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 **ORAL ARGUMENT REQUESTED**

ROCHE'S MOTION FOR SUMMARY JUDGMENT
THAT CLAIM 1 OF U.S. PATENT NO. 5,995,422 IS
INVALID FOR INDEFINITENESS AND LACK OF WRITTEN DESCRIPTION

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH and Hoffmann-La Roche Inc. (collectively "Roche") respectfully move for summary judgment that claim 1 of U.S. Patent No. 5,995,422 ("the '422 patent") owned by Plaintiff Amgen, Inc. ("Amgen"), is invalid under 35 U.S.C. § 112 because it is indefinite and/or fails to comply with the written description requirement.

Amgen attempts to distinguish the claimed erythropoietin-containing pharmaceutical composition of claim 1 from the prior art based on the claim term "wherein said erythropoietin is purified from mammalian cells grown in culture." Amgen maintains that the claim language is not merely a source limitation, but rather one that recites structure that physically distinguishes the claimed EPO product from EPO isolated from natural sources. Roche disagrees that the source language in the '422 patent claim 1, "wherein said erythropoietin is purified from mammalian cells grown in culture" imparts structural or functional limits on the human erythropoietin element recited earlier in the claim. However, if the claim language "purified from mammalian cells grown in culture"

is deemed to recite a structural distinction, as Amgen maintains, then claim 1 of the '422 patent is invalid under 35 U.S.C. § 112.

According to Amgen, the only physical difference between its claimed EPO products and EPO known in the prior art is the glycosylation.[1] Claim 1 of the '422 patent is invalid under 35 U.S.C. § 112 because this Court has previously held that claims which expressly distinguished the claimed EPO from prior art human urinary EPO based on unspecified glycosylation differences were invalid for indefiniteness and lack of written description owing to the "enormous heterogeneity" of the glycosylation found in human urinary erythropoietin.

This Court's previous decision, affirmed by the Federal Circuit, mandates that claim 1 of the '422 patent is invalid on indefiniteness and written description grounds.

Accordingly, Roche respectfully requests that this Court grant its motion for summary judgment that claim 1 of the '422 patent is invalid for indefiniteness and/or lack of written description. In support of this motion, Roche submits the accompanying memorandum of law, the Declaration of Peter Fratangelo including exhibits, and a Rule 56.1 Statement of Undisputed Material Facts.

[1] "Glycosylation" is the addition of carbohydrate side chains to amino acid residues in protein sequences to form glycoproteins. *Amgen, Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313, 1340 (Fed. Cir. 2003) ("*Amgen II*").

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
July 3, 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.

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