

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

ORAL ARGUMENT REQUESTED

**ROCHE’S MOTION FOR SUMMARY JUDGMENT THAT CLAIM 7 OF
PATENT NO. 5,756,349 IS INVALID UNDER 35 U.S.C. § 112 AND IS NOT INFRINGED**

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively, “Roche”) respectfully move this Court for summary judgment that claim 7 of U.S. Patent 5,756,349 (the “ ‘349 patent”) – the only claim of that patent asserted in this case by Plaintiff Amgen Inc. (“Amgen”) – is both invalid, under 35 U.S.C. § 112, on the grounds of indefiniteness, lack of written description, and lack of enablement, and is not infringed.

Claim 7 of the ‘349 patent is indefinite, lacks written description and is not enabled for at least the following reasons. The claim covers a process of using “vertebrate cells” that are “capable” of producing “U of erythropoietin . . . as determined by radioimmunoassay.” This limitation is impaired for three reasons. First, the test specified in the claims, radioimmunoassay (“RIA”), cannot distinguish erythropoietin (“EPO”) and other molecules that are not EPO, such as EPO fragments. Second, RIA does not quantify “U of erythropoietin,” because “U,” or “Units” of EPO is a measure of biological activity, which RIA cannot measure. Third, the patent

claims and specification do not identify which one of the many reference standards to use in the RIA, standards which are necessary to estimate, after making other critical assumptions, the number of Units of EPO present in a test sample. Claim 7 is also indefinite to the extent that vertebrate cells used in the process merely be “capable” of producing EPO, despite the fact that EPO production will vary depending on culture conditions.

Given these impairments, Amgen cannot meet its burden of proving infringement of claim 7 because it cannot show that Roche uses vertebrate cells capable of producing the specified number of “U of erythropoietin . . . as determined by radioimmunoassay.”

In support of this motion, Roche submits the accompanying Memorandum of Law, the Declaration of Howard S. Suh, including exhibits, and a separate Statement of Undisputed Facts according to Rule 56.1.

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 21, 2007
Boston, Massachusetts

Respectfully submitted,

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

By its attorneys,

/s/ Kimberly J. Seluga

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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 June 22, 2007.

/s/ Kimberly J. Seluga

Kimberly J. Seluga