

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

**MEMORANDUM IN SUPPORT 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 in support of their motion, pursuant to Local Rule 7.2, 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

Roche’s emergency motion is necessary to further the prior orders and rulings of this Court relating to Roche’s highly sensitive and confidential FDA materials. The Court’s Orders of 11/06/06 (Docket No. 142) and 11/30/06 (Docket No. 159) require documents containing trade secrets to be filed under seal. The documents and information which Amgen seeks to file

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”).

in connection with its motion to compel are highly confidential to Roche and constitute trade secrets under Massachusetts law (“the Trade Secret Materials”). This Court has already ordered that the materials that are the subject of this motion be accorded special treatment in discovery in this action, recognizing the highly confidential and unique nature of this FDA information for a product still pending approval. As Amgen well knows, the media is closely watching this action. The Court’s prior rulings and statements recognized the prejudice and harm that can come from extremely sensitive and protected company information needlessly becoming public for purposes of speculation and media commentary. Amgen’s goal is to prevent CERA from reaching the market by any means possible, and it is therefore imperative that the Court grant Roche’s motion and prevent Roche’s most sensitive information from being disclosed prior to FDA action. Public filing would destroy the trade secret nature of the material, severely disrupt Roche’s ongoing efforts to obtain FDA approval of its new products, and violate FDA procedures for maintaining secrecy of applications for approval. Thus, Roche respectfully requests that the Court order Amgen to file these documents under seal to protect them from being filed in the public record, which would unfairly and unnecessarily reveal Roche’s valuable and highly protected trade secrets.

The Court, in the alternative, may direct Amgen to remove the Trade Secret Materials from its motion, so that they do not become part of the public record in this action. Although Roche does not believe the Trade Secret Materials are necessary for consideration of Amgen’s motion to compel, Roche does not object to *in camera* review or filing under seal, should the Court wish to consider them. Roche is not attempting to prevent the Court from reviewing the Trade Secret Materials, but Roche strenuously objects to placing these highly confidential

materials in the public record, which would disrupt Roche's FDA process and Roche's rights under that process, and which would undermine their trade secret status.

Trade Secret Materials at Issue

The Trade Secret Materials include excerpts from Roche's highly confidential Biologics License Application ("BLA") and from its two Investigational Drug Applications ("IND") for CERA, technical, financial or marketing documents relating thereto, clinical trials, two highly confidential deposition transcript excerpts from the prior proceeding between these parties on the same patents before the International Trade Commission ("ITC"), *In the Matter of Certain Products and Pharmaceutical Compositions Containing Recombinant Human Erythropoietin* ("ITC proceeding") and documents relating to Roche's accounting for certain imports into the United States.²

This Court has already entered several orders recognizing and then imposing restrictions on discovery relating to Roche's extremely sensitive and highly confidential materials concerning its still pending BLA and INDs and the related communications with the FDA. (Order of 7/12/06 granting Defendants' Motion for Leave to File Under Seal the Recent Decision of the ITC; Order of 8/15/06 granting Defendants' Motion for Leave to File ITC Papers Under Seal; Docket No. 142; Docket No. 159). This Court has already recognized the harm and prejudice to Roche's pending FDA process if information about those ongoing discussions is interfered with by Amgen's tactics. The Court has protected this process throughout this litigation and should continue to protect it here.

² 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.

Amgen attempts to circumvent this Court's rulings and undermine all of this Court's carefully crafted protections by blithely attaching excerpts of these highly sensitive documents to a motion to compel, particularly after the purported basis for using these documents was rendered moot by discussions with Roche attorneys. Amgen's intent is clear and this tactic is intended solely to unnecessarily burden the Court and to prejudice Roche with the threat of the publication of its admittedly sensitive Trade Secret Materials. That these particular materials are deserving of special handling has been acknowledged by Amgen itself in the negotiations and rulings surrounding the protective order and the ITC proceeding. Amgen's campaign to attach these documents as exhibits is particularly egregious in light of the fact that Roche already agreed to provide another copy of these materials (both in paper and electronic version) to Amgen, which effectively mooted the bases for these documents being appended as exhibits to Amgen's motion. Amgen still refused to remove them, and this meritless refusal underscores Amgen's lack of good faith.

More particularly, the Trade Secret Materials include the following:

- a) documents containing excerpts of or drafts from Roche's BLA and/or one of its two INDs for CERA (Exhibits 8, 19, 20, 21, 26, and 27 to the Carter Declaration);
- b) internal Roche documents of a technical, financial, or marketing nature pertaining to the development of CERA (Exhibits 6, 7, 9, 12, 13, 14, 15, and 16 to the Carter Declaration);
- c) documents containing excerpts of Dr. Cynthia Dinella's deposition in the ITC proceeding (Exhibits 23, 24, and 25 to the Carter Declaration);
- d) documents containing excerpts of Joanne Franzino's deposition in the ITC proceeding (Exhibit 11 to the Carter Declaration);

e) documents which reference Roche's system for accounting of EPO and PEG-EPO imported into the United States (Exhibit 28 to the Carter Declaration); and

(f) references to highly confidential information regarding Roche's clinical trials and to excerpts of the BLA and INDs in Amgen's Memorandum (pp. 9, 12-13) and the Carter Declaration (pp. 3-4, 9-16, 19-20).

