

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 DEFENDANTS’ MOTION FOR LEAVE TO FILE  
UNDER SEAL DOCUMENTS CONTAINING DEFENDANTS’ TRADE SECRETS  
SUBMITTED IN CONNECTION WITH AMGEN INC.’S MOTION FOR SUMMARY  
JUDGMENT ON ROCHE’S ANTITRUST AND STATE LAW COUNTERCLAIMS AND  
IN CONNECTION WITH ROCHE’S OPPOSITION THERETO**

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 and the Protective Order, to file under seal documents which contain Roche’s confidential and trade secret materials submitted for *in camera* review in connection with Amgen Inc.’s Motion for Summary Judgment on Roche’s Antitrust and State Law Counterclaims, filed on June 15, 2007<sup>1</sup> and in connection with Roche’s Opposition to Amgen Inc.’s Motion for Summary Judgment on Roche’s Antitrust and State Law Counterclaims, filed on June 29, 2007.<sup>2</sup>

<sup>1</sup> The documents Amgen seeks to file in the public record were submitted for *in camera* review as attachments to the Declaration of James M. Fraser in Support of Amgen Inc.’s Motion for Summary Judgment on Roche’s Antitrust and State Law Counterclaims (Docket No. 521).

<sup>2</sup> The documents Roche seeks to file under seal were submitted for *in camera* review on June 29, 2007 as attachments to the Declaration of David Cousineau in Support of Roche’s Opposition to Amgen Inc.’s Motion for Summary Judgment on Roche’s Antitrust and State Law Counterclaims, filed concurrently

As set forth in greater detail below and in the accompanying declarations of Sonders Beimfohr (“Beimfohr Decl.”), Steven Platt (“Platt Decl.”), Chrys Kokino (“Kokino Decl.”), and Krishnan Viswanadhan (“Viswanadhan Decl.”), Amgen Exhibits 1, 2, 5, 7-9, 11-18, 20-23, 25-30, 33, 35-37, 41, 53, 59, 61, and 62 (collectively, the “Amgen Exhibits”) and Roche Exhibits 6-12, 21, 27, 31, 32, 34, 40, 43, 45-49, 64, 78-82, 84, 85, 122, 124-126, 139, 157, 162, 163, 166, 167, 185, 214, 215, 219, 220, 222, 223, 232, 244, 245, 249, 250, 253, and Exhibit A to the Declaration of Susan Graf, dated June 19, 2007 (collectively, “the Roche Exhibits,” and together with the Amgen Exhibits, the “Exhibits”), contain highly confidential and trade secret information related to Roche’s pricing and marketing models for Mircera® and its Biologics License Application (“BLA”) and Investigational New Drug Application (“IND”).<sup>3</sup> The materials that Roche is requesting to be filed under seal thus contain invaluable trade secrets concerning such details as its pricing and marketing forecasts, assumptions, and calculations for Mircera®, the chemical makeup and manufacture of Mircera®, its clinical studies of Mircera®, and its communications with the FDA related thereto. For these reasons, Roche considers this information to be trade secrets 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 assist Roche’s competitors in preventing Roche from entering the market. The disclosure of these documents in the public record would reveal Roche’s invaluable trade secrets and cause irreparable damage to Roche. For these reasons, Roche requests that both the Amgen Exhibits and the Roche Exhibits — and the trade secret information from the exhibits

---

<sup>3</sup> In the accompanying declarations, Mr. Beimfohr, Mr. Platt, Mr. Kokino, and Dr. Viswanadhan offer particularized testimony regarding the trade secret status of each Exhibit. Dr. Viswanadhan’s Declaration was filed with the Court on June 28, 2007 (Docket No. 562).

contained in Amgen's accompanying memorandum of law and statement of facts and in Roche's accompanying memorandum of law and response to Amgen's statement of facts — be filed under seal if the Court determines that they are necessary for its determination of the underlying motion.

While Roche maintains all of the documents submitted for *in camera* review are confidential, in light of the Court's requirement that only trade secrets be filed under seal, it has limited the present motion to the Amgen and Roche Exhibits listed above. To the extent that the Court finds any exhibit (or portion of an exhibit) to be unnecessary in its determination of the underlying motion, Roche respectfully requests that it not be filed at all, whether in the public record or under seal.

