UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMAN-LAROCHE LTD ROCHE DIAGNOSTICS GmbH and HOFFMAN-LA ROCHE INC. Defendants.	CIVIL ACTION No: 05-CV-12237WGY

AMGEN INC.'S OPPOSITION TO DEFENDANTS' REQUEST FOR PERMISSION TO FILE OPPOSITION TO AMGEN'S *IN LIMINE* MOTION REGARDING MIRCERA EUROPEAN APPROVAL AND LABEL

Roche's "request" to file an opposition to Amgen's Motion *in Limine* that European approval of MIRCERA® is irrelevant fails to address how Roche can now possibly claim that European approval is "highly relevant" when throughout discovery Roche refused to produce documents related to submissions to foreign governmental agencies because "documents and things concerning foreign governmental agencies and bodies … have no relevance to any claim or defense in this action.[1]" As set forth in Amgen's original motion, the European Commission's approval of MIRCERA® has no relevance to whether MIRCERA® infringes Amgen's U.S. patents. Statements made by the European Commission about the label for MIRCERA® in Europe or its uses in Europe, have no relevance to this patent case. Indeed, the European Commission has never made, as Roche appears ready to claim, a determination that

[1] *See* Responses 43 and 44 of Roche's Responses and Objections to Amgen's First Set of Requests for Production of Documents and Things (Nos. 1 to 224), attached as Exhibit A to Declaration of Daniel A. Curto in Support of Amgen's Motion *in Limine*.

MIRCERA® is not EPO within Amgen's patents. Moreover, even if it had, the European Commission has no basis under U.S. patent laws or this Court's claim construction to make that judgment. Roche will have every opportunity through opinion and fact testimony to explain its contentions as to whether MIRCERA® is materially changed.

Moreover, it is Roche that fails to set forth the facts regarding discovery in this matter. Throughout discovery, Roche refused to produce any documents related to Roche's submissions to foreign governmental agencies.[2] Roche claimed then that these documents were not relevant. That Roche — after the close of fact discovery — gave Amgen a handful of self-serving documents related to the European Commission's approval of MIRCERA®, makes Roche's failure to produce documents more, not less, prejudicial to Amgen. Roche, through its discovery tactics, denied Amgen the ability to obtain documents and conduct discovery related to Roche's submissions to foreign agencies. This prejudice alone demands that Roche not be able to use this information at trial.

Finally, the foundation of Amgen's motion *in limine* No. 13 regarding Roche's use of FDA documents was that Roche could not use those documents to show the potential FDA approved label and uses for MIRCERA® because Roche refused to produce them during discovery. The situation is practically identical regarding Roche's submissions to foreign agencies. Roche has refused to produce documents related to its submissions to foreign agencies. The fact that Roche received an approval letter in Europe after the close of fact discovery does not change Roche's failure during discovery to produce any of its regulatory documents. Like the FDA documents subject to motion *in limine* No. 13, Roche should not be allowed to use foreign regulatory documents to make statements about the characteristics of

[2] *Id.*

MIRCERA®.

Dated: October 3, 2007

Respectfully Submitted,

AMGEN INC.,
By its attorneys,

/s/ *Patricia R. Rich*

D. DENNIS ALLEGRETTI (BBO#545511)
MICHAEL R. GOTTFRIED (BBO#542156)
PATRICIA R. RICH (BBO#640578)
DUANE MORRIS LLP
470 Atlantic Avenue, Suite 500
Boston, MA 02210
Telephone: (857) 488-4200
Facsimile: (857) 488-4201

LLOYD R. DAY, JR
DAY CASEBEER
MADRID & BATCHELDER LLP
20300 Stevens Creek Boulevard, Suite 400
Cupertino, CA 95014
Telephone: (408) 873-0110
Facsimile: (408) 873-0220

WILLIAM GAEDE III
McDERMOTT WILL & EMERY
3150 Porter Drive
Palo Alto, CA 94304
Telephone: (650) 813-5000
Facsimile: (650) 813-5100

KEVIN M. FLOWERS
MARSHALL, GERSTEIN & BORUN LLP
233 South Wacker Drive
6300 Sears Tower
Chicago IL 60606
Telephone: (312) 474-6300
Facsimile: (312) 474-0448

Of Counsel:

STUART L. WATT
WENDY A. WHITEFORD
MONIQUE L. CORDRAY
DARRELL G. DOTSON
KIMBERLIN L. MORLEY
ERICA S. OLSON
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320-1889
(805) 447-5000

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 3, 2007.

/s/ *Patricia R. Rich*
Patricia R. Rich