

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

AMGEN'S MOTION IN LIMINE REGARDING FLAVELL NO. 4:
TO PRECLUDE RICHARD FLAVELL FROM OFFERING OPINIONS
REGARDING THE ASSERTED '933 CLAIMS THAT ARE BASED ON A
CONSTRUCTION THAT IS INCONSISTENT WITH THE COURT'S CLAIM
CONSTRUCTION OF THE CLAIM TERM "HUMAN ERYTHROPOIETIN"

Dr. Flavell 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.
However, Dr. Flavell'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 "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

1 Non-Infringement Expert Report of Richard A. Flavell, Ph.D., dated May 11, 2007, ¶139.
Excerpts from Dr. Flavell's May 11, 2007 Report referenced in this Motion are attached as
Exhibit 2 to the Declaration Of Linda Sasaki-Baxley In Support Of Amgen's Motions Regarding
The Testimony Of Richard Flavell, filed herewith.

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 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. Flavell’s opinion that CERA does not infringe the ‘933 patent claims on the grounds that “it only has 165 residues,”³ and by this motion, Amgen respectfully requests that the Court preclude Dr. Flavell from offering any opinion based on the improper construction of the claims of the ‘933 patent.

Dated: October 15, 2007

Respectfully Submitted,

AMGEN INC.,
By its attorneys,

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² 9/24/07 Tr. at 1237:5-7.

³ *Id.*

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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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