

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.: 05-12237 WGY

AMGEN'S BENCH MEMORANDUM THAT IT IS IMPROPER FOR DR. RICHARD A. FLAVELL TO OFFER OPINIONS BASED ON HIS IMPROPER REJECTION OF THIS COURT'S CLAIM CONSTRUCTION OF THE TERM "HUMAN ERYTHROPOIETIN"

Roche's Dr. Richard A Flavell has offered written description and definiteness opinions based on an incorrect claim construction of the term "human erythropoietin." This Court has held as a matter of law that "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."1

The Court's construction includes but is not limited to EPO with a 165 amino acid sequence and is entirely consistent with the written description in the specification of the patents-in-suit. For example, the specification states that "allelic forms of mature EPO polypeptides may vary from each other and from the sequences of FIGS. 5 and 6 in terms of length of sequence..."2 But instead of using this Court's construction, Dr. Flavell misinterprets and incorrectly narrows the claim construction of "human erythropoietin" to mean:

1 7/3/07 Memorandum and Order as to Claim Construction, at 13 (Dkt. No. 613) (emphasis added).

2 U.S. Patent No. 5,547,933 at col. 35.

“a polypeptide having the amino acid sequence of erythropoietin isolated from human urine, which [he] understands is 165 amino acids.”³

Based on this impermissible narrowing, Dr. Flavell renders a number of opinions that are entirely erroneous, including:

- Human erythropoietin is not adequately described because “the ‘subject matter’ of the claimed invention is human erythropoietin having a specific 165 amino acid sequence. As such, I believe the specification must set forth the boundaries of the claimed invention in a clear and unambiguous manner and provide information about this exact sequence.”⁴
- “But even if this change was one of the ‘allelic forms’ it wouldn’t matter. Human erythropoietin according to the claims is specifically limited to the 165-amino acid polypeptide isolated from human urine.”⁵

These opinions rest on the impermissible limitation that Dr. Flavell has placed on this Court’s construction of human erythropoietin. Dr. Flavell should not be permitted to testify regarding invalidity opinions based upon a redefinition of this Court’s claim construction – the foundation of the validity determination in this case. Expert opinions based on an incorrect claim construction are irrelevant to the issues in the case and can only serve to confuse the jury. All of the validity opinions in Dr. Flavell’s reports directed to the asserted claims including the term “human erythropoietin” are based on his incorrect claim construction. Accordingly, pursuant to Fed. R. Evid. 402 and 403, all such opinions should be excluded from evidence as likely to confuse and mislead the jury and as irrelevant to the determination of whether these claims, *as properly construed by the Court*, are valid.

³ Fourth Statement of Richard A. Flavell, Ph.D in Response to Various Arguments Raised by Amgen’s Experts, June 13, 2007, ¶ 9. Attached hereto as Exhibit A to the Declaration of Daniel A. Curto in Support of Bench Memo (“Curto Dec.”)

⁴ *Id.* at ¶ 69.

⁵ *Id.* at ¶ 74.

I. Expert Opinion Based on a Flawed Construction of a Claim Is Impermissible and Must Be Excluded.

An expert opinion based on an impermissible claim construction is irrelevant and will likely prejudice and confuse the jury.⁶ As the Supreme Court held in *Markman v. Westview Instruments*, claim construction is a question of law for the court to decide.⁷ As such, an expert's opinion on claim construction can never be helpful to the trier of fact,⁸ especially where a party attempts to rewrite a court's claim construction under the guise of expert testimony relying on such rewritten construction.⁹ Thus, when an expert's opinion is premised on a claim construction that is contrary to that of this Court — such as Dr. Flavell's opinions — the opinion is irrelevant and inadmissible.¹⁰

Roche — in blatant disregard of these well-settled claim construction principles — seeks to introduce through Dr. Flavell opinions that are based on a construction of the term “human erythropoietin” that is different from the construction this Court has already given that term.

