

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

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AMGEN INC.,		)
		)
Plaintiff,		)
		)
vs.		)
		)
	CIVIL ACTION No.: 05-CV-12237WGY	)
F. HOFFMANN-LA ROCHE LTD,		)
ROCHE DIAGNOSTICS GMBH,		)
AND HOFFMANN-LA ROCHE INC.,		)
		)
Defendants		)
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**DEFENDANTS’ MOTION FOR LEAVE TO FILE UNDER SEAL  
THE RECENT DECISION OF THE ITC REGARDING DEFENDANTS’ SECTION  
271(e) SAFE HARBOR DEFENSE**

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively “Roche”) respectfully request leave to file the ITC’s Initial Determination dated July 7, 2006, under seal because it contains highly confidential information that is subject to a Protective Order entered by the ITC.

As set forth in Roche’s supplemental memorandum dated July 10, 2006, the ITC issued an Initial Determination dismissing Amgen’s ITC case against Roche because it held that Roche’s CERA activities fell within the § 271(e)(1) safe harbor. Because this decision deals with the very same issue currently pending before this Court in connection with Roche’s pending motion to dismiss (Docket Nos. 44 & 45), Roche believes it would be beneficial for the Court to have the ITC’s opinion as part of the record in this case.

The Administrative Law Judge (“ALJ”) in the ITC case designated the Initial Determination as confidential in accordance with the Protective Order entered in that proceeding,

and did not disclose its rulings in the public record. *See* Protective Order, Exh. A. Indeed, the ITC's docket reflects only that a confidential Order was entered; the ITC's ruling and opinion are not publicly accessible. The ALJ appropriately treated the Initial Determination as confidential because it contains detailed information regarding Roche's clinical trials of CERA and other sensitive information not intended for public disclosure.

Under the Protective Order, Roche may disclose the ITC decision to this Court provided that the information is not made of public record. *See* Protective Order, Exh. 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 . . .”) (emphasis added).

Thus, Roche respectfully requests that the Court grant its motion for leave to file the ITC's Initial Determination 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 11, 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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