

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

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

**BRIEF IN SUPPORT OF 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**

## I. INTRODUCTION

Amgen asks the Court to exclude from evidence any references to testing performed by Roche's consultant, Dr. Cords, comparing Roche's Peg-EPO and EPO because, despite discovery requests and assurances that they would provide Amgen with a sample of Peg-EPO, Roche never produced any samples of Peg-EPO to Amgen. Dr. Cords ran certain tests comparing the *in vivo* biological activity of deglycosylated Peg-EPO and EPO, and then described these experiments and results in his expert report and declaration, which several of Roche's expert witnesses cite and rely upon in their expert reports to support their noninfringement opinions. Without a sample of Peg-EPO, Amgen was unable to replicate these tests and was limited in its ability to challenge Cords's test results. Roche should not be allowed to rely on its Peg-EPO test results at trial, or criticize Amgen's experts for failing to test a sample of Peg-EPO, since any such criticism arises from Roche's failure to produce the Peg-EPO sample in the first place. Similarly, during discovery, Roche refused to produce a non-redacted copy of the protocol run by Dr. Cords during his testing, without any justification. Roche should not be permitted to introduce such experiments, while denying Amgen discovery of the complete test protocol used by Dr. Cords. Accordingly, Amgen requests that the Court exclude evidence of Dr. Cords's tests and preclude Roche from referring to Amgen's failure to conduct experiments with Roche's Peg-EPO as part of its defense to infringement.

## II. ARGUMENT

### A. **Roche should be precluded from relying upon Peg-EPO testing because it failed to produce a sample of Peg-EPO to Amgen**

On October 30, 2006, Amgen served Roche with a set of Requests for Production of Documents and Things. Included was a request that Roche provide Amgen with: "A representative 10 mg purified bulk sample of Peg-EPO from which MIRCERA is produced, and such documents and things as are sufficient to identify the origin, production lot, date of

production, composition, characteristics, and all analytical test results of said purified bulk peg-EPO sample.”<sup>1</sup> Roche responded on December 4, objecting to the request on various grounds, and stating that it would not produce any samples of EPO to Amgen “as such samples are unnecessary and irrelevant.”<sup>2</sup> After a series of letters, on December 11, 2006, Roche agreed to produce samples of Peg-EPO,<sup>3</sup> however, Roche continued to stall on the production of a Peg-EPO sample and failed to produce a sample of Peg-EPO.

Roche should not be able to benefit from its vexatious discovery tactics and ultimate failure to produce a sample of Peg-EPO in this case. Roche’s failure to produce a sample of Peg-EPO made it impossible for Amgen to run any its own testing, and Amgen requests that the Court prevent Roche from relying on evidence it kept from Amgen.<sup>4</sup> Therefore, the Court should exclude any references to or reliance upon the testing of Peg-EPO performed by Dr. Cords, including any testimony from Roche expert and fact witnesses referring or relying upon Dr. Cords’s experiments.

**B. Roche should be precluded from questioning Amgen’s experts or arguing to the jury about Amgen’s failure to conduct tests on Roche’s Peg-EPO product**

Considering the fact that Roche denied Amgen the opportunity to test any samples of Peg-EPO, Roche should be precluded from questioning any of Amgen’s experts about their failure to test Roche’s Peg-EPO or otherwise refer to Amgen’s failure to test Peg-EPO. Roche has violated the Court’s orders to be forthcoming in discovery. In this situation, not only should Roche be precluded from relying on the evidence it refused to produce, but it also should be

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<sup>1</sup> Amgen’s First Set of Requests for the Production of Documents and Things at p. 8, No. 3.

<sup>2</sup> Roche’s Responses and Objections to Amgen’s First Set of Requests for Production of Documents and Things at p. 9, response to No. 3 [Docket No. 167-2].

<sup>3</sup> Declaration of Craig Casebeer In Support of Amgen’s Motion *In Limine* (hereinafter “Casebeer Decl.”), Casebeer Decl. Exh. 1 (Suh letter to Fishman, dated December 13, 2006).

<sup>4</sup> 1/22/07 Court Order (“No Party May Introduce In Evidence Any Document Called For In Discovery And Not Produced, Nor Any Data Derived From Such Document”).

precluded from putting Amgen at a further disadvantage by questioning Amgen's experts or arguing to the jury regarding testing that Roche kept Amgen from performing.

**C. Roche should also 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**

In addition to the fact that the Cords report relies upon Peg-EPO samples denied to Amgen by Roche, Roche *also* refused to produce to Amgen a non-redacted copy of the protocol used by Dr. Cords in his experiments. In this action, the parties agreed to and the Court entered a Stipulated Order Regarding Expert Discovery.<sup>5</sup> This Stipulated Order provides a limited exception, shielding “discovery into the substance of any drafts of expert reports, the substance of any comments made on drafts of expert reports, the substance of any proposed edits to expert reports, or the substance of any communications with counsel regarding the substance of the opinions expressed in the expert report....”<sup>6</sup> Despite that limited exception, the Stipulated Order expressly states that each party is entitled to discovery of documents underlying scientific or medical tests that an expert refers to or relies upon in an expert report or in testimony.

