

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’ POST-HEARING MEMORANDUM TO APPRISE THE COURT
OF THE RECENT ALJ DECISION BEFORE THE ITC AND IN FURTHER SUPPORT
OF THEIR MOTION TO DISMISS**

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively “Roche”) respectfully submit this post hearing memorandum to apprise the Court of the recent ALJ decision before the ITC and in further support of their motion to dismiss. The Administrative Law Judge (“ALJ”) issued an Initial Determination dismissing Amgen’s allegations of patent infringement because it found that all of Roche’s activities were reasonably related to the submission of information to the U.S. Food and Drug Administration (“FDA”), and therefore exempt from infringement under the safe harbor of 35. U.S.C. § 271(e)(1). Therefore, the ALJ decision provides even more compelling reasons to grant Roche’s motion.

On April 11, 2006, Roche filed a motion to dismiss this case for lack of subject matter jurisdiction and for failure to state a claim. (Docket No. 45) On the same day, Amgen instituted a parallel lawsuit involving the same patents and the same allegations of patent infringement

against Roche before the U.S. International Trade Commission. After the Court heard Roche's motion to dismiss on May 16, 2006, Roche filed a motion for summary determination to terminate the ITC investigation on May 19, 2006. Roche's summary determination motion before the ITC substantially contained the same arguments in Roche's pending motion to dismiss before this Court, namely that all of Roche's uses of its accused drug CERA was reasonably related to the submission of the information to the FDA, and therefore exempt from infringement under Section 271(e)(1). (Ex. A).

Rather than immediately opposing that motion, Amgen successfully moved to obtain discovery on Roche's Section 271(e)(1) in order to "develop a complete record" relating to Roche's motion. (Exhibit B at 2). Therefore, from May 26th to June 26th, the parties conducted expedited discovery on the full scope of Roche's Section 271(e)(1) defense. On July 7, 2006, after Amgen filed its opposition papers, and Roche successfully moved to file a reply memorandum, the ALJ granted Roche's motion, finding that Roche had satisfied its summary determination burden of demonstrating that all of its uses of CERA were protected under the Section 271(e)(1) safe harbor.

The ALJ decision contains confidential Roche business information, and as a result cannot be made publicly available under the ITC protective order. Roche will separately move for leave to file under seal the ALJ decision in order for that decision to be part of the district court record. Attached as Exhibit C is Amgen's press release announcing that the ALJ "issued a summary determination that Roche's importation and use of peg-EPO in the United States to date are subject to a clinical trial exemption to patent infringement" and that "[t]his decision will become final within thirty days unless modified by the Commission."

Because the ALJ decision was based upon Amgen's requested discovery into the Section 271(e)(1) defense, that decision provides an even more compelling reason to grant Roche's pending motion to dismiss before this Court.

DATED: Boston, Massachusetts
July 10, 2006

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

By its attorneys,

/s/ Julia Huston

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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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