

EXHIBIT A

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

AMGEN INC.,

Plaintiff,

v.

F. HOFFMANN-LA ROCHE LTD, a
Swiss Company, ROCHE DIAGNOSTICS
GMBH, a German Company, and
HOFFMANN LA ROCHE INC., a New
Jersey Corporation,

Defendants.

Civil Action No.: 1:05-cv-12237 WGY

**[PROPOSED] PLAINTIFF AMGEN INC.'S REPLY BRIEF IN SUPPORT OF ITS
MOTION *IN LIMINE* NO. 16: EXCLUDE SOFOCLEOUS TESTIMONY REGARDING
THE COMPETENCE OF THE EXAMINATION PROCESS IN THE U.S. PATENT &
TRADEMARK OFFICE**

I. INTRODUCTION

Mr. Sofocleous's proposed testimony under Rule 406 is an improper attempt to undermine the statutory presumption of validity of the patents-in-suit by an individual who lacks personal knowledge. Roche contends that Mr. Sofocleous will explain PTO customs, habit, and routine practices as they relate to "the presumption of validity afforded to Amgen's patents."¹ While Roche may deny that "Mr. Sofocleous's testimony is . . . directed at disparaging the competence of the examiners,"² that underlies the presumption, the opposite is true.

In his April 6, 2007 expert report, Mr. Sofocleous made general allegations that: (a) patent examiners did not have the expertise to search for important prior art or they reviewed the art in a "cursory" fashion;³ (b) the PTO did not employ qualified examiners due to high turnover;⁴ (c) examiners did not have sufficient time to review applications;⁵ and (d) examiners regularly made errors or failed to consider relevant evidence.⁶ Each of these general allegations are being proffered in an attempt to disparage the PTO and suggest to the jury, without any actual facts, that the examiners examining Dr. Lin's patents failed to give proper scrutiny or lacked proper qualifications. Compounding the error, Mr. Sofocleous lacks personal knowledge

¹ D.I. 905 at 2

² D.I. 905 at 2.

³ Expert Report of Michael Sofocleous, dated April 6, 2007 ("Sofocleous Report"), at ¶ 25 ("While patent examiners were placed into particular art units according to their technical background at the time the patents-in-suit were examined, they were typically generalists within their field. Many times, the most relevant prior art was cited by the applicant. . . .") *Id.* at ¶ 312 ("In my opinion, as stated above, any review of these references would have been cursory. . . .") *Id.* at ¶ 32 ("A reasonable examiner would not sift through subsidiary papers such as declarations, exhibits or transcripts to find information that possibly may be relevant. . . .")

⁴ *Id.* at ¶ 26 ("[T]here was a high turnover rate among the examiners in the relevant Group Art Unit . . . it was difficult to retain highly qualified examiners at the time and it was also difficult to find and quickly train replacement examiners.")

⁵ *Id.* at ¶ 30 ("In 1988, PTO examiners had less than 20 hours in total to devote to examination of a single application. . . . This means that a patent examiner has very limited time to read and consider each patent application.")

⁶ *Id.* at ¶ 33 ("[I]t is not unusual for an examiner's rejections and comments in an office action to be inaccurate or to fail to consider all the relevant factors and evidence.")

to make such allegations because he was not an examiner in the 1980s and 1990s when the patents were issued.

Mr. Sofocleous's uninformed and back door attempt to undermine the statutory presumption of validity is improper, and is flatly contradicted by the fact that the PTO's most qualified examiner, James Martinell, examined and issued all the Lin patents-in-suit. Mr. Sofocleous's testimony should be deemed inadmissible under Rules 402, 403, 406, and 702.

II. ARGUMENT

A. MR. SOFOCLEOUS'S PROPOSED TESTIMONY IS IMPROPER RULE 406 TESTIMONY AND IS INADMISSIBLE UNDER RULES 402 AND 403

Under the guise of labeling it as proper Rule 406 testimony, Roche is seeking to have Mr. Sofocleous testify in a manner that would persuade the jury to question the "understanding," "competence," and "gullibility" of the Patent Office examiners in general, and inferentially, to the specific examiners that examined Dr. Lin's patents.⁷ This attempt founders on several grounds.

