

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

_____)	
AMGEN INC.,)	
)	
Plaintiff,)	
)	
v.)	
)	CIVIL ACTION No.: 05-CV-12237WGY
F. HOFFMANN-LA ROCHE LTD)	
ROCHE DIAGNOSTICS GmbH)	
and HOFFMANN-LA ROCHE INC.)	
)	
Defendants.)	
_____)	

**DEFENDANTS’ MEMORANDUM OF LAW ON ADMISSION OF
MR. SOFOCLEOUS’S TESTIMONY IN THE VALIDITY PHASE**

While a patent is entitled to a presumption of validity, an infringement defendant is also entitled to rebut the presumption. One way Roche seeks to rebut the presumption is to show that the USPTO did not consider certain prior art and other information relevant to the validity of Amgen’s patents. Roche has the burden to do so. *See Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1579 (Fed. Cir. 1983) (“the burden was on Sunspool to show that the prior art had *not* been considered”). In turn, a showing that relevant information was not considered will make it easier for Roche to carry its burden of proof and thus rebut the presumption of validity. *See Lear Siegler, Inc. v. Aeroquip Corp.*, 733 F.2d 881, 885 (Fed. Cir. 1984) (affirming invalidation of patent based on prior art not considered by PTO); *see also, e.g., Alco Stnd. Corp. v. Tennessee Valley Authority*, 808 F.2d 1490, 1497 (Fed. Cir. 1986).

As detailed in the accompanying offer of proof, Mr. Sofocleous, a former patent examiner and Administrative Patent Judge, will testify on PTO practice and procedures, particularly on the interaction between the examination of a patent and an interference involving

the same patent. Mr. Sofocleous will testify, *inter alia*, that, as a matter of practice and procedure, pertinent prior art and information from an interference involving the Lin patent would not have been considered by the examiner during examination of the patent.

This testimony is relevant and admissible. Courts have universally admitted testimony on PTO practice and procedures--not just in support of inequitable conduct but also in support of validity. *See, e.g., Cargill, Inc. v. Sears Petroleum & Transp. Corp.*, 334 F. Supp. 2d 197, 250-251 (N.D.N.Y. 2004) (denying motion to strike testimony of former PTO examiner on PTO procedures and patent prosecution and expressly considering the testimony on the questions of anticipation and obviousness); *Voice Capture, Inc. v. Intel Corp.*, 354 F. Supp. 2d 997, 1007 (S.D. Iowa 2004) (denying motion to strike expert testimony offered to show that examiner's actions were consistent with PTO practice and procedure); *Bausch & Lomb, Inc. v. Alcon Labs., Inc.*, 79 F. Supp. 2d 252, 255 (W.D.N.Y. 2000) ("To the extent that Alcon intends to elicit testimony from Harmon concerning the general procedures involved in the patent application process, such testimony may be helpful to the jury, and is therefore admissible"); *Minnesota Mining and Mfg. Co. v. Appleton Papers Inc.*, 50 U.S.P.Q.2d 1636, 1638 (D. Minn. 1998) (permitting testimony on the operation of the USPTO, finding that "factual testimony concerning the practices and procedures in the USPTO could assist the jury in this case").¹

Roche recognizes that courts, including those in the cases cited above and this Court in particular, do not allow testimony on, for example, resource deficiencies at the PTO because such testimony may undermine the statutory presumption of validity. But Roche will not submit

¹ *Bausch & Lomb* is particularly instructive and is often cited. In that case, the expert on patent practice, Attorney Harmon (author of a treatise on patent law), sought to testify on interference and reexamination practice and procedure. The court held that such testimony would be helpful to the jury given that "PTO procedures are foreign to the average person." 79 F. Supp. 2d at 256. In this case, Mr. Sofocleous will likewise explain interference practice and its intersection with the patent examination process.

testimony to undermine the presumption. Rather, as argued above, and as seen in the offer of proof, the testimony will concentrate on PTO practice and procedure as it relates to Amgen's patents. This testimony will help the Court and jury understand that the PTO examiner likely did not consider certain information, which in turn will help Roche rebut the presumption of validity.

CONCLUSION

For these reasons and those stated in Roche's opposition to Amgen's motion *in limine* #16 [Document 905], Roche respectfully seeks admission of Mr. Sofocleous's testimony.

Dated: September 14, 2007
Boston, Massachusetts

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

By their Attorneys

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CERTIFICATE OF SERVICE

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