⁶ *Liquid Dynamics Corp. v. Vaughan Co.*, 449 F.3d 1209, 1224 n.2 (Fed. Cir. 2006) (stating that district court did not abuse its discretion when it held that an expert opinion based on an impermissible claim construction was irrelevant and could prejudice and confuse the jury).

⁷ 517 U.S. 370, 390-91 (1996).

⁸ *Id.* at 387 (“Questions of construction are questions of law for the judge, not questions of fact for the jury”) (quotation omitted); *see also* Fed. R. Evid. 702 (expert opinion must “assist the trier of fact”).

⁹ *See, e.g., Liquid Dynamics Corp. v. Vaughan Co.*, 449 F.3d at 1224 n.2 (affirming district court's refusal to admit expert testimony that was based on impermissible claim construction); *EZ Dock, Inc. v. Schafer Sys.*, 2003 U.S. Dist. LEXIS 3634, *34 n.4 (D. Minn. 2003) (“To the extent the analyses and opinions of Defendants' experts reflect a claim construction other than the Court's . . . those opinions and analyses have no relevance to the issues for trial and will be excluded.”).

¹⁰ *Liquid Dynamics Corp.*, 449 F.3d at 1224 n.2; *EZ Dock, Inc. v. Schafer Sys.*, 2003 U.S. Dist. LEXIS 3634, at *34 n.4. *See also Southwall Tech. v. Cardinal IG Co.*, 54 F.3d 1570, 1578 (Fed. Cir. 1995) (holding expert affidavits cannot alter court's claim construction); *Amazin' Raisins Int'l v. Ocean Spray Cranberries*, 2007 U.S. Dist. LEXIS 60808, at *37 (D. Mass. Aug. 20, 2007) (Wolf, C.J.) (rejecting expert opinion that was contrary to court's claim construction); *Trilithic, Inc. v. Wavetek United States*, 64 F. Supp. 2d 816, 822 (D. Ind. 1999) (conflicting expert opinion “does not create a genuine fact nor can the expert opinion bind the court”) (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 983 (Fed. Cir. 1995)).

Thus, below is Dr. Flavell’s proposed construction of “human erythropoietin” and the construction determined by this Court:

Court’s Construction	Dr. Flavell’s Construction
a protein having the amino acid sequence of human EPO, <i>such as</i> the amino acid sequence of EPO isolated from human urine. ¹¹	human erythropoietin in the context of the claims in suit means a polypeptide having the amino acid sequence of erythropoietin isolated from human urine, which I understand to be 165 amino acids. ¹²

Dr Flavell unambiguously limits the construction to human erythropoietin having a specific 165 amino acid sequence.¹³ Dr. Flavell’s definition misinterprets and narrows this Court’s construction of human erythropoietin. This Court did not, as Dr. Flavell claims to “understand,” limit the term “human erythropoietin” to EPO isolated from human urine with a 165 amino acid sequence. As set forth in the Court’s construction, a protein having the amino acid sequence of human EPO *includes* EPO with a 165 amino acid sequence isolated from human urine. But it is not limited to EPO with a 165 amino acid sequence. To claim otherwise — as Dr. Flavell does to render his opinions — reads out of the Court’s construction the term “such as.”¹⁴

Furthermore, Dr. Flavell’s narrowing of “human erythropoietin” to only a 165 amino acid sequence is inconsistent with the patent specification. As this Court recognized in construing the

¹¹ 7/3/07 Memorandum and Order as to Claim Construction, at 13 (Dkt. No. 613) (emphasis added).

¹² Fourth Statement of Richard A. Flavell, Ph.D in Response to Various Arguments Raised by Amgen’s Experts, June 13, 2007, ¶ 9. Dr. Flavell’s construction, rather than being consistent with this Court’s ruling, hews closely to the claims construction offered by Roche and rejected by the Court during *Markman* proceedings in this matter. See Docket 11 at 1 (limiting “human erythropoietin” to products “having the amino acid sequence of erythropoietin isolated from human urine . . .”). Curto Dec., Ex. A.

