IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMGEN, INC., Plaintiff, v. F. HOFFMANN-LA ROCHE, LTD, ROCHE DIAGNOSTICS GMBH, and HOFFMANN-LA ROCHE INC., Defendants.	Civil Action No. 05-12237 WGY U.S. District Judge Young

MEMORANDUM IN SUPPORT OF ROCHE'S MOTION *IN LIMINE* TO PRECLUDE INFRINGEMENT TESTIMONY BY DR. LODISH WHICH IS IRRELEVANT AND BEYOND HIS EXPERTISE

Amgen's expert witness, Dr. Lodish, should be precluded from offering infringement testimony regarding

- Roche's corporate relationships
- Amgen's evidence of infringement by Roche
- products and methods that Roche decided not to use or sell in the U.S.
- supposed inducement of infringement by Roche.

Any such testimony on these issues is not grounded on scientific expertise, is irrelevant, is predicated on pure speculation and subjective belief, and/or goes far beyond Dr. Lodish's expertise in molecular and cell biology.

I. LEGAL STANDARD

The Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), interpreting Fed. R. Evid. 702, "establishes the duty of a trial judge to play the role of a gatekeeper" in deciding what expert testimony. *See Sutera v. Perrier Group of Am.*, 986 F. Supp. 655, 660 (D. Mass. 1997). Under Rule 702, "the expert must be qualified; . . . the expert's testimony must be reliable; and . . . [the expert's testimony] must 'fit' the facts of the case." *Id.* at 661. To be "qualified," the expert must have "knowledge, skill, experience, or education" on the matters on which he will testify. *Id.* For the expert's testimony to be "reliable," "the expert's opinion [must] be based on the methods and procedures of science rather than on subjective belief or unsupported speculation." *Id.*; *see also Whiting v. Boston Edison Co.*, 891 F. Supp. 12, 24 (D. Mass. 1995) ("the word 'knowledge' connotes more than subjective belief of unsupported speculation"). The "fit" requirement "refers to the necessity of a connection between the expert's testimony and the facts of the case." *Sutera*, 986 F. Supp. at 655.

II. ARGUMENT

A. Dr. Lodish Should Be Precluded From Testifying Regarding Roche's Corporate Structure and Relationships

In Dr. Lodish's April 6, 2007 report ("Lodish I"), he states that "Roche is currently seeking approval from the [FDA] to sell peg-EPO in the United States. Given Roche's relationship with other companies who previously made or sold EPO, a short overview of those prior activities is warranted." (See Ex. 1 to Declaration of Patricia A. Carson In Support Of Roche's Motion In Limine To Preclude Infringement Testimony By Dr. Lodish Which Is Irrelevant And Beyond His Experience ("Carson Decl.") (Lodish I) at ¶ 74). The report goes on to detail Roche's relationship with Genetics Institute , Boehringer Mannheim and Chugai. (Ex. 1 to Carson Decl. (Lodish I) at ¶¶ 74-79, 149-51). The Court has already expressed its skepticism

regarding the relevance of corporate structure. (Trial Tr. 392:1). Moreover, even if Roche's corporate relationships had any relevance, the substance of Dr. Lodish's report in this regard is beyond his expertise and his personal knowledge.

B. Dr. Lodish Should Not Be Permitted to Speculate About Amgen's Proof of Infringement by Roche

In his June 4, 2007 report ("Lodish III") (attached as Ex. 2 to Carson Decl.), Dr. Lodish attempts to excuse the flaws in Amgen's proof that Roche infringes the '349 patent by asserting that "Roche did not send [to Amgen's infringement expert, Dr. Kolodner] the medium it actually uses in its accused processes" and that Dr. Kolodner "was under a time constraint that prevented him from exactly replicating that medium." (Ex. 2 to Carson Decl. (Lodish III) at ¶ 66). Dr. Lodish also criticizes Roche for not submitting experimental proof of non-infringement on the grounds that "Roche owns and controls the manufacturing plant in Germany" and could thus "easily perform the RIA measurements on its production cell line." (*Id*. at ¶ 68). In both instances, Dr. Lodish's statements are based neither on his scientific expertise nor on his personal knowledge. Therefore, such testimony by Dr. Lodish should not be allowed.

C. Dr. Lodish Should Be Precluded From Testifying About Products and Methods Roche Decided Not to Sell or Use

Dr. Lodish's April 6, 2007 expert report ("Lodish I") gratuitously mentions that "Roche apparently considered but decided not to sell NeoRecormon" -- an Epoetin beta product -- in the United States. (Ex. 1 to Carson Decl. (Lodish I) at ¶ 79). Plainly, this information is irrelevant and should not be put to the jury by Dr. Lodish. Similarly irrelevant and beyond Dr. Lodish's knowledge and expertise are the statements in Lodish I regarding Roche's decisions not to employ certain processes or market particular products. (Ex. 1 to Carson Decl. (Lodish I) at ¶¶ 176-77).

D. Dr. Lodish Should Be Barred from Testifying About Inducement of Infringement by Roche

Dr. Lodish's April 6, 2007 expert report ("Lodish I") addresses Roche's alleged inducement of infringement of '933 claims 11 and 14 by asserting: "I expect that Roche has either already encouraged or intends to encourage physicians to administer MIRCERA™ in a manner that would satisfy the limitations of '933 claims 11 and 14." (Ex. 1 to Carson Decl. (Lodish I) at ¶ 166). However, Dr. Lodish is not an M.D. and is not an expert in the marketing of pharmaceuticals. Hence, this opinion is not only speculation but also beyond his expertise.

III. CONCLUSION

For the reasons stated above, Roche respectfully requests that the Court grant Roche's motion in all respects.

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.

Dated: October 4, 2007
Boston, Massachusetts

Respectfully submitted,

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

By their Attorneys,

/s/ Nicole A. Rizzo
Lee Carl Bromberg (BBO# 058480)
Robert L. Kann (BBO# 258025)
Julia Huston (BBO# 562160)
Keith E. Toms (BBO# 663369)
Nicole A. Rizzo (BBO# 663853)
Kimberly J. Seluga (BBO# 667655)
BROMBERG & SUNSTEIN LLP
125 Summer Street
Boston, MA 02110
Tel. (617) 443-9292
nrizzo@bromsun.com

Leora Ben-Ami (*pro hac vice*)
Mark S. Popofsky *(pro hac vice)*
Patricia A. Carson (*pro hac vice*)
Thomas F. Fleming (*pro hac vice*)
Howard S. Suh (*pro hac vice*)
Peter Fratangelo (BBO# 639775)
Vladimir Drozdoff (*pro hac vice*)
David L. Cousineau (*pro hac vice*)
KAYE SCHOLER LLP
425 Park Avenue
New York, New York 10022
Tel. (212) 836-8000

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/ Nicole A. Rizzo
Nicole A. Rizzo

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