UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC.,	)	
	)	
Plaintiff,	)	
v.	)	Civil Action No.: 05 Civ. 12237 WGY
	)	
F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GmbH, and HOFFMANN-LA ROCHE INC.,	)	
Defendants.	)	

DEFENDANTS' MOTION *IN LIMINE* TO PRECLUDE PLAINTIFF AMGEN INC. FROM OFFERING TESTIMONY CONCERNING EPOGEN® FROM FACT WITNESS DR. LIN WHO LACKS PERSONAL KNOWLEDGE

LIN MOTION *IN LIMINE* NO. 1

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann La Roche Inc. (collectively "Roche") respectfully submit this motion in limine to preclude Amgen's witness Dr. Lin from testifying about the formulation and development of Epogen® because he has no personal knowledge.

I. INTRODUCTION

Critical to this motion is one fact: Dr. Lin was not involved in the clinical testing, formulation, or development of the purification process for the drug that became Epogen®. Therefore, as a fact witness, Dr. Lin should be precluded from testifying about the formulation and development of Epogen®, a matter about which he has absolutely no personal knowledge.

II. ARGUMENT

There is little question that Amgen intends to offer testimony of Dr. Lin as a fact witness in this case.[1] As a fact witness, Dr. Lin is bound to testify about facts within his personal knowledge.[2] Dr. Lin did not perform or participate in the clinical testing, purification, and formulation efforts required to make the pharmaceutical drug Epogen®. Thus he lacks the requisite personal knowledge to testify about the clinical testing, purification and formulation of that drug.

This Court has previously applied this longstanding rule of evidence to preclude improper testimony of Dr. Lin. In *TKT*, Amgen offered Dr. Lin's testimony as a fact witness. This Court properly struck Dr. Lin's testimony regarding Amgen's clinical trials because Dr. Lin did not have first hand knowledge of this work.

> Q. Did there come a time, to your knowledge, when any clinical testing of the material you made was conducted?

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[1] Joint Pre-Trial Memorandum, Exhibit E at p. 2 (D.I. 807); *Amgen v. Roche*, Daily Trial Tr. (Vol. 2), 131:23-132:2.
[2] FRE 602.

A. Yes. Amgen recombinant human erythropoietin was tested in -- was tested in a clinical trial in December 1981 -- I'm sorry, December 1985, that's for the combined Phase I, II trial. And have a Phase III trial in September 1986.

MR. SCHWARTZ: Your Honor?

THE COURT: Mr. Schwartz?

MR. SCHWARTZ: I think we're into hearsay now as to what went on in clinical trials. I didn't hear anything suggesting the witness had personal knowledge. I move to strike the rest of that.

MR. ALLEGRETTI: That --

THE COURT: Please, please, always talk to me. We'll let him try to fill that in. It sounds like hearsay to me.

MR. ALLEGRETTI: I asked him if he had any personal knowledge of that, your Honor.

THE COURT: Did you do these clinical trials?

THE WITNESS: I did not. But we have --

THE COURT: Who did them?

THE WITNESS: This Joe Eschbach, nephrologist at University of Washington.

THE COURT: How did you know about them?

THE WITNESS: Oh, I know him. Because we, for the clinical trial, initially, we have potential clinicians before we started.

THE COURT: And you selected him?

THE WITNESS: He was one of them.

THE COURT: He did the trials?

THE WITNESS: Yes, he was one Amgen selected.

THE COURT: But he's the one who did these trials?

THE WITNESS: That's right, yes. Correct.

THE COURT: He reported the results to you?

THE WITNESS: No. He reported result in the journal.

THE COURT: In a journal?

THE WITNESS: Yes.

THE COURT: And then you read the journal?

THE WITNESS: That's correct, yes.

THE COURT: And used the information?

THE WITNESS: That's correct, yes.

THE COURT: Motion to strike's allowed.[3]

Dr. Lin was also asked to testify about *in vitro* and *in vivo* tests described in the patent, although he admitted he had not personally done all the assays and the experiments had been designed in part by others. This Court prevented Dr. Lin from testifying about the details of these tests because he had no personal knowledge of them, explaining that to establish adequate foundation for the testimony, Dr. Lin must have either performed the experiments himself or observed them.[4] The Court stated the following after the hearsay objection:

> Sustained. I don't think that's an adequate foundation. We're going to need the people who did them, if you want them for the truth. After all, these things are in the patent from which one can infer, and I have gone over in some great detail the prosecution history. Maybe you need more evidence.
>
> It's not much of jump, an inferential jump to infer that the experiments were in fact done and they came up with conclusions that are set forth in the patent. Of course there is an error in the patent which you called it to my attention that things are not perfect.
>
> But strictly speaking, on evidence, not an adequate foundation. Sustained.[5]

Notably, the fact that these tests were described in patents naming Lin as the inventor was insufficient to demonstrate he had personal knowledge of those tests.

The circumstances are no different in this proceeding. Surely it follows that if Dr. Lin was precluded in the *TKT* trial from testifying about tests he did not perform that were described in his patent, he should not be allowed to testify here about tests that he did not undertake and that are not described in his patent. Dr. Lin should be precluded from testifying about clinical testing and development of Epogen®, because he has no personal knowledge about this issue.

[3] 6/7/00 Tr. at 955-956 (Exh. A).
[4] 10/17/03 *TKT* Trial Transcript pp. 563-568 (Exh. B).
[5] *Id.* at 567-568

First, Dr. Lin has already admitted that he did not participate in or perform the clinical testing necessary to formulate the drug that became Epogen®:

> Q Did you do any work on formulating pharmaceutical composition for EPO?
>
> A No, I did not. Those people who had to involve in doing the clinical trial, they would know how to formulate it, yeah.[6]

Second, Dr. Lin did not participate in developing the purification process used to make Epogen®, a highly purified pharmaceutical drug. Dr. Lin has already testified that he did not perform purification work necessary to obtain a pharmaceutical composition.

> Q Okay. So I don't know that we need to go through this word by word, and go through paragraph by paragraph. So who did the purification work?
>
> THE WITNESS: In terms of purification of erythropoietin?
>
> BY MS. BEN-AMI:
>
> Q Yes.
>
> A Okay. Was done by Tom Strickland's group.[7]

In fact, the purification process used to obtain Epogen® was patented by Dr. Strickland, not Dr. Lin.[8]

[6] 3/29/07 Lin Tr. at 377 (Exh. C).
[7] 3/28/07 Lin Tr. 260:9-21 (objection omitted) (Exh. D).
[8] U.S. Pat. No. 4,667,016 (Exh. E).

III. CONCLUSION

For the foregoing reasons, Roche respectfully requests that this Court preclude Amgen's fact witness Dr. Lin from testifying about the clinical testing or development of Epogen®.

Dated: September 27, 2007
Boston, Massachusetts

Respectfully submitted,

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

By its attorneys,

/s/ Thomas F. Fleming

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CERTIFICATE OF SERVICE

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