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 MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION *IN LIMINE* TO PRECLUDE TESTIMONY OF PROPOSED AMGEN WITNESS NANCY SPAETH

I. INTRODUCTION

Amgen, Inc. ("Amgen") has indicated that it intends to call as a fact witness in its case in chief on validity a motivational speaker, nurse and kidney disease patient, Nancy Spaeth, as a replacement for Dr. Joseph Eschbach who Amgen represented was too ill to testify as an expert in this case. Ms. Spaeth's proposed testimony goes far beyond any testimony Dr. Eschbach could have offered. In addition, Amgen has also already replaced Dr. Eschbach with two other witnesses (offered as both fact and expert) Drs. Friedman and Brugnara. According to what little Roche has been able to learn about this proffered witness, she proposes to provide her direct personal experience living with the anemia of chronic renal failure both before and after the advent of recombinant human EPO. It is clear that Ms. Spaeth does not have relevant knowledge going to any relevant issue of validity, and her testimony is intended to elicit emotional pathos from the jury for Amgen and unfairly prejudice Roche.

Amgen also has stated that Ms. Spaeth and another of Dr. Eschbach's purported replacements, Dr. Eli Friedman, will both testify as to the "the long-felt need for therapeutically effective treatment for the anemia of chronic renal failure, the failures of other [sic] as reflected by the inadequacy of previously available treatment, the surprising and unexpected benefits to patients, and the widespread adoption of the inventions claimed in the patents-in-suit."[1] Amgen has also indicated that no less than *six* additional witnesses will testify on these topics. Ms. Spaeth's testimony is thus duplicative of the proposed testimony of Dr. Friedman, cumulative of the testimony of several other Amgen witnesses, and should be precluded under Federal Rule of Evidence ("FRE") 403 as causing undue delay, a waste of time, and/or the needless presentation of cumulative evidence. The only distinction identified by Amgen between the proposed testimony of Ms. Spaeth and the throng of other witnesses is that she has been a kidney disease patient since 1959 and can "testify with direct personal experience as to living with the anemia of chronic renal failure before the advent of rEPO and the change in her life as a result of the advent of rEPO."[2] In addition to being a patient who has personally taken Amgen's products, Ms. Spaeth is a professional speaker affiliated with organizations financed by Amgen who regularly speaks to groups about her disease and treatment for a fee. Not only does Ms. Spaeth's testimony go far beyond that which Dr. Eschbach (who is a physician, not a kidney disease patient) could have offered, it creates a tremendous danger of unfair prejudice based on the jury's sympathy for her. Undoubtedly, Amgen's true purpose in calling Ms. Spaeth is to improperly play on the jury's emotions and sympathies in an attempt to curry their favor. Any marginal

---

1 Amgen Inc.'s Memorandum in Opposition to Defendants' Motion to Preclude Testimony from Amgen's Belatedly Disclosed Fact Witnesses, D.I. 781, filed 7/30/2007 ("Amgen's Opp. Belated Fact Wit."), at *1.

2 Joint Pretrial Memorandum ("JPM"), filed 8/10/2007, D.I. 807, at *16.

probative value that Ms. Spaeth's utterly cumulative testimony might have is substantially outweighed by the danger of unfair prejudice. As such, it should be precluded pursuant to FRE 403.

II. ARGUMENT

A. FACTUAL BACKGROUND

In its Second Supplemental Disclosures served May 7, 2007, Amgen for the first time identified to Roche Dr. Joseph Eschbach as a person likely to have discoverable information in this matter. Amgen identified Dr. Eschbach as a person having knowledge of "urinary erythropoietin" and "the state of the erythropoietin art as of the date of Lin's inventions." Later, on May 11, 2007, Amgen submitted an expert report by Dr. Eschbach relating to, *inter alia*, a long-felt need for therapeutically effective human erythropoietin prior to Dr. Lin's claimed invention. Before Dr. Eschbach could be deposed on either his expert report or late disclosed discoverable fact information, Amgen informed Roche that Dr. Eschbach had suddenly become gravely ill, and could not continue in this case as either a fact witness or an expert. Roche accepted Amgen's representation without question and agreed to allow a replacement for Dr. Eschbach. Almost two months later, on July 5, 2007, Amgen finally informed Roche of Dr. Eschbach's replacement.[3] Instead of the expected and reasonable one replacement, Amgen claimed that it needed **three** individuals to replace Dr. Eschbach, expert witness Dr. Carlo Brugnara, both fact and expert witness Dr. Eli Friedman, and fact witness nurse Nancy Spaeth, R.N. It did not seem possible that Amgen needed three people to replace the testimony that Dr. Eschbach would have given were he able. Indeed, it has become obvious that any even remotely