First, a patent is presumed valid,⁸ and this presumption is based in part on the expertise of patent examiners.⁹ As such, there is a presumption that patent examiners properly perform their duties, "which may be viewed as a presumption of administrative correctness. . . ."¹⁰ "After a patent has issued, validity is determined objectively based on prior art and the other requirements of patentability,"¹¹ and not by generalizations denigrating the PTO. The Court and the jury must presume that the patents-in-suit are valid and that the examiners involved with the patents-in-suit complied with their "responsibility of making sure that the standard of patentability enunciated by the Supreme Court and by the Congress [was] applied *in each and every case*."¹² It must also

⁷ *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1329 (Fed. Cir. 2004).

⁸ 35 U.S.C. § 282.

⁹ See *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984); *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1139 (Fed. Cir. 1985).

¹⁰ *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1576 (Fed. Cir. 1992).

¹¹ *Norian Corp.*, 363 F.3d at 1329.

¹² Manual of Patent Examining Procedure ("MPEP") section 706 (5th Edition). (emphasis in original).

be presumed that “[a]fter reading the specification and claims, the examiner searches the prior art.”¹³ In fact, “the presence and strength of the presumption of validity does not warrant inquiry into the examiner’s understanding or competence or gullibility.”¹⁴ Mr. Sofocleous’s intended testimony is nothing more than an impermissible attempt to go into and undermine the examiners’ understanding, competence or gullibility.

Second, “the issue of validity does not warrant findings of whether the examiner [understood] what he was ruling.”¹⁵ “Introspection and speculation into the examiner’s understanding of the prior art or the completeness or correctness of the examination process is not part of the objective review of patentability.”¹⁶ And yet, this is exactly the type of impermissible testimony that Roche seeks to have Mr. Sofocleous offer during the validity phase, e.g. performing a “cursory review of the prior art” or that “there was a high turnover rate” suggesting lack of experience.¹⁷

Third, the highly misleading nature of any suggestion that the examiners here lacked competence is particularly pernicious when the opposite is true. Examiner Martinell, Ph.D., was the examiner who allowed and issued each of the patents-in-suit. Examiner Martinell was a Senior Level Examiner which is the highest grade that an examiner can attain. In fact, the duration of the examinations demonstrate the exacting scrutiny applied by Examiner Martinell in the 1990s to these inventions even though the PTO had previously determined in 1989 that these inventions were patentable to Lin prior to the interferences that commenced in 1989 and ended in 1993.

Fourth, during his deposition, Mr. Sofocleous did not offer specific attacks against the competency or qualifications of the examiners who examined Dr. Lin’s patent applications:

¹³ MPEP section 704 (5th Edition); *see also* MPEP 904 “How to Search.”

¹⁴ *Norian Corp.*, 363 F.3d at 1329.

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *See* FRE 402, 403.

Q. Is it your opinion that Examiner Martinell was poorly qualified to examine these patents?

[objections].

A. No.

Q. Is it your opinion that Examiner Fitzgerald was poorly qualified to examine these patents?

[objections].

A. No.

Q. Is it your opinion that any of the other examiners involved in examining these patents were poorly qualified?

[objections].

A. No.¹⁸

Rather than provide specific testimony about the abilities of the actual examiners of the patents-in-suit, Mr. Sofocleous resorts to offering the type of inferential testimony that the presumption of validity serves to exclude.

Fifth, Mr. Sofocleous's intended testimony falls far short of meeting the requirements of Rule 406. Rule 406 provides that "[e]vidence . . . 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 . . . organization on a particular occasion was in conformity with the habit or routine practice." The advisory committee notes to Rule 406 define habit and routine practice as "one's regular response to a repeated specific situation." "Where the proponent of habit, custom, or practice evidence fails to 'allege adequately a frequency of specific conduct sufficient to be considered semiautomatic' such evidence is not admissible."¹⁹

Mr. Sofocleous failed to identify specific conduct at the PTO that supports contentions that examiners were ill-qualified due to turnover and made mistakes, and he also failed to provide any proof of the frequency at which these alleged errors occurred. For example, Roche claims that Mr. Sofocleous should be allowed to testify about a high turnover rate of examiners

¹⁸ Deposition of Michael Sofocleous at p. 47:2-23.

