

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

PLAINTIFF AMGEN INC.'S MOTION TO PRECLUDE ROCHE'S EXPERT DR.
KLIBANOV FROM OFFERING OPINIONS BASED ON AN INFRINGEMENT
ANALYSIS THAT IS INCONSISTENT WITH FEDERAL CIRCUIT PRECEDENT
AND WITH THE COURT'S CLAIM CONSTRUCTION RULING THAT
AMGEN'S CLAIMS ARE OPEN-ENDED

Based on the false premise that the "glycoprotein product" of '933 claim 3 excludes the
addition or attachment of further structure to the claimed product, Dr. Klibanov opines that
Roche's CERA product does not infringe that or any dependent '933 claim because an additional
structure is attached to the claim product by chemical synthesis, not a cell. Dr. Klibanov goes on
to state that "CERA is not the product of expression" as claimed.

But as the Federal Circuit in AmstarCorp. v. Envirotech Corp. teaches, Dr. Klibanov's
argument turns the law of infringement on its head. The issue is whether the accused product –

1 Rebuttal Expert Report of Professor Alexander M. Klibanov, dated May 11, 2007, ¶256.

2 Amstar Corp. v. Envirotech Corp., 730 F.2d 1476, 1482 (Fed. Cir. 1984) (holding that "[t]he
law of infringement requires that the asserted claims be compared with the products or processes
accused of infringement," and it is irrelevant that there are "apparatus distinctions in determining
infringement of process claims.").

CERA – meets every limitation of the claim, not whether the claim describes every attribute of the accused product.³ The fact that CERA contains an EPO glycoprotein product of the expression of a mammalian cell establishes its infringement. The fact that Roche adds additional structure to that product to make CERA is legally irrelevant.

As this Court held in the *Markman* Memorandum and Order, dated July 3, 2007

(“*Markman* Order”):

[t]he specification does not define “erythropoietin” by reference to the presence or absence of any attached molecules, such as the carbohydrate that can be attached to EPO proteins for glycosylated EPO. ‘933 Patent 10:28-33. In fact, the specification expressly contemplates that additional molecules may be attached to “human erythropoietin.” By implication, therefore, those additional molecules are not part of the amino acid structure that comprises the claimed product.⁴

The Court went on to state that it did not think “it ought alter the open construction of the term ‘human erythropoietin’ found in the patent because the patent itself “is silent as to the presence or absence of any structural characteristic beyond the required amino acid.”⁵ There can be no dispute that Dr. Klibanov’s construction of the claim contravenes this Court’s claim construction and the law of infringement.⁶ Accordingly, Dr. Klibanov should not be allowed to offer this opinion at trial.

³ *Id.*

⁴ *Markman* Order, dated July 3, 2007, p. 14.

⁵ *Id.*

⁶ *Phillips v. AWH Corp.*, 415 F.3d 1303, 1318 (Fed. Cir. 2005) (“[A] court should discount any expert testimony ‘that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent.’”); *see also Amstar*, 730 F.2d 1476.

Based on the foregoing, the Court should preclude Dr. Klibanov from offering any opinions that misconstrue the open-ended construction of Dr. Lin's product by process claims.

Dated: October 15, 2007

Respectfully Submitted,

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By its attorneys,

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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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