

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC.,)
)
)
 Plaintiff,)
)
 vs.)
)
 F. HOFFMANN-LA ROCHE LTD,)
 ROCHE DIAGNOSTICS GMBH,)
 AND HOFFMANN-LA ROCHE INC.,)
)
 Defendants)

CIVIL ACTION No.: 05-CV-12237WGY

DEFENDANTS’ EMERGENCY MOTION TO PRECLUDE AMGEN FROM PUBLICLY DISCLOSING ROCHE’S TRADE SECRETS WITHOUT PRIOR NOTICE TO ROCHE

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively “Roche”) respectfully submit this Emergency Motion to Preclude Amgen from Publicly Disclosing Roche’s Trade Secrets Without Prior Notice to Roche.

A. Amgen Misinterprets This Court’s Statements to Give Amgen “Carte Blanche” To Publicly Disclose Roche’s Trade Secrets As It Sees Fit

Amgen’s stated intention to “discuss and use excerpts from Roche’s BLA and/or IND in its infringement opening statement as well as the rest of [its] case-in-chief on infringement” in light of the Court’s statement that “[e]verything further in this trial is on the record” is a grave misinterpretation of the Court’s directive and will subject Roche to irreparable harm and a denial of its due process rights. *See* Letter from R. Brown to T. Fleming, dated September 29, 2007, attached hereto as Exhibit A; Letter from T. Fleming to R. Brown, dated September 30, 2007, attached hereto as Exhibit B. During the trial proceedings last Thursday, the Court stated the following during a sidebar conference on a topic unrelated to Roche’s BLA or IND:

“I take grave umbrage to the fact that a deposition was designated confidential. And this business of giving me confidential documents stops right now. Everything further in this trial is on the record.”

Trial Transcript at 1656:20-23 (September 27, 2007), attached hereto as Exhibit C.¹ Amgen apparently interprets this statement to completely vitiate the Amended Protective Order (D.N. 274) instituted in this case and the Court’s prior rulings regarding the trade secret status of Roche’s BLA and IND (portions of which it has previously accepted for filing under seal following Roche’s presentation of evidence in support of their trade secret status).

Amgen has much to gain by the public disclosure of Roche’s trade secrets. The parties are not similarly situated regarding the confidentiality of their scientific information, and Amgen has repeatedly exploited this fact to its benefit by seeking the public disclosure of Roche’s trade secrets without justification. Roche’s Mircera[®] product is pending FDA approval, a highly secretive process, and is still undergoing trials and studies; Amgen is suing on technology that is

¹ The Court’s comment was apparently based on the fact that Amgen submitted a portion of the Harlow deposition to the Court for *in camera* review. Prior to filing its motion regarding Harlow, Amgen sought Roche’s assent to file portions of the Harlow transcript publicly, and notified Roche of this fact at 10:30 pm, less than an hour and a half prior to filing. While Roche was not able to respond within the short time Amgen gave, Roche also did not move to seal that testimony after it was submitted in camera, so pursuant to Paragraph 14 of the Protective Order Amgen was permitted to publicly file it four days afterward. (The entire Harlow transcript, like all of the transcripts in this case, had been marked as presumptively confidential by the court reporter. Roche did subsequently assent to the public filing of a second portion of the Harlow transcript, which Amgen sought to file in connection with a separate bench memorandum, as Roche had sufficient time to evaluate the transcript excerpt and determine that it contained no information confidential to Roche.)

While Roche regrets any inconvenience to the Court that the unnecessary submission of the Harlow deposition excerpts may have caused, it is hardly fair to punish Roche for the acts of Amgen. In any event, counsel for Roche and Amgen have been operating under a letter agreement and working together in an effort to ensure that only true trade secrets are subject to the *in camera* procedure. In light of the concerns the Court recently expressed, Roche is proposing further changes to the parties’ procedures to ensure that the Court is not inconvenienced with any unnecessary *in camera* filings in the future. See Section C, below.

nearly 25 years old. Roche has alleged, as part of its antitrust counterclaims, that Amgen is engaging in a concerted effort to use this litigation not merely as a legitimate means to vindicate its patent rights, but as a cudgel with which to inflict harm on Roche's Mircera[®] program and maintain Amgen's market dominance at any cost. Indeed, in a prior Order, this Court stated, "This Ruling Has Been Made Without Any Reference to the So-Called Confidential Documents, A Procedure Which - It Is Becoming Increasingly Apparent - Is Being Employed Solely to Harass and Embarrass An Opposing Litigant and Cause Waste of Resources. This Court Will Not Continue to Tolerate Such Litigation Conduct." Electronic Order, dated February 28, 2007. Now more than ever, Roche needs the assistance of the Court to prevent Amgen from abusing the Court's procedures by disclosing Roche's trade secrets without adequate justification and without advance notice to Roche. This Court must not permit Amgen to violate the Amended Protective Order or its previous rulings regarding Roche's BLA and IND in furtherance of Amgen's anticompetitive strategy. At a minimum, Roche must be given advance notice of Amgen's intention to disclose Roche's trade secrets and an opportunity to seek relief from the Court.

