

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

**PLAINTIFF’S BENCH MEMORANDUM TO PREVENT ROCHE
FROM CROSS EXAMINING DR. TORCHILIN ABOUT AMGEN’S EFFORTS
TO PEGYLATE MOLECULES, INCLUDING EPO, AND THE PREDICTABILITY OF
PEGYLATION IN GENERAL AS IT IS IRRELEVANT
TO THE INFRINGEMENT INQUIRY**

Roche should be precluded during its cross-examination of Dr. Torchilin from questioning about Amgen’s efforts to pegylate molecules, including EPO, or about the predictability of pegylation in general. Such topics are red-herrings meant to divert the Jury’s attention away from the relevant infringement inquiry: whether Roche’s peg-EPO product contains Lin’s claimed EPO. As made clear in its Infringement Opening, Roche seeks to introduce misleading and non-relevant evidence relating to Amgen’s pegylation efforts, including pegylating EPO, and the predictability of pegylation.¹ Roche also designated deposition testimony of Dr. Torchilin relating to irrelevant subject matter including the predictability of pegylation and Amgen’s efforts to make peg-EPO.

¹ Trial Tr. at 2377:5-11 (The evidence will show that Amgen, wanting to make a new and better product, tried to make a pegylated product for just this year and they failed. They were unable to get a better product. They failed and, therefore, to stop this better product, this new product, they sued Roche. And Roche has the patent. They could not do it, so they sued.”).

Roche is improperly attempting to prove its non-infringement case by submitting acts of Amgen that are irrelevant. “Evidence which is not relevant is not admissible.”² Amgen’s peg-EPO is simply irrelevant to the Jury’s infringement analysis. Infringement is determined by comparing each claim of Amgen’s patents-in-suit (which do not relate to pegylation) with Roche’s alleged infringing product. It certainly does not involve a comparison of Amgen’s peg-EPO to Roche’s peg-EPO.

Amgen’s peg-EPO, and the predictability of pegylation techniques, are also irrelevant to the Jury’s “materially changed” determination. The Jury must compare the product of Amgen’s process claims, EPO, with Roche’s infringing peg-EPO. Amgen’s peg-EPO bears no relationship to these inquiries. Nor is the predictability of pegylation techniques relevant. To the extent that Roche argues that these topics support the patentability of its MIRCERA product, the validity of Roche’s patent is not at issue, and is irrelevant to the infringement question to be decided by the Jury. The sole issue is comparison of the asserted claims to MIRCERA.

Any alleged relevance that Amgen’s peg-EPO or the predictability of pegylation had in this case was in relation to the Invalidity phase. However, this Court’s summary judgment ruling that Dr. Lin’s patent claims were adequately described and enabled and that they did not need to describe or enable how to make pegylated EPO rendered Amgen’s pegylation efforts irrelevant. Roche should not be permitted now to raise such issues, irrelevant to the infringement issue, before the Jury.

While Roche argues that Amgen’s peg-EPO is relevant for infringement (it is not relevant), any alleged relevance to infringement is tenuous and inadmissible. “Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury. . . .”³ Roche wants to mislead the Jury by portraying that its construction of peg-EPO was difficult and is a worthy

² FRE 402.

³ FRE 403.

invention and that Amgen tried to pegylate EPO but failed (Amgen did not fail). Roche seeks to deceptively depict Amgen as incapable of doing what Roche did, and as litigious against Roche to compensate for its failure to pegylate-EPO (Amgen made peg-EPO).⁴ Comparing Amgen's peg-EPO with Roche's peg-EPO would mislead the Jury away from the proper infringement inquiry, namely, application of the claims to Roche's product.

As Amgen's peg-EPO work would be highly misleading and confusing to the Jury, and extremely prejudicial to Amgen without bearing any relevance to infringement, the Court should preclude Roche from questioning Dr. Torchilin about Amgen's pegylation efforts or about the predictability of pegylation techniques in general.

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Respectfully Submitted,

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⁴ Trial Tr. at 2377:5-11.

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/s/ Michael R. Gottfried

Michael R. Gottfried