

**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

**AMGEN’S MOTION IN LIMINE TO PRECLUDE ROCHE’S PURPORTED FRE 406  
WITNESS, MR. SOFOCLEOUS, AND PATENT LAW EXPERTS GENERALLY, FROM  
TESTIFYING IN THE INEQUITABLE CONDUCT PHASE OF THE TRIAL**

Roche should be precluded from proffering testimony from Mr. Sofocleous during the Inequitable Conduct portion of this case because he lacks personal knowledge of practice and procedure regarding patent office examination during the time the patents-in-suit were prosecuted and also lacks personal knowledge of any specific facts relating to the prosecution of the patents-in-suit. Moreover, Mr. Sofocleous has had no experience as an examiner in the biotechnology group. If allowed, Mr. Sofocleous would only offer generalizations about inequitable conduct and examination procedures that would denigrate the Patent Office without specific facts. Even during the Inequitable Conduct phase, therefore, Mr. Sofocleous’s testimony would unduly undermine the presumption of validity vested in the patents-in-suit.

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 Federal Rule of Evidence 406. At the outset of trial, the Court granted Amgen’s Motion In Limine No. 16,<sup>1</sup> and

<sup>1</sup> D.I. 866.

precluded testimony from Mr. Sofocleous on the habit and routine practice of the Patent Office and patent laws during the Invalidity and Infringement portion of the trial, reserving judgment as to the Inequitable Conduct phase.<sup>2</sup> As Mr. Sofocleous does not have a proper evidentiary basis to testify during the Inequitable Conduct phase, the Court should maintain its preclusion of testimony from patent experts throughout this entire trial.

Roche has failed to show that Mr. Sofocleous has the requisite personal knowledge to testify on PTO examination procedures and inequitable conduct. Mr. Sofocleous cannot properly offer Rule 406 testimony. A foundation for Rule 406 testimony by lay opinion must be established under Federal Rule of Evidence 701.<sup>3</sup> “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. . . .”<sup>4</sup>

Mr. Sofocleous lacks direct knowledge as he was not involved with examining any of the patents-in-suit or overseeing any of the interferences between Amgen and Genetics Institute. Roche admitted that Mr. Sofocleous will not offer specific testimony based on his knowledge, but rather testimony Roche believes will help the Court “understand that the PTO examiner *likely did not* consider certain information. . . .”<sup>5</sup> Such unsupported and speculative generalizations are highly prejudicial and improperly leave Amgen in the position of proving that the examiner actually considered that which Amgen submitted to the patent office. This sort of evidence is *not* part of the law of inequitable conduct, which concerns only whether the Applicant withheld material information with intent to deceive the patent office. Rebutting inequitable conduct does not require that Amgen prove that the examiner actually considered that which was properly disclosed under Rule 56. Roche’s generalized attack is flatly contradicted

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<sup>2</sup> Trial Tr. at 10:14 – 11:17 (“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. Phase three, maybe. Maybe. We’ll see.”)

<sup>3</sup> See Wright & Graham, 23 Fed. Prac. & Proc. Evid. § 5276 (1980) (2003 Supp.).

<sup>4</sup> FRE 701.

<sup>5</sup> D.I. 1077 at 3.

by the fact that one of the PTO's most qualified examiner, James Martinell, Ph.D., ultimately examined and issued all of the Lin patents-in-suit (following thorough scrutiny by other examiners), and was required as part of his duties to re-review submissions, references and rejections that were in the file histories prior to his taking over the cases and then considered all of Amgen's subsequent submissions. Roche must not be permitted to introduce blanket, unsupported statements to the contrary, especially by an individual who had no experience working in the examining division at the time the patents-in-suit were being prosecuted.

Furthermore, Mr. Sofocleous lacks the necessary foundational knowledge to testify generally about examination procedures in the biotechnology group during the 1980's and 1990's. As Roche itself admits, Mr. Sofocleous (a) has only seven years of experience as a patent examiner,<sup>6</sup> (b) only one 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, (c) he never worked in or managed the biotechnology group, and (d) his tenure as an examiner ended in 1975, nearly a decade before any of the applications relating to the patents-in-suit were filed.<sup>7</sup> 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 claimed expertise.<sup>8</sup> This disconnect between the testimony that an actual PTO examiner or official working in the prosecution area could provide, underscores the problems of allowing Mr. Sofocleous to testify about the general practices and procedures of examination at the PTO.

Mr. Sofocleous's proposed Rule 406 testimony is an improper attempt to undermine the statutory presumption of validity of the patents-in-suit by denigrating the PTO. It also conflates the law of inequitable conduct, which focuses on the Applicant's disclosures and intent, with

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<sup>6</sup> D.I. 905 at 4.

<sup>7</sup> D.I. 905 at 5.

<sup>8</sup> D.I. 866 at 5-6.

speculation about what an examiner would and would not have done. According to his April 6, 2007 expert report, and Roche's offer of proof,<sup>9</sup> Mr. Sofocleous would provide factually unsupported allegations that: (a) patent examiners did not have the expertise to search for important prior art or proper facilities to test the veracity of prior art experiments;<sup>10</sup> (b) the PTO did not employ qualified examiners due to high turnover and did not properly train junior examiners in the biotechnology examining group;<sup>11</sup> (c) examiners did not have sufficient time to review applications;<sup>12</sup> and (d) examiners failed to consider relevant evidence.<sup>13</sup> Indeed, in its Offer of Proof, Roche urges the Court to consider Mr. Sofocleous's knowledge concerning the Biotechnology Group in light of a hearsay document authored by others,<sup>14</sup> *not* Mr. Sofocleous. Ultimately, all of Mr. Sofocleous's attacks are irrelevant to Roche's Inequitable Conduct defenses.

"Expert testimony on patent procedures is rarely necessary or relevant."<sup>15</sup> Thus, it is within the Court's purview to preclude testimony from a PTO expert, particularly testimony not premised on personal knowledge.<sup>16</sup> To date, the Court has not allowed patent expert testimony in this case and to allow so at the eleventh hour would serve only to undermine the presumption

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<sup>9</sup> D.I. 1078.

<sup>10</sup> D.I. 1078 at p. 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.")

<sup>11</sup> 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.")

<sup>12</sup> 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.")

<sup>13</sup> D.I. 1078 at p. 15-16.

<sup>14</sup> D.I. 1078 at p.15.

<sup>15</sup> *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GMBH v. Dana Corp.*, 133 F. Supp. 2d 843, 852 n.11 (E.D. Vir. 2001).

<sup>16</sup> *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.)

of validity with generalizations about the PTO and not facts supporting inequitable conduct and invalidity.

The Court should maintain its previous preclusion of general patent expert testimony, from Mr. Sofocleous or any other witness, and should expressly preclude Mr. Sofocleous from testifying about the PTO and the practices relating to examining applications.

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Respectfully Submitted,

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**CERTIFICATE PURSUANT TO LOCAL RULE 7.1**

I certify that counsel for the parties have conferred in an attempt to resolve or narrow the issues presented by this motion and no agreement was reached.

/s/ Michael R. Gottfried  
Michael R. Gottfried

**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.

/s/ Michael R. Gottfried  
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