

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 ROCHE’S MOTION FOR LEAVE TO FILE
UNDER SEAL DOCUMENTS CONTAINING DEFENDANTS’ TRADE SECRETS
SUBMITTED IN CONNECTION WITH THE PENDLETON AND GALVIN
DECLARATIONS**

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 select portions of three documents under seal that contain Roche’s confidential and trade secret materials if the Court deems these select portions necessary for its ruling on the matters before it.

Introduction

As set forth in greater detail below and in the accompanying declaration of Susan Batcha, (“Batcha Decl.”), Pendleton Exhibits 36 and 48 and Galvin Exhibit 1 (collectively, “the Exhibits”) are excerpts from the highly confidential Chemistry, Manufacturing and Controls section of Roche’s BLA which contain sensitive, trade secret information relating to Roche’s proprietary cell line and growth media, and specific quantitative data regarding the positional

isomers of CERA. Roche considers the information in these documents to be trade secrets and has consistently and vigilantly guarded their secrecy.

Of the twenty-two (22) Roche confidential documents submitted for *in camera* review in connection with the Pendleton and Galvin declarations, Roche has limited its present motion to portions of three (3) documents which contain especially sensitive Roche trade secrets. Attached as Exhibit A, B, and C are redacted public versions of the Exhibits that omit only the most sensitive Roche trade secret information. Roche believes that the omitted information is unnecessary for the Court's ruling on the motions before it, and thus Roche respectfully requests that the Court accept the redacted public versions of these documents instead of the documents which contain Roche's trade secrets. To the extent that the Court requires the omitted information, however, Roche respectfully requests that the trade secret versions of these documents be filed under seal.

I. The Exhibits Contain Information Which Is Not Publicly Known and Which Would Cause Irreparable Harm To Roche If Revealed

A. Pendleton Exhibit 36

Pendleton Exhibit 36 is an excerpt from the CMC section of Roche's highly confidential BLA entitled *Control of Materials: Identity of the Working Cell Bank (WCB) 29/04.93: Phenotypic Analysis*. The redacted portions of this document contain highly detailed technical information regarding the properties of the cell line used in connection with Roche's formulation of Mircera. For example, it gives numerical values of the growth and productivity of the cell line. It also provides specific information regarding treatments these cells have undergone. Roche has spent a great deal of time and resources optimizing and perfecting its cell line, and this information has never been disclosed publicly. Roche would be irreparably harmed if the details contained in Exhibit 36 regarding the capabilities and productivity of Roche's cell line

were publicly disclosed because generic drug manufactures and other competitors would be able to follow Roche's procedures without having to duplicate Roche's research and development efforts. Thus, the public disclosure of these trade secret portions of Exhibit 36 would be harmful to Roche's ability to compete in the market. *See* Batcha Decl. at ¶ 6.

B. Pendleton Exhibit 48

Pendleton Exhibit 48 is an excerpt from the CMC section of Roche's highly confidential BLA entitled *Description of Manufacturing Process and Process Controls: Detailed Description of the Epoetin Beta Fermentation Process*. The portions redacted from this exhibit contain highly detailed technical information regarding the manufacture of the Epoetin beta starting material. For example, it gives specific information regarding the proprietary chemical formulation of the medium in which Roche's cell line is cultured. Roche has spent a great deal of time and resources optimizing and perfecting the combination and precise concentrations of ingredients in its cell culture media. This information has never been disclosed publicly, and, indeed, many of the ingredients in Roche's media are not commonly found in other cell growth media. Roche would be irreparably harmed if the redacted portions of Exhibit 48 were publicly disclosed because generic drug manufactures and other competitors would learn the formula for Roche proprietary cell media, which they could copy or use to optimize their own media, thereby eliminating Roche's competitive advantage. *See* Batcha Decl. at ¶ 7.

C. Galvin Exhibit 1

Galvin Exhibit 1 is an excerpt from the CMC section of Roche's highly confidential BLA entitled *Elucidation of Structure — Summary: Evidence of Structure*. The redacted tables from this document contain specific trade secret data regarding the distribution of positional isomers in CERA, which has never been disclosed at this level of detail. Were it publicly disclosed,

Roche's competitors could use this data to facilitate their own efforts of synthesizing a generic version of CERA. It would also give them some key information they require in order to design the process by which unwanted isomers are purified from the formulation. Thus, the public disclosure of the specific data contained in this document would harm Roche's ability to profit from its years of development and research. *See* Batcha Decl. at ¶ 8.