B. Allowing Amgen to Publicly Disclose Roche's Trade Secrets Without Giving Roche an Opportunity to Seek Court Intervention Would Violate Roche's Due Process Rights and the Prior Orders of This Court

Allowing Amgen to publicly disclose Roche's trade secrets without allowing Roche the opportunity to seek court intervention on the issue impinges upon Roche's due process rights. Trade secrets are held to be property that is afforded constitutional protection. *See Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1003-04 (1984) ("To the extent that Monsanto has an interest in its health, safety, and environmental data cognizable as a trade-secret property right under [state] law, that property right is protected by the Taking Clause of the Fifth Amendment."); *see Jenkins*

ex rel. Jenkins v. Mo., 216 F.3d 720, 726 (8th Cir. 2000) (“procedural niceties equate with due process and must be afforded the parties. ... The parties are entitled to notice and an opportunity to prepare for a unitary status hearing”). Further, as the defendants in this case, Roche has involuntarily been thrust into this litigation, making it highly unfair to bestow upon Amgen free rein over the public disclosure of Roche’s trade secret information by virtue of its decision to bring suit against Roche. Thus, due process weighs in favor of precluding Amgen from publicly disclosing Roche’s trade secrets so that the Court may hear Roche’s position on the matter.

Moreover, this Court has on multiple occasions issued rulings which reinforce the ability of the parties to protect their trade secrets from public disclosure. For instance, the Amended Protective Order, which remains in effect, provides that trade secret information may be protected from public disclosure and filed under seal.² It is simply not reasonable for Amgen to interpret the Court’s statement on September 29, 2007—made in the context of an unrelated matter with no allowance for oral or written argument by either party—to completely wipe out the protections provided in the Amended Protective Order across the board, and Roche remains entitled to seek protection of its trade secrets from public disclosure.

² Paragraph 14 of the Amended Protective Order states, “No document shall be filed in Court under seal absent allowance of a particularized motion to seal that would be allowed only if the filing includes a trade secret. A party seeking to file another party’s Confidential Discovery Material shall serve its papers on the Supplier and shall file a notice of service with the Court. The Supplier shall then have four (4) Court days in which to either consent to the request to file said information in the public record or to seek leave of the Court pursuant to Local Rule 7.2 to file such papers under seal as set forth above. The parties shall cooperate in good faith to obtain a prompt ruling on any motion for leave to file under seal pursuant to this paragraph, including by filing any opposition within two (2) Court days of the motion.” D.N. 274. The parties have implemented the provisions of Paragraph 14 in accordance with a letter agreement, a copy of which is attached as Exhibit D. As set forth in Section C, below, Roche now proposes certain changes to the procedures set forth in the letter agreement to address the concerns of the Court and eliminate the risk that materials will be submitted for *in camera* inspection that are not truly claimed a party to constitute trade secrets and will not be subject to a motion to seal.

Further, the Court previously granted Roche's motion for leave to file under seal several of its documents relating to its BLA and IND on the basis that they are trade secrets. (*See* D.N. 409; Electronic Order, dated May 2, 2007). In that instance, the documents which Amgen sought to file in the public record included technical internal Roche documents regarding information such as the details as to time frame, size and dosing used in individual ongoing and future clinical trials conducted in furtherance of Roche's BLA and IND and Roche's manufacturing processes and scale-up of its product. Roche successfully proved that the documents at issue represent the core of Roche's drug development and business strategy, and that Roche therefore considers them to be trade secrets whose secrecy it has consistently and vigilantly guarded and the public disclosure of which would irreparably harm Roche.

Indeed, Roche has consistently filed motions for leave to file under seal documents related to its BLA and IND on the basis that they contain trade secret information. Roche has on each occasion submitted declarations of its scientists and managers attesting to the trade secret status of Roche's BLA and IND, in order to make the particularized showing required by the Court.³ Although in most cases it has been unnecessary for the Court to rule on the trade secret status of the documents at issue because they were either unnecessary or irrelevant to the Court's ruling, Roche has unfailingly pressed the position that the information in its BLA and IND is trade secret and this Court has acknowledged the same.

³ *See, e.g.*, D.N. 192 (Declaration of Krishnan Viswanadhan, dated December 22, 2006), D.N. 193 (Declaration of Richard Beswick, dated December 22, 2006), D.N. 249 (Declaration of Dr. Reinhard Franze, dated January 17, 2007), D.N. 292 (Declaration of Krishnan Viswanadhan, dated February 22, 2007), D.N. 411 (Declaration of Richard Beswick, dated April 19, 2007), D.N. 561 (Declaration of Michael Jarsch, dated June 28, 2007), D.N. 562 (Declaration of Susan Batcha, dated June 28, 2007), D.N. 563 (Declaration of Susan Batcha, dated June 28, 2007), and D.N. 729 (Declaration of Susan Batcha, dated July 16, 2007).

