

**UNITED STATES DISTRICT COURT  
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. )

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

**PLAINTIFF AMGEN INC.'S BRIEF IN SUPPORT OF ITS MOTION *IN LIMINE* NO. 22  
TO PRECLUDE ROCHE FROM INTRODUCING, INCLUDING DURING ITS  
VALIDITY OPENING TESTIMONY, EVIDENCE OR ARGUMENT ON PEGYLATION  
DURING THE VALIDITY PHASE OF THE TRIAL AND TO EXCLUDE ANY  
PROFFERED TESTIMONY BY DR. ROBERT LANGER DURING THE TRIAL**

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## I. INTRODUCTION

The Court's August 27, 2007, Order granted Amgen's Motion for Summary Judgment That Dr. Lin's Asserted Claims "are described and enabled, because as a matter of law, Dr. Lin must enable one of ordinary skill in the art the full scope of his claimed invention, *not how to make pegylated erythropoietin.*" (emphasis added).<sup>1</sup> This rendered moot and irrelevant any lay or expert evidence during the invalidity phase of the trial on the question whether one of ordinary skill in the art could pegylate EPO in 1984, and whether Dr. Lin was in possession of the invention of pegylated EPO. As a consequence, Roche has no legitimate reason to introduce pegylation evidence or argument with respect to the validity of the Lin patents during the validity phase.

Nonetheless, Roche has not withdrawn its expert on these issues, Dr. Langer, from the list of witnesses, and its recent designations of deposition testimony of Amgen witnesses all show that Roche still intends to offer during the validity phase evidence on pegylation. However, as pegylation is irrelevant to the validity of Dr. Lin's claims, as the Court recently adjudicated, evidence on whether pegylation was predictable or whether one of skill in the art could pegylate EPO, as apparently Roche intends to introduce, serves no relevance to the issues in the validity phase and will confuse and mislead the jury.

With trial almost at hand Amgen requests the Court to consider this motion before opening oral arguments as it relates to significant issues that are likely to be among the first raised in the initial validity phase of the trial.<sup>2</sup> Specifically, Amgen moves to exclude any testimony by Dr. Langer on pegylation, and to exclude the testimony of two Amgen witnesses, Dr. Molineux, and Dr. Elliott, that address this issue.<sup>3</sup>

<sup>1</sup> The Court's August 27, 2007 Order did not grant part 3 of Amgen's motion relating to the definiteness of the term "human erythropoietin." That portion of Amgen's motion is unrelated to the issues presented in this motion *in limine*.

<sup>2</sup> Amgen files this motion mindful of the fact that the trial of this matter begins in a few days. This motion could not have been filed earlier because the issues it raises first crystallized with the Court's August 27, 2007 Order.

<sup>3</sup> Roche incorporated by reference the Expert Report of Dr. Langer into the Supplemental Rebuttal Expert Report of Dr. Klibanov. To the extent that Roche intends to call Dr. Klibanov to testify on these issues during the invalidity phase, such testimony is likewise irrelevant under the Court's summary judgment grant and should be excluded.

## II. EVIDENCE REGARDING PEGYLATION IS IRRELEVANT TO THE VALIDITY OF THE LIN PATENTS

Relevant evidence is “evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.” FED. R. EVID. 401. Given the Court’s August 27<sup>th</sup> Order, evidence relating to pegylation will have no impact on any fact of consequence to the determination of the validity of the Lin patents. Evidence and argument relating to pegylation during the validity phase of the trial is irrelevant and should be excluded under Federal Rule of Evidence 402. Moreover, such evidence and argument should also be excluded under Federal Rule of Evidence 403 due to the substantial likelihood that it would unfairly prejudice Amgen by allowing Roche to urge contentions it never disclosed. *See* FED. R. EVID. 403.

Moreover, any attempt by Roche to offer evidence relating to pegylation for any other purpose during the validity phase of the trial is barred by the Federal Rules of Civil Procedure. In particular, Rule 37(c)(1) would preclude a party who, without substantial justification, fails to supplement its interrogatory responses to disclose additional contentions. FED. R. CIV. PROC. 37(c)(1).

