

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.)	
_____)	

**OPPOSITION TO PLAINTIFF AMGEN INC.’S MOTION TO
PERMIT SUBMISSION OF MATERIALS PRODUCED IN THIS ACTION TO THE
INTERNATIONAL TRADE COMMISSION AND THE FEDERAL CIRCUIT**

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively “Roche”) oppose Amgen Inc.’s Motion to Permit Submission of Materials Produced in This Action to the International Trade Commission and the Federal Circuit (Docket No. 405). Amgen’s motion should be denied in full for at least two reasons.

First, Amgen is prohibited by the parties’ Protective Order in this case from using confidential documents from the present litigation in support of a motion made in another case and in another jurisdiction. Amgen willingly stipulated to the Protective Order, which clearly provides that counsel may “utilize discovery materials produced under the terms of this order for purposes of this litigation.” See Protective Order of 12/21/06 (Docket No. 189) and Amended Protective Order of 2/7/07 at ¶12 (Docket No. 274) (emphasis added). By the time the parties stipulated to the Protective Order in this case, the proceeding in the International Trade Commission (“ITC”) had been resolved, so there was no reason to address the use of confidential documents in other proceedings. This has not changed. Indeed, Amgen does not

contest that the Protective Order prohibits the course of conduct it intends. The documents Amgen seeks to file in the Federal Circuit in support of its appeal of the ITC's decision are designated by Roche as "Confidential" under the Protective Order entered in the present litigation. Amgen cannot now violate the Protective Order to which it agreed in order to satisfy its needs in a completely separate proceeding. The Order of this Court should not be subject to Amgen's whim.

Secondly, because the documents were not in evidence before the ITC, but were instead produced in this litigation after the decision of the ITC was rendered, Amgen cannot properly rely upon these documents in its appeal of the ITC decision to the Federal Circuit. It is black letter law that a Court of Appeals cannot consider evidence that was not part of the record below. *See* Federal Rules of Appellate Procedure, Title IV, Review or Enforcement of an Order of an Administrative Agency, Board, Commission, or Officer, Rule 16 ("(a) The record on review or enforcement of an agency order consists of: (1) the order involved; (2) any findings or report on which it is based; and (3) the pleadings, evidence, and other parts of the proceedings before the agency") (emphasis added). This is of course an issue for the Federal Circuit rather than this Court. But even if the Court accepted Amgen's invitation to delve into this issue, it is clear that Amgen's position is in error, and Amgen cannot show that the submission of new evidence to the Federal Circuit (whether confidential or not) is proper.

The cases Amgen cites to support its proposition that it is proper for the Court of Appeals to look at extra-record material if new evidence arises are inapposite. The two Federal Circuit cases, *Jackson v. Nicholson*, 449 F.3d 1204 (Fed. Cir. 2006), and *Davis v. Nicholson*, 475 F.3d 1360 (Fed. Cir. 2007) deal with a special rule applicable to veterans disability claims which provides that "new and material evidence" uncovered between the time of a regional Department

of Veteran Affairs decision and an appeal to the next level of review (the Board of Veterans' Appeals) can be considered by the Board. See 38 C.F.R. 3.156(b). However, a careful reading of the cases reveals that the rule applies only to appeals to the Board of Veterans' Appeals, not to appeals to the Court of Veterans' Appeals or the Federal Circuit. See *Jackson*, 449 F.3d at 1208 ("The purpose of the 'new and material evidence' provision is to permit veterans to reopen their claims by submitting new and material evidence to the Department of Veteran Affairs, which has the authority to reopen claims"). It has no applicability outside this specific subset of veterans' appeals.

Additionally, the Supreme Court case that Amgen cites is contrary to Amgen's position. *Florida Power & Light Co. v. Lorian*, 470 U.S. 729, 743-44 (1985), makes it clear that the Federal Circuit should not consider the type of evidence Amgen wants to submit. ("The focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court. ... The task of the reviewing court is to apply the appropriate APA standard of review ... to the record the agency presents to the reviewing court."). Thus, Amgen's argument that the Federal Circuit would want to consider the allegedly new evidence uncovered in the Massachusetts case is unsupported by the law.

Finally, Roche must note its objection to Amgen's submission of 13 confidential Roche documents to the Court for *in camera* review in support of Amgen's motion. It is completely unnecessary for the Court to consider the documents themselves, particularly as Amgen does not argue that the documents are non-confidential. Every time Amgen makes such a submission, it triggers an obligation on the part of Roche to make a motion to seal the documents that must be supported by detailed arguments and affidavits from Roche personnel. This procedure has imposed an enormous burden on Roche, and is distracting the Roche scientists from their

important work. Indeed, Roche just filed a 12-page declaration (Docket No. 411) by Richard Beswick, Associate Medical Director at Roche, in response to Amgen's latest improper attempt to put Roche's confidential documents before this Court. It is inconceivable that Roche must undertake this process again only days later. Amgen seems utterly impervious to this Court's prior warning of its February 28, 2007 Order: "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." Amgen has sought to file 70 confidential Roche documents so far in this case, 32 in the last three weeks alone, requiring Roche to supply 7 declarations, by 4 different scientists and other Roche personnel, and to submit extensive briefing. The Court has not found it necessary to refer to even a single one of these 70 documents in order to decide a motion. Roche has moved for sanctions due to Amgen's repeated abuse of the Amended Protective Order in this case (Docket No. 398), and that motion is pending.

In this instance, it is readily apparent that Amgen is submitting Roche's confidential documents to the Court not because the Court needs them to rule on the issues, but because Amgen knows the documents will lose their confidential status if the Court orders them to be filed in the public record on the ground that they do not contain trade secrets, thus giving Amgen the result it seeks without having to comply with the procedures set forth in the Amended Protective Order for challenging confidentiality designations.¹ This latest filing by Amgen only

¹ The Protective Order provides that if Amgen disagrees with Roche's confidentiality designations, it must notify Roche in writing, state the basis for its disagreement, and then confer with Roche in good faith, after which time either party may move to re-classify the documents in question. Amended Protective Order, ¶ 8. Amgen has not proceeded in this fashion, but is instead making an end run around this procedure by submitting Roche's confidential documents to the Court and thereby forcing Roche to show that the documents contain trade secrets (a much higher standard than set forth in the Amended Protective Order) with the knowledge that the documents may be ordered to be filed in the public record if their confidentiality does not rise to the level of trade secrets. When the

underscores Amgen's bad faith, and the need for Court intervention in order to prevent Amgen from further burdening this Court and Roche with its improper filing tactics.

Accordingly, Roche respectfully requests that the Court deny Amgen's motion in full.

DATED: Boston, Massachusetts
April 20, 2007

Respectfully submitted,

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

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Court ordered that only trade secrets would be accepted for filing under seal, it surely did not intend for one party to submit another party's confidential material without cause, just so that the confidentiality of those documents could be more conveniently attacked. Amgen's persistent and manipulative employment of this strategy is an abuse of this Court's Orders and should not be permitted.

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/ Julia Huston

Julia Huston

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