UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

ROCHE'S 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-La Roche Inc. (collectively "Roche") respectfully move for summary judgment that claims 3, 7, 8, 9, 11, 12 and 14 of U.S. Patent No. 5,547,933 ("the '933 patent") owned by Plaintiff Amgen Inc. ("Amgen"), are invalid under 35 U.S.C. § 112 because they are indefinite or violate the written description requirement.

Amgen's product claims of the '933 patent cannot be valid if they cover products having structures that are identical to products that existed prior to Dr. Lin's invention date because, like all claims to products, they must be limited to new products. Recognizing this fundamental principle of patent law, during prosecution of the '933 patent, Amgen attempted to distinguish the claimed erythropoietin ("EPO") glycoproteins over the prior art EPO by adding the term "non-naturally occurring" to the claims. This Court has since construed the claim term "non-naturally occurring" to refer to glycoproteins "not occurring in nature." The implication was that

the products of the claims are glycoproteins which are structurally distinct, regardless of source or process of making, from structures that occur in nature.

Amgen now seems to allege that it is not the "non-naturally occurring" limitation that saves the claims from covering the structures that are not novel, but rather, the requirement that the claimed product is the result of the expression in a mammalian host cell of an exogenous DNA sequence comprising a DNA sequence encoding erythropoietin. Regardless of Amgen's approach, the fact is that distinguishing the EPO products claimed in the '933 patent from prior art EPO products based on the source or process for making the EPO but not the structure of the claimed EPO products is not sufficient to make the claimed EPO patentable.

The asserted claims of the '933 patent are invalid under 35 U.S.C. § 112 because the undisputed fact is that the one and only alleged physical distinction between the claimed EPO products and EPO known in the prior art is their glycosylation. This Court has previously held that claims which expressly distinguished the claimed EPO from prior art human urinary EPO based on unspecified glycosylation differences were invalid for indefiniteness and lack of written description owing to the "enormous heterogeneity" of the glycosylation found in human urinary erythropoietin.

Given that the only structural distinction between the claimed EPO products and EPO in the prior art that is taught by the patents is their glycosylation and given that the glycosylation of naturally occurring EPO has already been held to be a "standardless standard," it follows that the asserted claims, which distinguish the claimed products as being "non-naturally occurring," or the product "in a mammalian host cell . . ." are invalid for indefiniteness and lack of written description.

Further, Amgen is now attempting to relitigate this Court's decision which was affirmed by the Federal Circuit. Amgen is collaterally estopped from disputing that glycosylation is an indefinite basis for distinguishing between the non-naturally occurring EPO products of the claims and naturally occurring EPO. Thus, this Court's previous decision, affirmed by the Federal Circuit, mandates that independent claim 3 of the '933 patent, which recites a "non-naturally occurring glycoprotein product," and asserted claims 7, 8, 9, 11, 12 and 14, which depend therefrom directly or indirectly, are invalid on indefiniteness and written description grounds.

Accordingly, Roche respectfully requests that this Court grant its motion for summary judgment that the asserted claims of the '933 patent are invalid for indefiniteness and lack of written description. In support of this motion, Roche submits the accompanying memorandum of law, the Declaration of Howard S. Suh including exhibits, and a Rule 56.1 Statement of Undisputed Material Facts.

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 could be reached.

Dated: June 14, 2007
Boston, Massachusetts

Respectfully submitted,

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

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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) and paper copies will be sent to those indicated as non-registered participants on the above date.

/s/ Nicole A. Rizzo
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