

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

_____)	
AMGEN INC.,)	
)	
Plaintiff,)	
)	
vs.)	
)	CIVIL ACTION No.: 05-CV-12237WGY
F. HOFFMANN-LA ROCHE LTD;)	
ROCHE DIAGNOSTICS GmbH; and)	
HOFFMANN-LA ROCHE INC.)	
)	
Defendants.)	
_____)	

**RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS IN
SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT
OF NONINFRINGEMENT OF THE '080 PATENT**

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 that the asserted claims of U.S. Patent No. 5,621,080 (the "'080 patent") are not infringed.

1. In this action, plaintiff Amgen, Inc. alleges that Roche infringes claims 3, 4 and 6 of the '080 patent. (Pl.'s Supp. Response to Defs.' First Set of Interrogs. (Nos. 1-12) No. 1, at p. 3).

2. Claims 3, 4 and 6 of the '080 patent all contain the operative limitation "wherein said erythropoietin glycoprotein comprises the mature erythropoietin amino acid sequence of FIG. 6." ('080 patent, claims 3, 4 and 6).

3. The Federal Circuit has construed this limitation to mean "that the claimed glycoprotein must have -- at minimum -- all 166 amino acids shown in Figure 6." *Amgen v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1345 (Fed. Cir. 2003).

4. Amgen maintains that Roche's accused product is a "165-amino-acid glycosylated EPO polypeptide." (Expert Report of Harvey F. Lodish, Ph.D. Regarding Infringement, ¶ 117).

5. Amgen asserts that Roche's product "comprises the equivalent of the mature erythropoietin amino acid sequence of Figure 6 of the '080 Patent because the difference" -- between Roche's product and the 166 amino acids of Figure 6 -- "is insubstantial." (Pl.'s Supp. Resp. to Defs.' First Set of Interrogs. (Nos. 1-12), Ex. A at 46).

6. The Federal Circuit has held that Amgen is foreclosed, by prosecution history estoppel, from arguing that a 165 amino acid protein can satisfy the "wherein said erythroprotein glycoprotein comprises the mature erythropoietin amino acid sequence of FIG. 6" limitation in the claims of the '080 patent under the doctrine of equivalents. *Amgen v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1316 (Fed. Cir. 2006).

Dated: May 21, 2007
Boston, Massachusetts

Respectfully submitted,

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

By its attorneys,

/s/ Julia Huston

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
jhuston@bromsun.com

Leora Ben-Ami (*pro hac vice*)
Patricia A. Carson (*pro hac vice*)

Thomas F. Fleming (*pro hac vice*)
Howard S. Suh (*pro hac vice*)
Christopher T. Jagoe (*pro hac vice*)
KAYE SCHOLER LLP
425 Park Avenue
New York, New York 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/ Julia Huston
Julia Huston

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