

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

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

**BRIEF IN SUPPORT OF AMGEN’S MOTION *IN LIMINE* NO. 16:
EXCLUDE SOFOCLEOUS TESTIMONY REGARDING THE COMPETENCE OF THE
EXAMINATION PROCESS IN THE U.S. PATENT & TRADEMARK OFFICE**

I. INTRODUCTION

Roche has made it clear that it will attempt to introduce evidence at trial, through its expert Michael Sofocleous, directed at disparaging the competence of the examiners at the U.S. Patent & Trademark Office (“PTO”) and alleging that the patents-in-suit were not well examined because examiners allegedly are generally overwhelmed, incompetent, and unable to give patent applications the attention they deserve. These unfounded allegations were included in Mr. Sofocleous’s expert report and Roche has now disclosed that it intends to call Mr. Sofocleous as a witness at trial.¹ Because Mr. Sofocleous’s professional experience is limited to interference practice within the PTO and he has no personal knowledge of the prosecution of the patents-in-suit, he should not be permitted to propound these unbased allegations and his factual testimony should likewise be limited to interference practice.²

During the July 17, 2007 pretrial conference, the Court indicated that it would not permit expert opinion testimony regarding issues of patent law. The Court stated that the testimony of patent law experts will be limited to evidence of routine practice pursuant to FRE 406. However, even if the allegations of examiner incompetence constituted evidence of “routine practice,” Mr. Sofocleous is still unqualified under FRE 602 and 701 to offer such evidence. His contemporaneous personal knowledge extends only to *interference* practice, *not* examination practice, and because he has no personal knowledge of the prosecution of the patents-in-suit. Accordingly, the Court should not permit Mr. Sofocleous to provide factual testimony regarding the U.S. Patent and Trademark Office (“PTO”) patent examining practice and procedure because he is not qualified to testify about those subjects.

¹ Roche’s Preliminary List of Trial Witness, docket no. 807-7 at Ex. F (Aug. 10, 2007).

² FRE 602.

II. ARGUMENT

Based on Roche's pretrial submissions and Mr. Sofocleous's expert report, Amgen expects Roche to elicit testimony from Mr. Sofocleous to discredit the skill and thoroughness of the PTO's patent examiners, including the examiners of the patents-in-suit. Specifically, in the "PTO Practice and Procedure" section of his initial report, Mr. Sofocleous suggests that examiners: (a) are ill-qualified;³ (b) have an inadequate amount of time to properly examine applications;⁴ (c) are generally unfamiliar with the applications at the time of issuance;⁵ (d) do not review the relevant portions of the record in an interference;⁶ and (e) are inaccurate and fail to consider all relevant factors and evidence.⁷

These statements are highly prejudicial and, lacking any particularized basis for application to the examination of the patents-in-suit, unduly undermine the presumption of validity, a heavy presumption based on "the expertise of patent examiners presumed to have

³ Expert Report of Michael Sofocleous, dated April 6, 2007 ("Sofocleous Report"), at ¶ 26 ("[T]here was a high turnover rate among the examiners in the relevant Group Art Unit . . . while a patent examiner in the art unit that examined the Lin applications was likely to have an undergraduate degree in biology or biochemistry and receive on-the-job training in legal and technical aspects of patent prosecution during his tenure at the PTO, it was difficult to retain highly qualified examiners at the time and it was also difficult to find and quickly train replacement examiners.").

⁴ *Id.* ¶ 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."). Mr. Sofocleous goes on to speculate—based solely on this generalized statistic—that the examiner spent only three minutes reviewing each reference disclosed to the PTO in an April 8, 1994 Information Disclosure Statement. *Id.* ¶ 408.

⁵ *Id.* ¶ 31 ("Once an interference is declared, the examiner generally will not see the application again until the interference has been terminated. Often that means an examiner will not be involved with an application for years and will become less familiar with the file at that time.") (citation omitted).

⁶ *Id.* ¶ 32 ("Very rarely does a reasonable examiner review the other portions of the interference file . . . A reasonable examiner would not sift through subsidiary papers . . ."). Moreover, these statements about a "reasonable examiner" are plainly of the nature of expert opinion testimony inadmissible under the applicable case law and the Court's instructions.

⁷ *Id.* ¶ 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.").

done their job.”⁸ In *EZ Dock, Inc. v. Schafer Systems*,⁹ the court granted plaintiff patent holder’s motion to preclude defendants from denigrating the patent office or its examiners. The court, noting that it could see no grounds on which it could introduce testimony—lay or expert—about the competence of the PTO’s examiners, stated:

As for assertions that the PTO and its examiners are not diligent or prone to error, the Court can find no relevance in either evidence to that effect or argument. It is Defendants’ burden to prove, *by the greater weight of the evidence*, that the [patent] is either invalid or unenforceable. Aspersions are not evidence.