#### **I. The Exhibits Contain 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 or management information, design, process, procedure, formula, invention or improvement.” M.G.L. ch. 266 § 30(4);<sup>4</sup> *see Trent Partners and Associates, Inc. v. Digital Equipment Corp.*, 120 F. Supp. 2d 84, 100 (D. Mass. 1999) (Woodlock, J.); *CVD, Inc. v. Raytheon Co.*, 769 F.2d 842, 850 (1st Cir. 1985) (citing *Eastern Marble Prods. Corp. v. Roman Marble, Inc.*, 372 Mass. 835, 839 (1977)); *SI Handling Sys., Inc. v. Heisley*, 753 F.2d 1244, 1260 (3d Cir. 1985) (holding that internal information related to pricing and profit margin “qualifies for trade secret protection” and “is not information that is readily obtainable by anyone in the industry”); *Corporate Relocation, Inc. v. Martin*, 2006 U.S. Dist. LEXIS 69098, at \*61 (N.D. Tex. Sept. 12, 2006) (holding price information warrants

---

<sup>4</sup> 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.

protection from public disclosure); *In re Gabapentin Patent Litig.*, 312 F. Supp. 2d 653, 659 and 667 (D.N.J. 2004) (affirming magistrate judge's holding that "the parties' products, research and development, processes, secret chemical formulas, [and] the parties' suppliers" constituted "clearly protectable and highly confidential trade secrets" in pharmaceutical patent case). As asserted by the declarants, the Exhibits concern secret business and scientific information belonging to Roche which, if revealed, would cause irreparable harm to Roche. *See* Beimfohr Decl. at ¶¶ 6-9; Platt Decl. at ¶¶ 7-8; Kokino Decl. at ¶¶ 6-8; and Viswanadhan Decl. at ¶¶ 7-8

## **II. The Trade Secret Information In The Exhibits Remains Confidential**

Trade secret status requires that reasonable steps be taken to keep the information confidential. *Trent Partners*, 120 F. Supp. 2d at 111. Here, Roche has never allowed the material in the Exhibits to enter the public domain and has taken all feasible measures to ensure that the information contained therein remains confidential. *See* Beimfohr Decl. at ¶¶ 4, 10; Platt Decl. at ¶ 4; Kokino Decl. at ¶ 4; and Viswanadhan Decl. at ¶ 5.

## **III. If The Trade Secret Information In The Exhibits Were Revealed Publicly, Roche Would Be Irreparably Harmed**

### **A. Public Disclosure of Roche's Highly Confidential Pricing Strategy Would Cause Roche Irreparable Harm**

Amgen Exhibits 5, 13, 15-17, 25, 27, and 35-37, and Roche Exhibits 9-12, 21, 27, 30-32, 34, 40, 49, 64, 84, 85, 126, 214, and 215 to Roche's Opposition relate to Roche's confidential and secret proprietary pricing strategy for Mircera®. The cornerstone of Roche's pricing strategy is its proprietary pricing model, which is a mathematical representation of the market which Roche uses to predict market behavior. Roche expends significant effort and resources designing and testing its proprietary pricing model, including the substantial time and effort it spends conducting market and branding research. Roche's method of setting price is more

thorough and detailed than its competitors, and thus more capable of finding and setting the optimal price for Roche's product. The Exhibits disclose details such as Roche's pricing forecasts, anticipated discounts, anticipated profit margins, cost of goods sold, and incremental costs of Mircera®. This proprietary information has not been disclosed to the public in any form, and confers on Roche a competitive advantage that must be protected from public disclosure. Beimfohr Decl. at ¶¶ 4, 8.

Roche's competitive position would severely be harmed if any of the sensitive trade secret information in the Exhibits regarding Roche's proprietary pricing model for Mircera® were made available to Roche's competitors in the highly competitive pharmaceutical industry. Were Roche's competitors to know with certainty the range of prices under consideration for Mircera® before Roche received FDA approval, they would be able to initiate specific, concrete steps in relation to their own price and marketing efforts to blunt Roche's entry into the market, which would potentially cost Roche millions of dollars. Beimfohr Decl. at ¶ 6.

In addition, Roche would be harmed if competitors had access to Roche's proprietary pricing model. With its pricing model, competitors could derive Roche's highly sensitive price projections for Mircera®. Moreover, the pricing model contains Roche's internal analysis and research regarding the marketplace. Beimfohr Decl. at ¶ 7.

Furthermore, the public disclosure of Roche's pricing model would destroy the competitive advantage that Roche gains from the proprietary trade secret methodology it uses to create its pricing model. Roche's approach to pricing, which is used across the company for other products in addition to Mircera®, provides to Roche a significant advantage in the highly competitive markets in which it competes. The disclose of its proprietary pricing models,

however, would teach competitors how to construct similar pricing models, thereby destroying Roche's advantage. Beimfohr Decl. at ¶ 8.

