

**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.)	

**AMGEN’S RESPONSE TO ROCHE’S BENCH MEMORANDUM (D.I. 1398)
OFFERING OPINIONS BASED ON A CLAIM CONSTRUCTION THAT IS
INCONSISTENT WITH THE COURT’S CLAIM CONSTRUCTION OF THE CLAIM
TERMS “ISOLATING” AND “COMPRISING,”
AS SET FORTH IN THE ASSERTED ‘698 CLAIMS**

Roche’s argument that CERA fails to meet the “isolating said glycosylated erythropoietin polypeptide expressed by said cells” limitation of the asserted claims of the ‘698 patent is inconsistent with the Court’s prior rulings.¹

Roche’s expert, Dr. Klibanov, offers non-infringement opinions regarding Dr. Lin’s ‘698 and ‘868 claims based on the assumption that these claims are limited to processes that result in crude EPO isolates, to the exclusion of purified EPO preparations or processes that include additional steps that would allow for the addition of peg to EPO. Dr. Klibanov does this in two ways, both of which contradict the Court’s July 3, 2007 *Markman* Memorandum and Order.

¹ See 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 (Docket No. 1398).

First, Dr. Klibanov opines that the human EPO in MICERA is materially changed because the “isolating... expressed by said cells” step of the asserted ‘868 and ‘698 claims² excludes further process steps beyond those recited in the claims.³ But, the Court’s construction of “isolating” is not limited to steps that only allow for the separation or EPO from cellular material. Second, he ignores that the asserted claims all use the open-ended term “comprising” when listing the steps of the claimed process.

Regarding the term “isolating,” contrary to Dr. Klibanov’s opinion, the Court’s construction does not exclude the possibility that “purifying” is encompassed within the term “isolating.” Rather, the Court simply recognized that “purifying” and “isolating” are not synonymous, and distinguished between, on the one hand, steps that can be satisfied only if a pure product results (*i.e.*, “purifying”) from, on the other hand, steps that merely require separation but are not limited only to “separated” products (*i.e.*, “isolating”), but may also include within their broader scope “purified” products.⁴

More to the point, Dr. Klibanov’s construction ignores the “comprising” language of the preamble, which expressly renders the claim process open-ended.⁵ As construed by the Court, Dr. Lin’s asserted process claims, all of which use “comprising,” are “open” and require only

² ‘349 Claim 7 does not include an “isolating” step and should not be affected by Dr. Klibanov’s opinion on this issue.

³ *See generally*, 5/11/07 Klibanov Report, ¶ 110-114. Dr. Klibanov expressly states that he understands the asserted process claims to be close-ended in ¶ 112.

⁴ Contrary to Dr. Klibanov’s unsupported contention that Amgen’s statements during an interference exclude from the claims processes that yield a pure product, Amgen’s prior statements are not so limiting and are consistent with this position. 5/11/07 Klibanov Report ¶ 112.

⁵ D.I. 613 at 28.

that the process “contain the named elements.”⁶ In so ruling, the Court rejected Roche’s attempt to preclude from the claimed processes the performance of additional steps, “leav[ing] open for later the discussion and argument to determine whether the additional steps Roche/Hoffmann apparently uses ‘materially change’ the accused product.”⁷ The Court would not have so commented had it intended to limit Dr. Lin’s claim as Dr. Klibanov opines.

Roche’s bench memorandum, claiming to seek “clarity” regarding the phrase “expressed by said cells” is really an attempt to avoid the open-ended nature of the process claims and to improperly limit the entire claim limitation “isolating said glycosylated erythropoietin polypeptide expressed by said cells.” By focusing only upon the term “expressed by said cells,” Roche hopes to avoid the problem that the claim construction offered by its expert is contrary to the Court’s definition of both “isolating” and the presence in the claim of “comprising.” This should not be permitted. Roche, through its expert Dr. Klibanov, should not be allowed to improperly limit the Court’s construction of the term “isolating” or read out of Dr. Lin’s process claims the term “comprising” or the Court’s construction of such term.⁸

Amgen therefore respectfully requests that this Court should preclude Dr. Klibanov from offering the opinion that Dr. Lin’s asserted process claims (‘698 claims 6-9, ‘868 claims 1-2, and ‘349 claim 7) should be read as “closed” ended or as limited to methods for making “crude EPO isolates” or “crude harvest material.”

⁶ *Id.*

⁷ *Id.*

⁸ As the Federal Circuit has held, because an expert report is generated in connection with litigation it can be biased and therefore, the Court should not rely upon it for determining the construction of the claims. *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.’”).

Dated: October 15, 2007

Respectfully Submitted,

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

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