**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

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| AMGEN INC.,<br><br>Plaintiff,<br><br>v.<br><br>F. HOFFMANN-LAROCHE LTD., a Swiss Company, ROCHE DIAGNOSTICS GmbH, a German Company and HOFFMANN LAROCHE INC., a New Jersey Corporation,<br><br>Defendants. | Civil Action No.: 05-12237 WGY |

**AMGEN'S BENCH MEMORANDUM THAT DR. RICHARD A. FLAVELL SHOULD BE PRECLUDED FROM TESTIFYING REGARDING HIS UNTIMELY OPINION THAT CLAIM 7 OF THE '349 PATENT LACKS ENABLEMENT**

Roche's last testifying expert in this portion of the case, Dr. Flavell, is apparently going provide an untimely and improper opinion that Claim 7 of the '349 Patent is invalid for non-enablement of the recited EPO radioimmunoassay. Roche should be precluded from proffering Dr. Flavell's opinions on this issue because it failed to disclose this invalidity contention in any of its responses to interrogatories, even though Amgen specifically asked Roche to state the bases for its challenges to the validity of the '349 patent.[1] Indeed, although Roche submitted five separate responses and objections to Amgen's Interrogatory No. 9,[2] Roche never

[1] Plaintiff Amgen Inc.'s First Set of Interrogatories to Defendants (Nos. 1-15), specifically Interrogatory No. 9 which, in pertinent part, states "[s]eparately, in claim chart form for each claim of Amgen's patents-in-suit that you contend . . . is invalid, identify: (a) on a limitation-by-limitation basis, the legal and factual grounds on which you contend that such claim is invalid . . . ."

[2] Including, most recently, its Fifth Supplemental Responses and Objections to Plaintiff Amgen Inc.'s First Set of Interrogatories to Defendants (Nos. 9-11), served on May 1, 2007. Roche's

supplemented its responses to include its contention that Claim 7 of the '349 patent was invalid for non-enablement of the EPO radioimmunoassay used to determine the production rate in the claimed process, even though it had a duty to do so.[3] Moreover, although Dr. Flavell submitted opinions about RIA in an untimely expert report, neither Roche's pleadings[4] nor its trial brief make any reference to non-enablement of the EPO radioimmunoassay as a basis for invalidity of '349 Patent.[5] Thus, Amgen, quite justifiably, prepared for trial with the understanding that Roche would not present testimony concerning RIA non-enablement as a basis for invalidity and would be unduly prejudiced if Roche were permitted to offer this testimony now.

## I. Roche's Failure to Properly Disclose Its Invalidity Contentions Constitutes a Waiver of its Right to Present Dr. Flavell's RIA Non-Enablement Opinion at Trial.

Roche should not be permitted to offer Dr. Flavell's opinion because a party who fails to disclose its contentions, or an expert's opinion supporting them, in interrogatories cannot later rely on the undisclosed opinion at trial.[6] In accordance with Fed. R. Civ. P. 26(e), a party has an

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Response to Interrogatory No. 9 was that Claim 7 of the '349 Patent was indefinite. On Aug. 27, 2007, the Court granted Amgen's motion for summary judgment that, *inter alia*, the claims of the '349 patent were definite (Docket No. 531).

[3] *See* Fed. R. Civ. P. 26(e)(2) (stating "[a] party is under a duty seasonably to amend" interrogatories to reflect "material" changes).

[4] Roche's bare notice pleading of invalidity under 35 U.S.C. § 112, coupled with its failure to adequately amend its interrogatory responses, does not amount to proper notice to Amgen.

[5] Dr. Flavell's non-enablement opinion on RIA, which first appears in his June 13, 2007 Fourth Supplemental report, is an improper supplemental opinion in contravention of Roche's agreement with Amgen, as discussed below, and does not remedy the prejudice caused by Roche's failure to supplement its interrogatory responses.

[6] *Omegaflex v. Parker Hannifan Corp.*, 425 F. Supp. 2d 171, 183-84 (D. Mass. 2006) (Ponsor, J.), *rev'd on other grounds*, 2007 U.S. App. LEXIS 14308 (Fed. Cir. June 18, 2007); *Rowe v. Case Equip. Corp.*, 1997 U.S. App. LEXIS 227, at *6-7 (6th Cir. Jan. 2, 1997) (holding expert opinion was untimely and properly excluded where supplemental interrogatory failed to reveal expert opinion); *Murray v. Dillard Paper Co.*, 1999 U.S. Dist. LEXIS 22630, at *8-9 (E.D. Va. June 14,1999) (same). Interrogatory 9(c) requested disclosure of all evidence, including testimony, tending to support Roche's contentions.

