

UNITED STATES DISTRICT COURT
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-CV-12237WGY

ROCHE’S OPPOSITION TO AMGEN INC.’S MOTION IN LIMINE NO. 16:
EXCLUDE SOFOCLEOUS TESTIMONY REGARDING THE COMPETENCE OF
THE EXAMINATION PROCESS IN THE U.S. PATENT AND TRADEMARK OFFICE

Roche opposes Amgen Inc.’s Motion In Limine No. 16 to Exclude Sofocleous Testimony
Regarding the Competence of the Examination Process in the U.S. Patent and Trademark Office.

At the pretrial conference with the Court on July 17, the parties discussed with the Court
the precise scope of the permissible testimony of the parties’ patent experts during the jury trial.
The Court made it very clear that these witnesses, Mr. Sofocleous and Mr. Kunin would be fact
witnesses who would be permitted to testify to the custom, practices, habits and procedures in
the U.S. Patent and Trademark Office (“PTO”). The Court also mentioned that these witnesses
could testify to matters under Fed. R. Evid. 406, “Habit; Routine Practice”. Rule 406 provides
that “Evidence of the habit of a person or of the routine practice of an organization, whether
corroborated or not and regardless of the presence of eyewitnesses, is relevant to prove that the
conduct of the person or organization on a particular occasion was in conformity with the habit
or routine practice.” Thus, the Court has already decided that this is the type of testimony that an

experienced Patent Examiner, Board Member and practitioner such as Mr. Sofocleous can provide to the jury. The objections raised in Amgen's Motion *in Limine* No. 16 are the identical protests that Amgen raised and the Court rebuffed during the July 17 conference. Amgen's motion, which is a disguised motion for reconsideration, should be denied.

This motion also should be denied because Mr. Sofocleous has personal knowledge of the patent examination practices and procedures of the PTO based on his 7 years of experience as a PTO patent examiner examining patent applications and his more extensive 23 years of experience as an Administrative Patent Judge (APJ) on the PTO's Board of Patent Appeals and Interferences ("BPAI") analyzing patent appeals from the PTO's examination corps. Amgen's motion is simply an attempt to avoid Mr. Sofocleous's testimony regarding the realities of the examination process -- which are rationally based on Mr. Sofocleous's perceptions of the process as an APJ and his interactions with patent examiners and review of their work during the relevant time period. Fed. R. Evid. 701. Mr. Sofocleous's testimony is not, as Amgen asserts, "directed at disparaging the competence of the examiners" (D.I. 866 at 1), but rather to explain these customs, habits and routine practices that occur in the PTO as they relate to Roche's inequitable conduct defenses and the presumption of validity afforded to Amgen's patents.

## **I. ARGUMENT**

### **A. The Law Permits Testimony On Patent Office Practice And Procedure**

Courts have repeatedly held that testimony regarding PTO practice and procedure, and even patent law, is admissible. *See Mars Inc. v. Coin Acceptors, Inc.*, 1996 U.S. Dist. LEXIS 21514, \*7 (D.N.J. July 27, 1996); *Revlon Consumer Prods. Corp. v. L'Oreal S.A.*, 1997 U.S. Dist. LEXIS 4117, \*9 (D. Del. Mar. 26, 1997); *Senior Indus., Inc. v. Thomas & Betts Corp.* 2001

U.S. Dist. LEXIS 16875, \*8-\*9 (N.D. Ill. Sept. 27, 2001); *see also Hawthorne Partners v. AT&T Tech., Inc.*, 831 F. Supp. 1398, 1400 (N.D. Ill. 1993).<sup>1</sup>

Amgen's reliance on *EZ Dock, Inc. v. Schafer Sys.*, 2003 U.S. Dist. LEXIS 3634 (D. Minn. Mar. 8, 2003) is misplaced. The proffered testimony in that case was directed to disparaging the PTO to suggest that the patent-in-suit should have never issued and that the patentee had a resultant monopoly due to the incompetence of the PTO. As explained herein, however, Mr. Sofocleous's testimony is not directed towards disparaging the PTO, but rather to explain, based on his own knowledge and experience, the custom, habit and routine practices and realities of PTO policy and examination procedures.

