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.	Civil Action No.: 05-12237 WGY

AMGEN'S OPPOSITION TO ROCHE'S MOTION IN LIMINE TO PRECLUDE AMGEN'S EXPERT WITNESS DR. LESLIE BENET FROM OFFERING TESTIMONY ON INFRINGEMENT

As Roche's proposed jury instructions acknowledge, "[t]o determine material change [under § 271(g)], one must look to the substantiality of the change between the product of the patented process and the imported product."[1] There is no dispute that a product of Dr. Lin's claimed processes is recombinant human erythropoietin.[2] As such, an appropriate analysis to determine whether the EPO component of Roche's peg-EPO product, CERA, is materially changed from the product of Dr. Lin's claimed process is to compare recombinant human erythropoietin and the EPO component of peg-EPO. This is especially true here, where Roche squarely put at issue in its opening statement whether differences between EPO and peg-EPO are material, referring to so-called differences between the two products' pharmacokinetic

[1] D.I. 917 at 53.

[2] Recombinant human erythropoietin is also referred to as "epoetin."

properties, including differences in the two products' half-lives, association and dissociation rates, and the like.[3]

Despite providing a grossly incomplete and inaccurate description of the substance of Dr. Benet's three reports, Roche's motion acknowledges that Dr. Benet's reports address the comparison that Roche asserts is relevant:

> Benet provides a general pharmacokinetic comparison between Roche's CERA and recombinant human EPO.[4]

As such, Dr. Benet should be allowed to offer opinions that are consistent with his reports and provide the bases for his opinion, including discussion about the pharmacokinetic properties of Roche's peg-EPO as compared to EPO, whether Roche's peg-EPO acts like a pro-drug, and the pharmacokinetic and hemoglobin variability of peg-EPO, as compared to EPO.

Having raised these issues, Roche should not be allowed to preclude Amgen from presenting evidence that directly contradicts Roche's position.

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Respectfully Submitted,

AMGEN INC.,

By its attorneys,

/s/ Patricia R. Rich

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[3] *See e.g.*, 10/3/07 Tr. at 2375:22-2378:20. Notably, Roche has asserted that the appropriate analysis is to compare the whole of Roche's peg-EPO product, CERA, and EPO. Amgen disagrees. The appropriate analysis focuses on whether the EPO component of peg-EPO is materially changed from EPO.

[4] D.I. 1261 at 2.

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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 and paper copies will be sent to those indicated as on-registered participants.

/s/ Patricia R. Rich
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