*[T]he parties shall 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 either (i) an expert relies on or refers to such a test in the expert's report or testimony, or (ii) an expert was involved in requesting, designing, planning, discussing, performing, reviewing or commenting on such a test, whether performed by that expert, another expert, or a consultant.*<sup>7</sup>

Roche served Amgen with Dr. Cord's expert report on May 11, but failed to produce the protocol, or any documents underlying the testing performed by Dr. Cords. On May 26, one

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<sup>5</sup> Docket No. 267.

<sup>6</sup> Docket No. 267 at 2.

<sup>7</sup> *Id.* at 2-3 (emphasis added).

business day before the Dr. Cords's deposition was to be taken, Amgen received a handful of documents from Roche, most of which were in the German-language, and not translated into English. Amgen notified Roche that it had not produced a copy of the test protocol. Roche responded that it had done so, and held to that position even when Dr. Cord's answers during his deposition suggested otherwise.<sup>8</sup> After Dr. Cords admitted that he performed the protocol given to him by Roche, and that it was not among the documents produced by Roche,<sup>9</sup> it became clear that Roche had indeed failed to produce the protocol.<sup>10</sup> Dr. Cords later admitted that he relied on the protocol that Roche withheld to perform the bioassays detailed in the expert reports.

Q: Did you consider the information contained in [the protocol] in connection with the expert report that you have submitted in this case?

A: Yes.<sup>11</sup>

Finally, with little more than an hour left in Dr. Cords deposition, counsel for Roche produced a redacted copy of the test protocol used by Dr. Cords.<sup>12</sup> Amgen never had a chance to determine the contents of the redacted portion. When Amgen asked Dr. Cords about the substance of the redacted portion, Roche's counsel instructed him not to answer the questions, claiming that the document was protected under attorney-client privilege.

Q: Dr. Cords, in the redacted portion of Page C15, is there an aspect of the parameters for a Normomouse bioassay that is discussed in that part of the document?

Mr. Leeman: Objection, same instruction not to answer.

Q: Dr. Cords, is there anything in the redacted portion of Page C15 that reflects any actual or potential modification to be made to the

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<sup>8</sup> 5/30/2007 Deposition Transcript of Dr. Sven Cords at 121-124.

<sup>9</sup> *Id.* at 120-121.

<sup>10</sup> *Id.* at 130-131, 143-146.

<sup>11</sup> *Id.* at 150.

<sup>12</sup> *Id.* at 143-146.

standard biomouse assay?

Mr. Leeman: Objection, instruction not to answer.<sup>13</sup>

Roche never included this document in any of its privilege logs. Instead, Roche simply argues that Dr. Cords did not rely on the redacted portion of the document, and therefore Roche should not have to produce it.<sup>14</sup> However, the test under the stipulated order for exclusion is not whether an expert relied on or referred to a portion of a document, but rather (1) whether the expert relied on or referred to a test, and then (2) whether the document in question contains data or test results that underlies the relied upon test. Dr. Cords unquestionably relied on the tests in his report and the redacted protocol underlies those tests.

Roche violated the stipulated order, denied that it had done so, and then relied upon tests, which the redacted protocol underlies, in its expert reports and in Dr. Cords's declaration. This Court has stated in several orders, consistent with the Federal Rules, that a party may not rely on evidence that was purposefully withheld from production.<sup>15</sup> Accordingly, The Court should exclude all references to the experiments performed by Dr. Cords.

### III. CONCLUSION

Amgen requests an order precluding Roche from (a) referring or relying upon any experiments performed by Dr. Cords and (b) referring to Amgen's failure to test Roche's Peg-EPO product.

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<sup>13</sup> *Id.* at 152-155.

<sup>14</sup> Docket No. 735 (Defendant's Opposition to Amgen Inc.'s Motion to Strike the Declaration of Dr. Sven Michael Cords).

<sup>15</sup> 5/2/07 Court Order ("Discovery Is Not A Game And Court Orders Are Not To Be Altered. What Is Expected And Required Is A Cooperative Venture To Ascertain The Truth. Should Any Party Have Wrongfully Failed To Make Discovery, The Appropriate Sanction Is A Preclusion Order, The Drawing Of Adverse Inferences, Or Both."); 5/16/07 Court Order ("No Witness May Rely On Evidence Withheld From Discovery"); 1/22/07 Court Order ("No Party May Introduce In Evidence Any Document Called For In Discovery And Not Produced, Nor Any Data Derived From Such Document").

Respectfully Submitted,

Date: August 24, 2007

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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 and paper copies will be sent to those indicated as non-registered participants on August 24, 2007.

*/s/ Michael R. Gottfried*  
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