UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, vs. F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GMBH, AND HOFFMANN-LA ROCHE INC., Defendants	CIVIL ACTION No.: 05-CV-12237WGY

DEFENDANTS' OPPOSITION TO 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

Dr. Flavell's testimony or any related evidence concerning non-enablement of claim 7 of the '349 patent was no surprise to Amgen. Over the course of this litigation, Roche fully complied with its discovery obligations, repeatedly asserting that '349 claim 7 is not enabled. Roche has not concealed this defense theory in the least. Amgen has been on notice of Roche's intent to present this non-enablement defense at trial for months, and has had ample time to prepare for rebuttal. Therefore, Amgen's motion to strike Dr. Flavell's testimony is improper and should not be granted.

I. Roche Repeatedly and Adequately Disclosed Its Non-Enablement Theory to Amgen

Amgen makes a last ditch effort to strike relevant and appropriate testimony which it chose not to oppose by claiming surprise at a so-called "brand new theory." Excluding expert

testimony is a drastic remedy.[1] It is generally reserved for cases where courts have found some evasion or concealment on the part of the litigant offering the evidence.[2] On the contrary, Roche adequately disclosed its argument that claim 7 of the '349 patent is invalid for lack of enablement numerous times in its interrogatory responses, expert reports, and throughout the discovery process.

Amgen mistakenly argues that Roche's disclosure was inadequate under FRE 26(e). The rule requires a party to supplement interrogatory answers "if the party learns that the response is in some material respect *incomplete or incorrect* or corrective information *has not otherwise been made known* to the other parties during the discovery process or in writing."[3] The purpose of the rule is to narrow the issues and eliminate surprise.[4] Amgen can claim no surprise.

Roche did supplement its interrogatory answers in compliance with its discovery obligations. Over five months ago, Roche incorporated the April 6 report of Dr. Charles Zaroulis into a supplementary interrogatory response asking for the basis of Roche's invalidity opinions.[5] In his report, Dr. Zaroulis states plainly that claim 7 is not enabled because "no information describing how to correlate RIA results with biological assay results or how to calculate or estimate biological activity from RIA results is provided someone of ordinary skill in the art would be unable to make and use the invention claimed in the '349 patent."[6] Thus, Amgen was aware Roche experts would testify that the ability to measure the amount of biologically active

[1] *Johnson v. Webster*, 775 F.2d1, 8 (1st Cir. 1985). Although Johnson interprets an older version of FRE 26(e), the conclusions in that case concerning the purposes of the rule are still applicable today. *See, e.g., Ferrara v. St. Paul Mercury Ins. Co.*, 240 F.3d 1, 10 (1st Cir. 2001).
[2] *Id.*
[3] Emphasis added.
[4] *Ferrara v. St. Paul Mercury Ins. Co.*, 240 F.3d 1, 10 (1st Cir. 2001) (stating that supplementation requirement increases the quality and fairness of the trial by narrowing the issues and eliminating surprise); *Johnson v. Webster*, 775 F.2d 1, 7 (1st Cir. 1985).
[5] Defendants' Fifth Supplemental Responses and Objections to Plaintiff Amgen Inc.'s first set of Interrogatories to Defendants (Nos. 9-11), May 1, 2007, at p. 3 (D.N. 878-29).
[6] Expert Report of Charles G. Zaroulis M.D. dated 4/6/07 at ¶ 75.

EPO present by RIA is critical to enablement of claim 7. EPO fragments may be present that are not biologically active, which would render RIA measurements inaccurate. This is the exact problem with RIA stated in Dr. Zaroulis' report and is the foundation for Roche's enablement defense.

In its brief, Amgen cites *Ferrara v. Balistreri & DiMaio* to claim that incorporation of an expert report cannot be an adequate interrogatory disclosure.[7] However, the application of FRE 26(e) is not so mechanical. Reference to other documents is primarily inappropriate only where those references "make it impossible to determine whether an adequate answer has been given."[8] However, Dr. Zaroulis' report explicitly states that claim 7 is not enabled because one could not calculate biological activity by RIA.

The First Circuit has declined to strike expert testimony even though defendants had not supplemented interrogatory answers or expert reports with the name of a substitute expert.[9] The purpose of FRE 26(e) is to narrow the issues and eliminate surprise. Rather than strict adherence, actual notice may suffice.[10] Importantly, "this is not a case in which the expert's testimony departed from the general scheme of his opinion or any other expert opinion submitted on behalf of [defendant]."[11]

In fact, Amgen was aware of the general scheme concerning non-enablement of '349 claim 7 expressed in Roche expert reports. Three months before this trial, Amgen received Dr. Flavell's supplemental expert report stating he expected to testify about non-enablement of '349 claim 7, and further incorporating Dr. Zaroulis' April 6 report which expresses the *same* opinion.

---

[7] 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 (D.I. 1249) ("Amgen Brief") at p.4 (citing *Ferrara v. Balistreri & DiMaio, Inc.*, 105 F.R.D. 147, 149-150 (D. Mass 1985)).
[8] *Ferrara v. Balistreri*, 105 F.R.D. at 150.
[9] *Ferrara & DiMercurio v. St. Paul Mercury Ins. Co.*, 240 F.3d 1, 10 (1st Cir. 2001).
[10] *Id.*
[11] *Id.*

Critically, in the same paragraph, Dr. Flavell explained that he would fully expand on his invalidity opinions concerning the '349 patent at trial, "having presented these opinions in summary form in my Non-Infringement Expert Report dated May 11, 2007."[12] Dr. Flavell's non-infringement report discusses the problem of fragments in relation to '349 claim 7. Amgen was therefore put on notice. Dr. Flavell testified consistent with the general scheme of his report.[13]

Amgen admits that it was aware of this "new opinion," but argues that because it was expressed in a rebuttal report, the opportunity to develop responsive expert opinions was limited.[14] Amgen's contentions are without merit because Amgen had more than sufficient opportunity to respond to Dr. Flavell. In particular, Dr. Lodish submitted two reports on June 20 and June 25 totaling over 60 pages together. Dr. Lodish made no attempt to address Dr. Flavell in these later reports, even though the non-enablement theory was put forth in direct response to statements of Amgen's experts that fragments are not present in an RIA.[15]

Roche again gave notice in the parties Joint Pre-trial Memorandum, explicitly listing issues of fact relating to enablement of claim 7 of the '349 patent based on RIA in the parties'.[16] Even after this, Amgen waited until Dr. Flavell was on the stand, to claim surprise although there was none.