### A. THE EXPERT TESTIMONY OF DR. ROBERT LANGER SHOULD BE ELUDED FROM THE TRIAL IN ITS ENTIRETY

Roche’s expert Dr. Robert Langer’s expert report is directed solely to the written description and enablement of the Lin patents. Specifically, Dr. Langer’s opinion was limited to:

“whether these patents would *enable a person of skill in the art* in 1983-84 *to generate* analogs of erythropoietin (“EPO”) such as a polyethylene glycol (“PEG”) *modified protein* having in vivo erythropoietin-like activity that is therapeutically useful, through routine experimentation” and

“whether the specification of the Lin patents provide [*sic*] *adequate written description of a PEG modified protein* having in vivo erythropoietin-like activity that is therapeutically useful.”

[Declaration of William G. Gaede, III (“Gaede Decl.”), Ex. 1]. Dr. Langer confirmed during his deposition that he was *not* providing an opinion on whether the patents-in-suit enable production of recombinant erythropoietin or a process for preparing human erythropoietin. [Gaede Decl.,

Ex. 2] Dr. Langer provided no opinions whatsoever relating to infringement or inequitable conduct. [Gaede Decl., ¶ 6].

Having opined on nothing more than enablement and written description of PEG-modified proteins, Dr. Langer cannot offer testimony at trial beyond this limited scope. FED. R. CIV. P. 26(a)(2)(B). And because the Court's Summary Judgment Order establishes that Dr. Lin's patents are enabled and adequately described, any testimony that Dr. Langer could give can have no relevance to the validity of the patents.

In addition, Dr. Langer cannot offer testimony during the infringement or inequitable conduct phases of the trial, having expressed no opinions in his report on these issues. *See Cell Genesys, Inc. v. Applied Research Systems ARS Holding, N.V.*, No. 05-12448-MLW and 04-11810-MLW, 2007 U.S. Dist. LEXIS 58658, at \*58-59 (D. Mass. Aug. 13, 2007) (an expert may not provide evidence or opinions that were not disclosed as required by Rule 26(a)(2)(B), except in certain, specified circumstances). "A party proposing to rely on evidence or testimony which it did not properly disclose to its adversary in discovery bears the burden of demonstrating a 'substantial justification' for the failure to disclose or that such failure was 'harmless.'" *Id.* (citing FED. R. CIV. P. 37(c)(1)). Neither branch of the exception applies to this case. Any attempt by Roche to have Dr. Langer testify during the infringement or inequitable conduct phases of the trial would be exactly the type of unfair tactical advantage that the disclosure rules were designed to eradicate. *See Lohnes v. Level 3 Commc'ns, Inc.*, 272 F.3d 49, 60 (1<sup>st</sup> Cir. 2001).

**B. ROCHE SHOULD BE PRECLUDED FROM INTRODUCING DEPOSITION DESIGNATIONS RELATED TO PEGYLATION AND/OR PEG-EPO**

The deposition testimony designated by Roche of two Amgen witnesses, Graham Molineux and Stephen Elliott, relate to pegylation and its predictability or unpredictability. The Court's grant of summary judgment renders irrelevant such testimony as it does not relate to an issue present during the validity phase of the trial. Because the Court has ruled that Dr. Lin's patent claims are adequately described and enabled, and the Lin patents need not describe or enable how to make pegylated erythropoietin, the designated testimony of witnesses Molineux

and Elliott has no relevance to any issue related to validity in this case. Roche should be precluded from offering these deposition designations as testimony during the validity phase of the trial, as more particularly set out in the deposition excerpts attached hereto. [Gaede Decl., Exs. 3 and 4].

**C. ANY OTHER EVIDENCE, TESTIMONY, OR ARGUMENT RELATING TO PEGYLATION SHOULD BE EXCLUDED FROM THE VALIDITY PHASE OF THE TRIAL AND ITS ADMISSION WILL LIKELY LEAD TO JUROR CONFUSION**

Other evidence, testimony, or argument relating to pegylation or Roche's product should be excluded from the validity phase of the trial because it is irrelevant to any issue of patent validity. Moreover, admission of any such evidence will lead to juror confusion. The validity phase of the case should be limited to an evaluation of Lin's inventions and not an explanation of Roche's peg-EPO. Introducing evidence of pegylation, its predictability, and whether it could have been done in 1984 will confuse the jurors, waste judicial resources, and may lead to an erroneous result. Such evidence has no probative value, but even if it did, its prejudicial effect far outweighs that value and should be excluded.

**III. CONCLUSION**

For the reasons stated above, Roche should be excluded at trial from introducing evidence or argument on pegylation during the validity phase of the trial.

DATED: August 31, 2007

Respectfully Submitted,

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#### **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.

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