affirmative obligation to supplement its answers to interrogatories when, as here, it knows that its prior responses are incomplete.[7] An additional rule requiring seasonable disclosure applies when, as here, an expert seeks to offer a previously undisclosed opinion.[8] A party's duty to supplement interrogatories is a separate, affirmative obligation, and therefore a party does not satisfy its duty simply by furnishing an expert report.[9] When a party's failure to respond to interrogatories or disclose an expert opinion will result in prejudice to its opponent, the proper remedy is to exclude the evidence from trial [10]

Despite its disclosure obligations under the Federal Rules, Roche did not supplement its interrogatories to reflect its theory that the RIA referred to in '349 Claim 7 is not enabled. Although it had repeated opportunities to do so, Roche failed to give proper notice to Amgen that it intended to present this theory at trial. Consequently, Amgen prepared for trial with the understanding that Roche would not be offering testimony on this point and this was confirmed when Roche submitted its 90-page trial brief with no reference to any invalidity theory predicated on non-enablement of the EPO radioimmunoassay. Given these deficient disclosures, Roche's last-minute injection of this issue into the trial will unduly prejudice Amgen.[11]

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[7] Fed. R. Civ. P. 26(e)(2) ("Supplementation of Disclosures and Responses"); *see also* Fed. R. Civ. P. 33(b)(5) (noting party may seek sanctions under Rule 37 for opponent's failure to respond to interrogatories).

[8] *See* Fed. R. Civ. P. 26(e)(1). The appropriate time for Dr. Flavell to offer all of his invalidity opinions was April 6, not June 13, 2007.

[9] *See id.; see also* Fed. R. Civ. P. 33(b)(1) "Each interrogatory shall be answered separately and fully . . . ."); *Ferrara v. Balistreri & DiMaio, Inc.*, 105 F.R.D. 147, 149-50 (D. Mass. 1985) (Collings, M.J.) (rejecting plaintiff's argument that its submission of expert reports satisfied its duty to respond to interrogatories).

[10] *See Omegaflex*, 425 F. Supp. 2d at 184 (noting that "[m]ore often than not, 'mandatory preclusion' is the required sanction" for defective disclosure of expert testimony) (quoting *Primus v. United States*, 389 F.3d 231, 234 (1st Cir. 2004).

[11] *See id.* (holding prejudice to opponent weighs in favor of excluding improperly disclosed expert opinion testimony); *The Themos Co. v. Nippon Sanso Corp.*, 1999 U.S. Dist. LEXIS 5079,

Therefore, the Court should preclude Roche from presenting any testimony at trial related to the contention that '349 claim 7 is invalid due to non-enablement of the EPO radioimmunoassay.

## II. Roche's Proffer of Dr. Flavell's RIA Opinion Violates Representations Made to The Court to Limit His Supplemental Report to Responding to Amgen's June 1 and June 4 Expert Reports.

Counsel for Roche informed this Court on June 6, 2007 that Roche's June 13, 2007 supplemental reports would serve the limited purpose of responding to the June 1 and June 4 reports of certain Amgen experts.[12] Yet, only a week later, Roche disregarded this representation and submitted Dr. Flavell's opinion that the EPO radioimmunoassay described in the '349 patent is not enabled. Dr. Flavell's opinion regarding RIA non-enablement bears no connection to any of the issues raised by Amgen's experts to which Dr. Flavell's supplemental report was supposed to respond. Thus, Roche's belated disclosure in Dr. Flavell's report was improper.

In light of Roche's failure to properly supplement its responses to interrogatories and its untimely and improper disclosure of Dr. Flavell's opinions regarding non-enablement of Claim 7 of the '349 Patent, Amgen respectfully requests that the Court preclude Roche from offering any testimony on this issue, including testimony by Dr. Flavell.

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at *14 (N.D. Ill. April 5, 1999) (noting duty to supplement under Rule 26(e) prevent "trial by ambush").

[12] Transcript of June 6, 2007 Scheduling Conference at 21:17-22 ("Ms Ben-Ami: All right. I understand that our agreement is, as follows. By June 13th, Roche will respond to the Amgen reports that were put in on June 1st and June 4th, and whatever needs to be done there for any new arguments that have been presented.")

Dated: September 24, 2007

Respectfully Submitted,

AMGEN INC.,
By its attorneys,

*/s/ Patricia R. Rich*

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
DAY CASEBEER
MADRID & BATCHELDER LLP
20300 Stevens Creek Boulevard, Suite 400
Cupertino, CA 95014
Telephone: (408) 873-0110
Facsimile: (408) 873-0220

WILLIAM GAEDE III
McDERMOTT WILL & EMERY
3150 Porter Drive
Palo Alto, CA 94304
Telephone: (650) 813-5000
Facsimile: (650) 813-5100

KEVIN M. FLOWERS
MARSHALL, GERSTEIN & BORUN LLP
233 South Wacker Drive
6300 Sears Tower
Chicago IL 60606
Telephone: (312) 474-6300
Facsimile: (312) 474-0448

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 91320-1889
(805) 447-5000

**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 September 24, 2007.

*/s/ Patricia R. Rich*
Patricia R. Rich