IN THE UNITED STATES DISTRICT COURT
FOR THE 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. 05-12237 WGY

ROCHE'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION *IN LIMINE* TO PRECLUDE TESTIMONY OF PROPOSED AMGEN WITNESS NANCY SPAETH BASED ON ADDITIONAL EVIDENCE

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Dated: Boston, Massachusetts
September 24, 2007

Amgen's proposed fact witness Nancy Spaeth should be precluded from testifying at trial pursuant to Fed. R. Evid. 602, 402, and 403 for at least the following reasons:

(i) Ms. Spaeth's recently obtained August 29, 2007 deposition testimony confirms that her testimony would violate Fed. R. Evid. 602 and 402, in that she does not know what drug, if any, she received from Dr. Eschbach in 1987 or 1988, and cannot say that she even received recombinant human erythropoietin.

(ii) Ms. Spaeth also confirmed at deposition that she does not know what inventions are claimed in the patents-in-suit and cannot give any relevant testimony regarding those claimed inventions.

(iii) Amgen's opening statement to the jury further confirms that even if Ms. Spaeth could give any relevant testimony (which she cannot as all she can discuss is her own personal health history), it is completely duplicative of the proposed testimony of other Amgen witnesses.

(iv) Any other testimony that Ms. Spaeth might offer concerning her personal health battles is irrelevant to any issue in the case and unfairly prejudicial to Roche.

I. INTRODUCTION

Additional important information has emerged since the Court last visited the issue of this proposed Amgen witness that bears on whether she should be permitted to testify at trial of this action beyond the lateness of her disclosure by Amgen. At the deposition of proposed Amgen fact witness Nancy Spaeth, taken August 29, 2007, which occurred only days before the commencement of the jury trial, Ms. Spaeth confirmed that she lacks competent first hand knowledge about any issue pending before the jury (Fed. R. Evid. 602), and that there is simply no basis for her proposed testimony relating to secondary considerations of non-obviousness. (Fed. R. Evid. 402). She admits that she is a single kidney disease patient who has been on dialysis at times, and does not treat (since she is not a nephrologist) nor propose to address what happened with any other kidney disease patient on dialysis. Her testimony can have no bearing on the issue of secondary considerations of non-obviousness. Because Ms. Spaeth's proposed

testimony is irrelevant to any issue in the case, and the probative value of any testimony from Ms. Spaeth is substantially outweighed by the danger of unfair prejudice from having a professional speaker tell the jury about her personal health history is extremely high, her testimony should be precluded pursuant to Fed. R. Evid. 602, 802, 402 and 403.

II. AMGEN CANNOT CARRY ITS BURDEN OF ESTABLISHING THAT THERE IS A NEXUS BETWEEN MS. SPAETH'S PROPOSED TESTIMONY AND ANY INVENTION CLAIMED IN THE PATENTS-IN-SUIT

Amgen cannot meet its burden of showing that Ms. Spaeth's testimony is relevant to any validity issue. Simply put, Amgen cannot establish that Ms. Spaeth's proposed testimony about her personal health experiences is probative of secondary indicia of non-obviousness as they may relate to the patent claims-in-suit. Amgen has the burden to establish a nexus between the evidence of secondary considerations and the merits of the claimed invention. *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995); *In re Vamco Machine & Tool, Inc.*, 752 F.2d 1564, 1577 (Fed. Cir. 1985). Indeed, the Federal Circuit has stated that, " When a patentee offers objective evidence of non-obviousness, there must be a sufficient relationship between that evidence and the patented invention." *In re Paulson*, 30 F.3d 1475, 1482 (Fed. Cir. 1994). Furthermore, "the term 'nexus' is used, in this context, to designate a legally and factually sufficient connection" between the proven facts and the alleged patented invention, "such that the objective evidence should be considered in the determination of non-obviousness. The burden of proof as to this connection or nexus resides with the patentee." *Id*.

Amgen maintains that Ms. Spaeth's testimony concerning her personal health experiences relates to the legal doctrine of 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] However, her recently obtained deposition confirmed that her testimony as to these legal issues would be totally irrelevant.

