UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

PLAINTIFF AMGEN INC.'S OPPOSITION TO ROCHE'S MOTION TO PRECLUDE THE TESTIMONY OF NANCY SPAETH

Roche's motion is its third attempt to have the testimony of Nancy Spaeth precluded from trial. However, like the motions before it, Roche's latest motion fails to provide the Court with a complete and accurate picture regarding the testimony that Ms. Spaeth will provide. Notwithstanding Roche's assertions to the contrary, Ms. Spaeth has, since 1987, been an EPO patient receiving EPO treatment both from her physician and through self-administration. As such, Ms. Spaeth clearly has relevant first hand knowledge regarding the effect that EPO has had on her anemia and her life; testimony, which is relevant to the long-felt, unmet need of kidney disease patients suffering from anemia and the failure of others to solve that problem, both of which are highly probative indicia of non-obviousness.[1]

As Ms. Spaeth testified at her deposition and will testify at trial, she has suffered from severe kidney disease and the chronic, debilitating anemia that accompanies the disease since she was 11 years old. For decades prior to the introduction of recombinant human erythropoietin,

[1] *Graham v. John Deere Co.*, 383 U.S. 684, 694 (1966).

she tried then available treatments under her doctors' care to address her anemia, all without appreciable success.[2]

Since EPOGEN came on the market in 1989, she has, at certain points, taken EPOGEN through physician administered treatments and through self-administered subcutaneous injections.[3] The use of EPOGEN has, as Ms. Spaeth will testify, reduced or eliminated her symptoms of anemia by providing her the energy and stamina needed to engage in certain day to day activities that previously were too difficult for her to do because of her chronic anemia.[4]

In addition, Ms. Spaeth has testified that beginning in 1987 she participated in a clinical study run by Dr. Joseph Eschbach at the University of Washington's Northwest Kidney Center that she believes and understands to have been a clinical study of EPOGEN.[5] Roche attempts to call Ms. Spaeth's testimony regarding the 1987-1989 clinical trial into question by highlighting snippets of her deposition testimony that do nothing more than show that Ms. Spaeth does not remember all of the details surrounding her participation in Dr. Eschbach's clinical trial. But a review of Ms. Spaeth's entire testimony, combined with the testimony that will be presented through other witnesses, shows that there can be no doubt that Ms. Spaeth participated in a clinical study in 1987-1989 during which she received EPOGEN under the care of Dr. Eschbach.

Ms. Spaeth testified that she was informed that the clinical trial was sponsored by Amgen for the purpose of testing a drug made by Amgen that would increase, and in fact did increase, her hematocrit level.[6] Ms. Spaeth will testify that she continued to receive the drug as part of the

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[2] *See* Spaeth Deposition, p. 25, ll. 7-10 and 19-20; p. 36, ll. 16-17.

[3] *See* Spaeth Deposition, p. 91, ll. 3-9 and 18-19; p. 92, ll. 17-19; p. 95, ll. 4-7.

[4] *See* Spaeth Deposition, p. 89, ll. 10-25; p. 90, ll. 1-8:

[5] *See* Spaeth Deposition, p. 63, ll. 15-17; p. 65, ll. 6-7 and 14-15; 86, ll. 2-4 and 24-25; p. 87, ll. 1-5 and 11-13; p. 88, ll. 24-25; p., ll. 1-7.

[6] *See* Spaeth Deposition, p. 65, ll. 14-25; p. 66, ll. 1-4; p.88, ll. 20-25; p. 89, ll. 4-9.

clinical trial until 1989, and was personally informed by Dr. Eschbach (now deceased) after her enrollment in the trial ended that the drug she had received was recombinant erythropoietin, tradename EPOGEN. While it is correct that at the time of the clinical study Ms. Spaeth does not recall that she was aware that the drug being tested was called EPOGEN, she will testify that she subsequently learned this fact from Dr. Eschbach, and recently confirmed it with him.[7] Moreover, she will testify that she learned from Dr. Eschbach that she was one of the original kidney disease patients enrolled in his clinical study of recombinant erythropoietin for Amgen.

In addition, Amgen will proffer the testimony of Jeff Browne, a coordinator of Dr. Eschbach's 1987 clinical trial, that EPOGEN was the only Amgen drug that Dr. Eschbach tested at the Northwest Kidney Center in 1987-1989, and that no placebo nor other test drug was provided in this study. Moreover, the evidence will show that all of the patients in the study received EPOGEN, which was the only drug that Amgen had at that time to treat anemia.[8]

Put into complete and proper context, it cannot be said that Ms. Spaeth lacks the personal knowledge to testify with respect to the long felt unmet need of kidney failure patients suffering from anemia and the fact that the advent of EPOGEN provided, as Ms. Spaeth testified, significant benefits in her life.[9]

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[7] As the Court is aware, Dr. Eschbach recently passed away. Amgen will introduce evidence regarding Dr. Eschbach's Phase III clinical trial through one of the coordinators of the clinical trial.

[8] *See* Trial Exhibit CUQ, *Recombinant Human Erythropoietin in Anemic Patients with End-Stage Renal Disease, Results of a Phase III Multicenter Clinical Trial*. Annals of Internal Medicine, Vol. 111, Dec. 15, 1989.

[9] *See* Spaeth Deposition, p. 89, ll. 10-25; p. 90, ll. 1-8:

Q. In what way were you feeling better?

A. Would you like me to give a comparative statement?

Q. Whichever way you would like.

A. Prior to getting the EPO I was tired, I wanted to sleep all the time, I was

CONCLUSION

As set forth above, a full reading of the deposition transcript of Ms. Spaeth placed properly within the context of the other evidence that will be shown at trial demonstrates that there is no basis to preclude Ms. Spaeth from testifying. Ms. Spaeth clearly has first hand personal knowledge that is probative of the secondary indicia of nonobviousness – long felt unmet need-- and, therefore, Roche's motion should be denied.

> really, really cold. I couldn't walk up a flight of stairs without sitting down every couple of steps to rest. It frightened my children. I really could do very little. It was all – it took all the energy I had to fix them breakfast, lunch and dinner and do the laundry and those kinds of things. And sometimes I had someone living in my house that helped me.
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> After I got it I could climb the stairs without being short of breath, I could do activities with my children, we could play, we could goof around, I could punish them without being exhausted. Reprimand maybe is a better work, send them to their room. Those things used to just wear me out, I would have to take a nap afterwards.

Q. And how long after you started first taking it do you remember feeling better?

A. I don't really remember. Maybe within a month or so.

Dated: September 25, 2007

Respectfully Submitted,

AMGEN INC.,
By its attorneys,

/s/ Patricia R. Rich

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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 September 25, 2007.

/s/ Patricia R. Rich
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