I. The Trade Secret Materials Constitute Trade Secrets Under Massachusetts Law

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.). The Trade Secret Materials include excerpts from the BLA and INDs, which are the most sensitive documents in this case, as well as highly confidential internal Roche documents, and deposition testimony which was designated as "Confidential" or "Highly Confidential – Attorneys' Eyes' Only" under the Protective Order entered into in the ITC proceeding.⁴ As Roche's in-house counsel, Patricia Rocha-Tramaloni attests in the accompanying 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 Materials ("Rocha-Tramaloni Declaration"), Roche maintains the Trade Secret

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.

⁴ A copy of the ITC Protective Order and accompanying side letter agreement are collectively attached hereto as Exhibit A.

Materials in strict confidentiality and maintains close safeguards in the ordinary course of business to ensure that they do not become public⁵.

The Trade Secret Materials manifestly concern secret scientific, technical, production, design, process, procedure, formula, invention and improvement information and thus constitute trade secrets under Massachusetts law. Indeed, the Carter Declaration provides that Exhibit 8 is a “true and correct cop[ies] of a June 26, 2006 draft of Roche’s IND,” and that Exhibits 20 and 21 are “true and correct cop[ies] of “BLA pages” and an attachment to Roche’s “April 2006 BLA filing.” *See* Carter Decl. at 19-21. Information relating to filings and communications with the FDA, such as the BLA and the INDs, are not only inherently confidential, they are definitively trade secrets. *See* 21 C.F.R. § 601.51(d)(1) (if a BLA has not yet been approved “no data or information contained in the file is available for public disclosure before such license is issued”); *see also* Richard S. Fortunato, FDA Disclosure of Safety and Efficacy Data: The Scope of Section 301(j), 52 Fordham L. Rev. 1280, 1299 (1984) (citing Business Record Exemption of the Freedom of Information Act: Hearings Before a Subcomm. of the House Comm. on Gov't Operations, 95th Cong., 1st Sess. 93 at 70 (1977) (statement of Dr. Donald Kennedy, Comm'r, FDA) (“We have interpreted, since, 1938, the term ‘method [or] process which as a trade secret is entitled to protection’ under section 301(j) of [the Food, Drug, and Cosmetic Act] as encompassing animal and human testing data.”); McGarity & Shapiro, The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies, 93 Harv. L. Rev. 837, 862 & n.127 (1980) (citing cases holding safety and efficacy data to be trade secrets); Review Panel on New Drug Regulation, U.S. Dep't of Health, Educ. & Welfare, Final Report 33-34 at 33 (1977) (safety and efficacy data exempt from disclosure as trade secrets)).

⁵ *See* Rocha-Tramaloni Declaration at ¶¶ 4, 5, 6, 7, 22, and 23.

Further, the Dinella and Franzino depositions were already deemed by the ITC to be worthy of protection from public disclosure due to the secret scientific and technical nature of the testimony. These deponents discussed confidential preparations for (Franzino) and issues related to (Dinella) the FDA approval process which, by its very definition, is a secret procedure. Roche's current efforts in obtaining FDA approval for CERA would be seriously undermined if the Court were to allow these trade secrets to be publicly revealed.

II. Roche Has Taken All Possible Measures To Keep The Trade Secret Materials Confidential.

Trade secret status requires that reasonable steps be taken to keep the information confidential. Such steps may include the existence of an express agreement restricting disclosure, the nature and extent of security precautions taken, the circumstances under which the information was disclosed to the other party in the matter, and the degree to which the information has been placed in the public domain. *See Trent Partners and Associates*, 120 F. Supp. at 110-111. Roche has taken all proper and reasonable steps to keep the Trade Secret Materials from public disclosure. As Patricia Rocha-Tramaloni attests, it is standard company practice in the pharmaceutical industry to maintain information such as that contained in the Trade Secret Materials in the strictest confidence, and it is Roche's practice in the ordinary course of business to do so.⁶ Additionally, as discussed above, the parties here entered into an express agreement - the ITC Protective Order - restricting the disclosure of the Trade Secret Materials. The ITC Protective Order is extremely rigorous for the very reason that the parties and the tribunal recognized the great degree of sensitivity of documents such as the BLA and INDs. In fact, the ITC Protective Order not only shielded the Trade Secret Materials from public disclosure, it completely shielded the Materials from Amgen's in-house counsel. As such, the

⁶ See Rocha-Tramaloni Declaration, ¶¶ 4, 22 and 23.

only circumstances in which Roche has ever disclosed portions of this information to Amgen's outside counsel has been pursuant to the rigorous ITC Protective Order.

