**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MASSACHUSETTS**

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| AMGEN, INC.,<br><br>Plaintiff,<br><br>v.<br><br>F. HOFFMANN-LA ROCHE, LTD, ROCHE DIAGNOSTICS GMBH, and HOFFMANN-LA ROCHE INC.,<br><br>Defendants. | Civil Action No. 05-12237 WGY |

**DEFENDANTS' OPPOSITION TO PLAINTIFF'S MOTION *IN LIMINE* NO. 3: TO EXCLUDE REFERENCES TO DOCUMENTS AND EXPERIMENTS FROM DR. BARBER**

Defendants F. Hoffmann-La Roche, Ltd, Roche Diagnostics GmbH and Hoffmann-La Roche Inc. (collectively "Roche") submit this opposition to Amgen's motion *in limine* No. 3 to exclude references to documents and experiments from Dr. Dwayne Barber.

## I. INTRODUCTION

Amgen's motion seeks to falsely characterize Dr. Barber's studies as prejudicially untimely. Moreover, Amgen inappropriately seeks as a remedy the preclusion of some of Dr. Barber's studies, while themselves relying on other studies by Dr. Barber to argue the infringement issue.[1] However, Amgen suffered no prejudice because Roche provided timely supplementation to the initial Dr. Barber studies with newly generated studies, as prescribed by Federal Rule of Evidence 26(e). Notably Roche's supplementary production came very shortly after the close of fact discovery, and over forty-five days before the deposition of Roche's expert relying on Dr. Barber's studies. Amgen certainly had ample time to request to depose Dr. Barber regarding the studies but never did. Even if the Court determines the supplemental disclosure was untimely, preclusion of the documents is not the proper remedy. Roche should not be punished for following the Federal Rules regarding supplemental disclosure, especially when Amgen itself produced documents regarding experiments from its own Dr. Elliott over *two months later* than Roche's supplemental production.

[1] Supplemental Expert Report of Dr. Harvey F. Lodish, dated 6/4/07, ¶ 132.

## II. ARGUMENT

Federal Rule 37(c)(1) provides that a party which, without substantial justification, fails to disclose information or amend a prior response to discovery is not allowed to use such evidence at trial -- unless such error is harmless. However, in implementing this rule, Federal Courts often "consider four factors in determining whether the exclusion of evidence is an appropriate sanction for the failure to comply with discovery duties: 1) the prejudice or surprise of the party against whom the excluded evidence would have been admitted; 2) the ability of the party to cure that prejudice; 3) the extent to which allowing the evidence would disrupt the orderly and efficient trial of the case and other cases in the court; and 4) bad faith or willfulness in failing to comply with a court order or discovery obligation." *Merisant Co*. v. *McNeill Nutritionals*, 242 F.R.D. 315, 326 (E.D.Pa. 2007). Courts have also noted that the exclusion of evidence is "an extreme sanction, not normally to be imposed absent a showing of willful deception or flagrant disregard of a court order by the proponent of the evidence." *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 904 (3d Cir. 1977) (*quoting Dudley v. South Jersey Metal, Inc*., 555 F.2d 96, 99 (3d Cir. 1977)). "Limiting the automatic sanction to violations 'without substantial justification,' coupled with the exception for violations that are 'harmless,' is needed to avoid unduly harsh penalties...." Fed. R. Evid. 37 advisory committee's note. "Even if the failure was not substantially justified, a party should be allowed to use the material that was not disclosed if the lack of earlier notice was harmless." Fed. R. Evid. 37 advisory committee's note.

Roche's supplemental production discharged its discovery duties as outlined by Federal Rule 26(e), as Roche supplemented their initial response to Amgen's document request very shortly after Dr. Barber concluded the series of studies. By the close of fact

discovery, Roche had already disclosed to Amgen Dr. Barber's initial study regarding signaling pathways.[2] However, Dr. Barber had not yet concluded several continuing studies. Prior to the completion of the studies and prior to the close of fact discovery, Roche alerted Amgen to continuation studies by Dr. Barber.[3] Shortly after Dr. Barber completed the chain-of-studies, Roche supplemented its production as required by Federal Rule 26(e) to include the recently concluded studies.[4] Dr. Richard Flavell used these documents to form the basis of several opinions in his expert report dated May 8, 2007.[5] Federal Rule 37(c)(1) does not apply here, where Roche made a supplementary production in a timely fashion. The rule is written to preclude evidence that was produced either on the eve of trial, or was not at all produced. Amgen has yet to articulate any real reason why the supplemental production was not harmless.