But beyond that, Mr. Sofocleous’s disparaging remarks, made in the capacity of a fact witness, are simply without foundation. As such, they should not be permitted before the jury.

FRE 602 states that a witness “may not testify to a matter unless evidence is introduced sufficient to support a finding that the witness has personal knowledge of the matter.”¹⁰ FRE 701 likewise requires that lay opinion or inference testimony is limited to that which is “rationally based on the perception of the witness.”¹¹

It is undisputed that Mr. Sofocleous had no involvement whatsoever in the examination or prosecution of any of the patents-in-suit, and has no personal knowledge concerning the qualifications or performance of the particular examiners assigned to the asserted patents’ applications. As Mr. Sofocleous readily admits, he is neither an expert nor one of ordinary skill in the art of the patents-in-suit.¹² The admissibility of Mr. Sofocleous’s testimony at trial thus

⁸ *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1574 (Fed. Cir. 1992) (citation omitted).

⁹ No. 98-2364, 2003 U.S. Dis. LEXIS 3634 (D. Minn. Mar. 8, 2003).

¹⁰ FRE 602.

¹¹ FRE 701(a); *see also Walton v. NALCO Chem. Co.*, 272 F.3d 13, 25 (1st Cir. 2001) (upholding district court’s decision to exclude lay opinion testimony about lost profits where sales manager witness *lacked personal knowledge* and relied on information concerning a *different time period* from the one in which the losses were alleged to have occurred).

¹² Depo. at p. 33, line 2 to page 37, line 1.

depends on whether he has sufficient personal knowledge concerning the practices of the PTO as they relate to the examination of the patents-in-suit. He does not. Mr. Sofocleous was not directly involved in patent examination *at all* at the time the asserted patents were prosecuted, and thus lacks the requisite personal knowledge to testify as a fact witness about the routine examination practices of the PTO during that period.

Mr. Sofocleous left the PTO's examinations unit in 1975, *nearly a decade before the prosecution of any applications related to the patents-in-suit*.¹³ During the time between his reassignment in that year to the Board of Patent Interferences and the prosecution of the applications that became the patents-in-suit in 1983-1999, numerous substantial changes were made to both the practices and procedures of patent examination. For example, the entirety of Mr. Sofocleous's career as an examiner occurred *long prior* to the 1992 revision of Rule 56 that narrowed the materiality element of the duty of disclosure.¹⁴ And Mr. Sofocleous last acted as a patent examiner *twenty years* before the numerous significant changes made to the patent regulations between 1995 and 1997,¹⁵ a period in which each of the patents-in-suit was still actively being prosecuted.

Similarly, the emergence of electronic databases marked a sea change in the examination of patent applications. It was not until 1986 that all examiners had access to full-text computerized patent searches,¹⁶ and databases allowing chemical structure searches did not become available

¹³ Sofocleous Report at ¶¶ 3-6.

¹⁴ Duty of Disclosure, 57 Fed. Reg. 2021 (Jan. 1992).

¹⁵ For example, the implementation of the GATT agreement alone during this period entailed amendments to 22 sections or tables of Title 35 of the United States Code and 40 amendments to Title 37 of the Code of Federal Regulations. Uruguay Round Agreements Act, Pub. L. No 103-465, 108 Stat. 4809 (1994); Changes to Implement 20-Year Patent Term and Provisional Applications, 60 Fed. Reg. 79 (Apr. 1995); Revision of Affidavits Under 37 CFR 1.131, 60 Fed. Reg. 21043 (May 1995).

¹⁶ *Automated Patent System: Information on PTO's Program to Automate Patent Information and Processes: Hearing Before Subcomm. on Intellectual Property and Judicial Admin. of the H.*

to either examiners or applicants until the mid 1980s.¹⁷ Mr. Sofocleous’s personal knowledge, and any knowledge rationally based on his perception, about the examination practices of the PTO substantially predates these significant innovations that characterized the era in which the patents-in-suit were prosecuted.

Indeed, as Mr. Sofocleous demonstrated at his deposition, his claimed expertise—which he limited to “practices and procedures before the U.S. patent office”¹⁸—actually derives from his work on *interferences*, not on his earlier career as an examiner:

Q. Do you consider your expertise to include patent office policy?

[A]: That depends.

Q. Depends on what?

A. On what the patent office policy is you’re talking about.

Q. There is a patent office policy that you consider your expertise in this case to include?

[A]: Interference practice. And anything associated therewith.

Q. Any other areas of patent office policy that you consider your expertise in this case to include?

[A]: To the extent any other parts of office policy referred to interferences, yes. That’s the scope of my expertise and maybe more.