[3] Madrid Letter to Fleming, July 5, 2007, attached as Exh. A to the Declaration of Peter Fratangelo ("Fratangelo Decl.") submitted in support of Roche's motion.

relevant testimony that Ms. Spaeth might give is duplicative and cumulative of that which will be given by several other of Amgen's witnesses including at least Drs. Friedman, Orkin, Berk, Goldwasser and Ullrich.

Following the identification of Drs. Brugnara and Friedman and Ms. Spaeth as Dr. Eschbach's purported replacements on July 5, Amgen served its Third Supplemental Disclosures on July 10, 2007, identifying both Ms. Spaeth and Dr. Friedman as persons who may have discoverable information related to "State of the Relevant Art Before, As of, and After Dr. Lin's Inventions and Objective Evidence of the Non-Obviousness of Dr. Lin's Inventions." Amgen also lists twelve other individuals as having discoverable information for this topic, including Arnold Berk, Dennis Fenton, Eli Friedman, Eugene Goldwasser, Stuart Orkin, and Axel Ullrich.[4]

The subject matter and testimony that Amgen initially identified Ms. Spaeth would give was completely duplicative of that which Amgen identified for Dr. Friedman, claiming they were both needed on the same exact topics to replace Dr. Eschbach's proposed fact testimony. Beyond just being listed for the same topic in the third supplemental disclosures, Amgen has indicated that both Dr. Friedman and Ms. Spaeth possess knowledge relevant to the same exact issues. Dr. Friedman's purported factual testimony, as well as his expert report goes on at great length on these topics, including his opinions about the validity of the patents-in-suit.[5]

---

4 Plaintiff Amgen Inc.'s Third Supplemental Disclosures Pursuant to Fed. R. Civ. P. 26(a)(1), served July 10, 2007 ("Amgen's Third Suppl. Disclosures").

5 Expert Report of Eli A. Friedman, M.D., M.A.C.P., F.R.C.P., served July 26, 2007, pp. 18-45. To avoid burdening the Court with exhibits designated as confidential and subsequent further motions to seal, the reports of Amgen's experts cited in this memorandum have not been submitted to the Court, but if the Court desires to see any of these reports, Roche will provide them.

Amgen has also indicated that several other of its witnesses will testify on these topics. In his report served May 11, 2007, Dr. Eugene Goldwasser gives lengthy opinions that "Dr. Lin's invention is not obvious in light of the failed attempts of others and the long-felt, but unmet need for a supply of EPO for clinical use."[6] Amgen has also stated that "Drs. Orkin, Ullrich and Berk each possess knowledge regarding the long-felt need, failure of others, and the technical accomplishments of the inventions claimed in the patents-in-suit."[7] Indeed, in his May 11, 2007 expert report, Dr. Berk includes opinions related to the scope and content of the art prior to Dr. Lin's claimed invention for the production of an *in vivo* biologically active recombinant EPO.[8] Amgen thus has at least six witnesses besides Ms. Spaeth who can and will testify as to secondary considerations of non-obviousness. Ms. Spaeth's testimony is thus completely unnecessary and cumulative of many of Amgen's witnesses several of whom do not raise the prospect of unfair prejudice under FRE 403, such as Dr. Friedman's testimony.[9]

In the Joint Pretrial Memorandum ("JPM") filed August 10, 2007, Amgen for the first time tried to differentiate Ms. Spaeth's testimony from the testimony of Dr. Friedman and others, and claimed that Ms. Spaeth's testimony was relevant and not cumulative because Ms. Spaeth "is the only individual on Amgen's Rule 26(a) list who is able to testify with direct personal

---

6 Rebuttal Expert Statement of Eugene Goldwasser, Ph.D., served May 11, 2007, pp. 20-26.

7 Amgen's Opp. Belated Fact Wit. at * 1.

8 Expert Report of Arnold J. Berk, M.D., served May 11, 2007, pp. 56-101.

9 The fact that the proposed testimony of Ms. Spaeth is identical to part of the testimony in Dr. Friedman's expert report exemplifies that Ms. Spaeth is not really being called as a fact witness but rather an attempt by Amgen to have further expert testimony and opinion beyond its identified ten experts, and Amgen's real purpose in calling Ms. Spaeth is to provoke an inappropriate emotional response in the jury as discussed *infra*.