Not only did Roche's supplemental production discharge its discovery duties as outlined by Federal Rule 26(e), but the production of the documents only one month after the close of fact discovery prevented any prejudice to Amgen and was harmless. Amgen had over forty-five days to examine the documents in advance of Dr. Flavell's deposition on July 26, 2007. Despite having Dr. Barber's subsequent studies for over one-and-a-half months, Amgen chose not to ask any questions regarding the documents. The Federal Rules certainly were not written to allow a party to create their own prejudice by choosing not to ask about documents they had for an ample amount of time. Amgen should not be allowed to manufacture prejudice by choosing to not ask questions of the

[2] Progress Report #1 dated September 26, 2005, Dr. Dwayne Barber, R008891068-1074.

[3] Deposition of Dr. Anton Haselbeck, dated 3/02/2007 at 264.

[4] Exhibit A, Letter from Hank Heckel to Peter Day, 5/09/07.

[5] Supplemental Expert Report of Dr. Richard Flavell, dated 5/8/07, ¶¶ 113-117.

Barber documents during their deposition of Dr. Flavell. In addition, the documents were produced to Amgen approximately four months ahead of trial. Amgen had ample opportunity to subpoena and depose Dr. Barber, but did neither -- heading off any reasonable claim of prejudice or harm. While Amgen is entitled to pursue the litigation strategy of its choice, it also bears responsibility for the resulting consequences. *See McCarthy v. Option One Mortgage Corp.* 362 F.3d 1008, 1012 (7th Cir. 2004) (affirming denial of exclusion under 37(c)(1) where party seeking exclusion failed to pursue discovery relating to disputed items).

Following the test employed in several federal courts to determine whether or not to exclude evidence, the supplemental Barber production should not be excluded. First, there is neither prejudice against Amgen nor surprise about the continued Barber studies. Amgen knew of the existence of the documents as early as March 2, 2007, and received the documents only two months later. Amgen cannot seriously claim that the documents prejudiced them, when they obtained them four months ahead of trial. Second, even if there was prejudice against Amgen, they had enough time and ample opportunity to remedy such prejudice. Amgen could have deposed Dr. Barber. They chose not do so. Amgen could have also asked Dr. Flavell about the Barber studies on which he relied to form his opinions. Again, they chose not to do so. Third, allowing the balance of the Barber studies would not disrupt the court's schedule. Amgen has already chosen not to depose Dr. Barber or ask Dr. Flavell about the documents in deposition, so allowing the documents would not vary the Court's existing schedule. Fourth, Roche acted in good faith in complying with the Federal Rule 26(e) by supplementing its initial disclosure.

Amgen has failed to provide any evidence of bad faith, and in its absence, the Court should not rely on Amgen's unfounded implications.

Amgen's position with respect to the supplemental production of the Barber documents is inconsistent. On one hand, Amgen relies on one Barber study, in isolation, to aid their infringement case. Now they wish to exclude those studies that do not behoove them. Amgen should not be allowed to cherry-pick the study they want to use, and summarily exclude the Court from considering the conclusion of the studies. Dr. Barber noted in his initial study, titled "Progress Report #1" that he "initially concentrated on performing signaling experiments on UT-7 EPO cell line" and "intend[s] to compare and contrast EPO and CERA signaling…." R008891070. Amgen wishes to exclude Progress Reports Nos. 2-4 and the supporting data. This would necessarily cause the single study to be taken out of the context that the author intended, skewing any conclusions.

Lastly, Amgen's position is also inconsistent with respect to when documents should be excluded. Amgen produced a series of 59 documents on July 27, 2007, well over three months after the close of fact discovery.[6] Now, Amgen complains that Roche's production of ten documents, one month after the close of fact discovery is prejudicially late and should be excluded.

[6] Exhibit B, Letter from Protas to Fratangelo, 6/27/2007.

## III. CONCLUSION

Contrary to Amgen's assertions, pursuant to F.R.E. 26(e), Roche's supplemental production of the rest of Dr. Barber's signaling studies should be allowed into evidence and Roche should not be barred from relying on, or referring to, the experiments described during the examination of any expert witnesses. Accordingly, Amgen's motion should be denied in all respects.

**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 that no agreement could be reached.

/s/ *Thomas F. Fleming*

DATED: September 1, 2007

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/ *Thomas F. Fleming*