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'S MOTION *IN LIMINE* NO. 13:
EXCLUDE EVIDENCE AND ARGUMENT REGARDING ROCHE'S FDA FILINGS AND COMMUNICATIONS WITHHELD THROUGHOUT FACT DISCOVERY

Pursuant to Fed. R. Civ. P. 37(c)(1), Plaintiff Amgen Inc. ("Amgen") requests that this Court preclude Defendants F. Hoffmann-La Roche Ltd., Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively "Roche") from introducing into evidence at trial all FDA-related documents that were withheld during fact discovery and the expert opinions relying on those requested but withheld documents. Roche fought for and won the right to withhold from discovery its supplemental FDA submissions and communications, and Roche cannot now introduce these submissions and correspondence into evidence through its experts' testimony, which cite to self-serving portions of those withheld materials. Further, because Roche never produced its communications with FDA, including its product label negotiations, Roche should be precluded from presenting any evidence or argument regarding the potential label and approved uses for its accused peg-EPO product.

Having foreclosed discovery into these documents, Roche cannot offer a belated and self-serving selection of its supplemental BLA submissions into evidence nor can it offer expert testimony relying on these documents that it withheld from discovery. Rather, as this Court has previously warned—"No Witness May Rely on Evidence Withheld from Discovery"—Roche should be precluded from introducing this evidence at trial.

Amgen requests that the Court preclude from evidence at trial the following FDA-related documents that were withheld during fact discovery and the expert opinions relying on those documents, as set forth below:

a. Evidence and arguments relating to the safety of peg-EPO, including documents bearing production numbers R008888255- R008888342; R008888343- R008888595; and R008888596- R008890732;

b. Expert testimony relying on such documents, specifically including: 5/11/07 Borer Report, ¶¶ 24-25, 30-41; 5/11/07 Vollmar Report, ¶¶ 58, 63, and 82; 5/11/07 Lieberman Report, ¶¶ 93, and 96-98; 5/11/07 Fishbane Report, ¶¶ 107, and 111-114; and 6/13/07 Spinowitz Report, ¶¶ 76-77; and

c. Evidence and arguments relating to the potential FDA approved label and uses for peg-EPO.

Dated: August 22, 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 August 22, 2007.

/s/ Michael R. Gottfried
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