¹⁹ *Bell v. Consolidated Rail Corp.*, 299 F. Supp. 2d 795, 800 (N.D. Ohio, Feb. 11, 2004) (citing *Simplex, Inc. v. Diversified Energy Systems, Inc.*, 847 F.2d 1290, 1294 (7th Cir. 1988)).

at the PTO because it is based on his “personal knowledge.”²⁰ But Roche has not offered any statistics of how “high” this turnover rate was. Likewise, Roche also incorrectly contends that Mr. Sofocleous can properly testify that examiners might err.²¹ In order to testify that examiners habitually or routinely err, Mr. Sofocleous must establish that pattern of conduct with actual examples “numerous enough to base an inference of systematic conduct and to establish [that the PTO’s] regular response to a repeated specific situation” is to err.²² This he has not done.

Roche cites four cases to support its contention that courts permit testimony “regarding PTO practice and procedure, and even patent law.” Those case are inapplicable here, and certainly do not support the view that a party may attack the presumption of validity through Rule 406 testimony. Moreover, they address the admissibility of expert testimony on PTO practice under Federal Rule of Evidence 702, not under Rule 406²³, and the Court has already rejected such testimony under Rule 702.²⁴ None of Roche’s cited cases address the scope of

²⁰ D.I. 905 at 3.

²¹ D.I. 905 at 3-4.

²² *G.M. Brod & Co., Inc. v. U.S. Home Corp.*, 759 F.2d 1526, 1533 (11th Cir. 1985) (citing *Wilson*, 561 F.2d at 511). In *G.M. Brod & Co.*, the Eleventh Circuit held that the district court erred in allowing Rule 406 testimony about the defendant’s prior instances of breaching contracts, given that the defendant had entered into thousands of differing contracts. The Eleventh Circuit stated that the instances of contract breach fell “far short of the adequacy of sampling and uniformity of response which are the controlling considerations governing admissibility.” *Id.*

²³ Rule 702 is inapplicable here, and thus, so are these cases. In addition, Roche’s citation to *Hawthorne Partners v. AT&T Tech., Inc.*, is misplaced as it is a real estate case that is wholly inapplicable to patent cases. 831 F.Supp. 1398 (N.D. Ill. 1993).

²⁴ These cases actually support excluding testimony similar to Mr. Sofocleous’s testimony, that is, testimony offered by patent law experts concerning patent law. In *Mars Inc. v. Coin Acceptors, Inc.*, 1996 U.S. Dist. LEXIS 21514, *5-7 (D. N.J. June 27, 1996), the court granted a motion to exclude testimony by patent law experts concerning patent law and legal conclusions. In *Revlon Consumer Prods. Corp. v. L’Oreal S.A.*, 1997 U.S. Dist. LEXIS 4117, *10 (D. Del. Mar. 26, 1997), the court specifically refused to permit testimony concerning inequitable conduct, holding that under Rule 702, the patent law expert “may not testify as to substantive issues of patent law, including inequitable conduct. . . . [T]his holding precludes, among other things, [the expert’s] proposed testimony regarding the duties and responsibilities of an inventor, his or her attorney or agent, and others substantively involved in the preparation and prosecution of a patent application in the PTO” In *Senior Indus., Inc. v. Thomas & Betts Corp.*, 2001 U.S. Dist. LEXIS 16875, *7-8 (N.D. Ill., Sept. 28, 2001), the court stated that “[the expert’s] testimony could be viewed as creating a prejudice with the jury as his opinions relating to the laws on proper claim construction could influence a jury into believing that the Court, the proper entity responsible for construing claims, has misconstrued or misapplied the law. . . .”

permissible testimony about the PTO under Rule 406, and thus do not support Roche's attempt to allow testimony from Mr. Sofocleous that generally denigrates the PTO in an attempt to undermine the statutory presumption of validity.

Mr. Sofocleous's testimony is a carefully crafted attack on the presumption of validity by explaining alleged "realities" that are flatly contradicted by the record of the examination of the patents-in-suit and insupportable because they fail to rise to the level of habit or custom. Such evidence is inadmissible under Rule 402, highly prejudicial under Rule 403, and represents improper Rule 406 testimony to sway the jury.

