

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

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AMGEN INC., )  
 )  
 Plaintiff, )  
 )  
 v. )  
 )  
 F. HOFFMANN-LA ROCHE LTD, )  
 ROCHE DIAGNOSTICS GMBH, )  
 and HOFFMANN-LA ROCHE INC., )  
 )  
 Defendants. )

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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 STRIKE ROCHE’S NON-INFRINGEMENT, INVALIDITY, AND INEQUITABLE CONDUCT ALLEGATIONS DISCLOSED AFTER THE CLOSE OF FACT DISCOVERY OR, IN THE ALTERNATIVE, MOTION FOR LEAVE TO SUPPLEMENT AMGEN’S EXPERT REPORTS AND MOTION FOR PROTECTIVE ORDER TO POSTPONE DEPOSITIONS OF CERTAIN WITNESSES**

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, to file under seal documents which contain Roche’s confidential and trade secret materials submitted for *in camera* review by Amgen if the Court deems them necessary for its ruling on Amgen’s Motion to Strike Roche’s Non-Infringement, Invalidity, and Inequitable Conduct Allegations Disclosed After the Close of Fact Discovery or, in the Alternative, Motion for Leave to Supplement Amgen’s Expert Reports and Motion for Protective Order to Postpone Depositions of Certain Witnesses (Docket No. 447).<sup>1</sup> The present motion relates solely to the confidentiality of

<sup>1</sup> The documents Amgen seeks to file in the public record were submitted for *in camera* review on May 24, 2007 and correspond to Exhibits 4-10 of Amgen’s Declaration of Mario Moore in Support of Plaintiff Amgen Inc.’s

Amgen's motion papers; as to the substantive issues, Roche will file its opposition to Amgen's motion on or before the deadline of June 7, 2007.

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. If the Court determines that some or all of these exhibits are necessary for its decision, however, Roche requests that Exhibits 9 and 10 be filed under seal to protect Roche trade secrets contained in these documents.

### **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. If the Court determines that some or all of these exhibits are necessary for its decision, however, Roche requests that Exhibits 9 and 10 be filed under seal to protect Roche trade secrets contained in these documents.<sup>2</sup>

As set forth in greater detail below and in the accompanying declaration of Dr. Hans Koll, Research Leader at Roche Diagnostics GmbH ("Koll Declaration"), the Roche documents which Amgen seeks to file in the public record ("the Trade Secret Materials") are excerpts of Roche's highly confidential expert reports of Dr. Barbara Imperiali and Dr. Richard Flavell.

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Motion to Strike Roche's Non-Infringement, Invalidity, and Inequitable Conduct Allegations Disclosed After the Close of Fact Discovery or, in the Alternative, Motion for Leave to Supplement Amgen's Expert Reports and Motion for Protective Order to Postpone Depositions of Certain Witnesses (Docket No. 447).

<sup>2</sup> 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 4-8 and Appendix A being filed in the public record if the Court determines that they are necessary to decide Amgen's motion.

Thus, the materials which Roche is requesting to be filed under seal contain invaluable trade secrets concerning the details of internal Roche studies conducted in Germany and the results of those studies. For this reason, Roche considers them 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 facilitate Roche's competitors in developing and introducing competing drugs. 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 4-10 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. Amgen's primary argument in the underlying motion to strike is that Roche has allegedly caused discovery delays and improperly supplemented its expert reports. The Court does not need to review the details of highly confidential Roche studies contained in these expert reports in order to determine the appropriateness of Roche's supplemental reports and whether Amgen had sufficient time to respond.

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 9 to the Moore Declaration**

Exhibit 9 is an excerpt from the expert report of Dr. Richard Flavell, submitted by Roche in connection with the present litigation on May 11, 2007. As Dr. Koll attests, this report contains highly confidential information which is internal to Roche and is not made public. This is particularly true of paragraphs 167 and 168, which contain highly confidential and trade secret information about internal Roche studies in which Dr. Koll was involved. These studies were conducted in Germany for the purpose of characterizing the biological activity of CERA and were conducted at the time for internal Roche scientific use only. According to Dr. Koll, compositions and testing methods used in these studies are internal to Roche and have never been publicly disclosed. Public disclosure of the details of these studies provided in paragraphs 167 and 168 would be extremely harmful to Roche if revealed because, for example, the information could be used by a competitor to develop competing products. This information constitutes a trade secret which must not be disclosed in the public record. *See* Koll Declaration, ¶ 4.

**B. Exhibit 10 to the Moore Declaration**

Exhibit 10 is an excerpt from the expert report of Dr. Barbara Imperiali, submitted by Roche in connection with the present litigation on May 11, 2007. As asserted by Dr. Koll, this report contains highly confidential information which is internal to Roche and is not made public. This is particularly true of paragraphs 128-130, 133-137, 139-144 and 179, which contain highly confidential and trade secret information about internal Roche studies in which

Dr. Koll participated. These studies were conducted in Germany for the purpose of characterizing the biological activity of CERA and were conducted at the time for internal Roche scientific use only. As Dr. Koll attests, compositions and testing methods used in these studies are internal to Roche and have never been publicly disclosed. Public disclosure of the details of these studies provided in paragraphs 128-130, 133-137, and 139-144 would be extremely harmful to Roche if revealed because, for example, the information could be used by a competitor to develop competing products. This information constitutes a trade secret which must not be disclosed in the public record. *See* Koll Declaration, ¶ 5.

### **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).<sup>3</sup> *See Trent Partners and Associates, Inc. v. Digital Equipment Corp.*, 120 F. Supp. 2d 84 (D. Mass. 1999) (Woodlock, J.). As asserted by Dr. Koll, the Trade Secret Materials at issue concern secret scientific information belonging to Roche which, if revealed, would cause irreparable harm to Roche. *See* Koll Declaration at ¶ ¶ 4-5.

#### **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

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<sup>3</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.

public domain and has taken all possible measures to ensure that the information contained therein remains confidential. *See* Koll Declaration at ¶¶ 4-5.

**C. If The Trade Secret Materials Were Revealed, Competitors Develop Competing Products and Misappropriate Roche's Trade Secrets.**

The Trade Secret Materials relate to studies of the biological activity 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. 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 9 and 10 be filed under seal to protect Roche's trade secrets.

**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 counsel for Amgen does not assent.

DATED: Boston, Massachusetts  
June 5, 2007

Respectfully submitted,

F. HOFFMANN-LA ROCHE LTD,  
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HOFFMANN-LA ROCHE INC.

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**CERTIFICATE OF SERVICE**

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non registered participants on the above date.

/s/ Nicole A. Rizzo

Nicole A. Rizzo

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