

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
THAT THE ASSERTED CLAIMS OF THE '933 PATENT ARE
INVALID FOR INDEFINITENESS AND LACK OF WRITTEN DESCRIPTION**

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH and Hoffmann-LaRoche Inc. (collectively "Roche") submit the following statement of undisputed material facts, pursuant to Local Rule 56.1, in support of their motion for partial summary judgment that the asserted claims of U.S. Patent Nos. 5,547,933 (the '933 patent) and 5,621,080 (the '080 patent) are invalid, under 35 U.S.C. § 112, for indefiniteness and lack of written description.

1. In this action, Plaintiff Amgen Inc. ("Amgen") alleges that Roche infringes claims 3, 7-9, 11-12 and 14 of the '933 patent. (Suh Decl., Ex. K at p. 3).
2. In *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp. 2d 69, 91 (D. Mass. 2001) ("*Amgen I*"), this Court construed the term "non-naturally occurring," as used in the claims of the '933 patent, to mean "not occurring in nature." The Court stated that "[b]y

including this limitation,” the applicant “meant to stand clear of the unpatentable, naturally occurring products. He intended nothing more.” *Id.*

3. The ‘933 patent describes only one supposed physical distinction between the non-naturally occurring erythropoietin glycoproteins of the claims and naturally occurring erythropoietin, *i.e.*, glycosylation. (Suh Decl., Ex. A: col. 10:28-40; 28:51-29:7).

4. In *Amgen I*, this Court held that because the glycosylation of naturally occurring EPO varies, claims 1, 2 and 9 of the ‘933 patent, which distinguish the claimed non-naturally occurring erythropoietin glycoproteins from naturally occurring erythropoietin based on the “glycosylation” or “average carbohydrate composition,” were not infringed or, alternatively, were invalid for indefiniteness (“one of ordinary skill would be unable to determine whether a particular erythropoietin has a glycosylation which differs from that of human urinary erythropoietin”) and lack of written description (“the patent fails to convey to one of ordinary skill in the art as of 1984 that Dr. Lin invented in erythropoietin product having glycosylation which differs from human urinary erythropoietin”). *Amgen I* at 155-56.

5. In *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, Civil Action No. 97-10814-WGY (D. Mass), Amgen fully litigated whether the glycosylation of human urinary erythropoietin varies such that one of ordinary skill in the art as of 1984 reading the ‘933 patent would have understood that Dr. Lin invented an erythropoietin product having glycosylation which differed from the glycosylation of human urinary erythropoietin.

6. In *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, Civil Action No. 97-10814-WGY (D. Mass.), Amgen fully litigated whether one of ordinary skill in the art reading the claims of the ‘933 patent would have been able to determine whether the glycosylation of a

particular erythropoietin glycoprotein differed from the glycosylation of human urinary erythropoietin.

7. In *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313 (Fed. Cir. 2003), the Federal Circuit affirmed this Court's holding that claims 1, 2 and 9 of the '933 patent were invalid for indefiniteness.

8. Claims 3, 7-9, 11-12 and 14 of the '933 patent distinguish the structure of the claimed erythropoietin glycoproteins from naturally occurring erythropoietin based on the claimed products being "non-naturally occurring." The limitation was added to the claims to "distinguish the subject matter claimed from all prior art references relating to erythropoietin isolates." (Suh Decl., Ex. E, p. 7).

Dated: June 14, 2007
Boston, Massachusetts

Respectfully submitted,

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

By its Attorneys,

/s/ Nicole A. Rizzo
Lee Carl Bromberg (BBO# 058480)
Timothy M. Murphy (BBO# 551926)
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)
Vladimir Drozdoff (*pro hac vice*)
David L. Cousineau (*pro hac vice*)
KAYE SCHOLER LLP
425 Park Avenue
New York, New York 10022
Tel. (212) 836-8000

CERTIFICATE OF SERVICE

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/s/ Nicole A. Rizzo
Nicole A. Rizzo

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