UNITED STATES DISTRICT COURT
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 BENCH MEMORANDUM THAT DR. RICHARD FLAVELL PROPERLY TESTIFIED REGARDING HIS OPINION THAT CLAIM 7 OF THE '349 PATENT LACKS ENABLEMENT

Roche respectfully submits this memorandum to clarify that Dr. Richard Flavell's opinion that Claim 7 of the '349 patent was properly disclosed and known to Amgen. Amgen argues that it was not provided notice that Roche was maintaining its position that claim 7 of the '349 patent was invalid for lack of enablement in its use of the term radioimmunoassay (RIA), and that Dr. Richard Flavell should be precluded from testifying on this issue. First, Amgen waited until the day Dr. Flavell was to testify to raise this issue or any objection to his testimony, despite knowing of Roche's position and Dr. Flavell's opinion for several months. Amgen should not be allowed to wait until the last possible moment to raise an objection over something they have known about and said nothing about for months.

Secondly, Amgen is incorrect in claiming that it was provided no notice that Roche contended claim 7 of the '349 patent was not enabled based on its inclusion of RIA to measure EPO production, or that Dr. Flavell would provide this testimony. In his expert report of June

13, 2007, Dr. Flavell clearly explains his opinions on RIA (to which he testified consistently to the jury) and explicitly states that "Claim 7 of the '349 patent is invalid for lack of enablement for several reasons."[1] Furthermore, Dr. Flavell stated that "Claim 7 is not enabled because there is no instruction on how to discriminate between 'erythropoietin' according to the claims and erythropoietin fragments or analogs, or other materials that are not erythropoietin."[2] This is entirely consistent with Dr. Flavell's testimony in court on September 24 when he explained to the jury that Claim 7 of the '349 patent was not enabled because RIA cannot distinguish EPO fragments from complete erythropoietin molecules. Amgen cannot claim surprise at this testimony - it was disclosed to Amgen over three months ago and they never raised objection. Dr. Flavell was disclosed to Amgen as one of Roche's ten trial expert witnesses on July 24, 2007, and again Amgen did not object or indicate that it believed Dr. Flavell was precluded from giving his opinion.

Furthermore, Amgen knew long before Dr. Flavell's report was served that Roche contended that claim 7 of the '349 patent was invalid for lack of enablement. One of Roche's experts, Dr. Charles Zaroulis, stated in his April 6, 2007 expert report that "the '349 patent does not enable one skilled in the art to make (and use) the claimed invention because one could not practice the claimed method and obtain the required number of units of erythropoietin as determined by radioimmunoassay."[3] Amgen's complaint that Roche did not disclose this defense in its Interrogatory Responses is likewise incorrect as Dr. Zaroulis's April 6, 2007 report

[1] *See* Exhibit A, excerpt of Fourth Expert Statement of Richard A. Flavell, Ph.D. In Response to Various Arguments Raised by Amgen's Experts, June 13, 2007, at ¶ 67.

[2] *Id*.

[3] *See* Exhibit B, excerpt of Expert Report of Charles G. Zaroulis, M.D., April 6, 2007, at ¶ 75.

was incorporated by reference in Roche's Supplemental Response to Interrogatory No. 9 asking for the basis of Roche's invalidity defenses.[4]

Likewise, Amgen cannot claim that they didn't know Roche was maintaining this position and would present evidence at trial on lack of enablement based on RIA of Claim 7 of the '349 patent. In the Joint Pretrial Memorandum, filed August 10, 2007, Roche explicitly listed the following as contested issues of fact relating to enablement of claim 7 of the '349 patent based on RIA:

> 55. Whether the specification of the '349 patent fails to enable the erythropoietin production levels required by the claims of the '349 patent.
>
> 56. Whether the specification of the '349 patent fails to provide sufficient teaching that a person of ordinary skill in the art on the effective filing date could determine "*U[nits] of erythropoietin*" using radioimmunoassay, as required by the claims, without undue experimentation.
>
> 57. Whether the specification of the '349 patent fails to provide sufficient teaching that a person of ordinary skill in the art on the effective filing date would know when to measure production of "*U of erythropoietin*" using radioimmunoassay, without undue experimentation.[5]

Once again, Amgen did not object, or otherwise notify Roche that it was taking the position that Roche could not present evidence on this issue to the jury or that Dr. Flavell could not testify as to lack of enablement of claim 7 of the '349 patent based on RIA.

Amgen's feigned surprise and claim that it did not prepare for lack of enablement of claim 7 of the '349 at trial is just that - feigned. Roche's defense and the facts underlying it were disclosed to Amgen long ago, and Roche reiterated that it was pressing this defense at trial in the

[4] 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).

[5] Roche's Contested Issues of Fact in Joint Pretrial Memorandum, August 10, 2007, D.N. 807-3.

Joint Pretrial Memorandum. Amgen waited until the day Dr. Flavell testified to raise its objection. While Roche's defense has been known by Amgen for at least five months, and Amgen is not in any way prejudiced by Dr. Flavell being allowed to testify on this subject, Roche would be severely prejudiced if Dr. Flavell had not been allowed to give his testimony to the jury as Amgen knew about this defense, knew about Dr. Flavell's opinion, and waited until the day Dr. Flavell testified to raise any objection. Dr. Flavell properly testified about the invalidity of claim 7 of the '349 patent to the jury on September 24, 2007.

Dated: September 25, 2007
Boston, Massachusetts

Respectfully submitted,

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

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