

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-12237WGY

ROCHE’S OPPOSITION TO AMGEN’S MOTION *IN LIMINE* NO. 14: EXCLUDE PEG-EPO EXPERIMENTS CONDUCTED BY CORDS AND CRITICISM OF AMGEN’S FAILURE TO TEST PEG-EPO BASED UPON ROCHE’S FAILURE TO PRODUCE A SAMPLE OF PEG-EPO

This motion is Amgen’s second bite at the apple in its attempt to exclude the experiments conducted by Dr. Sven-Michael Cords. In Amgen’s motion to strike the Cords Declaration (D.I. 681), it argued “Roche withheld part of the complete protocol for the Cords tests.” (D.N. 681 at 3). This Court denied Amgen’s motion to strike on July 18, 2007. Amgen now argues that “Roche should be precluded from relying on the Cords testing because it refused to provide Amgen with a non-redacted copy of the protocol followed by Cords, which was provided to him by Roche.” (Amgen’s Motion at 3). This argument has already been considered and denied by this Court and is without merit. Further, Amgen’s complaint about not having a sample of MIRCERA® is not the result of Roche’s conduct, but rather of Amgen’s failure to properly pursue its discovery request.

I. Roche Produced the Complete Test Protocol Used by Dr. Cords

As set forth in detail in Roche’s opposition to Amgen’s motion to strike (D.I. 735), Dr. Cords confirmed in his deposition that the redacted document produced to Amgen, which was marked at his deposition as Cords. Ex. 11 (D.I. 683, Ex. E), set forth the complete protocol. *See*

Cords Deposition Transcript at 163; D.I. 735 at 2. A reading of the entirety of Dr. Cords's deposition, as opposed to the selected excerpts that Amgen has taken out of context, demonstrates that Amgen's contention that Roche did not provide the protocol is false. Further, Dr. Cords signed a sworn declaration stating that he "did not rely on or refer to the redacted portion of Cords Exhibit 11 conducting my experiment."¹ (D. I. 736 at 2).

Contrary to Amgen's contentions, the redacted portion of Cords Ex. 11 is properly redacted pursuant to the Stipulated Order (D.I. 267), which requires, in relevant part, that the parties "produce all scientific test results and all underlying data and documents for any scientific or medical tests performed in connection with or in furtherance of this action by, for, or on behalf of any party, or a party's expert or any other consultant where . . . (1) an expert relies on or refers to such a test in the expert's report or testimony." Because Dr. Cords did not rely on or refer to the information in the redacted portion of Cords Ex. 11, Roche is not required to produce the redacted portion, and Amgen's argument is without merit. (*See* D.I. 735 at 5). Because the redacted material does not meet the requirements of Paragraph 1 of the Stipulated Order and falls under Paragraph 2 as non-discoverable communications with counsel it was properly withheld.

II. Roche Has Not Improperly Withheld MIRCERA[®] From Amgen

Amgen's contention that Roche has engaged in "vexatious discovery tactics" with respect to the production of a MIRCERA[®] sample to Amgen is factually inaccurate and equally without merit. While Amgen made an initial request for a sample of MIRCERA[®] from Roche, Roche properly objected to providing samples of MIRCERA[®]. (*See* Letter from Howard S. Suh to

¹ Amgen's statement that "Dr. Cords later admitted that he relied on the protocol that Roche withheld to perform the bioassays detailed in the expert reports" mischaracterizes Dr. Cords's testimony. While Dr. Cords stated generally that he considered the information in the protocol, the redacted portion of Cords Ex. 11 is not part of the protocol, nor was it considered by Dr. Cords. At no point in the deposition did Dr. Cords state that the redacted portion was part of the protocol or that he considered it in conducting the experiments.

Deborah Fishman, dated December 13, 2006, attached hereto as Exhibit A). Roche stated to Amgen, however, that it would be amenable to providing a sample to Amgen subject to reaching a non-assert agreement that would use the material. (*See Id.*).

In response, Amgen offered in a letter (not a formalized agreement) to not assert a claim of infringement against Roche based on the samples, and to treat the samples as highly confidential material, but failed to specify any details relating to the handling of the material. (*See* Letter from Krista M. Carter to Howard S. Suh, dated December 14, 2006, attached hereto as Exhibit B). Amgen did not follow up its requests subsequent to the December 14, 2006 letter, despite the fact that it knew that Roche had expressed concern about restrictions on the use of the samples.² Had Amgen followed up with Roche and entered into an agreement acceptable to both parties under which the samples would be provided to Amgen, such samples would have been provided under properly negotiated terms. However, Amgen's failure to pursue an acceptable agreement with Roche to obtain the samples can hardly be characterized as a vexatious tactic on the part of Roche.³ Indeed, it is Amgen's own failure to pursue the matter which led to Amgen not obtaining samples of MIRCERA[®].

Moreover, Amgen's decision to file the present motion one week before trial belies its purportedly arduous mission to obtain samples of MIRCERA[®]. Amgen has had numerous opportunities to request MIRCERA[®] samples from Roche, but failed to pursue such discovery. As disagreement over the terms of the non-assert persisted, Amgen failed to renew its request for

² The December 14, 2006 letter from Amgen does not constitute a non-assert agreement, nor an agreement as to the restrictions that would apply to any MIRCERA[®] samples produced to Amgen. As such, it was unreasonable for Amgen to believe the samples would be forthcoming. Any such agreement entered into by Roche would have more closely resembled the Court's February 27, 2007 Modified Order, which comprised a two-page document rather than the two sentences unilaterally offered by Amgen in its letter. (*See* D.I. 298).

³ Further, Amgen fails to offer any evidence that Roche "continued to stall on the production of a Peg-EPO sample." (*See* Amgen's Motion at 2).

MIRCERA[®] samples, or to bring a motion to compel a sample, even after receiving the Cords expert report in May 2007 discussing experiments conducted with MIRCERA[®]. Amgen had yet another opportunity to seek relief from the Court with respect to its allegedly disregarded request for MIRCERA[®] samples when it filed its motion to strike the Cords Declaration in June 2007 (D.N. 683). However, Amgen made no mention in its brief of any need to obtain MIRCERA[®] or any failure by Roche to provide it with MIRCERA[®]. Roche's ability to present its case should not now be prejudiced by Amgen's lack of interest in pursuing samples of MIRCERA[®] from December 2006 until the present. Further, Amgen's failure to raise the issue of samples between then and now suggests that Amgen is now engaging in tactical gamesmanship over discovery requests it failed to pursue.

CONCLUSION

For the reasons set forth above, Amgen's Motion in Limine No. 14, should be denied in its entirety.

Dated: September 4, 2007
Boston, Massachusetts

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

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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) and paper copies will be sent to those indicated as non registered participants on the above date.

/s/ Kimberly J. Seluga
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