

**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. 05-12237 WGY

U.S. District Judge Young

**ROCHE'S OPPOSITION TO AMGEN'S BENCH MEMORANDUM
THAT IT IS IMPROPER FOR RICHARD A. FLAVELL TO OFFER OPINIONS
THAT RESTATE ARGUMENTS REJECTED BY GRANT OF SUMMARY
JUDGMENT THAT CLAIM 7 OF THE '349 PATENT IS DEFINITE**

Amgen's motion asks for an advisory opinion from the Court before this witness has even taken the stand. The bases asserted in Amgen's motion for summary judgment were very specific and discrete and did not address all of the bases for the opinions advanced by this expert clearly in his expert reports. Now, recognizing the limitations of their motion, Amgen seeks to improperly bootstrap the Court's decision to restrict the invalidity theories that Roche can advance at trial. For these reasons, Amgen's applications as to Dr. Flavell should be rejected by the Court and denied.

Among the theories that were set forth in Dr. Flavell's report regarding claim 7 of the '349 were opinions relating to the term "human erythropoietin", which this Court DENIED in Amgen's motion for summary judgment. Accordingly, this Court has already found that Dr. Flavell may opine on invalidity based on indefiniteness, lack of written description and other invalidity opinions regarding this term. Moreover, Amgen's motion did not address other

opinions of this expert such as specific non-enablement issues not even raised in Amgen's motions. For example:

(i) Amgen's "definiteness" summary judgment with respect to '349 claim 7 focused the phrase "capable of" and its position that RIA was a known and accepted technique at the time the patent was filed. To the extent that the Court resolved those factual issues in Amgen's favor in granting summary judgment, those facts say nothing about whether the patent specification describes or enables the use of RIA to measure a protein having a specific amino acid sequence as claimed. Dr. Flavell will speak to those highly relevant facts.

(ii) Non-enablement and lack of written description are two entirely distinct statutory bases for invalidity from indefiniteness. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991). Amgen *never* moved for summary judgment on either of these grounds. Thus, both of these defenses are very much alive with respect to claim 7 of the '349 patent.¹

Amgen's assertion that Dr. Flavell intends to "recycle" Roche's same arguments conflates Roche's written description and enablement defenses with the distinct issue of indefiniteness and invites error. As a matter of law, indefiniteness, written description and enablement are distinct requirements that each and every claim must meet. *Crown Oper. Int'l v. Solutia Inc.*, 289 F.3d 1367, 1379 n.5 (Fed. Cir. 2002); *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1358 n.2 (Fed. Cir. 1999). The test for indefiniteness is whether one of skill in the art would understand the bounds of the claim when read in light of the specification to determine whether or not he is infringing. *Morton Int'l. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470 (Fed. Cir. 1993); *Process Control*, 190 F.3d at 1358 n.2. The written description requirement mandates that the patent specification -- on its face -- describe the invention to "clearly allow persons of ordinary skill in the art to recognize that [the named inventor] invented

¹ Roche has maintained throughout this litigation that claim 7 of the '349 patent lacks written description and is not enabled. Joint Pre-Trial Memorandum (D.I. 807), Roche's Position at p.8 and Exh. B at p. Roche Statement of Contested Issues of Fact at pp. 3-4, 6-7; Roche's Motion for Summary Judgment that Claim 7 of Patent No. 5,756,349 is Invalid Under 35 U.S.C. § 112 and is Not Infringed dated 6/21/07 (D.I. 539) at pp. 1-2.

what is claimed.” *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991) (when determining whether there is adequate written description the “invention is, for purposes of the ‘written description’ inquiry, ***whatever is now claimed.***”) (emphasis in original). Enablement, on the other hand, requires the specification teach one of skill in the art how to make and use the claimed invention without undue experimentation. *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1371 (Fed. Cir. 1999); *Process Control*, 190 F.3d at 1358.

Although the definiteness, written description and enablement requirements may spring from the same factual predicates, they have separate statutory purposes and must be analyzed independently. *Crown*, 289 F.3d at 1378-79. Thus a finding of definiteness, as a matter of law, does not dictate that a claim is adequately described or enabled. Nor does a finding that the language of a claim is definite have any impact on the analysis undertaken to determine whether that same claim is adequately described or enabled. *Union Pacific Resources Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 692 (Fed. Cir. 2001) (“Even if the written description does not enable the claims, the claim language itself may still be definite.”); *In re Hyatt*, 708 F.2d 712, 715 (Fed. Cir. 1983) (“[A] claim which is of such breadth that it reads on subject matter as to which the specification is not ‘enabling’ should be rejected under the first paragraph of §112 rather than the second.”)

Without knowing what Dr. Flavell will testify about, Amgen bases its motion on pure speculation. Amgen recognizes that its motion was limited and did not address all of Roche’s defenses, and now it seeks to impermissibly limit what this witness may opine about at trial, even though these opinions are clearly set out in his numerous reports. In its summary judgment ruling, the Court did not find facts, just ruled on legal issues that related to the specific and

limited arguments advanced by Amgen. That leaves Roche and the jury free to entertain all other relevant theories and supporting facts on Roche's invalidity theories.

For the foregoing reasons, there is no basis to preclude Dr. Flavell from offering relevant opinions and testimony on whether '349 Claim 7 lacks adequate written description and is not enabled.

DATED: September 24, 2007
Boston, Massachusetts

F. HOFFMANN-LA ROCHE LTD,
ROCHE DIAGNOSTICS GMBH, and
HOFFMANN-LA ROCHE INC.

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CERTIFICATE OF SERVICE

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/s/ Thomas F. Fleming
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