

**IN THE UNITED STATES DISTRICT COURT
FOR THE 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-12237 WGY

**ROCHE'S BENCH MEMORANDUM IN SUPPORT OF ITS ARGUMENT THAT ROCHE'S
EPOETIN BETA STARTING MATERIAL USED TO SYNTHESIZE CERA FAILS TO
MEET THE "EXPRESSED BY SAID CELLS" LIMITATION IN THE ASSERTED CLAIMS
OF THE '698 PATENT**

Roche respectfully submits this bench memorandum to inform the Court of its argument that Roche's epoetin beta starting material Roche uses as a reagent to synthesize CERA fails to meet the "expressed by said cells" limitation of the asserted claims of the '698 patent. Roche seeks clarification as to whether this argument is consistent with the Court's prior rulings.

In the July 23, 2007 Claim Construction Order, the Court construed the following term from the asserted claims of the '933 patent: "a non-naturally occurring glycoprotein *product of the expression in a mammalian host cell* of an exogenous DNA sequence comprising a DNA sequence encoding human erythropoietin" as "a glycoprotein (not occurring in nature) that is the product of the expression¹ in a mammalian host cell of a DNA sequence that does not originate in the genome of the host, and which contains the genetic instructions (or a DNA sequence) encoding human erythropoietin." The Court did not, however, construe the term "*expressed by*

¹ "Wherein expression means that the glycoprotein was produced in a cell and recovered from the cell culture."

said cells” found in the asserted claims of the ‘698 patent, and it is not clear if the Court intended its construction of “expression” in the ‘933 patent to define the phrase “expressed by” in the ‘698 patent. If not, and “expressed by” is given its normal and ordinary meaning, then Roche’s expert Dr. Alexander Klibanov intends to testify -- consistent with his expert report -- that Epoetin beta starting material is not a polypeptide “expressed by said cells” but rather is the product of further processing to a fragment of an expressed peptide.²

Roche believes that the issue of whether epoetin beta is “expressed by said cells” is open and seeks the Court’s guidance to confirm that it may present evidence on this issue.

Dated: October 15, 2007
Boston, Massachusetts

Respectfully submitted,

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

By its attorneys,
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² Klibanov 5/11/07 Expert Report at ¶¶111, 260.

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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/ Thomas F. Fleming

Thomas F. Fleming