

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

_____)	
AMGEN INC.,)	
)	
Plaintiff,)	
)	
vs.)	
)	CIVIL ACTION No.: 05-CV-12237WGY
F. HOFFMANN-LA ROCHE LTD,)	
ROCHE DIAGNOSTICS GMBH,)	
AND HOFFMANN-LA ROCHE INC.,)	
)	
Defendants)	
_____)	

DEFENDANTS’ MOTION FOR LEAVE TO FILE ITC PAPERS UNDER SEAL

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively "Roche") respectfully request leave to file under seal two documents that are necessary to put in proper context Amgen’s Petition Objecting to the ITC Administrative Law Judge’s Initial Determination (“Amgen’s Petition”), a document that Amgen recently filed under seal. The two documents that Roche moves for leave to file under seal in this case are:

- (a) Roche’s Opposition to Complainant’s Petition for Review of Initial Determination, filed July 21, 2006 (“Roche’s Opposition”), and
- (b) the ITC’s Office of Unfair Import Investigations’ Reply to Complainant Amgen Inc.’s Petition for Review of Initial Determination Granting Summary Determination, filed July 21, 2006 (“ITC Staff Attorney Opposition”), which also opposes Amgen’s petition.

On July 7, 2006, the ALJ in the ITC proceeding issued an Initial Determination dismissing Amgen’s allegations of patent infringement on the ground that all of Roche’s activities regarding the subject drug product were reasonably related to the submission of information to the United States Food and Drug Administration, and therefore exempt from

infringement under the safe harbor of 35 U.S.C. §271(e)(1). Thereafter, Roche moved for leave to file the ALJ decision in this proceeding under seal (over Amgen's objection), which this Court granted on July 12, 2006. The ALJ decision deals with the very issue currently before the Court in connection with Roche's pending motion to dismiss, and as such would be significant to this Court's consideration of Roche's motion.

Amgen has now filed its entire 53-page Petition to the ITC in this case despite its argument that materials outside its complaint should not be considered in connection with Roche's pending dismissal motion. *See* Amgen's Post Hearing Memorandum, dated July 13, 2006, at 4-5. Roche submits that this burdening of the record with the briefing of the parties on Amgen's Petition is not necessary for the Court to understand the import of the ALJ decision and its pertinence to Roche's dismissal motion. However, if the Court is inclined to review Amgen's Petition it is only fair that the Court have the opportunity to consider the opposition to the petition that Roche has filed, as well as the ITC Staff Attorney Opposition. The ITC Staff Attorney supports Roche's position arguing that the ALJ correctly ruled that all Roche's activities fell within the section 271(e)(1) safe harbor.

Because the opposition to Amgen's Petition of both Roche and the Staff Attorney contain Roche's confidential information subject to the terms of the ITC Protective Order, those documents, like the Amgen Petition, may be disclosed to this Court provided that the information is not made of public record. *See* ITC Protective Order, Docket No. 100, Ex. A, at ¶ 5 (“Confidential business information obtained in the Commission proceeding may be used with the consent of the supplier in a parallel district court proceeding under a protective order issued by the district court without losing its confidential status under the protective order in this proceeding as long as the information is not made public in the district court proceeding”).

Thus, Roche respectfully requests that the Court grant its motion for leave to file Roche's Opposition and the ITC Staff Attorney's Opposition to Amgen's Petition under seal.

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. No agreement was reached.

DATED: Boston, Massachusetts
July 26, 2006

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

By its 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/ Julia Huston
Julia Huston

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