**B. Mr. Sofocleous Has Personal Knowledge Of PTO Examination Practices And Procedures During The Time The Patents-In-Suit Were Prosecuted**

Mr. Sofocleous should be allowed to provide factual and lay opinion testimony regarding the PTO's examination practices and procedures, including the realities of the examination practice in the biotechnology examining corps during the time the patents-in-suit were pending, because Mr. Sofocleous has personal knowledge of these practices and procedures based on his former experience as a patent examiner and APJ on the BPAI. Fed. R. Evid. 406, 701.

Amgen's attempt to belittle the personal knowledge and experience of Mr. Sofocleous fails. For example, Amgen cites an excerpted portion of Mr. Sofocleous's expert report where he discusses the high turnover rate in the relevant Group Art Unit, and Amgen suggests he has no personal knowledge to corroborate this statement. However, Amgen conveniently places an ellipsis to exclude Mr. Sofocleous's statement about his "personal knowledge of this high turnover rate." (April 6, 2007 Expert Report of Michael Sofocleous ¶ 26 ("Sofocleous Report")). Amgen also suggests that Mr. Sofocleous has no basis to suggest that an examiner might err

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<sup>1</sup> Although the Court indicated that Mr. Sofocleous will appear as a fact witness, case law regarding admissibility of expert testimony regarding PTO procedure shows that such testimony is relevant and helpful.

during the course of examining an application, (D.I. 866 at 1 n.7), all the while ignoring that its own witness, Mr. Kunin, shares the same opinion. (See Kunin Report ¶ 116 (“failure to record his review of the interference files could have very well been a *formal oversight* by Dr. Martinell”) (emphasis added)). Accordingly, despite Amgen’s argument, and as further explained herein, Mr. Sofocleous is well-qualified to offer testimony and evidence, based on his own personal experience and knowledge, regarding the realities of patent examining policies and procedures.

Mr. Sofocleous spent 7 years working as a patent examiner, including at least one year as a Primary Examiner, before his promotion to the Board of Patent Appeals and Interferences. (Sofocleous Report ¶¶ 3-5). In that time period, he examined hundreds of patent applications for compliance with the requirements of 35 U.S.C. (*e.g.*, patentable subject matter, anticipation, obviousness, written description, and enablement), as well as 37 C.F.R. (*e.g.*, completeness of replies, double patenting, and entry of amendments after final action). See 37 C.F.R. § 1.104 (“examination shall be complete with respect both to compliance...with the applicable statutes and rules and to the patentability of the invention as claimed, as well as with respect to matters of form.”). Furthermore, as a patent examiner, Mr. Sofocleous was required to follow PTO examination procedures outlined in the Manual of Patent Examining Procedure (MPEP) in his examination of a patent application. See, *e.g.*, MPEP Foreword (8<sup>th</sup> ed. Rev. 5, Aug. 2006) (“contains instructions to examiners...and outlines the current procedures which the examiners are required or authorized to follow...in the normal examination of a patent application.”). As a Primary Examiner, Mr. Sofocleous had full signatory authority from the PTO’s Director to, among other things, allow a patent application to issue as a patent. *Id.* at § 1005 (delineating agency decisions requiring signature of Primary Examiner).

Subsequently, Mr. Sofocleous became a member of the BPAI, spending 10 years as a Patent Interference Examiner. (Sofocleous Report ¶ 6). In 1985, Mr. Sofocleous was promoted to Administrative Patent Judge -- a position he held until he left the Patent Office in 1999. (*Id.* at ¶ 7). An APJ is “a person of competent legal knowledge and scientific ability...appointed by the Director.” 35 U.S.C. § 6(a). During this nearly 15 year time frame, Mr. Sofocleous was a participating judge (of a three-member panel) in over 600 patent cases -- more than half of which involved an appeal from an examiner’s adverse decision in a patent application. (Sofocleous Report ¶ 8). Furthermore, Mr. Sofocleous authored more than 220 final agency decisions. (*Id.*). Once again, the majority of these decisions involved an appeal from an examiner’s adverse decision in a patent application. (*Id.*).

Mr. Sofocleous’s experience at the PTO coincides with the time that the patents-in-suit were being examined. Indeed, as Amgen acknowledges, Mr. Sofocleous testified that he “consider[s] [his] expertise to include the examination of patents” and he “last examine[d] a patent” in 1999. (Sofocleous Depo. Tr. 38:3-14). Thus, Mr. Sofocleous needed to remain current on all changes made to the PTO’s practices and procedures in examining patent applications, including changes in how patent searches are conducted and the availability of search databases (such as the new electronic databases and the Chemical Abstract Service Registry). Accordingly, even though he was no longer examining applications in the role of a patent examiner after 1975, the realities of patent examination procedure and the burdens placed on patent examiners were still very much a part of Mr. Sofocleous’s day-to-day experiences up until he left the PTO in 1999.

