

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.)	

**DECLARATION OF SUSAN BATCHA 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**

I, Susan Batcha, hereby declare that:

1. I am the Program Director for Chemistry, Manufacturing, and Controls for Hoffmann-La Roche Inc. (“Roche”). I have been an employee of Roche since February 26, 2001. My educational background includes a BS in Medical Technology from Kent State University.

2. I make this declaration based upon my own personal knowledge and company information.

3. I have been asked to examine documents which correspond to Exhibits 36 and 48 of the Declaration of Cullen N. Pendleton in Support of Amgen’s Opposition to Roche’s Motion for Summary Judgment That Claim 7 of Patent No. 5,756,349 Is Invalid Under 35 U.S.C. § 112 and Is Not Infringed (Docket No. 628), which were submitted to the Court for *in camera* review on July 5, 2007. I have also been asked to examine a

document which corresponds to Exhibit 1 of the Declaration of Robert M. Galvin in Support of Amgen Inc.'s Reply in Support of Its Motion for Summary Judgment of Infringement of '422 Claim 1, '933 Claim 3, and '698 Claim 6 (Docket No. 665), which was submitted for *in camera* review on July 9, 2007. I have been asked to review these documents to determine whether they contain information regarded as trade secret by Roche.

4. The Pendleton and Galvin Exhibits are taken from, or incorporate information from, the *Chemistry, Manufacturing, and Controls* ("CMC") section of Roche's highly confidential BLA for Mircera®, which contains specific detailed information regarding the proprietary chemical composition and the manufacturing process for Mircera. To obtain regulatory approval, the FDA requires that the CMC section describe in exacting detail the "recipe" for Mircera®, including the steps taken to insure the quality of the finished product, as well as a complete list of the specifications for each component of the process. Thus, the CMC section is required to contain Roche's most closely guarded trade secrets, such as detailed descriptions regarding Roche's manufacturing process and process controls for Mircera. Indeed, this is one of the principal reasons why the confidentiality of the BLA is insured by law. This highly sensitive, confidential information is the culmination of years of effort in the drug development process. It is the core of Roche's development efforts for Mircera.

5. I have done a detailed review of the Pendleton and Galvin Exhibits, and in the paragraphs below I have set forth a description of the highly sensitive information contained in these documents that is confidential and trade secret to Roche.

6. 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*, which contains 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.

7. 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*, which contains 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 Exhibit 48 were publicly disclosed because generic drug manufacturers 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.

8. Galvin Exhibit 1 is an excerpt from the CMC section of Roche's highly confidential BLA entitled *Elucidation of Structure — Summary: Evidence of Structure*. This document contains 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.

9. Roche deems it necessary to maintain the confidentiality of the information contained in the Exhibits in order to safeguard its trade secrets and competitive business information and to avoid giving a competitive advantage to competitors or other who might use the information to the detriment of Roche's business.

10. Disclosure of the 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. Accordingly, it is of critical importance that

the Exhibits, which contain Roche's highly confidential trade secret information, not be disclosed.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on: July 16, 2007

/s/ Susan Batcha
Susan Batcha

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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