¹³ Fourth Expert Statement of Richard A. Flavell, Ph.D., ¶69 (“[T]he ‘subject matter’ of the claimed invention is human erythropoietin” having a specific 165 amino acid sequence.”); *Id.* at ¶74 (“Human erythropoietin is specifically limited to the 165-amino acid polypeptide isolated from human urine.”). Curto Dec., Ex. A.

¹⁴ Dr. Flavell justifies reading “such as” out this Court’s construction by pointing to Amgen statements made *prior* to this Court’s claim construction, Fourth Statement of Richard A. Flavell, Ph.D., ¶ 76. Curto Dec., Ex. A.

term “human erythropoietin,” one of the reasons it accepted Amgen’s construction of the term was to render the claim consistent with “other claims, the patent specification, and the prosecution history.”¹⁵ Amgen’s ‘933 patent describes human erythropoietin as “allelic.”¹⁶ In column 35 of the patent, Amgen expressly states that “mature EPO polypeptides may vary from each other and from the sequences of FIGS. 5 and 6 in terms of length of sequence”¹⁷ This Court’s claim construction of “human erythropoietin” as including the amino acid sequence of EPO isolated in human urine, but not being limited to such a sequence, is entirely consistent with these statements in the ‘933 patents. Dr. Flavell’s claimed construction, on the other hand, inappropriately seeks to create a conflict between the construction and statements in the patent specification.

It is this Court, not the jury or an expert, who is charged with the responsibility of construing the term “human erythropoietin.” By presenting Dr. Flavell’s opinion, Roche is asking the jury to circumvent this Court’s prior construction and render a judgment based on an irretrievably flawed analysis. This is precisely what *Markman* and its progeny forbid. It is the Court’s construction that must control, and expert opinions that attempt to use a different construction are “entitled to no weight.”¹⁸ Accordingly, Dr. Flavell’s opinions based on his flawed construction of “human erythropoietin” are meaningless to the issues in this case and Amgen respectfully requests that this Court preclude Dr. Flavell from offering these opinions into evidence.

¹⁵ 7/3/07 Memorandum and Order as to Claim Construction, at 14 (Dkt. No. 613).

¹⁶ U.S. Patent No. 5,547,933 col.21 & col.35.

¹⁷ *Id.* at col.35.

¹⁸ *See Southwall Tech.*, 54 F.3d at 1578.

Dated: September 14, 2007

Respectfully Submitted,

AMGEN INC.,
By its attorneys,

Of Counsel:

Stuart L. Watt
Wendy A. Whiteford
Monique L. Cordray
Darrell G. Dotson
Kimberlin L. Morley
Erica S. Olson
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320-1789
(805) 447-5000

/s/ Michael R. Gottfried

D. Dennis Allegretti (BBO#545511)
Michael R. Gottfried (BBO# 542156)
Patricia R. Rich (BBO# 640578)
DUANE MORRIS LLP
470 Atlantic Avenue, Suite 500
Boston, MA 02210
Telephone: (857) 488-4200
Facsimile: (857) 488-4201

Lloyd R. Day, Jr. (*pro hac vice*)
DAY CASEBEER, MADRID &
BATCHELDER LLP
20300 Stevens Creek Boulevard, Suite 400
Cupertino, CA 95014
Telephone: (408) 873-0110
Facsimile: (408) 873-0220

William G. Gaede, III (*pro hac vice*)
McDERMOTT WILL & EMERY
3150 Porter Drive
Palo Alto, CA 94304
Telephone: (650) 813-5000
Facsimile: (650) 813-5100

Kevin M. Flowers (*pro hac vice*)
MARSHALL, GERSTEIN & BORUN LLP
233 South Wacker Drive
6300 Sears Tower
Chicago, IL 60606
Telephone: (312) 474-6300
Facsimile: (312) 474-0448

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.

/s/ Michael R. Gottfried

Michael R. Gottfried