

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

AMGEN, INC.,

Plaintiff,

v.

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

Defendants.

Civil Action No. 05-12237 WGY

**ROCHE'S RESPONSE TO AMGEN'S BENCH MEMORANDUM  
REGARDING PEGYLATION OF NON-EPO COMPOUNDS**

Roche relies on its Bench Memorandum to Preclude Amgen From Introducing Testimony Related to Pegylation of Non-EPO Compounds (D.I. 1260), but makes the following comments regarding Amgen's Response to Roche's Bench Memorandum (D.I. 1272).

- Amgen mischaracterizes Roche's argument and totally misses the point by arguing that its experts should be permitted to testify regarding pegylation of compounds other than EPO because Amgen claims its experts do not rely on any information that Amgen refused to produce in discovery. The point is that Amgen refused to produce documents related to pegylation of compounds other than EPO that contradict Amgen's position and that of its experts - that pegylation was well-known and established. Roche was denied discovery into documents on the very issue Amgen wants its experts to testify - whether pegylation is simple or difficult -and Amgen should be precluded from offering such testimony.
- Amgen interprets Fed. R. Civ. P. 34 as allowing Amgen to claim that any documents related to pegylation of compounds other than EPO which contradict Amgen's position are not relevant, while its experts rely on documents concerning pegylation of non-EPO compounds that Amgen contends support its position. Fed. R. Civ. P. 34 does not allow such picking and choosing.
- Amgen engages in revisionist history by trying to deny that it took the position that documents related to pegylation of non-EPO compounds are not relevant to this case

in successfully having the Court deny Roche's motion to compel production of documents related to Amgen's GCSF, MGDF, and NESP. Amgen's opposition to Roche's motion to compel, which is Exhibit 1 to Amgen's Bench Memorandum, contains a multi-page section entitled "Documents Relating to Amgen's Pegylated Proteins Other Than EPO Are Not Relevant And Production Would be Unduly Burdensome."

Amgen mischaracterizes Roche's argument regarding Amgen's non-production of documents related to Amgen's attempts to pegylate compounds such as Amgen's GCSF, MGDF, and NESP when it argues that Amgen's experts do not rely on any information that Amgen refused to produce in discovery. As explained in Roche's Bench Memorandum (D.I. 1260), Amgen refused to provide any discovery at all into Amgen's work on pegylation of its own molecules such as GCSF, NESP and MGDF, arguing that "whether pegylation is simple or difficult or whether pegylation affects the structure, composition or properties of specific molecules that are not accused of infringement" is not at issue in this case.<sup>1</sup> Amgen's attempts to pegylate, the difficulty encountered, and failed attempts to pegylate directly contradict the position advanced by Amgen and its experts - that pegylation was well-known, established and easy to do. It is not surprising that Amgen's experts do not rely on these non-produced documents. Amgen's experts should be precluded because they attempt to give testimony that would be contradicted by documents Amgen refused to produce by arguing they were not relevant.

Amgen apparently reads Fed. R. Civ. P. 34 as allowing production and disclosure of documents on a topic - pegylation of non-EPO compounds - which Amgen believes support its position, while refusing to produce documents on the same topic that undermine Amgen's position by arguing the "bad" documents are not relevant. Such picking and choosing is clearly

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<sup>1</sup> Amgen Inc.'s Opposition to Defendants' Motion to Compel Production of Documents, D.I. 201, filed 12/12/06 ("Amgen's 12/12/06 Opp."), at \*2.

not permitted by Rule 34. Having argued that documents related to pegylation of non-EPO compounds were not relevant to any issue in this litigation, and successfully having the Court deny Roche's motion to compel these documents and issue an order stating, "This case involves EPO, including Pegylated EPO, not Other Pegylated Compounds," Amgen cannot now engage in revisionist history and argue that it never took this position. Even a cursory review of Amgen's December 29, 2006 Opposition to Roche's Motion to Compel (D.I. 1272-2) completely shows Amgen's re-couching of the past to be untrue. Amgen titles one multi-page section of the opposition, "Documents Relating to Amgen's Pegylated Proteins Other than EPO Are Not Relevant and Production Would be Unduly Burdensome." In that section, Amgen argues that "[d]iscovery regarding these proteins is therefore in no way related to the subject matter of Lin's patents - or this litigation."<sup>2</sup> In its opposition, Amgen argued that "whether pegylation is simple or whether pegylation affects the structure, composition or properties of specific molecules that are not accused of infringement, are not at issue - the infringement issue on the context of the patents-in-suit is whether Defendants' peg-EPO product contains EPO."<sup>3</sup> Amgen very clearly argued that documents related to pegylation of non-EPO compounds were not relevant and succeeding in having Roche's motion to compel denied. The Court's order denying the discovery is clear - Amgen never sought to alter the Court's order by saying that some documents related to pegylation of non-EPO compounds were relevant and some were not relevant. Any argument now by Amgen that the documents relied on by its experts that relate to pegylation of non-EPO compounds are relevant and the testimony should be allowed is directly contradicted by Amgen's position denying Roche discovery. Additionally, Amgen misleadingly

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<sup>2</sup> Amgen's 12/12/06 Opp. at \*10.

<sup>3</sup> Amgen's 12/12/06 Opp. at \*2.

suggests that Roche did not specifically ask for documents related to pegylation of Amgen's products MGDF, NESP and GCSF. As described in Roche's Bench Memorandum, Roche specifically asked for documents concerning pegylation of these compounds in its interrogatories. Further, Amgen's contention that Roche's interrogatories were unduly burdensome is completely undermined by the fact that Amgen produced zero documents relating to pegylation of its non-EPO compounds.

### **CONCLUSION**

For the reasons stated in its previously filed Bench Memorandum (D.I. 1260) and all of the foregoing reasons, Amgen should be precluded from offering evidence or testimony, including expert testimony, whether pegylation was a routine, predictable procedure or causes a substantial change to any starting compound other than erythropoietin.

DATED: October 4, 2007  
Boston, Massachusetts

Respectfully submitted,

F. HOFFMANN-LA ROCHE, LTD,  
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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). Pursuant to agreement of counsel dated September 9, 2007, paper copies will not be sent to those indicated as non registered participants.

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