The Court's offhand statement regarding confidentiality was clearly not meant to vitiate the rights which both parties possess with respect to their trade secret information. Given the prejudice that would befall Roche should it be denied the opportunity to address Amgen's proposed course of action with the Court and the utter inconsistency of Amgen's present intention to publicly disclose Roche's trade secrets with this Court's prior rulings, Amgen should be precluded from publicly disclosing information from Roche's BLA and IND without prior notice to Roche.

C. Roche's Proposal for Advance Notice Is Reasonable

It is eminently reasonable for Amgen to give Roche advance notice of any public disclosure of information that Roche has claimed to constitute trade secrets, so that Roche has an opportunity to apply to the Court for protection, and due process requires no less. Such notice will impose a burden on neither Amgen nor the Court.

The parties have been addressing the public filing of materials designated as confidential pursuant to Paragraph 14 of the Amended Protective Order (D.N. 274) and a letter agreement dated January 31, 2007. *See* note 2, above. Roche proposes certain changes to the letter agreement in order to avoid inconveniencing the Court with *in camera* submissions or other confidentiality-related motions that may be unnecessary.

With respect to the filing of documents with the Court, Roche proposes that the parties continue their current practice of conferring with each other prior to filing documents that the other party previously identified as confidential, but that if the other party fails to respond within an agreed time, the party seeking to file the materials in the public record may do so. Specifically, Roche proposes that notice be given by email and fax to a list of attorneys that each side will designate in advance, and each party be required to respond within 5 hours if such

notice is delivered between 8:00 am and 6:00 pm on a business day, and otherwise the earlier of 18 hours or 12:00 noon on the next business day. Only if a party responds by indicating that the materials constitute a trade secret and will be the subject of a motion to seal will they be withheld from public filing and submitted to the Court *in camera* so that a determination as to their trade secret status can be made. This minor change in the parties' procedures will ensure that no documents are submitted to the Court for *in camera* review unless there is a legitimate and serious concern about their confidentiality, and the party seeking to avoid the public filing is prepared to make a particularized showing as to why the documents would reveal that party's trade secrets.

With respect to the disclosure of documents in open court during the course of trial, Roche proposes that the parties agree to give each other advance notice of the disclosure of information at trial that has been designated as "Highly Confidential" or "Restricted Access BLA/IND Material" (but not the lower "Confidential" tier of protection), so that the designating party may seek Court intervention if it feels that it is necessary to address confidentiality issues prior to disclosure. This would include documents designated as "Highly Confidential" or "Restricted Access BLA/IND Material," as well as testimony and questions seeking to elicit such information. This should not require anything additional with respect to documents sought to be used on direct examination, as the parties have already agreed to a schedule by which all documents and demonstratives to be used with such witnesses are disclosed to the other side. *See* D.N. 1186 (letter agreement between the parties as to trial exchanges), "so ordered" by the Court on September 28, 2007. With respect to cross-examination, Roche proposes that such disclosure be made 24 hours in advance of the time the cross-examination is expected to begin, but would also accept a shorter time if ordered by the Court.

The procedures proposed by Roche will not inconvenience the Court or Amgen, and will not impede the progress of the trial, yet will provide Roche with the minimum protection it needs to protect its trade secrets. Roche needs advance notice of the proposed disclosure of its trade secrets, so that it can seek to limit or prevent their disclosure when such disclosure would be unnecessary or unfair to Roche (because, for example, the trade secrets are not relevant to an issue in dispute or are cumulative of evidence already admitted). Roche's proposal is consistent with the Amended Protective Order and this Court's prior Orders allowing certain BLA and IND information to be filed under seal. Roche urges the Court to adopt Roche's proposal, which is reasonable and comports with due process, rather than Amgen's unreasonable interpretation of this Court's statement that would completely vitiate the parties' valuable trade secrets.

Conclusion

Accordingly, Roche respectfully requests that the Court grant its emergency 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 no agreement was reached.

Dated: October 1, 2007
Boston, Massachusetts

Respectfully submitted,

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

By their Attorneys

/s/ Julia Huston

Lee Carl Bromberg (BBO# 058480)
Robert L. Kann (BBO# 258025)
Julia Huston (BBO# 562160)
Keith E. Toms (BBO# 663369)
Nicole A. Rizzo (BBO# 663853)
Kimberly J. Seluga (BBO# 667655)
BROMBERG & SUNSTEIN LLP
125 Summer Street
Boston, MA 02110
Tel. (617) 443-9292
jhuston@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)
Vladimir Drozdoff (*pro hac vice*)
David L. Cousineau (*pro hac vice*)
KAYE SCHOLER LLP
425 Park Avenue
New York, New York 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). Pursuant to agreement of counsel dated September 9, 2007, paper copies will not be sent to those indicated as non registered participants.

/s/ Julia Huston

Julia Huston