

**IN THE UNITED STATES DISTRICT COURT  
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. 05-12237 WGY

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

The defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively "Roche") respectfully request that Amgen be precluded from presenting any evidence or testimony from its expert witness Dr. Valdimir Torchilin relating to the following topics:

- (1) chemical reactions of polyethylene glycol reagents (hereinafter "pegylation") with any compounds other than EPO, and
- (2) whether pegylation of compounds is a routine process that does not materially affect the structure, composition, or properties of a molecule.

This evidence and testimony should not be allowed for the following reasons:

- Amgen refused to provide any discovery whatsoever 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> In response to Amgen's opposition to providing this

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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 12/6/07 Opp."), at \*2.

discovery, this Court ruled that “The Case Involves EPO, Including Pegylated EPO, Not Other Pegylated Compounds.”<sup>2</sup>

- Consistent with this Court’s ruling that “No Witness May Rely On Evidence Withheld From Discovery,” Amgen should be barred now from raising this evidence before the jury.
- The Court previously ruled during Dr. Lodish’s testimony that testimony of pegylation of compounds besides erythropoietin was not permitted when the Court sustained an objection at sidebar to a question asking Dr. Lodish about pegylation of such compounds.<sup>3</sup> The Court noted that it was aware from Roche’s previously submitted bench memos on the issue (D.I. 1260 and 1298) that Amgen refused to provide discovery of pegylation of non-EPO products and sustained objection to the question “Do you have an understanding as to whether or not other proteins have been pegylated before peg-EPO?”<sup>4</sup>

In support of this motion, Roche relies upon the accompanying memorandum of law.

#### **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 that no agreement could be reached.

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<sup>2</sup> Court’s Order dated 1/3/07 on Motion (D.I. 170).

<sup>3</sup> Trial Tr., Day 17, 2457:25 - 2458:16

<sup>4</sup> Id.

Dated: October 14, 2007  
Boston, Massachusetts

Respectfully submitted,

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

*By their Attorneys*

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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.

/s/ Keith E. Toms

Keith E. Toms

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