshots of the BLA including substantive text regarding clinical trials and therefore will be submitted for the Court's consideration in a sealed envelope, along with the rest of the Exhibits at issue, per the Court's Order of 12/21/06. Pages 19-20 are excerpts from the Exhibits and therefore are not separately submitted for the Court's consideration.

[3] Roche does not object to public filing of certain Exhibits proposed by Amgen constituting communications between parties' counsel referencing the above mentioned material (Exhibits 2, 3, and 18 to Carter Declaration), or to Exhibit 10 which is a page of a publication that is included in Roche's IND. Roche maintains its position that all of the exhibits identified in the Declaration Of Patricia Rocha-Tramaloni In Support Of Emergency Motion For Order Requiring Plaintiff To File Under Seal Documents Containing Defendants' Confidential And Trade Secret Material (Docket No. 180) contain highly confidential, trade secret materials; however, in the interest of narrowing the issue, Roche is limiting its current motion to those documents and references thereto which, if revealed would be the most damaging to Roche.

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. Thus, Roche respectfully requests that the Court reconsider its denial of Roche's Emergency Motion and order Amgen to file these Trade Secret Materials under seal.

I. 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 6 to the Carter Declaration

Exhibit 6 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 global 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. 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.

In particular, Exhibit 6 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.

Exhibit 6 also 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.

Exhibit 6 also 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 6 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. *See* Beswick Decl. at ¶ 11.

In addition, Roche has strict obligations under securities laws regarding forward-looking statements and speculation as to the success of its product. Under the Private Securities Litigation Reform Act of 1995 (PSLRA)[4], a forward-looking statement, *inter alia*, includes "a statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer." 15 U.S.C. § 77z-2(i)(1). Absent additional cautionary language, a forward-looking statement may become the basis of liability. *In re Cardinal Health Inc. Securities Litigations*, 426 F. Supp. 2d 688, 747 (S. D. Ohio 2006). Exhibit 6 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 6 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. Publication of the medical team's plans for its product CERA via use of the document in this lawsuit without accompanying cautionary language may deprive Roche of the opportunity to take advantage of the safe harbor provision in the PLSRA and comply with applicable laws and regulations. This Court should not deprive Roche of the opportunity to take available protective steps afforded by federal law if this document were to be made public and, due to no fault of Roche's, may lead to securities issues. 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.

[4] Section 102 of the Private Securities Litigation Reform Act of 1995 (PSLRA) provides a safe harbor from liability for a forward-looking statement of a corporation so long as that statement is not false or misleading. 15 U.S.C. § 78u-5(c)(1)(A)(i). Under Section 102, there is no liability for any (1) forward-looking statement, (2) that is identified as such, and (3) is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement. *Limantour v. Cray*, 432 F. Supp. 2d 1129, 1157 (W.D. Wash. 2006) (citing PSLRA Section 102).

B. Exhibit 7 to the Carter Declaration

Exhibit 7 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 ¶ 12.

In particular, Exhibit 7, on page 8 and the preceding page, 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, 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.

Pages 4, 5 and 7 of Exhibit 7 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.

C. Exhibit 27 to the Carter Declaration

Exhibit 27 is an excerpt from Roche's BLA containing information regarding individual patients' data in clinical trials. This document discloses the private information of at least four patients involved in Roche's clinical studies. *See* Viswanadhan Decl. at ¶ 8. If disclosed in the public record, this document could create problems for Roche in complying with applicable privacy laws ***vis a vis*** its use of human subjects in its clinical studies. Under federal law, specifically the Health Insurance Portability & Accountability Act of 1996 ("HIPAA"), Roche is prohibited from disclosing protected health information without patient authorization. 45 CFR §164.502. In conjunction with HIPAA, every state also has specific laws governing patient privacy and the disclosure of patient records (see, e.g., M.G.L. c. 111 § 70E ("Patients' and residents' rights"). Roche is responsible for complying with the general common dictate to keep all patient information strictly confidential, and this Court should not potentially subject Roche to privacy law vulnerabilities by disclosing this document in the public record. To the extent that this document reveals information which may be in violation of federal or state privacy laws, Roche would be greatly harmed by its disclosure.

Moreover, this information constitutes Roche's highly confidential trade secrets in that, as explained above, the data underlying a study is routinely held in the strictest confidence and is rarely revealed in the public record, even where the results of a study may be announced. Roche

has never publicly revealed individual patient information or data underlying its clinical studies in such a high level of detail, and to do so would cause irreparable harm, give competitors an unfair advantage, and potentially cause Roche to inadvertently violate privacy laws. *See* Viswanadhan Decl. at ¶ 8.

D. Exhibit 8 to the Carter Declaration

Exhibit 8 is a portion of a draft of Roche's IND containing highly confidential, trade secret information. 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. Roche's unique and valuable chemical and the methods used to reliably produce it are the result of years of testing and development. Disclosure to Roche's competitors on the public record would permit them to circumvent these efforts in an instant, at essentially no cost, and would deprive Roche of any competitive advantage they are entitled to enjoy for the effort invested in developing their novel product. *See* Viswanadhan Decl. at ¶ 9.

E. Exhibit 19 to the Carter Declaration

Exhibit 19 is an excerpt from Roche's BLA, containing specific information about development of the product Roche hopes to market in the United States. This document contains information about certain purification processes. It is generally accepted in the pharmaceutical industry that purifying molecules of any variety is rarely straightforward, and development of an efficient purification method can be an extremely time-consuming and costly endeavor. This document reveals steps in a purification process that has taken years to develop and perfect. Disclosure of this information to the public would destroy its trade secret status, would enable competitors to take advantage of Roche's painstaking efforts without investing the resources that

Roche invested in developing the process, and would confer an unfair competitive advantage on these parties, to Roche's detriment. *See* Viswanadhan Decl. at ¶ 10.

