

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’ REPORT TO THE COURT
PURSUANT TO ORDER DATED MAY 11, 2006**

On May 10, 2006, the Court heard oral argument on the motions of F. Hoffmann-La Roche Ltd (“Roche Swiss”) and Roche Diagnostics GmbH (“Roche Germany”) to dismiss for lack of personal jurisdiction.¹ The Court took the motions under advisement, and ordered the parties “to confer as to the corporate relationship between the various Roche/Hoffmann-LaRoche corporate entities and the allegedly infringing drug” and “report back to the Court within 10 days as to the nature of the corporate relationship of these entities.” Order dated May 11, 2006.

On May 18, 2006, Roche Swiss and Roche Germany withdrew their motions to dismiss and sent a letter to the Court the same day explaining the circumstances of the withdrawal. Thus, the Defendants believe that the Court’s Order of May 11, 2006 is now moot. In the event that

¹ At the same time, the Court heard oral argument on a motion to dismiss for failure to state a claim filed by Roche Swiss, Roche Germany, and Hoffmann-La Roche Inc. (“Roche U.S.”) (collectively, “Defendants”), and a motion by Ortho Biotech Products, L.P. to intervene as a plaintiff in the action. Those motions are still pending.

the Court does not consider the Order moot, however, the Defendants report to the Court as follows:²

The parties have conferred and Defendants have communicated documents and information to plaintiff's litigation counsel setting forth additional details regarding the various Roche/Hoffmann-LaRoche corporate entities and the allegedly infringing drug known as "CERA." Roche U.S. is a New Jersey corporation with its headquarters in Nutley, New Jersey. Roche Swiss and Roche Germany are European companies, organized under the laws of Switzerland and Germany, respectively, which do not have offices in the United States. Defendants have confirmed that all Investigation New Drug Applications filed with the United States Food and Drug Administration ("FDA") for CERA were sponsored by Roche U.S. Defendants have further confirmed that the Biologic License Application for CERA was submitted by Roche U.S. This addresses the issue raised by counsel for Amgen at hearing on May 10, 2006. Defendants also have clarified that both of the Roche European companies have shipped CERA into the United States to Roche U.S. Defendants have further produced documents confirming *inter alia*, that (i) there have been no sales of CERA to third parties in the United States; (ii) there have been no offers to sell CERA to third parties in the United States; and (iii) CERA has not been and is not currently being stockpiled in the U.S. for sale if FDA approval is granted. The documents further identify the individuals responsible for receiving and distributing CERA to generate information relevant to the FDA's decision process.

² By e-mail dated May 24, 2006, Defendants sought to enlist Plaintiff's cooperation in submitting a joint submission but Plaintiff did not accept.

By stipulation submitted to this Court on May 23, 2006, the parties have agreed that all information, documents, and things exchanged pursuant to the Court's May 11, 2006 Order will be maintained as highly confidential subject to outside counsel review only at this time.³

As Amgen has pled only a single count seeking a declaratory judgment against future acts if there is FDA approval of CERA, with no count of actual infringement, and as the personal jurisdiction motions have been withdrawn, Roche requests that the Court dismiss or stay this case as soon as possible to prevent the "expensive, resource-draining, and personnel-distracting litigation" that § 271(e)(1) was designed to avoid. *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1290 (N.D. Cal. 1991), *aff'd*, 991 F. 2d 808 (Fed. Cir. 1993).

DATED: Boston, Massachusetts
May 25, 2006

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

By its attorneys,

/s/ Julia Huston
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³ Amgen moved this Court today, for leave to file under seal certain of the documents provided by Roche to Amgen pursuant to the May 23rd stipulation. Although Roche does not believe that the Court needs to have this information, Roche offered to review Amgen's submission to the Court to attempt to work out confidentiality issues. Amgen did not accept Roche's offer.

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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

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