UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

DEFENDANTS' SUPPLEMENTAL PROPOSED JURY INSTRUCTIONS

Defendants, F. Hoffman-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc., respectfully requests that the Court instruct the jury that a claimed product shown to be within the prior art cannot be rendered patentable solely by adding source or process limitations to the claim. Such an instruction would comport with Federal Circuit precedent and would clarify a complex issue of patent law for the jury. A copy of the proposed jury instruction is attached as Exhibit A.

This Court has held that source or process limitations on product claims are proper when they impart novel structures to the product claims. *See* Markman Order at 18 (citing *In re Luck*, 476 F.2d 650, 653 (C.C.P.A. 1973)) (D.N. 613). Thus, Amgen has asserted that the phrases "purified from mammalian cells grown in culture" in claim 1 of the '422 patent and "non-naturally occurring" in the '933 patent claims impart novel structural limitations to the claimed inventions. *See* Docket No. 312 at 17 ("The limitation 'purified from mammalian cells grown in culture' . . . recites the source from which the 'human erythropoietin' component of the claimed

composition may be obtained and necessarily imparts a further structural requirement that the product also be glycosylated.").

In construing the '422 patent in a previous litigation involving Amgen, the Federal Circuit stated that "a claimed product shown to be present in the prior art cannot be rendered patentable solely by the addition of source or process claims." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F. 3d 1313, 1354 (Fed. Cir. 2003). Similarly, the Federal Circuit held invalid two product-by-process claims in a pharmaceutical composition patent, stating that "a prior art disclosure of a product precludes a future claim to that same product, even if it is made by an allegedly novel process." *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1319 n.7 (Fed. Cir. 2006). *See also General Electric Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 373 (1938) ("a patentee who does not distinguish his product from what is old except by reference, express or constructive, to the process by which he produced it, cannot secure a monopoly on the product by whatever means produced.").

Thus, source and process limitations only make a product patentable if the limitations impart novel structures which distinguish the claimed product from products that existed in the prior art. Whether the claim terms "purified from mammalian cells grown in culture," in the '422 patent, and "non-naturally occurring," in the '933 patent, actually impart novel structures to the claimed products is the subject of expert testimony. Roche respectfully requests that the Court explain to the jury that the asserted claims of the '422 and the '933 patents are directed to specific products, and that the source or process limitation only render the products patentable if they distinguish the structure of the product from products found in the prior art.

A copy of Roche's proposed jury instruction is attached as Ex. A. Such an instruction would limit jury confusion in a case where numerous patents and even more asserted claims are at issue.

Dated: September 10, 2007
Boston, Massachusetts

Respectfully submitted,

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

By their attorneys,

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/s/ Keith E. Toms
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