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 TESTIMONY BY DR. LODISH ON AMGEN'S VALIDITY CASE ON MATTERS THAT ARE OF NO RELEVANCE TO THIS CASE

I. INTRODUCTION

Dr. Lodish should be precluded from proffering testimony and evidence regarding the following matters which either never were or are no longer relevant to this case:

(i) prior Amgen legal proceedings;

(ii) the relative quality of Dr. Lin's patent specifications;

(iii) Dr. Lodish's failures in cloning other (non-EPO) proteins;

(iv) statements made by Genentech in the file histories of Genentech's tPA patents[1]; and

(v) issues not being tried in this litigation.

[1] Dr. Lodish's report on this subject matter was also untimely and should be precluded on that independent basis as well.

II. ARGUMENT

A. Dr. Lodish Should Be Precluded From Testifying Regarding Prior Legal Proceedings

In his expert reports, Dr. Lodish discusses and quotes at length from the opinions of prior legal proceedings. For example, Dr. Lodish reproduces an extended section of Magistrate Judge Saris' opinion in *Amgen Inc. v. Chugai Pharm. Co.*, 13 U.S.P.Q.2d 1737 (D. Mass. 1989) explaining the impact of incorrect protein sequence on the efforts of Amgen and Genetics Institute. (*See* Rebuttal Expert Report of Harvey F. Lodish, Ph.D.("Lodish II") at ¶ 209). Dr. Lodish also discusses Judge Saris' opinion relating to the timeline of Dr. Lin's alleged inventions. (Lodish II at ¶¶ 164-65, 316, 451). With regard to prior art EPO-producing cell lines, Dr. Lodish discusses and quotes from the decisions in both *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 339 F. Supp. 2d 202 (D. Mass. 2004) ("*TKT*") (Lodish II at ¶ 288), and *Chugai* (Lodish II at ¶ 273; *see also* 6/20/07 Second Supplemental Report ¶ 38). He quotes – across the full length of five pages – the District Court and Federal Circuit decisions in *TKT* regarding written description of claim 7 of the '349 patent. (Lodish II at ¶ 500; *see also id*. ¶¶ 547, 550; 6/4/07 Supplemental Report ¶ 42). Dr. Lodish also discusses the Federal Circuit's holding that certain claims of the '008 patent were invalid. (*Id*. ¶¶ 372, 384, 399, 416). In addition, Dr. Lodish raises prior claim construction (*Id*. ¶ 427); the Court's discussion of his own expert trial testimony (*Id*. ¶ 433, 500); and the *Chugai* litigation generally (*Id*. ¶ 451; *see also* 4/6/07 Expert Report ¶ 75). Furthermore, Dr. Lodish opines with respect to the *Fritsch v. Lin* interferences (Lodish II at ¶ 452), and statements by Amgen in its Interference Briefs. (*Id*. ¶¶ 164, 457, 460).

As this Court has made clear to both the parties and the jury, "what came out of [prior] proceeding[s], if anything, what some other judge thought, what some other jury thought, what some other administrative agency thought, we don't care. You're [the jury] going to decide this

case, nobody else." (Trial Tr. 458:21-24). Accordingly, Dr. Lodish should be precluded from referring to, quoting from or opining on prior proceedings involving Amgen, including, but not limited to the proceedings involving Chugai, TKT and Dr. Fritsch. Such testimony would only serve to confuse the jury and prejudice Roche.

B. Dr. Lodish Should Be Precluded From Testifying Regarding the Relative Quality of Dr. Lin's Patent Specification

Dr. Lodish's May 11 report further states:

> I have had the opportunity to closely examine the contents of Dr. Lin's patent specification. I have compared it to the disclosures of other contemporaneous patent applications, as well as contemporaneous research publications in well-regarded scientific journals. In my opinion, Dr. Lin's specification stands out as a seminal example of some of the earliest and best work in cloning, recombinantly producing, and characterizing a human therapeutic protein. I find Dr. Lin's specification to be far-ranging, exacting and scientifically convincing.

(Lodish II at ¶ 189). Dr. Lodish should be precluded from so testifying at trial because his comments have no relevance to any of the issues in this case. Fed. R. Civ. P. 402. Dr. Lodish's assessment of the quality of Dr. Lin's patent specification -- as compared to contemporary publications by other scientists -- does not bear on whether, under the patent statute, the specification adequately describes the claimed inventions or enables one of ordinary skill to make the claimed inventions without undue experimentation. Dr. Lodish's opinion that Lin's specification is a "seminal example" will serve only to confuse and mislead the jury. Fed. R. Civ. P. 403.