[12] 6/13/07 Flavell Report ¶ 59
[13] Amgen should not be allowed to exploit the fact that Dr. Flavell testified rather than Dr. Zaroulis. Roche laid out this theory in both expert reports. In an effort to respect time limitations of trial, agreed with Amgen to limit the number of witnesses for each party. Roche did not agree to forfeit legal theories in the process.
[14] Amgen Brief at p.4.
[15] Fourth Expert Statement of Richard A. Flavell, Ph.D. in Response to Various Arguments Raised By Amgen's Experts dated 6/13/07 at ¶ 57.
[16] Roche's Contested Issues of Fact in Joint Pretrial Memorandum, August 10, 2007 (D.N. 807-3).

II. Amgen's Actions Belie Knowledge that Roche Arguments Concerning Invalidity Would Include Non-Enablement of '349 Claim 7 Due to Fragments

Amgen's actions during discovery reveal awareness that Roche's experts would testify that fragments confound the measurements required by '349 claim 7. For example, Amgen asked a number of questions at the June 6 deposition of Dr. Zaroulis indicating it was aware of the possibility that Roche's experts would testify that fragments confound RIA results:

> Q. You state in bold italicized print, quote, "RIA measures materials that are not erythropoietin," correct?
> A. Correct.[17]
>
> * * * * *
>
> Q. Did Dr. McLawhon acknowledge that the antibody used in an RIA may detect fragments of EPO or other materials present in a test mixture that cross-react with the antibody being used?
> A. I'm going to quote my -- **what I have in this document is what I believe to be true and I've said here**, I pronounce his name differently, "Dr. McLawhon acknowledged that a radioimmunoassay is an immunoassay that relies on the ability of an antibody to recognize a particular part of a protein known as an epitope, and that **the antibody used in an RIA may detect fragments of EPO or other material present in a test mixture** to cross-react with the antibody being used," and I reference his deposition.[18]

Dr. Zaroulis did not limit his criticism that RIA might measure fragments to the infringement context, but instead expressed his general belief and intent to testify that pieces of EPO that may not be intact and have little or no biological activity, would obscure *any* RIA reading.

Amgen also acknowledged awareness of Roche's non-enablement argument concerning claim 7 when it specifically cited this was a contested issue of fact in the Joint Pre-Trial Memorandum:

[17] 6/6/2007 Zaroulis Tr. 262:23-263:2.
[18] 6/6/2007 Zaroulis Tr. 233:10-234:2.

> Whether Roche has presented clear and convincing evidence showing that as of the time of Dr. Lin's inventions, applying the teachings of Lin's specifications, one of ordinary skill in the art would not have been able to practice the following inventions without undue experimentation: . . . claim 7 of the Lin '349 patent . . . .[19]

III. Striking Expert Testimony is A Drastic Measure

Even assuming Amgen is correct that Dr. Flavell's testimony was improper, which it is not, striking testimony is a drastic measure not appropriate in this case. It is generally reserved for cases where courts have found some evasion or concealment on the part of the litigant offering the evidence. In the unlikely event that the non-mechanical requirements of FRE 26(e) have not been fulfilled, courts generally favor a less disruptive course of action such as a continuance of the trial.[20]

Amgen has had adequate notice of Roche's non-enablement of '349 theory for months via Roche's interrogatories, expert reports, depositions, and the like. It is certain that striking Dr. Flavell's testimony would be extremely disruptive to this case, especially because the jury has already heard the testimony and evidence and demonstratives have been published to the jury. Thus, even accepting Amgen's argument that Dr. Flavell's testimony was improper, Amgen's motion to strike should not be granted.

IV. Conclusion

For the foregoing reasons, Roche respectfully requests that this court deny Amgen's motion to strike Dr. Flavell's testimony concerning non-enablement of '349 claim 7.

[19] Joint Pre-Trial Memorandum (D.N 807-3), Ex. A at p.2.
[20] *Ferrara*, 240 F.3d at 10.

Dated: October 4, 2007
Boston, Massachusetts

Respectfully submitted,

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

By their Attorneys

/s/ Kimberly J. Seluga
Lee Carl Bromberg (BBO# 058480)
Robert L. Kann (BBO# 258025)
Julia Huston (BBO# 562160)
Keith E. Toms (BBO# 663369)
Nicole A. Rizzo (BBO# 663853)
Kimberly J. Seluga (BBO# 667655)
BROMBERG & SUNSTEIN LLP
125 Summer Street
Boston, MA 02110
Tel. (617) 443-9292
kseluga@bromsun.com

Leora Ben-Ami (*pro hac vice*)
Mark S. Popofsky *(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*)
David L. Cousineau (*pro hac vice*)
KAYE SCHOLER LLP
425 Park Avenue
New York, New York 10022
Tel. (212) 836-8000

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 (NEF). Pursuant to agreement of counsel dated September 9, 2007, paper copies will not be sent to those indicated as non registered participants.

/s/ Kimberly J. Seluga
Kimberly J. Seluga

03099/00501 751603.1