Ms. Spaeth cannot testify that she received recombinant human erythropoietin or that it alleviated her anemia symptoms in the 1980's because there is simply no evidence to support such a statement. At her deposition, Ms. Spaeth stated that she participated in a clinical trial with Dr. Joseph Eschbach in 1987 or 1988, designed to test a drug that was supposed to raise her hematocrit.[2] When specifically asked if the drug being administered by Dr. Eschbach contained recombinant human erythropoietin, Ms. Spaeth stated, "I didn't know the name, I just knew that I was testing a drug. I didn't know the name of the drug. I was testing a drug for a company named Amgen that was supposed to increase my hematocrit."[3] Ms. Spaeth has no idea what substance was being administered to her or how frequently, only that she went into a room with a nurse and Dr. Eschbach and something was administered to her.[4] There has likewise been no other evidence that Ms. Spaeth received recombinant human erythropoietin in the clinical trial in which she participated in 1987 or 1988. Moreover, there is no foundation in the record that anyone, much less this witness received the product of Example 10 of the patents-in-suit. Ms. Spaeth's anemia was not cured by any substance she received from Dr. Eschbach, but by a

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[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] Deposition of Nancy Spaeth, August 29, 2007 ("Spaeth Depo. Tr.") at 63:12-17, attached as Ex. A to the Declaration of Peter Fratangelo ("Fratangelo Decl.").

[3] Id. at 88:20-25.

[4] Ms. Spaeth could not even remember if the substance was given by injection or some other method. Id. at 87:20-88:12.

kidney transplant she received in May 1989.[5] Thus, there is no foundation for Ms. Spaeth to speculate in her testimony as to what she received almost 20 years ago. The first time Ms. Spaeth can say she actually received a drug containing recombinant human erythropoietin was in 1995 when she lost her kidney transplant, went back on dialysis and started taking Epogen.[6]

Any testimony regarding the effects of Epogen when she began taking it in 1995 is likewise irrelevant to any issue in this case and should be precluded. At her deposition, Ms. Spaeth's testimony revealed that she had never seen any of Amgen's patents, and doesn't know how any of Amgen's patents relate to Amgen's product Epogen® or to any relevant issue in this case.[7] With respect to the long-felt need for therapeutically effective treatment for the anemia of chronic renal failure, Ms. Spaeth has no knowledge of whether the inventions claimed in Lin's expired '008 patent satisfied any long-felt need for therapeutically effective treatment for the anemia of chronic renal failure.[8] Ms. Spaeth also has no knowledge of any differences between Lin's '008 patent and the patents-in-suit or whether any invention claimed in the patents-in-suit satisfied a long-felt but unresolved need.[9]

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[5] Id. at 75:7-12.

[6] Id. at 79:13-15; 91:10-14.

[7] Id. at 159:20-160:5.

[8] Id. at 161:9-161:15.

[9] Id. at 162:18-24; 163:25-164:10. For example, Ms. Spaeth testified to the following:

> Q. Okay. So all - - as far as any long-felt need for a therapeutically effective product that treats anemia for chronic kidney disease, you know that EPOGEN was a product that met that need but you have no opinion or knowledge on how - - on whether any of these patents relate to that satisfaction of that long-felt need?
>
> A. Correct.

Spaeth Depo. Tr. at 165:11-18.

Amgen cannot meet its burden of showing that any testimony Ms. Spaeth may give about effects she felt when she took Epogen in 1995 has any nexus to the patents-in-suit. *See In re Huang*, 100 F.3d 1685 (Fed. Cir. 1996) (patentee bears burden of proving nexus between alleged secondary considerations and alleged novel features of claimed product). Since Ms. Spaeth can't identify any alleged invention of the patents-in-suit, has not been identified as an expert (no report proffered) and has no relevant information at the time from 1983-1984, with respect to this invalidity case, she can have no relevant evidence to present to the jury. Additionally, Ms. Spaeth's testimony is based entirely on her personal experience and she has no knowledge of Epogen beyond her own use.[10]

Similarly, Ms. Spaeth has no relevant testimony to offer on any of the other topics that Amgen has indicated Ms. Spaeth will testify. When asked about the failure of others to produce a therapeutically effective treatment for anemia of kidney disease, Ms. Spaeth stated , "I have no information."[11] With respect to the issue of widespread adoption of the inventions claimed in the patents-in-suit, Ms. Spaeth has no knowledge about the widespread adoption of any invention claimed in the patents-in-suit.[12] To the extent that she would offer observations of communications with other patients, as a fact witness, her testimony would be pure hearsay. Fed. R. Evid. 802. As to widespread use of Epogen, Ms. Spaeth said she knows patients began using it, but she also knows "a lot of doctors unfamiliar with it for some time, so it may have been used only in a small area, but I don't know any specifics of that."[13] Ms. Spaeth has nothing

[10] Id. at 99:14-25; 22:18-25 and 23:7-9.