Finally, the public release of the sensitive confidential information contained in the Exhibits would harm Roche's business relationships with potential customers. If Roche's customers were armed with detailed knowledge of Roche's profit margin and the anticipated discounts built into its pricing strategy, they would have undue leverage when negotiating their purchasing contracts with Roche, which would unfairly prejudice Roche's competitive position in the marketplace. Beimfohr Decl. at ¶ 9.

Given the severe harm that would befall Roche if this sensitive pricing model information was released to the public, the Exhibits containing this information should not be disclosed in the public record.

**B. Public Disclosure of Roche's Highly Confidential OPAC Statements Would Cause Roche Irreparable Harm**

Amgen Exhibits 5, 8, 9, 11, 12, and 29 relate to Roche's confidential and secret Operating Profit After Capital Charge ("OPAC") statement. Roche's OPAC statement is created to provide Roche management an estimate of the economic value associated with particular brands. OPAC statements have been created for Mircera® based on projections of sales and costs, and are subdivided into statements for the dialysis market and the non-dialysis market based upon allocations of, as applicable, budgeted, actual and anticipated costs and revenues. This proprietary information has not been disclosed to the public in any form, and confers on Roche a competitive advantage that must be protected from disclosure. Platt Decl. at ¶¶ 5-6.

A competitor with access to Roche's OPAC statements or documents relating to these statements would have the ability to use this information against Roche in the market by tailoring its own pricing and marketing strategies based on Roche's internal figures. Because competitors

will be privy to Roche's pricing and marketing strategies if this document or its contents is revealed publicly, they will be able to make adjustments to their own pricing and marketing strategies before Roche enters the market, which will have a strong negative effect on Roche's future sales. Placing this confidential information in the hands of Roche's competitors would therefore be extremely harmful to Roche. Platt Decl. at ¶ 7.

Roche would further be harmed if its OPAC statements or its contents were revealed in the public record because it would interfere with Roche's contractual and business relations. More specifically, Roche would lose its basic ability to negotiate if its customers had access to information such as Roche's cost, pricing, and discounting strategies. Platt Decl. at ¶ 8.

Given the severe harm that would befall Roche if this sensitive information regarding Roche's OPAC statements was released to the public, the Exhibits containing this information should not be disclosed in the public record. Platt Decl. at ¶ 9.

**C. Public Disclosure of Roche's Highly Confidential Marketing Strategy Would Cause Roche Irreparable Harm**

Amgen Exhibits 2, 5, 14, 17, 18, 26, 28, 30, 33, and 41, and Roche Exhibits 8, 12, 21, 27, 43, 45, 46, 47, 48, 79, 80, 81, 82, 84, 85, 122, 124, 125, 126, 139, 157, 162, 163, 167, 185, 219, 220, 222, 232, 244, 245, 249, 250, 253 and Exhibit A to the Declaration of Susan Graf, dated June 19, 2007 relate to Roche's confidential and secret marketing strategy for breaking into the market. These Exhibits disclose information regarding Roche's marketing strategy, including details such as Roche's market assumptions, forecasting, marketing expenditures, customer and market segmentation, and its analysis and methodology for making these determinations. This proprietary information has not been disclosed to the public in any form, and confers on Roche a competitive advantage that must be protected from public disclosure. Kokino Decl. at ¶¶ 4.

Roche's competitive position would be harmed severely if any of the sensitive trade secret information regarding its internal marketing strategies were disclosed publicly. If this information is made public, Roche's competitors will be able to adjust their own marketing strategies before Roche even enters the market, which could have a strong negative impact on Roche's future sales. Giving this confidential information to Roche's rivals would thus cause a great deal of harm to Roche. Kokino Decl. at ¶ 6.

Indeed, armed with invaluable knowledge of the precise markets and customers Roche intends to target, Roche's competitors would likely focus their energies on securing dominance in those areas by entering into agreements with their current customers that would significantly, if not completely, prevent Roche from entering the market. For example, competitors may seek exclusivity agreements or lucrative research and development partnerships with those particular customers known to be targeted by Roche. Kokino Decl. at ¶ 7.

Roche would further be harmed if this information were revealed in the public record because competitors could also take additional steps to exclude Roche from the market. For instance, competitors could adjust their current contracts with customers known to be targeted by Roche to create disincentives for those customers to purchase from Roche by. Competitors may also tie up particular customers of interest to Roche with clinical trials, during which periods those customers would not be able to purchase Roche's products. Kokino Decl. at ¶ 7.

