

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

AMGEN INC.,

Plaintiff,

v.

F. HOFFMANN-LA ROCHE LTD, a
Swiss Company, ROCHE DIAGNOSTICS
GMBH, a German Company, and
HOFFMANN LA ROCHE INC., a New
Jersey Corporation,

Defendants.

Civil Action No.: 1:05-CV-12237 WGY

**AMGEN’S OPPOSITION TO ROCHE’S MOTION IN LIMINE TO PRECLUDE
AMGEN FROM INTRODUCING TESTIMONY OF VLADIMIR TORCHILIN
RELATED TO PEGYLATION OF NON-EPO COMPOUNDS**

Roche’s motion to preclude the expert opinion of Dr. Torchilin on whether Roche’s process for pegylating EPO materially changes the claimed EPO fails to adequately acknowledge that this Court, on three occasions, effectively addressed the issue regarding discovery into Amgen’s specific pegylation programs of non-EPO compounds and that Amgen’s experts do not rely on any unproduced documents. At its core, Roche’s motion rests on a fundamental misrepresentation of what Amgen represented to this Court by selectively quoting from a January brief without quoting the entire section. Amgen never represented to the Court that general background and scientific principles of pegylation were not at issue in this suit. What Amgen represented was that “*the* infringement issue in the context of the patents-in-suit is whether Defendants’ peg-EPO product contains EPO, which it plainly does.” (Tab 1 at 2.) Notably, Roche’s motion repeatedly fails to quote the entire sentence Amgen wrote, and from that omission, attempts to prohibit Dr. Torchilin from testifying in general on the field of

pegylation. Roche's attempt to preclude Dr. Torchilin from testifying on general pegylation background and issues should be precluded on several grounds.

First, Dr. Torchilin does not rely on any information that Amgen refused to produce in discovery.

Second, last May, Roche sought to strike Dr. Torchilin's expert opinion based on the same theory. The Court denied that motion to strike without prejudice, stating that "no witness may rely on evidence withheld from discovery." Roche has not shown any reliance on withheld Amgen evidence, nor is there any.

Third, on January 3, 2007, the Court entered an order denying Roche's far-ranging and burdensome discovery requests into all other Amgen pegylation programs. The Court stated: "This case involves EPO, including Pegylated EPO, not Other Pegylated Compounds." Amgen properly withheld such documents on Amgen's other pegylated proteins in light of the Court's order. There is no discovery issue here.

Fourth, Roche mischaracterizes Amgen's position in opposing that original motion to compel. Contrary to Roche's position, Amgen did not contend that pegylation or whether or not a protein could be pegylated was not relevant. Rather, what Amgen contended was that pegylation was well-known and established in that the scientific literature, and the *burdensome and unfocused discovery requests* aimed at hundreds of thousands of pages of Amgen documents failed to satisfy the requisites of Rule 26. Amgen statements to this Court included:

"Defendants argue that they are entitled to virtually all Amgen documents relating to pegylation of *any* substance. Defendants elevate "peg" over EPO, in an attempt to divert this Court's attention away from the indisputable fact that their peg-EPO products contains EPO. EPO, not peg, is at the heart of this dispute."¹

"Unfocused discovery into Amgen's pegylation projects is unwarranted. There can be no dispute that *pegylation is a well-known and commonly used technique to increase the serum half-life of therapeutic proteins. Amgen-authored publications cited in Defendants' Memorandum state*

¹ Docket 201 at 7.

as much. Defendants’ representations in their BLA are not to the contrary.”²

“Defendants’ request, seeking *all* documents related to pegylating *any* “compound” (the “compounds” are not even limited to proteins) are unreasonably broad.”³

*“Defendants admit that pegylation is a standard technique, on which there is extensive scientific literature. There is no compelling justification to force Amgen to produce the enormous amounts of proprietary information on Amgen’s research and development of products other than EPO.”*⁴

Amgen was very clear that pegylation and the scientific literature in general was at issue, but that the relevance of Amgen work on non-EPO pegylated proteins did not justify the overbroad, unfocused and burdensome discovery that Roche sought. The Court agreed, denying Roche’s Motion to Compel. All Dr. Torchilin relies upon is the very scientific literature that both parties informed the Court existed and was not at issue in the Motion to Compel the large quantity of Amgen proprietary documents.⁵

The one sentence that Roche points to from Amgen’s opposition, but Roche does not quote in full, states: “Thus, contrary to Defendants’ assertions, whether pegylation is simple or difficult or whether pegylation affects the structure, composition or properties of specific molecules that are not accused of infringement, *are not the issue – the infringement issue* in the context of the patents-in-suit is whether Defendants’ peg-EPO product contains EPO, which it plainly does.” There can be no doubt that *the* infringement issue is exactly as Amgen stated it, and the infringement issue in the case is not whether other specific molecules would infringe.

Roche’s motion improperly and unconvincingly tries to revise Amgen’s position in opposing the Motion to Compel to be that pegylation in general is irrelevant, or that Amgen stated that general scientific knowledge of the pegylation arts and what it showed was not relevant to the structure and function of peg-EPO -- a position *never* taken by Amgen. Rather,

² Docket 201 at 8 (emphasis added).

³ *Id.* at 8-9.

⁴ *Id.* at 10 (emphasis added).

⁵ Roche did not then and has never since articulated any relevance for requests so overly broad and burdensome and did not move for reconsideration.

Amgen argued that document requests for all of its research and development documents relating to pegylation of any compound failed to satisfy Rule 26.⁶ Roche's motion is wrongfully aimed at prohibiting opinions of Dr. Torchilin (1) that are directly in line with Amgen's statements to this Court regarding the well-known and common use of pegylation as established in the scientific literature, and (2) that rest on documents Amgen and Roche produced in discovery.

Fifth, Roche cites two instructions not to answer where Roche was seeking to question Dr. Mollineux about specific work he performed at Amgen on peg-GCSF that was disclosed in an article on his work at Amgen. Roche makes no showing that the work was related to peg-EPO, as counsel requested that Roche make at the deposition, consistent with the Court's January 3 Order.

In sum, Amgen provided discovery within the scope of the Court's Order, and Roche's attempt to prevent Dr. Torchilin from relying on the general pegylation literature and Roche's internal documents is without basis. The request to preclude should be denied, just as was done last Spring. For the convenience of the Court, Amgen attaches as exhibits hereto its previous three oppositions to Roche's various motions aimed at this issue.

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Respectfully Submitted,

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⁶ Docket 201 at 8-9.

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