UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMGEN INC. Plaintiff, v. F. HOFFMANN-LA ROCHE LTD., ROCHE DIAGNOSTICS GMBH, and HOFFMAN-LA ROCHE INC. Defendants.	Civil Action No. 05 CV 12237 WGY

RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF 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. (collectively "Roche") submit the following statement of undisputed material facts, pursuant to Local Rule 56.1, in support of their motion for summary judgment of non-infringement of Claim 1 Patent No. 5,955,422 (the '422 patent) and claims 9 and 12 of Patent No. 5,547,933 (the '933 patent).

1. In this action, plaintiff Amgen Inc. alleges that Roche infringes claim 1 of the '422 patent and claims 9 and 12 of the '933 patent. (Suh Decl,[1] Ex. D at p. 3).

2. Claim 1 of the '422 patent and claims 9 and 12 of the '933 patent all contain the limitation "a pharmaceutical composition comprising . . . a pharmaceutically acceptable diluent, adjuvant or carrier." (*Id.* Ex. A, claim 1; Ex. B, claims 9 and 12).

[1] "Suh Decl." refers to the Declaration of Howard S. Suh in Support of 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.

3. On April 17, 2007, this Court construed the phrase "a pharmaceutical composition comprising . . . a pharmaceutically acceptable diluent, adjuvant or carrier" common to claim 1 of the '422 patent and claims 9 and 12 of the '933 patent to mean " a composition suitable for administration to humans containing a diluent, adjuvant or carrier." (*Id.* Ex. C at 77:1-3).

4. Amgen's expert, Dr. Lodish, admits that during the formulation process Roche adds "a diluent and carrier" to the active ingredient CERA. (*See id.* Ex. F ¶ 92).

5. The common specification of the '422 and '933 patents states that ""[a]lso comprehended by the invention are pharmaceutical compositions comprising effective amounts of polypeptide products of the invention together with suitable diluents, adjuvants and/or carriers. . . ." (*Id.* Ex. A at col. 12, ln. 5-8; Ex. B at col 12, ln. 1-4).

6. During an interference with U.S. Patent No. 4,806,524, applicant Lin's counsel suggested the count: "An erythropoietin preparation containing one or more selected from the group consisting of bovine serum albumin, human serum albumin and gelatin." (*Id.* Ex. J at 4; *see also* Ex. K; Ex. L).

DATED: Boston, Massachusetts
June 11, 2007

Respectfully submitted,

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

By their Attorneys,

/s/ Nicole A. Rizzo
Lee Carl Bromberg (BBO# 058480)
Julia Huston (BBO# 562160)
Keith E. Toms (BBO# 663369)
Nicole A. Rizzo (BBO # 663853)
BROMBERG & SUNSTEIN LLP
125 Summer Street
Boston, MA 02110
Tel: (617) 443-9292
nrizzo@bromsun.com

Leora Ben-Ami (*pro hac vice*)
Mark S. Popofsky (*pro hac vice*)
Patricia A. Carson (*pro hac vice*)
Thomas F. Fleming (*pro hac vice*)
Howard S. Suh (*pro hac vice*)
Peter Fratangelo (BBO# 639775)
KAYE SCHOLER LLP
425 Park Avenue
New York, NY 10022
Tel: (212) 836-8000

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
Nicole A. Rizzo

03099/00501 684827.1