In addition, the public release of the sensitive confidential information contained in the Exhibits listed above would harm Roche's bargaining position in its contract negotiations with potential customers. If Roche's customers are armed with detailed knowledge regarding Roche's profit margin and the potential discounts that are built into its pricing strategy, they would have undue leverage when negotiating their purchasing contracts with Roche. Kokino Decl. at ¶ 8.



Given the severe harm that would befall Roche if this sensitive marketing information was released to the public, the exhibits containing this information should not be disclosed in the public record. Kokino Decl. at ¶ 9.

**D. Public Disclosure of Roche's Highly Confidential BLA and IND Would Cause Roche Irreparable Harm**

Exhibits 6, 7, 166, and 223 to Roche's Opposition relate to highly sensitive, confidential trade secret information belonging to Roche, including information from confidential internal Roche documents regarding both the preclinical and clinical testing for Roche's Mircera®, and highly confidential Roche communications with the FDA.

The exhibits listed above include documents that have been submitted to the FDA as part of Roche's highly confidential BLA and INDs. Pursuant to FDA policy and Roche company policy, the BLA and IND 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). Furthermore, pursuant to Roche company policy, all of these exhibits, the information contained in these exhibits, and any communications involving these exhibits and their information are maintained in confidence and secrecy. Disclosure of these exhibits in the public record would destroy the trade secret status of the information contained therein and irreparably harm Roche in the highly competitive pharmaceutical industry. Viswanadhan Decl. at ¶ 5.

Roche would be harmed if the data from its preclinical and clinical studies, and Roche's analysis of that data, were publicly disclosed at the level of detail contained within the exhibits listed above. The results of Roche's preclinical and clinical studies, and Roche's analysis of those results, reveal critical information regarding Mircera®, including specific information regarding its effectiveness, potency, biological activity, and toxicity. Competitors, including

generic drug manufacturers in jurisdictions without adequate patent protection, could use this information in designing and qualifying competing products. Furthermore, Roche invests a great deal of resources during its rigorous preclinical and clinical testing regimens to gather the necessary data, which are expenditures a competitor could forego if they had direct access to Roche's data and analysis. Thus, Roche would be harmed in the highly competitive pharmaceutical market were this information to be disclosed. Viswanadhan Decl. at ¶ 7.

Roche would also be harmed by the disclosure of the methodology and results of the preclinical and clinical studies that it has conducted on Mircera®. In addition to the expense of conducting the experiments, Roche expends significant resources designing specific parameters for its proprietary preclinical and clinical studies to maximize the efficiency of the studies and the reliability of the results. Roche also expends significant resources in designing its overall clinical and preclinical regimens to maximize the efficiency and speed of its drug development process. The public disclosure of the information contained in the exhibits listed above would thus unfairly benefit Roche's competitors, such as generic drug manufacturers, who could use it to copy Roche's proprietary studies, thereby avoiding the expense Roche has incurred in developing its own preclinical and clinical protocols. Viswanadhan Decl. at ¶ 8.

Given the severe harm that would befall Roche if this sensitive scientific information were released to the public, the exhibits containing this information should not be disclosed in the public record. Viswanadhan Decl. at ¶ 5.

### **Conclusion**

For all the foregoing reasons, Roche respectfully requests that the Exhibits be accepted for filing under seal.

DATED: Boston, Massachusetts  
June 29, 2007

Respectfully submitted,

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

*By its Attorneys,*

/s/ Keith E. Toms

Lee Carl Bromberg (BBO# 058480)  
Julia Huston (BBO# 562160)  
Keith E. Toms (BBO# 663369)  
Nicole A. Rizzo (BBO # 663853)  
BROMBERG & SUNSTEIN LLP  
125 Summer Street  
Boston, MA 02110  
Tel: (617) 443-9292  
[ktoms@bromsun.com](mailto:ktoms@bromsun.com)

Leora Ben-Ami (*pro hac vice*)  
Mark S. Popofsky (*pro hac vice*)  
Patricia A. Carson (*pro hac vice*)  
Thomas F. Fleming (*pro hac vice*)  
Howard S. Suh (*pro hac vice*)  
Peter Fratangelo (BBO# 639775)  
KAYE SCHOLER LLP  
425 Park Avenue  
New York, NY 10022  
Tel: (212) 836-8000

### **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/ Keith E. Toms

Keith E. Toms

03099/00501 696605.1