Roche has never allowed the portions of the BLA and INDs, as well as the other information that Amgen seeks to disclose, to enter the public domain and has taken all possible measures to ensure that it remains confidential.⁷ Thus, Roche has filed numerous motions to protect confidentiality of its highly sensitive materials and is presently completing negotiation of a protective order in this case to preserve confidentiality and to limit disclosure of its trade secrets to counsel solely for purposes of this litigation. Such efforts demonstrate Roche's efforts to preserve the confidentiality of the trade secrets contained in these documents. Moreover, Roche produced this information to Amgen many months ago (pursuant to the appropriate restrictions) when it became necessary for purposes of this litigation, which evidences Roche's willingness to cooperate while maintaining the confidentiality of its trade secrets. In the instant motion, Roche simply seeks to prevent these trade secrets from becoming public information by obtaining a Court order for filing under seal.

III. The Trade Secret Materials Confer An Economic Benefit

The Trade Secret Materials also have trade secret status because they derive independent economic value from not being generally known to or ascertainable by the public or others who can obtain economic value from their disclosure.⁸ *See Trent Partners and Associates*, 120 F. Supp. at 110-111. 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. Roche's CERA product is still undergoing FDA review, and indeed, FDA

⁷ At the 39th annual meeting of the American Society of Nephrology in San Diego on November 20, 2006, Roche disclosed a summary of positive results from their phase III clinical trials. Roche has no objection to that abstract being filed in the public record. However, no part of the BLA or IND has ever been disclosed in the public record. *See Rocha-Tramaloni Declaration*, ¶¶ 4, 22 – 25.

⁸ *See Rocha-Tramaloni Declaration*, ¶¶ 4, 24 – 25.

approval is the very crux of the economic benefit on which Roche's efforts are focused. Roche cannot sell its CERA product until the product is approved; thus, the highly confidential information contained in the documents pertaining to the FDA approval process, such as the BLA and INDs, is central to Roche's business. 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.

Public disclosure of the Trade Secret Materials would unfairly confer an economic benefit on Amgen, proving that the Materials are trade secrets. Amgen stands to derive an independent economic benefit from the disclosure of these documents. Amgen has monopolized the market for anemia drugs for over 20 years, and it has every motivation to prevent Roche from

entering this market as a top competitor. Amgen is well aware that disclosure of the Trade Secret Materials would disrupt Roche's efforts to obtain FDA approval. Thus, Amgen's strategy in seeking to file this material in the public domain is not simply to support its Motion to Compel, but in addition to force disclosure of Roche's highly protected Trade Secret Materials and thereby gain the economic advantage of maintaining its monopoly. If the Court were to allow Amgen to file the Trade Secret Materials in the public record, Amgen would have succeeded in its goal of impeding Roche's entry into the market.

IV. The Confidential Documents Amgen Seeks To File Are Not Necessary To The Court's Consideration Of Amgen's Motion to Compel

Finally, in weighing the benefit of the disclosure versus the burden of filing the Trade Secret Materials under seal, the balance tips significantly in favor of maintaining confidentiality because the Trade Secret Materials are not necessary to the Court's consideration of Amgen's Motion. Amgen has included several exhibits to the Carter Declaration and many references throughout the Memorandum regarding the details of the parties' discovery disputes. These exhibits and references, while making mention of the BLA and other confidential information, do not directly reveal Roche's Trade Secrets and are, for that reason, appropriate for disclosure in the public record. As stated above in Note 2, Roche has no objection to Amgen's filing of these materials. Yet, the inclusion of actual excerpts of the highly confidential BLA, INDs, internal Roche documents, and deposition testimony is completely unnecessary for the Court's attention and is extraneous to this motion practice. Amgen appears to be looking for a way to disclose this information in order to disadvantage Roche in its FDA approval process. Amgen has already filed redacted versions of its Memorandum and Declaration, which are sufficient and appropriate for its purpose in relaying the information the Court needs to decide this Motion. Roche respectfully requests that the Court consider the superfluous nature of these exhibits and

references in the context of the great harm that Roche would suffer should these Trade Secret Materials be disclosed in the public record.

V. 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.

CERTIFICATE PURSUANT TO LOCAL RULE 7.1

I certify that counsel for the parties have conferred in an attempt to resolve or narrow the issues presented by this motion and that Amgen stated it would not oppose this motion.

DATED: Boston, Massachusetts
December 18, 2006

Respectfully submitted,

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

By its Attorneys,

/s/ Nicole A. Rizzo

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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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