C. Dr. Lodish Should Be Barred From Testifying Regarding His Personal Failures to Clone Other Proteins

In his May 11 report, Dr. Lodish also describes the difficulties that he and his research partners encountered in trying to clone various non-EPO proteins, including the erythrocyte glucose transport protein and the TGF-beta type III receptor. (Lodish II at ¶¶ 241-43). Dr. Lodish opines: "As demonstrated by my own experience, therefore, the successful application of

the techniques said by Drs. Lowe and Kellems to be 'routine' was fraught with uncertainty and potential pitfalls, even many years later." (Lodish II at ¶ 243). Dr. Lodish's personal failures in cloning other proteins are irrelevant to the question of whether Dr. Lin's claimed inventions would have been obvious to one of ordinary skill in the art. While the failure of others is a pertinent secondary consideration of obviousness, it is only the "failure of others *to develop the invention*" that is relevant. *Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371, 1378 (Fed. Cir. 2005) (emphasis added). Dr. Lodish's inability to develop an entirely different invention has no relevance to the obviousness inquiry in this case. Accordingly, Dr. Lodish should be precluded from misleading and confusing the jury by testifying regarding his own failures in working with other proteins. See Fed. R. Civ. P. 402, 403.

D. Dr. Lodish Should Be Precluded From Testifying Based on His Untimely and Irrelevant Third Supplemental Expert Report

Dr. Lodish should be barred from testifying at trial based on his June 25, 2007 Third Supplemental Expert Report ("Lodish V").

First, the report was untimely. At a June 6, 2007 case management conference, the parties agreed to a limit of three more expert reports.[2] In a letter to Roche's counsel of the same date, Amgen's counsel acknowledged that Amgen would have the right to submit by June 20 up to three additional expert reports in response to Roche's June 13 reports.[3] On June 20, Amgen submitted the Second Supplemental Expert Report by Dr. Lodish, the Fourth Expert Report of

[2] *See* 6/6/07 Hearing Tr. at 21:17–22:20, attached as Exh. A to Huston Declaration ("MS. BEN-AMI: June 20th, Amgen puts in three reports. Agreed? MR. DAY: I agree.").

[3] *See* 6/6/07 Ltr. from Krista Carter to Thomas Fleming, attached as Exh. B to Huston Declaration (Amgen has "the right to submit up to three additional expert reports in response to Roche's June 13 Reports on or before June 20.").

Dr. Torchilin and the Second Supplemental Expert Report of Dr. Varki.[4] Nevertheless, on June 25, 2007, Amgen decided unilaterally to serve a fourth report – the Third Supplemental Expert Report of Dr. Lodish, responsive to Roche expert reports of April 10 and May 8 – containing arguments that should have been included (if at all) in Dr. Lodish's May 11th, June 6th or June 20th reports. Plainly, it would be inequitable to permit Dr. Lodish to testify based on this untimely report.

Second, the report is utterly irrelevant. The report is devoted entirely to arguing that statements made by Genentech in the prosecution histories of Genentech's tPA patents -- which are not at issue here -- somehow demonstrate that Dr. Lin's claimed invention was not obvious. Given that the cited statements were not made by defendants and did not concern the patents-in-suit, they are not relevant here.

E. Dr. Lodish Should Be Barred from Testifying Based on Information in Expert Reports Directed To Matters Which Are Not Longer Part of the Case

Dr. Lodish devotes a substantial portion of Lodish II (*see* ¶¶ 370-496, 518-52) to discussing the obviousness of the asserted claims in view of the Lin '008 and Lai '016 patents and the restriction requirement during prosecution of the '008 patent. A portion of Lodish V (¶¶ 7-22) is also devoted to obviousness-type double patenting in light of Amgen's original '008 patent. To the extent that the Court has eliminated those obviousness-type double patenting issues from the jury case, Roche would be prejudiced if Dr. Lodish were now permitted to repurpose those portions of his expert reports and put them to some use other than the use for which they were plainly intended.

[4] Pursuant to a separate agreement between the parties, Amgen also submitted, on June 20, a Second Rebuttal Expert Report of Dr. Benet and a Second Supplemental Expert Report of Dr. Varki.

Similarly, because the claims of Amgen's '080 patent are no longer at issue, Dr. Lodish should not be permitted to testify based on the portions of Lodish I which are directed to alleged infringement by Roche of the '080 patent under the doctrine of equivalents. (Lodish I at ¶¶ 110, 208-14).

III. CONCLUSION

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

Dated: October 2, 2007
Boston, Massachusetts

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

By its attorneys,

/s/ *Julia Huston*

Lee Carl Bromberg (BBO# 058480)
Julia Huston (BBO# 562160)
Keith E. Toms (BBO# 663369)
Nicole A. Rizzo (BBO# 663853)
Kimberly J. Seluga (BBO# 667655)
Emily J. Schaffer (BBO# 653752)
BROMBERG & SUNSTEIN LLP
125 Summer Street
Boston, MA 02110
Tel. (617) 443-9292
jhuston@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)
KAYE SCHOLER LLP
425 Park Avenue
New York, NY 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/ Julia Huston
Julia Huston

03099/00501 749585.1