

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

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

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**AMGEN INC.’S MOTION TO STRIKE EVIDENCE REGARDING ROCHE’S  
ALLEGATION THAT CLAIM 7 OF THE ‘349 PATENT IS NOT  
ENABLED BECAUSE ROCHE DID NOT PREVIOUSLY IDENTIFY  
SUCH DEFENSE IN INTERROGATORY RESPONSES.**

Over Amgen’s objection, Dr. Richard Flavell, Roche’s last testifying validity expert, offered at trial his cursory opinion that Claim 7 of Amgen’s ‘349 patent is not enabled because a radioimmunoassay (“RIA”) cannot accurately distinguish fragments of EPO and whole EPO molecules. At the time that Dr. Flavell offered such testimony, the Court stated that it was taking Amgen’s motion to strike under advisement, suggesting that Amgen renew its motion at a later time.<sup>1</sup>

By this motion, Amgen renews it motion to strike Dr. Flavell’s testimony as it pertains to Roche’s assertion that ‘349 claim 7 is not enabled as a result of RIA detecting EPO fragments. The opinion offered by Dr. Flavell at trial was never identified by Roche in any of its six separate interrogatory responses to Amgen, despite an Amgen interrogatory that Roche state the

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<sup>1</sup> See e.g., 9/24/07 Tr. at 1256:2-1257:6; 12665:15-12666:11.

entire basis for its invalidity claims as to each of Amgen's patents.<sup>2</sup> Indeed, Roche also failed to identify this defense in its 88-page Pre-Trial Brief, filed on the eve of trial. Roche's attempt to introduce in its invalidity case theories that Roche did not describe in interrogatory responses is inappropriate gamesmanship. Because Roche should not be allowed to present evidence beyond the scope of the alleged defenses set forth in its interrogatory responses, the Court should strike the testimony.

**I. Roche Must Be Bound By Its Interrogatory Responses Regarding The Scope of Its Defenses.**

A party who fails to disclose its contentions in interrogatories cannot later rely on the undisclosed contentions at trial.<sup>3</sup> In accordance with Fed. R. Civ. P. 26(e), a party has an affirmative obligation to supplement its answers to interrogatories when, as here, it knows that its prior responses are incomplete.<sup>4</sup> In this case, Amgen served its First Set of Interrogatories on Roche on December 11, 2006 — more than 9 months in advance of this trial. Interrogatory No. 9 of Amgen's request asked that Roche:

[s]eparately, in claim chart form for each claim of Amgen's patents-in-suit that you contend . . . is invalid, identify:

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<sup>2</sup> 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 . . . ." Roche's Responses to Interrogatory No. 9 are attached hereto as Exhibit A to the Declaration of Daniel A. Curto ("Curto Decl.").

<sup>3</sup> See *Omegaflex v. Parker Hannifan Corp.*, 425 F. Supp. 2d 171, 183-84 (D. Mass. 2006), *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).

<sup>4</sup> 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).

(a) on a limitation-by-limitation basis, the legal and factual grounds on which you contend that such claim is invalid . . . ; and ...

(c) all evidence on which you rely in support of each contention, including all documents, testimony, prior knowledge, or public uses tending to support your contention ... that a claim is invalid.

Although Roche submitted, over a number of months, six separate responses and objections to this Interrogatory — totaling over a hundred pages<sup>5</sup> — Roche never once included within its response a contention that Claim 7 of the ‘349 patent was not enabled because RIA detects fragments of EPO.

Despite Roche’s failure to ever identify this theory in any of its interrogatories purporting to detail the legal and factual basis for Roche’s contention that claim 7 of the ‘349 patent was not enabled, Roche elicited testimony at trial from Dr. Richard Flavell regarding this topic.<sup>6</sup> As set forth above, the purpose of Amgen interrogatories was to frame and clarify the issues in this litigation. It is highly unfair for Roche’s expert to insert a new theory of invalidity that Roche’s interrogatories purporting to state the basis and support for Roche’s claims never discussed.

It is not sufficient — as Roche claims — that Roche identified in cursory fashion the defense as part of a supplemental rebuttal report for Dr. Flavell.<sup>7</sup> First, as set forth below, the expert report that Roche claims this contention appears was intended to be a supplemental expert report, limited to a rebuttal of reports that Amgen proffered on June 1 and June 4, 2007. These

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<sup>5</sup> 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 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). As this Court is well aware, Fed. R. Civ. P. 26(e)(2) requires a party to seasonably amend” its interrogatories to reflect “material” changes.

<sup>6</sup> Sept. 24, 2007 Trial Transcript. Curto Dec. Exh. B.

<sup>7</sup> Dr. Flavell’s non-enablement opinion regarding the RIA limitation of ‘349 claim 7 was buried amongst his arguments regarding why ‘349 claim 7 was not infringed and/or was indefinite.

reports were not permitted to raise brand new theories that Roche had never raised previously in its Interrogatory responses, its Answer or other discovery. Moreover, a party's duty to supplement interrogatories is an affirmative obligation that is not satisfied by furnishing an expert report.<sup>8</sup> Thus, even if Roche's submission of Dr. Flavell's report was timely – which it was not – Roche still had an affirmative duty to supplement its interrogatories, which it did not do.<sup>9</sup>

As a result of Roche's failure to disclose, Amgen has been prejudiced at trial because it did not have adequate notice that Roche would press this contention. First, because Dr. Flavell submitted this new opinion as part of a rebuttal report, Amgen's opportunity to develop responsive expert opinions on this theory was significantly limited. Moreover, because Roche never supplemented its interrogatories — as it has done five other times — to include this new theory, Amgen prepared for trial with the belief that Roche would not offer testimony on this point. Indeed, Amgen's understanding was confirmed when Roche submitted an 88-page trial brief with no reference to any invalidity theory predicated on non-enablement of claim 7 of the '349 patent because of RIA detecting fragments. Therefore, it is appropriate to strike any evidence by Roche going to its contention that '349 claim 7 is invalid due to non-enablement from RIA detecting fragments.<sup>10</sup>

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<sup>8</sup> *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).

<sup>9</sup> Roche's further assertion that Amgen was placed on notice of its contentions regarding non-enablement because it “incorporated by reference” the April 6, 2007 report of Dr. Zaroulis is unavailing because Dr. Zaroulis's report did not make the non-enablement argument Amgen seeks to strike, but rather a different enablement argument that Roche did not advance at trial.

<sup>10</sup> *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, at \*14 (N.D. Ill. April 5, 1999) (noting duty to supplement under Rule 26(e) prevent “trial by

**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.**

As mentioned above, another reason to exclude any contentions by Roche related to its new theory that claim 7 of the '349 patent is not enabled because of RIA fragments is Roche's disregard of expert disclosure requirements. 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.<sup>11</sup> 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 because RIA could detect EPO fragments. Dr. Flavell's opinion 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 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 this Court strike Dr. Flavell's testimony regarding this new contention, including all of his testimony from page 1255, line 15 to page 1273, line 16 of the Trial Transcript.

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ambush”).

<sup>11</sup> 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: October 1, 2007

Respectfully Submitted,

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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 2, 2007.

/s/ Michael R. Gottfried\_\_\_\_\_

Michael R. Gottfried