Case 1:05-cv-12237-WGY

# UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

AMGEN INC.,	)	
Plaintiff,	)	
vs.	)	Civil Action No. 05-12237 WGY
F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GmbH and HOFFMANN-LA ROCHE INC.,	) ) )	
Defendants.	) ) )	

# **DEFENDANTS' MOTION IN LIMINE TO PRECLUDE** AMGEN'S EXPERT DR. TORCHILIN FROM OFFERING TESTIMONY ON LITERAL INFRINGEMENT OR INFRINGEMENT UNDER THE DOCTRINE OF EQUIVALENTS

Roche submits this *motion in limine* asking the Court to preclude Amgen's Dr. Torchilin from providing any infringement testimony apart from the opinions disclosed in his expert reports relating to whether CERA is materially changed pursuant to 35 U.S.C. § 271(g). In particular, Dr. Torchilin should be precluded from offering opinions on literal infringement or infringement under the doctrine of equivalents. As discussed below, Dr. Torchilin fails to provide any proper analysis of these issues in his expert reports.

It is settled law that a proper infringement analysis requires an element-by-element analysis. See Tex. Instruments, Inc. v. United States ITC, 846 F.2d 1369 (Fed. Cir. 1988)(rejecting the "invention as a whole" standard for doctrine of equivalents); See also Rohm and Haas Co. v. Brotech Corp., 127 F.3d 1089, 1091-1093 (Fed. Cir. 1997)(affirming noninfringement judgment where Plaintiff's expert failed to show how every claim element was met).

Dr. Torchilin admits that for the purposes of his opinions he was "asked to assume that the EPO polypeptide of peg-EPO (the active ingredient of Roche's MIRCERA product) is made by Roche outside the United States using a method that satisfies each limitation of the asserted method claims of Amgen's '868 Patent, '698 Patent, and '349 Patent." Dr. Torchilin merely provides opinions as to whether epoetin beta has been materially changed by pegylation. Nowhere in any of his four expert reports, does Dr. Torchilin provide any claim-by-claim or limitation-by-limitation analysis comparing Roche's accused product to the elements of the asserted claims. In short, Dr. Torchilin does not provide any analysis as to whether Roche's intended product MIRCERA<sup>TM</sup> meets each claim limitation of any of the asserted Lin patent claims either literally or under the doctrine of equivalents, including any analysis of whether the process Roche uses in Europe to make epoietin beta does so, and therefore should be precluded from providing any such testimony at trial.

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<sup>&</sup>lt;sup>1</sup> Torchilin First Expert Report dated April 6, 2007 at 43.

<sup>&</sup>lt;sup>2</sup> Torchilin First Expert Report dated April 6, 2007 at 44-45.

<sup>&</sup>lt;sup>3</sup> *See* First Expert Report of Dr. Vladimir Torchilin, Ph.D., dated April 6, 2007; Second Expert Report of Dr. Vladimir Torchilin, Ph.D., dated May 10, 2007; Third Expert Report of Dr. Vladimir Torchilin, Ph.D., dated June 1, 2007; and Fourth Expert Report of Dr. Vladimir Torchilin, Ph.D., dated June 20, 2007;

<sup>&</sup>lt;sup>4</sup> While in his first expert report, Dr. Torchilin provides a table of the claim constructions proposed by the parties, he never applies that construction in a proper claim-by-claim, element-by-element infringement analysis.

#### **CONCLUSION**

For all of the foregoing reasons, Dr. Torchilin should be precluded from providing testimony or opinions on literal infringement or infringement under the doctrine of equivalents.

### **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 and that no agreement was reached.

DATED: October 4, 2007

Boston, Massachusetts

Respectfully submitted,

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

By its attorneys,

### /s/ Thomas F. Fleming

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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). Pursuant to agreement of counsel dated September 9, 2007, paper copies will not be sent to those indicated as non registered participants.

> /s/ Thomas F. Fleming Thomas F. Fleming