UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

AMGEN INC.,))
Plaintiff,)
v.)
F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GmbH and HOFFMANN-LA ROCHE INC.))))
Defendants.)

CIVIL ACTION No.: 05-CV-12237WGY

DEFENDANTS' MOTION TO ADMIT TRIAL EXHIBIT NUK INTO EVIDENCE

Trial exhibit NUK -- a 1981 article by Gordon Ringold titled "Coexpression and

Amplification of Dihydrofolate Reductase cDNA and the Escherichia Coli XGPRT Gene in

Chinese Hamster Ovary Cells" published in the Journal of Molecular and Applied Genetics --

should be admitted into evidence for at least the following reasons:

- (i) This article is relevant prior art with respect to the issue of obviousness-type double patenting for claim 7 of the '349 patent.
- (ii) The relevant authority -- including the Federal Circuit's decision *In re Longi*, 759
 F.2d 887 (Fed. Cir. 1985) -- requires that a court deciding obviousness-type double patenting consider both the claims of the reference patent *and* any relevant prior art that may render the claims of the challenged patent obvious.

See Exhibit NUK attached as Exhibit A.

The doctrine of obviousness type double patenting prohibits the issuance of the claims of a second patent if those claims are not patentably distinct from the claims of an earlier patent. *Carman Industries, Inc. v. Wahl*, 724 F.2d 932 (Fed. Cir. 1983); *In re Thorington*, 418 F.2d 528 (C.C.P.A. 1969). In deciding whether the claims of the later patent are obvious, a court must

consider the claims of the reference patent in conjunction with the relevant prior art. *In re Longi*, 759 F.2d 887, 893 (Fed. Cir. 1985) ("we must direct our inquiry to whether the claimed invention in the application for the second patent would have been obvious from the subject matter of the claims in the first patent, *in light of the prior art*") (emphasis added).

Exhibit NUK is clearly relevant prior art. The asserted claim 7 of Amgen's '349 patent describes a process for producing erythropoietin, as does claim 4 of Amgen's earlier-issued '698 patent. Ostensibly, the '349 patent is distinguished from the '698 patent by the inclusion of language describing minimum measurable amounts of erythropoietin produced by the process in question. As Dr. Kadesch testified, however, the EPO minimum production levels described in claim 7 of the '349 patent were readily achievable during the relevant time period using methodology that was known in the prior art.¹ Exhibit NUK is part of that prior art and, as such, the court should admit this exhibit into evidence to consider for the issue of obviousness-type double patenting.

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 was reached.

¹ 10/1/07 Daily Tr. of Hr'g in re Obviousness-Type Double Patenting (Vol. 1) at 14:20-15:13.

DATED: Boston, Massachusetts October 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). Pursuant to agreement of counsel dated September 9, 2007, paper copies will not be sent to those indicated as non registered participants.

/s/ Nicole A. Rizzo Nicole A. Rizzo

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