

**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'S EXPERT WITNESS  
DR. LESLIE BENET FROM OFFERING TESTIMONY ON INFRINGEMENT**

Amgen's pharmacokinetics expert, Dr. Leslie Z. Benet, has submitted three expert reports in this case, yet has not provided any specific opinion relating to the infringement of the asserted claims of the patents-in-suit by Roche's MIRCERA<sup>®</sup> or CERA<sup>®</sup> products. None of Dr. Benet's reports discuss: (a) any of the patents-in-suit, (b) any of the asserted claims, (c) this Court's claim construction, (d) comparison of Roche's accused products to any of the asserted claims, or (e) any standards by which the accused products are, or are not, materially changed as related to infringement of the asserted process claims.

The Federal Circuit has consistently reaffirmed that

[a]n infringement analysis involves two steps. First, the court determines the scope and meaning of the patent claims asserted, and then the properly construed claims are compared to the allegedly infringing device.

*Cybor Corp. v. FAS Techs. Inc.*, 138 F.3d, 1448, 1454 (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 371 (1996) and *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 821 (Fed. Cir. 1992)).

A simple glance at Dr. Benet's disclosed opinions in this case demonstrates that he cannot provide an opinion concerning infringement because there is no indication that the analysis set forth by *Cybor* was undertaken. Dr. Benet submitted three Expert Reports in this case.<sup>1</sup> Benet I provides a general pharmacokinetic comparison between Roche's CERA product and recombinant human EPO, and comments on potential hemoglobin intra-patient variability. Benet I never states that Roche's products infringe any claim of the Lin patents, nor does Benet I discuss the scope of the asserted claims of the Lin patents. In fact, the list of materials considered by Dr. Benet in forming the opinions enumerated in his first report does not even include the Lin patents themselves.

Neither Benet II nor Benet III discuss the patents-in-suit or the asserted claims. Benet II was put forward to rebut certain invalidity arguments raised by Roche's Expert Dr. Spinowitz. There are no infringement opinions in this report. Benet III addresses two discrete topics: (1) whether the Roche's novel chemical entities act like a "prodrug" when administered to humans, and (2) whether data generated by third party Dr. Veng-Pedersen is reliable. There is no opinion concerning the Lin patents, the asserted claims, or whether Roche's products or processes meet each and every limitation of the claims either literally or under the doctrine of equivalents.

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<sup>1</sup> Expert Report of Leslie Z. Benet, Ph.D., dated April 6, 2007 ("Benet I"); Rebuttal Expert Report of Leslie Z. Benet, Ph.D., dated May 11, 2007 ("Benet II"); and Second Rebuttal Expert Report of Leslie Z. Benet, Ph.D., dated June 20, 2007 ("Benet III").

For the foregoing reasons, Roche respectfully requests that the Court preclude Dr. Benet from offering any opinion relating to infringement of the asserted claims of the patents in suit.

**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 was reached.

DATED: October 2, 2007

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

By its 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/ Thomas F. Fleming  
Thomas F. Fleming