UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

DEFENDANTS' OPPOSITION TO PLAINTIFF AMGEN INC.'S MOTION TO PRECLUDE ROCHE'S EXPERTS FROM CLAIMING UNPROVEN AND UNDISCLOSED FDA CERTIFICATION

Amgen's motion to preclude relevant testimony of Roche's experts concerning CERA as a new chemical entity is entirely without basis. CERA is not only a new chemical entity under federal regulations, but this fact was long ago disclosed to Amgen during discovery.

As one of Roche's experts, Dr. Longmore correctly states in his expert report, CERA is a new chemical entity. 21 C.F.R. 320.31 sets forth the requirements for applicability to file an Investigational New Drug Application (IND). That section provides:

> (a) Any person planning to conduct an in vivo bioavailability or bioequivalence study in humans shall submit an "Investigational New Drug Application" (IND) if:
>
> (1) **The test product contains a new chemical entity** as defined in 314.108(a) of this chapter...

Furthermore, according to 21 C.F.R. 314.108, a new chemical entity is an entity that contains "no active moiety that has been approved by FDA." Notably, this is the same section of the statute cited in Dr. Longmore's report.

Roche lawfully submitted an IND for CERA in order to conduct exactly the type of studies that the statute specifies -- in vivo bioavailability or bioequivalence studies. Roche filed the IND because it believed it was obligated as CERA is a new chemical entity. It stands to reason that the FDA, in approving Roche's application to conduct studies covered under the statute, also concluded that CERA is a new chemical entity that does not contain an active moiety previously approved by the FDA.

Amgen cannot now argue that there was no disclosure. Amgen has had access to Roche's CERA IND for over a year. Moreover, Amgen has had Dr. Longmore's expert report for more than five months and could easily have looked up the statute cited therein to determine that INDs are filed for new chemical entities.

Amgen's jury confusion argument is equally baseless. For example, Amgen had several hours at Dr. Longmore's deposition to ask him about this statement in his report. Even so, Amgen is certainly not foreclosed and indeed will have ample opportunity to cross examine Dr. Longmore, or any other Roche expert, on this point. If Roche's experts understand the provision (as they have indicated in their reports), they should be allowed to testify about it. Amgen has expressed no argument that can contradict this conclusion as this is relevant expert testimony previously disclosed and consistent with the reports of Roche's experts.

For the foregoing reasons, Roche respectfully requests that this Court deny Amgen's motion to preclude relevant expert testimony.

Dated: October 15, 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*
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