experience as to living with the anemia of chronic renal failure before the advent of rEPO and the change in her life as a result of the advent of rEPO."[10] Amgen thus intends on having Ms. Spaeth testify to the jury as to her own kidney disease, which Ms. Spaeth developed in 1959, and presumably how taking rEPO has had a dramatic and beneficial effect on her life. As explained below, this proposed testimony of Ms. Spaeth's own illness and battle with kidney disease and anemia is completely different from any testimony that Dr. Eschbach would have given. To the extent any of it is relevant, it is cumulative of the testimony of Amgen witnesses Drs. Friedman, Goldwasser, Orkin, Berk and Ullrich and Mr. Fenton, and would be extremely prejudicial.

Although testimony from any patient suffering from disease is emotional and has great danger of leading to unfair prejudice, this is particularly true for Ms. Spaeth. Not only is Ms. Spaeth a kidney disease patient who has personally taken Amgen's products, but she is a motivational speaker who gives presentations to groups of kidney disease patients, for which Ms. Spaeth charges a fee.[11] According to her website, Ms. Spaeth offers expert testimony and frequently shares her own personal struggle with kidney disease and her own experiences with others, including other patients.[12] Rather than a fact witness providing facts relevant to the case to the jury, Ms. Spaeth is a professional speaker whose testimony is designed and offered by Amgen to provoke an improper emotional response in the jury and make them unfairly sympathetic to Amgen regardless of the hard facts. Ms. Spaeth has no particular relevant

---

10 JPM, at *16.

11 Ms. Spaeth's website states that, "Many of the services Nancy offers require her to see your specific needs in order to quote a price." Nancy's Services, http://www.nancyspaeth.com/id2.html, printed 8/19/07, Fratangelo Decl., Exh. B.

12 Nancy's History of Hope, http://www.nancyspaeth.com/, printed 8/19/07, Fratangelo Decl., Exh. C.

information about a secondary indicium, and her proffered testimony is the type of emotional appeal that is impermissible and should be precluded.[13]

B. MS. SPAETH'S TESTIMONY SHOULD BE PRECLUDED AS CUMULATIVE OF THE TESTIMONY OF SEVERAL OTHER AMGEN WITNESSES INCLUDING DR. FRIEDMAN

Federal Rule of Evidence 403 provides:

> Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence.

Ms. Spaeth can at best speak to her own personal situation, not as a doctor involved in the treatment of any patients, and any testimony beyond this would be hearsay and more particularly irrelevant. The issue for which she is offered can be addressed better and more appropriately (not conceding that Amgen is incorrect in this argument) by one of several other Amgen witnesses who will certainly testify in this case. These issues are duplicative of the indicated testimony of at least Drs. Friedman, Berk, Goldwasser, and Orkin.

Ms. Spaeth was disclosed very late in this case, long after fact discovery closed, and is purportedly only being called by Amgen as one of three people needed to replace Dr. Eschbach. Unlike Ms. Spaeth, however, Dr. Eschbach was not a patient who suffered from kidney disease and could not testify to the jury as someone personally afflicted and someone who has personally taken Amgen's products. Rather, Dr. Eschbach, like Drs. Friedman, Orkin and Berk, is a treating physician who could testify as to the purported long-felt need and effectiveness of Amgen's

---

[13] Ms. Spaeth is affiliated with several programs which are subsidized by Amgen. See, e.g., Life Options Rehabilitation Advisory Council (LORAC), http://www.lifeoptions.org/lorac.php, printed 8/19/07, Fratangelo Decl., Exh. D; Our Sponsor Amgen, http://www.lifeoptions.org/sponsor.php, printed 8/19/07, Fratangelo Decl., Exh. E; Welcome to Kidney School, http://www.kidneyschool.org/splash/about.shtml, printed 8/19/07, Fratangelo Decl., Exh. F.

Epogen® product from a doctor's perspective. Dr. Eschbach is familiar with kidney disease and recombinant human erythropoietin as a professional, not as a patient. Ms. Spaeth should be precluded from testifying at trial because her proposed testimony is substantially different from that which Dr. Eschbach would given at trial.