Q. Do you consider your expertise to include any parts of patent office policy that do not refer to interferences?

[A]: It’s—that’s a difficult question to answer, because a lot of things dealing with interferences relate to other parts of the office.

...

Q. Have you acted within any policymaking capacity within the patent office?

Comm. on the Judiciary, 102d Cong. 5 (1992) (statement of JayEtta Z. Hecker, Director, Resources, Community, and Economic Development Information Systems).

¹⁷ For example, the widely-used Chemical Abstract Service (CAS) Registry was not available in an electronic, searchable format until the advent of CAS Online in 1980, and access using software running on nonspecialized desktop computers became available only in 1988. *CAS History: Milestones*, available online at <http://www.cas.org/aboutcas/cas100/annivhistory.html> (viewed August 1, 2007).

¹⁸ Depo. at 37:8-16.

[A]: I've made suggestions to change in policy, and I was also involved in rule making.

Q. In what areas did you make suggestions to change in policy?

A. It was on the section in the MPEP dealing with incorporation by reference, which I dealt with in the interference context.

...

Q. In what areas did you participate in rule making?

A. I was responsible for the rule making on the interference area of arbitration. And also I think I did the correction to the final rule making for the 1985 rules.

...

Q. What did those pertain to?

A. Interferences.

...

Q. Do you consider your areas of expertise to include the law of inequitable conduct?

[A]: Yes.

Q. What's the basis for that expertise?

A. That was an issue that was considered in interferences during my time at the PTO.

...

Q. Are there any differences in the way inequitable conduct is addressed in interference practice, as opposed to other contexts?

[A]: It depends on how the issue was raised in the interference.

Q. I guess put another way, your claimed expertise in the law of inequitable conduct is based on your experience with inequitable conduct in the course of your work in the interference division?

[A]: Yes. I said it was an issue that was raised in interferences.

Q. Do you consider your expertise to include the law of the duty of disclosure?

[A]: By duty of disclosure, what do you mean?

Q. Rule 56 and related doctrines?

[A]: Yes.

Q. And what's the basis for that?

A. Also interference practice.¹⁹

¹⁹ Depo. at 38:16-41:7, 73:13-75:10 (objections to form omitted). When asked when he had last examined a patent, Mr. Sofocleous replied that he had "reviewed" patents as a member of the Board of Patent Interferences in 1999, an answer irrelevant to his experience *examining* patent

Any knowledge Mr. Sofocleous may have concerning *interference* practice during the era of the asserted patents' prosecution is simply insufficient to support FRE 406 fact testimony about PTO *examination* practice at that time,²⁰ about which he lacks adequate personal knowledge. He should be precluded from testifying about such examination practice under both FRE 602, due to his lack of personal knowledge, and under FRE 701, because such testimony is beyond the rational basis of his perceptions.²¹

III. CONCLUSION

For the above reasons, Amgen respectfully requests that the Court enter an order precluding Mr. Sofocleous from testifying about the supposed routine practices of the examination division of the PTO during periods in which he was not employed in that division and from speculating in any manner about the prosecution of the patents-in-suit.

applications. *Id.* at 38:6-14.

²⁰ By contrast, Amgen's witness Mr. Kunin, following twelve years of service as an examiner, *managed* patent examining groups at the PTO during the entirety of the patents' prosecution, and, from 1989 to 1994, was responsible for the supervision of the PTO's entire patent examining corps. Kunin Report at ¶¶ 8-10.

²¹ Any attempt by Mr. Sofocleous to introduce statistical evidence concerning the amount of time spent on patent examination during the time of the prosecution of the patents-in-suit would similarly lack foundation. *See* Sofocleous Report at ¶ 30 (citing U.S. General Accounting Office, Biotechnology: Backlog of Patent Applications, GAO/RCED-89-120BR at 20 ("Average Time Spent Per Patent Application") (Apr. 1989)). Since Mr. Sofocleous will not be testifying as an expert, FRE 703's provision for an expert's reliance on inadmissible materials in forming an opinion is inapplicable; FRE 701 plainly requires that lay opinion testimony be limited to that "rationally based on the perception of the witness." Mr. Sofocleous did not compile the statistics he cites. For that reason, moreover, he is unqualified to provide foundation for their admission into evidence. *See Commonwealth v. Drayton*, 386 Mass. 39, 50 (1982) (statistical fingerprint evidence inadmissible without expert explanation of calculation on which it is based). And the probative value of the twenty-hours-per-application statistic here is minimal to non-existent, since such a mathematical mean could reflect an examiner spending one hour on one application and thirty-nine on another as accurately as it could reflect twenty hours being spent on both. As such, it should also be excluded under FRE 402 and 403.

Date: August 24, 2007

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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 and paper copies will be sent to those indicated as non-registered participants on August 24, 2007.

/s/ Michael R. Gottfried
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