II. The Trade Secret Versions of the Exhibits Should Not Be Accepted for Filing in the Public Record or Otherwise If They are Unnecessary To The Court's Decision

Roche has a great deal of valuable trade secret information that is implicated by this lawsuit. Unlike Amgen, however, Roche's participation isn't voluntary. Although Roche understands that, due to the public nature of this proceeding, some of its sensitive internal information may inevitably be disclosed, it would be fundamentally unfair to destroy the value of these most sensitive trade secrets when they are unnecessary to the motions before the Court. Arthur R. Miller, *Confidentiality, Protective Orders, and Public Access to the Courts*, 105 Harv. L. Rev. 427, 470 (1991) ("A business entity caught up in litigation simply must assume the risk of disclosure; its best — indeed, its only — hope of protecting its property is the court's willingness to exert its full authority to prevent further dissemination of the information.").

Thus, to the extent that the Court decides the pending motions before it on other grounds or finds that it does not require the trade detailed technical information that has been redacted from the public versions of the Exhibits, Roche respectfully requests that the Court not accept the trade secret versions of these documents for filing at all. Furthermore, Roche in particular believes that the trade secret information contained in Galvin Exhibit 1 is not necessary to the Court for the reasons set forth in Roche's Emergency Motion to Strike Portions of Eight Exhibits Containing Roche Manufacturing Trade Secrets that are Not Necessary for Amgen's Infringement Motions or in the Alternative to Seal these Select Exhibits (Docket No. 720).

III. The Exhibits Are Trade Secrets Under Massachusetts Law And Should Not Be Filed In The Public Record

A. The Exhibits 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).¹ *See Trent Partners and Associates, Inc. v. Digital Equipment Corp.*, 120 F. Supp. 2d 84 (D. Mass. 1999) (Woodlock, J.). As asserted by Ms. Batcha, the Exhibits contain secret scientific data and formulas belonging to Roche, which, if revealed, would cause irreparable harm to Roche. *See* Batcha Decl. at ¶¶ 4-8.

B. The Exhibits Remain Confidential

Trade secret status requires that reasonable steps be taken to keep the information confidential. Here, Roche has never allowed the Exhibits to enter the public domain and has taken all possible measures to ensure that the information contained therein remains confidential. *See* Batcha Decl. at ¶¶ 6-8.

C. If The Exhibits Were Revealed Publicly, Competitors Develop Competing Products and Misappropriate Roche’s Trade Secrets

The Exhibits 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 Exhibits would destroy the economic advantage that Roche has as a company in the position of creating a new drug. Roche would be irreparably harmed if the Exhibits were made public because they contain information that Roche’s competitors — such as generic

¹ 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.

manufacturers in jurisdictions without adequate patent protection — could use to develop a product identical to Mircera. Public disclosure of this information 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 Mircera. *See* Batcha Decl. at ¶¶ 4–8.

In addition, Roche would also be harmed if the information contained in the Exhibits relating to the its proprietary manufacturing process and cell line were made public. Roche commits significant resources in optimizing its manufacturing process by experimenting with different ratios and formulations of its cell culture medium. These optimized processes give Roche a significant competitive advantage by increasing the yield and potency of its product. The disclosure of this secret formula, however, would allow Roche's competitors to use the fruits of Roche's labor to optimize their own manufacturing processes, thereby destroying Roche's competitive advantage. *See* Batcha Decl. at ¶ 4–8.

Thus, if the Court finds the Exhibits necessary to its decision, then Roche respectfully asks that the Exhibits be filed under seal.

Conclusion

For all the foregoing reasons, Roche respectfully requests that the trade secret portions of the Exhibits not be accepted for filing because they are not necessary to the disposition of Roche's motion. However, if the Court deems them necessary, then Roche requests that the Court grant Roche's motion to file these documents under seal.

DATED: Boston, Massachusetts
July 16, 2007

Respectfully submitted,

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

By their Attorneys,

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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/ Keith E. Toms

Keith E. Toms

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