

**IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF MASSACHUSETTS**

AMGEN INC.,)	
)	
Plaintiff,)	
)	
v.)	
)	
F. HOFFMANN-LA ROCHE LTD, a)	Civil Action No.: 1:05-cv-12237 WGY
Swiss Company, ROCHE DIAGNOSTICS)	
GMBH, a German Company, and)	
HOFFMANN LA ROCHE INC., a New)	
Jersey Corporation,)	
)	
Defendants.)	
)	
)	

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

This Court has already precluded Roche from offering Mr. Sofocleous’s testimony during the validity portion of this trial, and Roche offers nothing new to support its attempt to relitigate this issue.¹ The Court specifically stated “I don’t suppose we’re going to get any witnesses who are going to get on the stand and give us habit and routine practice of patent laws . . . that would be immaterial, candidly.”² Roche offers no new and persuasive arguments to permit Mr. Sofocleus to testify and it is clear that the proposed testimony from Mr. Sofocleus serves little purpose other than to denigrate the PTO, its examiners, and every patent at issue in this case.

Roche’s reassertion that Mr. Sofocleous will not denigrate the PTO is belied by his statements throughout Roche’s Offer of Proof Regarding Mr. Sofocleous.³ This offer of proof makes general and factually unsupported allegations that: (a) patent examiners did not have the

¹ Trial Tr. at 10:14 – 11:17 (“You’re not trashing the Patent Office . . . We’re not hearing anything about the Patent Office in phase one and we’re not hearing anything about the Patent Office in phase two.”)

² Trial Tr. at 10:17-20.

³ D.I. 1078. Amgen will file Responses and Objections to Defendants’ Offer of Proof Regarding the Testimony of Michael Sofocleus.

expertise to search for important prior art or facilities to test the veracity of prior art experiments;⁴ (b) the PTO did not employ qualified examiners due to high turnover and did not properly train junior examiners in the biotechnology examining group;⁵ (c) examiners did not have sufficient time to review applications;⁶ and (d) examiners failed to consider relevant evidence.⁷ Furthermore, Mr. Sofocleous lacks personal knowledge under Fed. R. Evid. 602 to make such allegations because he was not an examiner in the 1980s and 1990s when the patents were issued, and he never worked in the biotechnology examining group.

Roche's reliance on four district court cases to support its argument that "[c]ourts have universally admitted testimony on PTO practice and procedures . . . in support of validity"⁸ is unpersuasive. None of these cases allowed the type of generalized testimony denigrating the PTO that Roche insists is admissible.⁹ Moreover, it is within the Court's purview to preclude all

⁴ D.I. 1078 at pp. 5-7, 10 ("[E]xaminers were . . . typically generalists in their field." "[T]he most relevant prior art was most often cited by the applicant. . . ." "[E]xaminers are only responsible for cursorily reviewing references. . . ." "[I]f an examiner wanted to verify the accuracy of experimental data submitted by an applicant, he could not have done so because the Patent Office does not have laboratory testing facilities.")

⁵ D.I. 1078 at p. 16-17 ("[T]he biotechnology examining group could not hire as many examiners as it needed because of the lack of experienced senior staff to train them in this area.")

⁶ D.I. 1078 at p. 15-16 ("PTO examiners in the biotechnology area had less than an average of 20 hours [per application] . . . [and had] very limited time to read and consider each patent application.")

⁷ D.I. 1078 at p. 15-16.

⁸ D.I. 1077 at 2.