B. MR. SOFOCLEOUS'S PROPOSED TESTIMONY ABOUT THE PTO'S EXAMINING DIVISION IS NOT RATIONALLY BASED ON HIS PERCEPTION

Roche has further failed to show that Mr. Sofocleous has the requisite personal knowledge to testify on PTO examination procedures. A foundation for Rule 406 testimony by lay opinion must be established under Federal Rule of Evidence 701.²⁵ "If the witness is not testifying as an expert, his testimony in the form of opinions or inference is limited to those opinions or inferences which are rationally based on the perception of the witness. . . ."²⁶

As Roche itself admits, Mr. Sofocleous (a) has only seven (7) years of experience as a patent examiner,²⁷ (b) only one (1) year as a Primary examiner, meaning that for the majority of his experience as an examiner, he had junior status and no signatory authority to issue a patent, and (c) his tenure as an examiner ended in 1975, long before any of the applications relating to the patents-in-suit were filed.²⁸ While Mr. Sofocleous worked as a patent interference judge on the Board of Patent Appeals and Interferences for 23 years, all of his insights about the "routine practice" of the examining division were filtered through his position on the Interference Board. He repeatedly confirmed this fact during his deposition when asked about the basis for his

²⁵ See Wright & Graham, 23 Fed. Prac. & Proc. Evid. § 5276 (1980) (2003 Supp.).

²⁶ FRE 701.

²⁷ D.I. 905 at 4.

²⁸ D.I. 905 at 5.

claimed expertise.²⁹ This disconnect between the testimony that an actual PTO examiner or official working in the prosecution area could provide, such as Mr. Kunin, underlines the problems of allowing Mr. Sofocleous to testify about the general practices and procedures of examination at the PTO.

C. THE GAO REPORT IS IRRELEVANT AND PREJUDICIAL TO THE EXAMINATION OF THE PATENTS IN SUIT

Mr. Sofocleous's reliance on and testimony regarding the contents of the Government Account Office Report GAO/RCED-89-120BR ("GAO Report") is improper under Rules 406, 403, and 402.

First, this report issued in 1989, several years before the prosecution of Lin's applications for the patents-in-suit. At the time the GAO Report issued, prosecution of the relevant Lin applications was suspended because interferences were declared between Amgen's pending Lin applications, and interfering applications by Genetics Institute. Prosecution remained suspended until late 1993. As such, the state of the PTO's Biotech Unit in 1989 is irrelevant to the prosecution of the Lin patents and their validity. Tellingly, Roche contends that the GAO Report is "relevant to Roche's contentions that Amgen buried material information"³⁰ during prosecution of the patents-in-suit, but this alleged "burying" took place in the mid-to-late 1990s. Thus, the general findings addressed in the GAO Report do not apply to the relevant period of time for the applications of the patents-in-suit.

Second, the general findings in the GAO Report do not apply to the actual examiner of the patents-in-suit. Following the conclusion of the interferences between Genetics Institute and Amgen in 1993, the applications for the patents-in-suit were all given to Examiner Martinell to prosecute in 1994. As stated before, Examiner Martinell was a Senior Level Examiner, the highest grade of examiner at the PTO. General or averaged findings in the GAO Report are not relevant evidence to determining the actual competence of an examiner of Martinell's caliber.

²⁹ D.I. 866 at 5-6.

³⁰ D.I. 905 at 7.

Accordingly, the GAO Report is irrelevant and any probative value of the GAO Report would be outweighed by the confusion and prejudice caused by admitting the findings.

Third, Mr. Sofocleous's reliance on the GAO Report is improper as it is not rationally based on his perceptions and therefore outside of the scope of Rule 406. He was not an author of the GAO Report. He was not an examiner in 1989. Mr. Sofocleous cannot properly rely on this report to testify about the routine practices of examiners in the mid-1990s. The relevance and probative value of the findings in this 1989 report are greatly outweighed by the prejudice caused by a report that does not temporally apply to the patents-in-suit nor apply to the actual qualified examiner of these patents. Reliance on the GAO Report is improper and beyond the permissible boundaries of Rules 402, 403, and 406.

III. CONCLUSION

The Court should prevent Mr. Sofocleous from overstepping the boundaries of Rule 406 testimony and preclude any attempts by him to denigrate the PTO, or offer generalizations about the qualifications of examiners, what patent examiners did or did not review, and the average time examiners had to review patent applications. The GAO Report should likewise be excluded.

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Respectfully Submitted,

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