D. MS. SPAETH'S TESTIMONY SHOULD BE PRECLUDED BECAUSE ITS PROBATIVE VALUE IS SUBSTANTIALLY OUTWEIGHED BY THE DANGER OF UNFAIR PREJUDICE

As discussed, the probative value of Ms. Spaeth's testimony is extremely low given the fact that it may all be hearsay and totally irrelevant to the secondary indicia of non-obviousness. The danger of unfair prejudice that would result from having a patient who suffers from the disease central to this case, and who regularly takes the drugs made by the plaintiff in the case testify to the jury concerning the impact plaintiff's drugs have had on her life is extremely high, and Ms. Spaeth's testimony should be precluded pursuant to FRE 403.

Testimony from a patient suffering from a disease that is treated by products at issue in a case, particularly where the witness is a professional speaker about her illness with ties to the party who wants to call her as a witness, is the ultimate type of testimony that should be prohibited under FRE 403 because the probative value is so substantially outweighed by the danger of unfair prejudice. *CPC Int'l, Inc. v. Northbrook Excess and Surplus Ins. Co.*, 144 F.3d. 35, 45 (1st Cir. 1998) (""Unfair prejudice,' as the Advisory Committee Note teaches, means an 'undue tendency to suggest decisions on an improper basis, commonly, though not necessarily, an emotional one.'"). The probative value of Ms. Spaeth's testimony is very low as it is the only arguably relevant, and not admissible from a fact witness. There is simply no legitimate need for Ms. Spaeth's testimony on this score. *See U.S. v. Lentz*, 58 Fed. Appx. 961, 967 (4th Cir. 2003) (upholding the exclusion of statements laden with references to O.J. Simpson case where "[t]he

court weighed the probative value of the statements and took into account other means of proof available to the government").

Emotional appeals to a jury are the essence of what FRE 403 is designed to avoid. *Lynch v. Merrell-National Labs.*, 830 F.2d 1190, 1196 (1st Cir. 1987) (upholding district court's rejection of unnecessary expert testimony because of the "very real possibility of runaway emotion overcoming judgment."); *In re Richardson-Merrell, Inc. "Bendectin" Products Liability Litigation*, 624 F. Supp. 1212, 1224 (S.D. Ohio 1985) ("Emotional battles . . . should not be staged in the federal courtroom."). This extremely high danger of unfair prejudice together with the low or nonexistent probative value of Ms. Spaeth's cumulative testimony, dictate that Ms. Spaeth's testimony should be precluded under FRE 403. *CPC Int'l,* 144 F.3d. at 45 (where there is a danger that certain emotional evidence would lead to "a decision based on emotion, . . . [w]e have said exclusions under Rule 403 were appropriate where such dangers are strong."); *U.S. v. Paccione*, 949 F.2d 1183 (2d Cir. 1991) ("It is well within the court's discretion to draw the line to exclude testimony that had no bearing on his honesty or integrity and that could well cause the jury to be influenced by sympathies having no bearing on the merits of the case.").

III. CONCLUSION

For all of the foregoing reasons, the proposed irrelevant and inadmissible testimony of motivational speaker, nurse and kidney disease patient Nancy Spaeth should be precluded pursuant to FRE 403.

Dated: August 27, 2007
Boston, Massachusetts

Respectfully submitted,

F. HOFFMANN-LA ROCHE LTD,
ROCHE DIAGNOSTICS GMBH, and
HOFFMANN-LA ROCHE INC.

By their Attorneys

/s/ Kregg T. Brooks
Lee Carl Bromberg (BBO# 058480)
Timothy M. Murphy (BBO# 551926)
Julia Huston (BBO# 562160)
Keith E. Toms (BBO# 663369)
Nicole A. Rizzo (BBO# 663853)
Kregg T. Brooks (BBO# 667348)
BROMBERG & SUNSTEIN LLP
125 Summer Street
Boston, MA 02110
Tel. (617) 443-9292
kbrooks@bromsun.com

Leora Ben-Ami (*pro hac vice*)
Mark S. Popofsky *(pro hac vice)*
Patricia A. Carson (*pro hac vice*)
Thomas F. Fleming (*pro hac vice*)
Howard S. Suh (*pro hac vice*)
Christopher T. Jagoe (*pro hac vice*)
KAYE SCHOLER LLP
425 Park Avenue
New York, New York 10022
Tel. (212) 836-8000

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 (NEF) and paper copies will be sent to those indicated as non registered participants on the above date.

/s/ Kregg T. Brooks
Kregg T. Brooks

03099/00501 729545.1