UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN, INC., Plaintiff, v. F. HOFFMANN-LAROCHE LTD., a Swiss Company, ROCHE DIAGNOSTICS GMBH, a German Company, and HOFFMANN LAROCHE INC., a New Jersey Corporation, Defendants.	)	Civil Action No. 05 CV 12237 WGY

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

Roche's experts should be precluded from providing testimony stating or implying that the FDA "certified" CERA as a "new chemical entity" because Roche never put forward any proof of such FDA or regulatory certification during discovery. It would thus be improper, misleading, and highly prejudicial to Amgen for any Roche expert to suggest that the FDA "certified" "approved" or "recognized" CERA as a "new chemical entity" or "new molecule." Such testimony would only serve to confuse the jury by implying a finding by the FDA that does not exist.

ARGUMENT

Roche's expert Dr. Longmore claims in his report that the "FDA …certified CERA as a new chemical entity."[1] However, Dr. Longmore cites no proof or evidence for this "certification" by the FDA. Other Roche experts make similar claims, again without citing any FDA or regulatory documents in support of their claims.[2] Roche should not be allowed to make such baseless and unsupported claims which will confuse the jury by suggesting an official FDA determination has been made which Roche has never proven actually occurred.

No FDA materials produced in discovery support the claims of Roche's experts. As detailed previously in Amgen's Motion in Limine No. 13: Exclude Evidence and Argument Regarding Roche's FDA Filings and Communications Withheld Throughout Fact Discovery,[3] Roche refused to provide Amgen discovery of Roche's supplemental data and submissions to the FDA. This Court granted Amgen's motion to exclude FDA information that was not produced to Amgen.[4] Thus, if there are any documents which support Roche's claim of FDA certification that were not produced to Amgen, Roche should be precluded from relying upon them, and Roche's experts may not so testify.

Furthermore, the mere fact that Roche has filed a Biologic License Application ("BLA") for its peg-EPO product is not proof that peg-EPO is a "new chemical entity." Under existing FDA regulations, all biologics must file either a BLA or a New Drug Application ("NDA") in

[1] 5/11/2007 Expert Report of Gregory D. Longmore, M.D., at ¶ 86.
[2] *See* 6/13/2007 Supplemental Rebuttal Expert Report of Professor Alexander M. Klibanov at ¶ 58; 4/06/2007 Expert Report of Dr. Robert Langer at ¶ 47.
[3] *See* Docket No. 856 (Motion) and 857 (Memorandum).
[4] *See* 9/24 Docket Order.

order to obtain regulatory approval. The mere fact that Roche filed a BLA does not mean the FDA has certified peg-EPO as a "new chemical entity."

CONCLUSION

For the foregoing reasons, Roche's experts should be precluded from testifying or implying that the FDA has certified peg-EPO as a "new chemical entity."

Dated: October 14, 2007

Respectfully Submitted,

AMGEN INC.,
By its attorneys,

/s/ Michael R. Gottfried

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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 no agreement was reached.

/s/ Michael R. Gottfried
Michael R. Gottfried

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 and paper copies will be sent to those indicated as non-registered participants on October 14, 2007.

/s/ Michael R. Gottfried
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