⁹ In *Minnesota Mining and Mfg. Co. v. Appleton Papers Inc.*, the court granted a motion to exclude "proposed testimony concerning the limitations placed upon patent examiners and the alleged deficiencies of the examination in this case conflict with the statutory presumption of validity." 1998 U.S. Dist. LEXIS 22597, *6 (D. Minn. 1998). In *Voice Capture, Inc. v. Intel Corp.*, the court denied a motion to strike PTO expert testimony because "it was not the proper method" to challenge an affidavit and it was "unnecessary to eliminate the challenged declaration through a motion to strike." 354 F. Supp. 2d 997, 1007-08 (S.D. Iowa 2004). In *Bausch & Lomb, Inc. v. Alcon Lab., Inc.*, while the court allowed limited testimony about interferences, it held that "generalized testimony about 'problems' in the PTO is not admissible." 79 F. Supp. 2d 252, 255-56 (W.D.N.Y. 2000). In *Cargill, Inc. v. Sears Petroleum & Transp. Corp.*, during summary judgment, while the court stated the PTO expert "could be permitted to testify on certain matters" the court expressed concern about the extent of his proposed testimony, and made not definitive ruling on the scope of admissible testimony. 334 F. Supp. 2d 197, 250 (N.D.N.Y. 2004).

testimony from a PTO expert, particularly testimony that is not premised on personal knowledge.¹⁰ Numerous courts have refused to provide testimony by patent law experts.¹¹

Mr. Sofocleous's proposed testimony would improperly undermine the presumption of validity attributed to issued patents. While Roche seeks to prove that certain prior art disclosed to the examiner by Amgen was not considered,¹² it is Roche's burden to prove by specific evidence and not generalizations.¹³ "After a patent has issued, validity is determined objectively based on prior art and the other requirements of patentability."¹⁴ Roche admits that Mr. Sofocleous will not offer specific testimony based on any factual knowledge, but rather will help the "jury understand that the PTO examiner *likely did not* consider certain information. . . ."¹⁵ Such generalizations are highly prejudicial given that they are flatly contradicted by the fact that the PTO's most qualified examiner, James Martinell, examined and issued all of the Lin patents-in-suit.¹⁶

CONCLUSION

For the same reasons that the Court initially precluded Mr. Sofocleous testimony, and for those reasons stated in Amgen's Motion *in limine* #16,¹⁷ Amgen's Proposed Reply in support of

¹⁰ See *EZ Dock, Inc. v. Schafer Systems*, 2003 U.S. Dist. LEXIS 3634 (D. Minn. 2003) (Finding no grounds on which to admit lay or expert testimony about the competence of the PTO examiners, the court granted plaintiff patent holder's motion to preclude defendants from denigrating the patent office or its examiners.)

¹¹ *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1325 (Fed. Cir. 2005) (not an abuse of discretion to preclude patent attorney from testifying that claims were invalid for lack of adequate written description, but noting that this ruling "should not be read as expressing a view on the propriety of the use of patent attorneys as experts on patent law issues generally"); *Pfizer Inc. v. Teva Pharm. USA, Inc.*, 2006 WL 3041097, *1, *2-3 (D. N.J. 2006); *Proctor & Gamble Co. v. Teva Pharms. USA, Inc.*, 2006 WL 2241018, *1 (D. Del. 2006); *UCB Societe Anonyme v. Mylan Labs., Inc.*, 2006 WL 839397, *2 (N.D. Ga. 2006); *Medtronic Vascular, Inc. v. Advanced Cardiovascular Sys.*, 2005 WL 67086 (D. Del. 2005); *Arthrocare Corp. v. Smith & Nephew, Inc.*, 2003 WL 1905636 (D. Del. 2003) (same).

¹² D.I. 1077 at 1.

¹³ Roche cites *Richdel*¹³ for the proposition that Roche has the burden to show that prior art was *not* considered by the examiner. This much is correct.

¹⁴ *Norian Corp. v. Strker Corp.*, 363 F.3d 1321, 1329 (Fed. Cir. 2004).

¹⁵ D.I. 1077 at 3.

¹⁶ Roche's attempt to read into "considered" to require a certain level of carefulness or detail of review by the examiner fails. The MPEP places no such requirement. See MPEP §609.05(b)-(c).

¹⁷ D.I. 905.

Motion *In Limine* #16,¹⁸ and herein, the Court should uphold its preclusion of Mr. Sofocleous testimony.

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¹⁸ D.I. 978.

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the Electronic Case Filing (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.

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