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

ROCHE'S MOTION *IN LIMINE* TO PRECLUDE DR. LODISH FROM OPINING IMPROPERLY REGARDING PRIOR ART REFERENCES

Leora Ben-Ami (*pro hac vice*)
Patricia A. Carson (*pro hac vice*)
Thomas F. Fleming (*pro hac vice*)
Howard S. Suh (*pro hac vice*)
Christopher T. Jagoe (*pro hac vice*)
Peter Fratangelo (BBO# 639775)
Krista M. Rycroft (*pro hac vice*)
Kaye Scholer LLP
425 Park Avenue
New York, New York 10022
Tel. (212) 836-8000

Lee Carl Bromberg (BBO# 058480)
Timothy M. Murphy (BBO# 551926)
Julia Huston (BBO# 562160)
Keith E. Toms (BBO# 663369)
Nicole A. Rizzo (BBO# 663853)
Bromberg & Sunstein LLP
125 Summer Street
Boston, MA 02110
Tel. (617) 443-9292

Counsel for Defendants
F. Hoffmann-La Roche Ltd,
Roche Diagnostics GmbH, and
Hoffmann-La Roche Inc.

Dated: Boston, Massachusetts
October 2, 2007

I. INTRODUCTION

Roche submits this memorandum of law in support of its motion *in limine* to preclude expert testimony by Amgen's expert witness, Dr. Harvey Lodish, regarding prior art references which (i) is based on an analysis that is incorrect as a matter of law; (ii) invades the province of this Court by addressing the admissibility or prior art status of specific scientific references; and (iii) is contrary to admissions in the specification of the patents-in-suit.

II. ARGUMENT

A. Dr. Lodish Should Be Precluded From Testifying Regarding The Admissibility or Prior Art Status of Specific References

In his May 11, 2007 expert report, Dr. Lodish offers a number of what are, in essence, legal opinions regarding the prior art status of certain references:

- ¶¶ 252-55: "Dr. Gaylis had no evidence that his cells were actually producing any erythropoietic activity until 1984. The Gaylis cells could not have been an 'obvious' source of human EPO to one of ordinary skill based on unknown and unreported results."
- ¶¶ 257-58: "the Fisher report, although it ostensibly is directed to describing what one of ordinary skill would have known as of October, 1983, relies on documents that were either (1) not publicly known or available, such as unpublished laboratory notebook pages, or (2) published well after the fact."
- ¶¶ 268-69: Opining as to the legal relevance, for purposes of an obviousness analysis, of "subsequently published articles" and "unpublished data or information in Dr. Shoval's laboratory notebooks."
- ¶ 293: "In addition, because this paper was published in 1985, it would have provided no information to one of ordinary skill at the relevant time period and cannot be used as evidence that the use of such cells were an 'obvious' source of human EPO mRNA at that time." (referring to a paper by Jacobs *et al.*)
- ¶¶ 295-97: Evidence regarding this issue simply cannot be supplied by hindsight"; relevance of "later-published scientific data."
- ¶¶ 359-60: Opining on prior art relevance of Collen study that "was not published until July 1984."

Dr. Lodish's opinions regarding obviousness of the asserted claims are predicated on his erroneous understanding that an unpublished reference cannot be prior art. This is not a correct application of the law. *See* 35 U.S.C. §§ 102(e), (f) and (g); *see also* D.I. 1141-5 (setting forth law relating to §102 and §103). In addition, after-published papers may indicate what was known earlier to the hypothetical person of ordinary of skill in the art and may also be relevant evidence of contemporaneous invention (a secondary indication of obviousness). *See Ecolochem, Inc. v. Southern California Edison Co.*, 227 F.3d 1361, 1379 (Fed. Cir. 2000); *Monarch Knitting Machinery Corp. v. Sulzer Morat GMBH*, 139 F.3d 877, 883-84 (Fed. Cir. 1998).

Where expert opinions, such as those proffered by Dr. Lodish, are reached by applying a standard that is wrong as a matter of law, the expert's testimony is properly excluded. *See Noskowiak v. Bobst SA*, 2005 WL 2146073, *5 (E.D. Wis. Sept. 2, 2005) (excluding expert testimony premised on the wrong legal standard); *see also Integra Lifesciences I, Ltd. v. Merck KgaA*, 2007 WL 2142878, *7 (Fed. Cir. July 27, 2007) ("when an expert witness' statement of the law is incorrect, that view of the law cannot be relied upon to support the verdict"); Fed. R. Evid. 402, 403.

Furthermore, Dr. Lodish's scientific expertise does not permit him to invade the province of this Court and opine on whether certain references are prior art or whether they can "be used as evidence" of obviousness. *See Nieves-Villanueva v. Soto-Rivera*, 133 F.3d 92, 99 (1st Cir. 1997) (it is improper for an expert to testify regarding issues of law); *see also* Fed. R. Evid. 702, 703. Accordingly, Dr. Lodish should be precluded from testifying that certain references and evidence of work by third parties would not be considered by the hypothetical person of ordinary skill in the art in evaluating obviousness of the asserted claims. *Custom Accessories, Inc. v. Jeffrey-Allan*

Indus., Inc., 807 F.2d 955, 962 (Fed. Cir. 1986) ("person of ordinary skill is a hypothetical person who is presumed to be aware of all the pertinent prior art").

B. Dr. Lodish Should Not Be Permitted to Contradict Admissions in the Patents-In-Suit

In his Second Supplemental Expert Report, dated June 20, 2007 ("Lodish IV"), Dr. Lodish questions the results reported by Farber in *Blood* in 1983 regarding the *in vitro* translation of human kidney mRNA by frog oocytes. (Lodish IV at ¶ 48). However, the Farber reference is cited by Dr. Lin in the specification of the patents-in-suit as a prior art teaching of the recombinant expression of biologically active erythropoietin. ('933 patent, col. 9, lines 49-63; TRX 2080). "Admissions in the specification regarding the prior art are binding on the patentee for purposes of a later inquiry into obviousness." *Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1362 (Fed. Cir. 2007).

Accordingly, Dr. Lodish should be precluded from questioning the Farber results reported in the specifications of Amgen's asserted patents.

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 2, 2007

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

By its attorneys,

/s/ *Christopher T. Jagoe*

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*)
Christopher T. Jagoe (*pro hac vice*)
Peter Fratangelo (BBO# 639775)
Krista M. Rycroft (*pro hac vice*)
KAYE SCHOLER LLP
425 Park Avenue
New York, New York 10022
Tel. (212) 836-8000

and

Lee Carl Bromberg (BBO# 058480)
Julia Huston (BBO# 562160)
Keith E. Toms (BBO# 663369)
Nicole A. Rizzo (BBO# 663853)
BROMBERG & SUNSTEIN LLP
125 Summer Street
Boston, MA 02110
Tel. (617) 443-9292

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) and paper copies will be sent to those indicated as non registered participants on the above date.

/s/ *Thomas F. Fleming*