Furthermore, despite Amgen’s suggestion, (D.I. 866 at 4-5), the routine practices and customs of patent examination procedure and the burdens on patent examiners did not change

with the advent of electronic databases. Twelve years after the emergence of electronic databases, in 1998, when Amgen's witness Mr. Kunin was Deputy Commissioner, the PTO, under his direction, released an Initiative entitled "Changes To Implement the Patent Business Goals." (Kunin Depo. Tr. 134:14-135:4; D.I. 635 Ex. 120). In this Initiative, the PTO notes that "[a]pplications containing an excessive number of claims present a specific and *significant obstacle* to the PTO's meeting its business goals" and pose a "*severe burden* on [the] PTO..., as they are *extremely difficult* to properly process and examine." (D.I. 635 Ex. 120 at 53506 (emphasis added)). In the same Initiative, the PTO said that it "is being *overwhelmed* with voluminous IDS submissions which, in many situations, make it *very difficult, if not impossible*, for an examiner to evaluate all of the citations that have been submitted." (D.I. 635 Ex. 120 at 53512 (emphasis added)). Accordingly, the realities and burdens facing the PTO remained relatively constant over the past 30 years, regardless of the implementation of technological advances, so Mr. Sofocleous's extensive experience in and exposure to patent examination practice and procedure renders him qualified to testify on these matters.

To the extent there were significant changes in patent examination procedure following Mr. Sofocleous's departure from the Examining Division of the PTO, Mr. Sofocleous spent nearly 15 years as an APJ reviewing examiners' decisions in patent cases -- many of which came from the biotechnology examining corps. Thus, his observations not only cover a significant period of time, they directly relate to the specific art group responsible for examining the patents-in-suit.

**C. The GAO's Report Is Admissible, Relevant Evidence Regarding The Competency Of The PTO's Biotechnology Examining Corps During The Time Period The Patents-In-Suit Were Prosecuted In The PTO**

In his report, Mr. Sofocleous references Government Account Office Report GAO/RCED-89-120BR, which issued in April 1989 and is entitled *Biotechnology Backlog of*

*Patent Applications* (“GAO Report”). (D.I. 635 Ex. 182). The GAO Report reviews and analyzes, among other things, the PTO’s “catch-up plan” for the biotechnology examining corps, the amount of time the examiners in this group were allotted for examining patent applications, the skill levels of these examiners and their retention rates. This analysis sheds considerable light on the workings of the biotechnology examining corps during the time period the patents-in-suit were prosecuted in the PTO -- making the GAO Report relevant to the issue of the real-world ability of this group of examiners to evaluate applications. Fed. R. Evid. 401. It is particularly relevant to Roche’s contentions that Amgen buried material information within large submissions and filings in the PTO in a way that a reasonable examiner would not consider the information. *Golden Valley Microwave Foods Inc. v. Weaver Popcorn Co. Inc.*, 24 USPQ2d 1801 (N.D. Ind. 1992) *aff’d*, 11 F.3d 1072 (Fed. Cir. 1993).

The GAO Report is also admissible as a public record under the hearsay exception. Fed. R. Evid. 803(8). In particular, it was prepared by the U.S. Government Accounting Office at the request of U.S. Congressmen Robert A. Roe and James H. Scheuer. The Congressmen requested the GAO’s investigation in their official capacities as chairmen of a House committee and a House subcommittee, respectively. This document corroborates Mr. Sofocleous’s personal knowledge and demonstrates that his experience -- as officially acknowledged by the PTO -- is reliable and consistent with the findings of the U.S. government.

## II. CONCLUSION

Amgen's requested relief will have the effect of denying the jury the ability to consider relevant evidence in determining inequitable conduct as well as assessing the presumption of validity afforded to issued patents. For the foregoing reasons, Roche respectfully requests that the Court deny Amgen's Motion *In Limine* No. 16.

Dated: August 31, 2007  
Boston, Massachusetts

Respectfully submitted,

F. Hoffmann-La Roche Ltd, Roche  
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/s/ Keith E. Toms  
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