Case 1:05-cv-12237-WGY

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

AMGEN INC.,)
Plaintiff, v.)) Civil Action No.: 1:05-CV-12237 WGY
F. HOFFMANN-LA ROCHE LTD, a Swiss Company, ROCHE DIAGNOSTICS GMBH, a German Company, and HOFFMANN LA ROCHE INC., a New Jersey Corporation,)))))
Defendants.)))

PLAINTIFF'S MOTION IN LIMINE PRECLUDE ROCHE FROM OFFERING EVIDENCE REGARDING AMGEN'S EFFORTS TO PEGYLATE MOLECULES, INCLUDING EPO, AS IT IS IRRELEVANT TO THE INFRINGEMENT INQUIRY

Roche should be precluded from using Amgen's efforts to pegylate molecules, including EPO, 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.¹ Roche has also designated deposition testimony of Amgen employees Thomas Boone and Graham Molineaux relating to Amgen's pegylation of EPO. This effort to introduce evidence on these collateral issues should be denied.

Roche is improperly attempting to prove its non-infringement case by submitting acts of

AMGEN'S MIL TO PRECLUDE EVIDENCE OF AMGEN'S PEGYLATION OF EPO CIVIL ACTION NO. 1:05-CV-12237 WGY

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.").

Amgen that are irrelevant. "Evidence which is not relevant is not admissible." 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 is 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. To the extent that Roche argues that Amgen's peg-EPO supports 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 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.

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. . . ." Roche intends to mislead the jury by portraying that its construction of peg-EPO was difficult and is a worthy 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). Comparing Amgen's peg-EPO with Roche's peg-EPO would mislead the Jury away from the proper infringement

² FRE 402.

³ FRE 403.

⁴ Trial Tr. at 2377:5-11.

inquiry.

As Amgen's peg-EPO 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 introducing evidence of Amgen's peg-EPO, and properly instruct the Jury as to the irrelevance of such facts.

DATED: October 15, 2007

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/s/ Michael R. Gottfried

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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 no agreement was reached.

/s/ Michael R. Gottfried
Michael R. Gottfried

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the Electronic Case Filing (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/ Michael R. Gottfried
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