IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMANN-LA ROCHE LTD, a Swiss Company, ROCHE DIAGNOSTICS GmbH, a German Company and HOFFMANN-LA ROCHE INC., a New Jersey Corporation, Defendants.	Civil Action No. 05-12237 WGY U.S. District Judge Young **ORAL ARGUMENT REQUESTED**

DEFENDANTS' MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT OF CLAIM 1 OF PATENT NO. 5,955,422 AND CLAIMS 9 AND 12 OF PATENT NO. 5,547,933

Defendants F. Hoffmann-La Roche LTD, Roche Diagnostics GmbH and Hoffmann-La Roche, Inc. ("Roche") respectfully move for summary judgment that asserted claim 1 of U.S. Patent 5,955,422 ("the '422 patent") and claims 9 and 12 of U.S Patent No. 5,547,933 (the '933 patent) owned by Plaintiff Amgen Inc. ("Amgen"), are not infringed by Roche's importation and sale of MIRCERA™.

This motion addresses the specific limitation common to the claims at issue, "[a] pharmaceutical composition comprising. .. . a pharmaceutically acceptable diluent, adjuvant or carrier." In filing this motion, Roche does not concede that its product MIRCERA™ meets any of the other limitations of the claims at issue. CERA, the active pharmaceutical ingredient in MIRCERA™, *inter alia*, (i) is not, and does not contain "human erythropoietin" or its equivalent, (ii) does not contain a "therapeutically effective amount of human erythropoeitin" (iii) is not "purified from mammalian cells grown in culture," and (iv) does not contain a

"glycoprotein product of the expression in a mammalian host cell of an exogenous DNA sequence comprising a DNA sequence encoding human erythropoietin."

For the purposes of this motion it is not necessary to consider whether MIRCERA™ meets any of these limitations. Infringement of '422 patent claim 1 and '933 patent claims 9 and 12 can be disposed of by looking at the single limitation, "[a] pharmaceutical composition comprising. . . . a pharmaceutically acceptable diluent, adjuvant or carrier." This Court has construed this phrase to mean "a composition suitable for administration to humans containing a diluent, adjuvant or carrier." Under the Federal Circuit's holding in ***Abbott Labs. v. Baxter Pharm. Prods., Inc.***, 334 F.3d 1274, 1280 (Fed. Cir. 2003), the limitation as construed embraces a closed Markush group. As such, the claim encompasses ***only*** pharmaceutical compositions containing one and only one of the specified alternatives, i.e., a diluent, adjuvant, or carrier.

The undisputed evidence in this case establishes that MIRCERA™ is not such a pharmaceutical composition because it contains ***multiple*** diluents and carriers and Amgen's expert admits that MIRCERA™ contains more than one diluent, adjuvant or carrier. The relevant claim language of '422 claim 1 and '933 claims 9 and 12, as construed by this Court, thus does not encompass pharmaceutical compositions such as MIRCERA™. Consequently, there are no issues of fact.

Accordingly, Roche respectfully requests that this Court grant its motion for summary judgment that claim 1 of the '422 patent and claims 9 and 12 of the '933 patent are not infringed by Roche's importation and sale of MIRCERA™. In support of this motion, Roche submits the accompanying memorandum of law, the Declaration of Howard S. Suh including exhibits, and a Rule 56.1 Statement of Undisputed Material Facts.

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 could be reached.

DATED: Boston, Massachusetts
June 11, 2007

Respectfully submitted,

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

By their Attorneys,

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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) and paper copies will be sent to those indicated as non registered participants on the above date.

/s/ Nicole A. Rizzo
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