

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. 7:
TO PRECLUDE RICHARD FLAVELL FROM OFFERING OPINIONS
BASED ON A CLAIM CONSTRUCTION THAT REQUIRES THAT
THE TERM "OBLIGATE" GLYCOPROTEIN BE READ
INTO THE ASSERTED '933 CLAIMS

Based on the premise that the asserted '933 claim 3 requires an "obligate" glycoprotein, Dr. Flavell opines that CERA does not infringe the term "human erythropoietin" as it appears in the limitation "DNA sequence encoding human erythropoietin."1 Dr. Flavell's premise, however, is false because it contravenes the Court's construction of "human erythropoietin" as set forth in the Markman Memorandum and Order dated July 3, 2007 ("Markman Order").

1 See, e.g., 5/11/07 Flavell Report at ¶ 170 ("As explained below deglycosylation experiments demonstrate that CERA is not an 'obligate glycoprotein' as its biological activity persists after N-deglycosylation. Thus, CERA does not meet the 'human erythropoietin' limitation of claim 3 of the '933 patent and so does not infringe this claim."). See also id. at ¶¶165-175, 178, 182. Dr. Flavell's opinion not only includes '933 claim 3, but also extends to '080 claim 3 (which is not before the jury) and '422 claim 1 which is not before the jury unless Roche pursues the defense of reverse doctrine of equivalents. 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.

This Court has construed the term “human erythropoietin” to mean: “A protein having the amino acid sequence of human EPO, such as the amino acid sequence of EPO isolated from human urine.”² During the *Markman* proceedings in this case, Roche advocated reading a “glycosylation” requirement into the term “human erythropoietin.”³ The Court rejected Roche’s position and, in fact, the Court held that the term “human erythropoietin” does not require *any* glycosylation.⁴ Thus, Roche’s expert’s infringement analysis is inconsistent with the Court’s claim construction and should be precluded.⁵

Even if the Court were willing to entertain further consideration of its claim construction, Dr. Flavell should be precluded from offering any testimony on the issue. The proper time for claim construction arguments was during the *Markman* proceedings. During *Markman*, the Court properly made its decisions based on intrinsic evidence, not expert witness opinion.⁶ It was incumbent on Roche to abide by the Court’s scheduling orders and present its arguments concerning the meaning and scope of Dr. Lin’s claims during the *Markman* proceedings — not at trial. Indeed, to put this claim construction issue before the jury is improper under *Markman v. Westview Instruments*. Determination of the meaning of the claims-in-suit by consideration of

² *Markman* Order, p. 15.

³ *Markman* Order, p. 13 (chart reflecting Roche’s construction to include the requirement that “human erythropoietin” be a “glycoprotein”).

⁴ *Amgen, Inc. v. F. Hoffmann La Roche, LTD.*, 2007 U.S. Dist. LEXIS 47886, at *18-*21 (D. Mass. 2007).

⁵ Any attempt by Dr. Flavell to shift his opinion to read the limitation “obligate” into the term “glycoprotein” would fall outside the scope of his Reports.

⁶ *Phillips v. AWH Corp.*, 415 F.3d 1303, 1318 (Fed. Cir. 2005); (holding that 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.).

the intrinsic record is entirely within the province of the Court.⁷ Having chosen not to raise this issue at the appropriate time in the appropriate forum, Roche should be precluded from making this purely legal argument at trial via its expert witnesses. Pressing such an argument outside of the claim construction proceedings and via expert testimony is legally incorrect.⁸

Based on the foregoing, the Court should preclude Dr. Flavell from offering any opinion that seeks to read the additional limitation of “obligate” glycoprotein into the asserted ‘933 claims.

Dated: October 15, 2007

Respectfully Submitted,

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⁷ *Markman v. Westview Instruments*, 517 U.S. 370, 372 (1996) (“We hold that the construction of a patent, including terms of art within its claim, is exclusively within the province of the court.”).

⁸ *See Phillips*, 415 F.3d at 1318.

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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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