[11] Id. at 166:23-167:9

[12] Id. at 171:23-172:4.

[13] Id. at 171:10-171:17.

relevant to contribute to the validity issues the jury must decide in this case, and her testimony should be precluded pursuant to Fed. R. Evid. 402. Amgen cannot meet its burden of establishing that Ms. Spaeth's testimony has the required nexus to the inventions claimed in the patents-in-suit to be relevant to any validity matter before the jury. The only reason to present Ms. Spaeth is for the purpose of evoking an emotional response in the jury that will lead to unfair prejudice, as described below, and Ms. Spaeth should be prevented from testifying pursuant to Fed. R. Evid. 403.

Additionally, there has been no evidence that Epogen® is the product of the patents-in-suit. In fact just the opposite is true; evidence adduced at trial confirms that Epogen is not the direct product of any of the Lin patents-in-suit, but rather is derived from teachings of other patents not at issue in this case. There has been no evidence that the product of Example 10 of the patents-in-suit, which is the alleged product of the asserted claims, has been administered to any animal other than a mouse.[14]

Amgen intends on having Ms. Spaeth testify to the jury about her own kidney disease, which Ms. Spaeth developed in 1959. She doesn't even take Epogen currently, instead she receives Aranesp®, a product Amgen has argued should not be talked about in this case. She has also had two kidney transplants since participating in Dr. Eschbach's clinical trial. As a nurse, Ms. Spaeth does not treat patients with kidney disease on dialysis nor has she ever administered an ESA to anyone but herself.[15] In addition to being a patient who suffers from kidney disease, Ms. Spaeth is a professional speaker who gives presentations on kidney disease, including facts

[14] Furthermore, Ms. Spaeth knows of no difference between the inventions claimed in the expired '008 patent and any of the patents-in-suit. Ex. A, Spaeth Depo. Tr., at 162:18-24; 163:25-164:10.

[15] Id. at 22:24 - 23:9; 107:13-18.

about her own life for which Ms. Spaeth charges a fee.[16] Such emotional testimony is exactly the type of testimony Fed. R. Evid. 403 is designed to exclude. *CPC Int'l, Inc. v. Northbrook Excess and Surplus Insur. Co.*, 144 F3d. 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.'"); *Lynch v. Merrell-National Labs.*, 830 F.2d 1190, 1196 (1st Cir. 1987); *In Re Richardson-Merrell, Inc. "Bendectin" Products Liability Litigation*, 624 F. Supp. 1212, 1224 (S.D. Oh. 1985). Ms. Spaeth's testimony should be precluded under Fed. R. Evid. 403.

Moreover, the testimony so far is that the work and human trials with the pharmaceutical compositions of Drs. Goldwasser and Baron, Eschbach and Essers pioneered "EPO replacement therapy" as a means of treating anemia due to Chronic Renal Failure (CRF). These other prior art scientists understood that to treat anemia due to CRF, patients were to be administered pharmaceutical compositions with human EPO. The undisputed evidence in Amgen's own words states: "Therapy with erythropoietin has been shown to be effective in selected patients with ESRD. These studies have been small in scale because of the limited quantities of purified or semi-purified erythropoietin available." TRX 2054, at AM-ITC 00056318. As to recombinant DNA technology, the testimony is clear that this technology was developed and successfully used in the prior art by others to create bioactive human proteins. Ms. Spaeth's testimony does not go to any of these issues, and is irrelevant.

[16] 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, attached as Fratangelo Decl. Ex. B. *See also* Ex. A, Spaeth Depo. Tr. at 179:7-11.

III. CONCLUSION

For all of the foregoing reasons, the proposed irrelevant and inadmissible testimony of professional speaker, nurse and kidney disease patient Nancy Spaeth should be precluded as irrelevant and also pursuant to Fed. R. Evid. 602, 802, 402 and 403.

DATED: Boston, Massachusetts
September 24, 2007

Respectfully submitted,

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