

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

AMGEN, INC.,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 05 CV 12237 WGY
)	
F. HOFFMANN-LAROCHE LTD.,)	
a Swiss Company, ROCHE DIAGNOSTICS)	
GMBH, a German Company, and)	
HOFFMANN LAROCHE INC., a New)	
Jersey Corporation,)	
)	
Defendants.)	

**MOTION *IN LIMINE* TO PRECLUDE ROCHE’S EXPERT DR. KLIBANOV
FROM OFFERING OPINIONS BASED ON A CONSTRUCTION THAT IS
INCONSISTENT WITH THE COURT’S CLAIM CONSTRUCTION OF THE
CLAIM TERM “HUMAN ERYTHROPOIETIN”**

Dr. Klibanov asserts that Roche’s CERA product does not infringe the asserted claims of the ‘933 patent because the EPO in CERA has 165 amino acids rather than 166 amino acids.¹ However, Dr. Klibanov’s opinion is based upon an improper construction of “non-naturally occurring glycoprotein product,” as further limited by the term “DNA sequence encoding human erythropoietin.”

The ‘933 claims are product-by-process claims that define the product by a “DNA sequence encoding human erythropoietin” used to make such products:

“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”: a glycoprotein (not occurring in nature) that is the product of the expression [wherein expression means that the glycoprotein was produced in a cell and recovered from the cell culture] in a mammalian host cell of a DNA sequence that does not originate in the genome of

¹ Rebuttal Expert Report of Professor Alexander M. Klibanov, dated May 11, 2007, ¶¶ 259-260.

the host, and which contains the genetic instructions (or a DNA sequence) encoding human erythropoietin.

As set forth in this Court's *Markman* Memorandum and Order, dated July 3, 2007 ("*Markman* Order"), "human erythropoietin" means "a protein having the amino acid sequence of human EPO, such as the amino acid sequence of EPO isolated from human urine." Nothing in the claim or the Court's construction of "non-naturally occurring glycoprotein" or "DNA sequence encoding human erythropoietin" refers to a 166 amino acid glycoprotein. Indeed, regarding "human erythropoietin," the Court specifically made plain at trial that its construction "doesn't say anything about 165 or 166. It says what it says."²

Accordingly, this Court should exclude Dr. Klibanov's opinion that CERA does not infringe the '933 patent claims on the grounds that it contains "a 165 amino acid residue,"³ and by this motion, Amgen respectfully requests that the Court preclude Dr. Klibanov from offering any opinion based on the improper construction the claims of the '933 patent.

Dated: October 15, 2007

Respectfully Submitted,

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By its attorneys,

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² 9/24/07 Tr. at 1237:5-7.

³ Rebuttal Expert Report of Professor Alexander M. Klibanov, dated May 11, 2007, ¶260.

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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 no agreement was reached.

/s/ Michael R. Gottfried
Michael R. Gottfried

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 and paper copies will be sent to those indicated as non-registered participants on October 15, 2007.

/s/ Michael R. Gottfried
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