F. Exhibit 12 to the Carter Declaration

Exhibit 12 is an internal Roche document showing Roche's analysis of production batches and validation of its purification processes. This information is basic to Roche's manufacturing process. The details of how Roche validates its manufacturing process is extremely sensitive, highly confidential, trade secret information which gives Roche a competitive advantage over other entities attempting to create similar compounds. Its disclosure in the public record would destroy its trade secret status. *See* Viswanadhan Decl. at ¶ 11.

G. Exhibit 14 to the Carter Declaration

Exhibit 14 is an internal Roche document showing information regarding drug development and manufacturing strategy. More specifically, this document pertains to current, long-term contractual relations between Roche and its vendors. Roche's strategic efforts to manage the adequate supply of goods necessary for manufacturing of all its products are the result of years of careful planning and implementation. Disclosure of internal discussions evaluating Roche's present position and considering alternate options for the future has the potential to harm Roche's existing business and contractual relationships, which, in turn, would severely compromise Roche's business operations. *See* Viswanadhan Decl. at ¶ 12.

H. Exhibit 20 to the Carter Declaration

Exhibit 20 is also an excerpt from Roche's BLA, containing information regarding demographic data of phase II clinical studies. This document contains data populations and analyses which are not in the public record in this level of detail. While pharmaceutical companies at times reveal the results of various clinical studies that may be presented in the

BLA, the data itself is kept in confidence, especially in the high level of detail supplied in this document. This document, which is part of the inherently confidential BLA, if placed in the public record would reveal all the data and analysis of the study itself, which is highly sensitive, proprietary trade secret information. Disclosure of this information to a competitor would confer an unfair competitive advantage and cause irreparable harm to Roche, in that a competitor could detect differences between its efficacy and safety data and Roche's, and use this information against Roche. This type of information, especially given that the product has not yet been approved, is exactly the type of information that Roche should have the prerogative to determine its disposition. *See* Viswanadhan Decl. at ¶ 13.

II. 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).[5] *See Trent Partners and Associates, Inc. v. Digital Equipment Corp.*, 120 F. Supp. 2d 84 (D. Mass. 1999) (Woodlock, J.). As asserted by Roche employees Krishnan Viswanadhan and 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* Viswanadhan Declaration at ¶ ¶ 5, 7, 14-17; *see* Beswick Declaration at ¶ ¶ 5, 7, 16-19.

[5] 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.

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* Viswanadhan Declaration at ¶ ¶ 5, 14-17; *see* Beswick Declaration at ¶ ¶ 5, 16-19.

Additionally, Roche and Amgen recently entered into an express agreement – the Protective Order - restricting the disclosure of the Trade Secret Materials. *See* Court's Order of 12/21/06 granting the parties' Joint Motion For Entry Of A Protective Order. This Protective Order is extremely rigorous for the very reason that Roche, Amgen and this Court all recognized the great degree of sensitivity of documents such as the BLA and INDs and the trade secret information contained therein. In fact, the Protective Order restricts access to much of the Trade Secret Materials to the parties' outside counsel, and in-house counsel are only permitted access to the actual documents (whether in hard copy or electronic form) in a locked room. *See* Protective Order at ¶ 4. As such, public disclosure of these Materials would be completely inconsistent with the parties' Protective Order and would undermine the agreement the parties have reached that these Materials are highly sensitive and deserve the greatest protection possible.

Notwithstanding its recent assertions, Amgen cannot cut through the secrecy surrounding the Roche Trade Secret Materials by citing to public disclosures of unrelated or generalized information. *See* Amgen Opposition, p. 2 (Docket No. 186). That Roche participated in a conference call for industry analysts and discussed the general status of its Phase III studies does not justify Amgen's position that the actual underlying data of those studies – including private

patient data – and the detailed results of those studies should now be made publicly available. Similarly, the generalized description contained in Roche's prior pleadings regarding the manner in which its CERA drug is synthesized does not mean, as Amgen would have it, that the detailed specifications for the formulation of that drug, as well as the process for its purification and validation, is now in the public domain. Abstracts and summaries of the results of clinical trial results give the view of these studies from 30,000 feet – they do not give the highly detailed, instructive data and information which is contained in the Trade Secret Materials.

Finally, Amgen makes much of the fact that Roche has secured patent protection for certain inventions relevant to Roche's CERA drug, but as Amgen well knows, unlike much of the BLA and IND information contained in Roche's Trade Secret Materials, the disclosure in that patent does not give details of the synthesis, manufacture, purification, testing, production, or formulation of a specific commercial product. A patent discloses and claims a chemical compound, but the details of making a commercial product, such as the information contained in Roche's BLA, IND, and the exhibits at issue in this motion are protected trade secrets. In addition, a patent certainly does not contain the confidential strategy, marketing, and business information contained in the Trade Secret Materials.

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 its highly sensitive BLA and INDs and other 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.

III. Conclusion

For all the foregoing reasons, Roche respectfully requests that the Court order Amgen to file the Trade Secret Materials under seal, if at all, and that the Court enter the Proposed Order of Impoundment submitted concurrently with Roche's Motion.

DATED: Boston, Massachusetts
December 22, 2006

Respectfully submitted,

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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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