IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMGEN, INC., Plaintiff, v. F. HOFFMANN-LA ROCHE, LTD., ROCHE DIAGNOSTICS GMBH, and HOFFMANN-LA ROCHE, INC. Defendants.	Civil Action No. 05-CV-12237 WGY

ROCHE'S OPPOSITION TO 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"

No longer content with disrupting the testimony of Roche's expert witnesses with a string of unfounded objections that the witness is straying outside their expert report, Amgen now asks the Court to render an advisory opinion and preemptively preclude testimony that *may* be given by Dr. Richard A. Flavell.[1] Amgen's request should be denied for at least the following reasons:

(i) Dr. Flavell has in the past, and will continue to conscientiously apply this Court's claim construction in offering his opinions. Dr. Flavell's second expert report reproduces the Court's construction of "human erythropoietin" *verbatim*, followed by the unambiguous statement "[g]iven this meaning, in my opinion..."

(ii) Dr. Flavell has not even taken the stand yet. Dr. Flavell's testimony should be evaluated at the time that it is delivered, not based on Amgen's speculation.

[1] 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," filed Sep. 14, 2007 (D.I. 1068) ("Amgen's Bench Memo").

Based only on pure speculation and a few out-of-context passages from an expert report,[2] Amgen concludes that Dr. Flavell will confuse the jury by applying his own "proposed construction" of the term "human erythropoietin." The entirety of Dr. Flavell's expert opinion in this case, however, demonstrates the fallacy of Amgen's conclusions. Dr. Flavell expressly acknowledges and relies upon this Court's construction for the claim element "human erythropoietin" in arriving at his expert opinions concerning the invalidity of certain claims:

> The Court has recently said the term human EPO will be defined as 'a protein having the amino acid sequence of human EPO, such as the amino acid sequence of EPO isolated from human urine.' ***Given this meaning, in my opinion,*** the asserted claims containing this term, namely claim 1 of the '422 patent, claims 3, 7-9, 11-12 of the '933 patent, claim 1 of the '868 patent, and claim 7 of the '349 patent, would be invalid for lack of definiteness and/or written description under 35 U.S.C. § 112.[3]

Although raised in the Second Flavell Report, this understanding has not since changed and continues to apply equally to the opinions contained in all four of his expert reports.[4] Dr. Flavell will testify consistent with this Court's claim construction. Amgen's assertion that Dr. Flavell has not applied the Court's claim construction is simply without basis. Therefore its request to preclude Dr. Flavell's testimony is improper, untimely and should be denied.

Amgen's specious arguments further confuse critical issues surrounding Roche's defense that the claims of the patent are invalid for indefiniteness and lack of written description under

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[2] Dr. Flavell submitted four expert reports that set forth the full scope of his expert opinion concerning the subject matter of this litigation: (1) Expert Report of Richard A. Flavell, Ph.D., dated Apr. 6, 2007 (the "First Flavell Report"); (2) Corrected Supplemental Expert Report of Richard A. Flavell, Ph.D., dated May 8, 2007 (the "Second Flavell Report"); (3) Non-Infringement Expert Report of Richard A. Flavell, Ph.D., dated May 11, 2007 (the "Third Flavell Report"); and (4) Fourth Expert Statement of Richard A. Flavell, Ph.D. In Response to Various Arguments Raised by Amgen's Experts, dated Jun. 13, 2007 (the "Fourth Flavell Report").

[3] Second Flavell Report at ¶ 14 (emphasis added).

[4] Dr. Flavell specifically incorporates his prior reports, including this Court's construction for "human erythropoietin," into the Fourth Flavell Report.

35 U.S.C. § 112. Foremost, Dr. Flavell's testimony will provide relevant evidence to resolving a ***factual dispute*** concerning the ***identity*** of "a protein having the amino acid sequence of human EPO" as stated in the first clause of the Court's claim construction. Amgen contends that this clause covers any one of a number of "polypeptides of the invention" -- an undefined and undescribed suite of nearly 14,000 unique chemicals that can exist, each having unspecified portions of the amino acid sequence deduced from the human EPO gene.[5] In light of this factual dispute, it is entirely proper for Dr. Flavell to offer his opinion that the full scope of "a protein having the amino acid sequence of human EPO" is not definite and is not adequately described in the patent. *See Chen v. Bouchard*, 347 F.3d 1299, 1306-07 (Fed. Cir. 2003) (finding no evidence of a reduction to practice where the specification "failed to disclose any characteristics of those products that would evidence possession of the invention."); *Amgen, Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313, 1330 (Fed. Cir. 2003) ("The purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not; the applicant for a patent is therefore required to 'recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.'") (citation omitted).

Moreover, Dr. Flavell should be permitted to explain to the jury that the patent does not describe a protein having "the amino acid sequence of EPO isolated from human urine" according to the second clause of the Court's claim construction. Dr. Flavell's opinion is not that

[5] The human EPO gene as disclosed in Figure 6 of the patent specification encodes a 166-amino acid polypeptide. Amgen's position that "polypeptides of the invention" covers portions of this sequence means that all possible polypeptides (two or more amino acids joined together by peptide bonds") are within the scope of the Court's claim construction. According to Amgen's position, a protein of this length would encompass 13,695 "polypeptides of the invention," each uniquely defined by its amino acid sequence.

this language limits the element to a single species, but that the particular species singled out in this Court's construction must at least be described in the specification, which it is not.

For the above reasons, the Court should reject Amgen's request to prevent Dr. Flavell from providing his opinion to the jury.

Dated: September 24, 2007
Boston, Massachusetts

Respectfully submitted,

F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc.

By their Attorneys,

/s/ *Thomas F. Fleming*
Leora Ben-Ami (*pro hac vice*)
Patricia A. Carson (*pro hac vice*)
Thomas F. Fleming (*pro hac vice*)
Howard S. Suh (*pro hac vice*)
Peter Fratangelo (BBO# 639775)
Vladimir Drozdoff (*pro hac vice*)
Kaye Scholer LLP
425 Park Avenue
New York, New York 10022
Tel. (212) 836-8000

and

Lee Carl Bromberg (BBO# 058480)
Timothy M. Murphy (BBO# 551926)
Julia Huston (BBO# 562160)
Keith E. Toms (BBO# 663369)
Nicole A. Rizzo (BBO# 663853)
Bromberg & Sunstein LLP
125 Summer Street
Boston, MA 02110
Tel. (617) 443-9292
ktoms@bromsun.com

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/s/ *Thomas F. Fleming*
Thomas F. Fleming