

**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 ASSAYS FROM FACT WITNESS  
DR. LIN BECAUSE HE LACKS PERSONAL KNOWLEDGE**

**LIN MOTION *IN LIMINE* NO. 2**

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 assays he did not conduct because he has no personal knowledge.

## **I. INTRODUCTION**

Critical to this motion is one fact: Dr. Lin did not conduct, oversee or observe any in vivo assay, in vitro assay, or radioimmunoassay that are described in the Amgen EPO patents. Therefore, as a fact witness, Dr. Lin should be precluded from testifying about the procedures and results of any in vivo assay, in vitro assay, or radioimmunoassay described in the AMGEN EPO patents because he has absolutely no personal knowledge about these experiments.

## **II. ARGUMENT**

There is little question that Amgen intends to offer testimony of Dr. Lin as a fact witness in this case.<sup>1</sup> As a fact witness, Dr. Lin is bound to testify about facts within his personal knowledge.<sup>2</sup> Dr. Egrie, a colleague of Dr. Lin’s at Amgen, performed all the in vitro assays and radioimmunoassays described in the Amgen EPO patents. Dr. Dukes of Childrens’ Hospital performed the in vivo assays described in the Amgen EPO patents. Dr. Lin did not conduct, participate in, oversee or observe any of the assays described in the Amgen EPO patents. Thus, he lacks the requisite personal knowledge to testify about the procedures or results of any in vivo assay, in vitro assay, or radioimmunoassay described in the Amgen EPO patents.

This Court has previously applied FRE 602, a longstanding rule of evidence, to preclude improper testimony of Dr. Lin. In *TKT*, Amgen offered Dr. Lin’s testimony as a fact witness. Dr. Lin was asked to testify about *in vitro* and *in vivo* tests described in the patent, although he

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<sup>1</sup> Joint Pre-Trial Memorandum, Exhibit E at p. 2 (D.I. 807); *Amgen v. Roche*, Daily Trial Tr. (Vol. 2), 131:23-132:2.

<sup>2</sup> FRE 602.

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.<sup>3</sup> 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 a 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.<sup>4</sup>

Notably, the fact that these assays were described in patents naming Lin as the inventor was insufficient to demonstrate that 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 assays he did not perform that were described in his patent, so he should not be allowed to testify here about the *in vivo* assays, *in vitro* assays, or radioimmunoassays described in the Amgen EPO patents because he did not conduct, participate in, or observe any of them. Thus, Dr. Lin should be precluded from testifying about the *in vivo* assays, *in vitro* assays, or radioimmunoassays described in the Amgen EPO patents because he has no personal knowledge about these experiments.

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<sup>3</sup> 10/17/03 *TKT* Trial Transcript pp. 563-568 (Exh A).

<sup>4</sup> *Id.* at 567-568.

First, Dr. Lin has already admitted that he did not perform the in vivo assays necessary to determine whether there was EPO being produced by E.Coli:

A After we had purify the E.coli EPO -- I believe E.Coli EPO has also assay in the in vivo system, it have some activity.

Q And who did that work?

A That I believe was -- in vivo assay would have been done through Joan Egrie's group --

Q Okay.

A -- or maybe someone else. If it's not by her, it would be by someone else outside. Because I think, at the time, we had -- EPO assay -- part of EPO assay -- part is carried out outside.<sup>5</sup>

Second, Dr. Lin has already admitted that he did not conduct the in vitro or in vivo assays described in example 9 of the Amgen EPO patents; nor did he oversee or observe such assays:

Q Who did the work in example 9?

A For the in vitro assay -- again, I think -- I believe it's done by Joan Egrie's group. For the in vivo assay, I don't know at the time we already set our own in vivo system -- it's a system in-house or not. It could be done by outside consultant. I think we, at one time -- some of the assay was carried out by Peter Dukes' group at the children hospital.

Q So did you tell anybody how to do the work that was in example 9?

A Oh, we know -- how to do this. I don't have to tell them. This is individual who -- in charge of setting up this assay. They know how to do it. I don't have to tell them what to do.

Q These in vitro and in vivo assays that are described in example 9, those were assays that were commonly known at the time; right?

A Yes.<sup>6</sup>

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<sup>5</sup> 3/28/07 Lin Tr. 47:1-13 (Exh. B).

<sup>6</sup>3/28/07 Lin Tr. 239:25-240:22 (Exh. B).

Third, Dr. Lin has also already testified that he did not conduct the in vitro or in vivo assays described in example 10 of the patent:

Q Column 29, line 16 through 22 up until where it says, "Amino acid sequencing."

A (Examining document) Yes. The question again?

Q That work was done by Dr. Egrie's group and Dr. Dukes'?

A The in vitro assay -- I think is done by -- it's carried out by Jeff -  
- I mean Joan Egrie's group. In terms of in vivo, I think it's carried  
out -- still at the time carried out by Peter Dukes' group, I believe.<sup>7</sup>

Summarily, at no time did Dr. Lin perform an in vivo or in vitro assay for the EPO project:

Q And whenever it's in vitro assays -- whenever it is bioassays,  
whether it's in vitro or in vivo, it's either Dr. Egrie's group or Peter  
Dukes' group?

A At the time for EPO assay. I'm not talking about any other assay.

Q Right. We're just talking about --

A For EPO assay, it's Joan Egrie's group. And in vivo assay at the  
time, I believe, was carried out by -- only by Peter Dukes' group.<sup>8</sup>

Nor did Dr. Lin conduct or oversee any radioimmunoassays that are described in the Amgen EPO patents. Dr. Lin has already testified that he did not conduct, oversee or observe the radioimmunoassays conducted by Dr. Egrie.

Q My question was: Those procedures described in column 17  
under the RIA were created by Dr. Egrie; is that correct?

A I cannot tell you it's created by her or not. I don't know. That's  
the procedure that she use.

Q Okay. Did you tell her to use that procedure?

A No, I did not.<sup>9</sup>

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<sup>7</sup> 3/28/07 Lin Tr. 251:14-25 (Exh. B).

<sup>8</sup> 3/28/07 Lin Tr. 252:19-253:7 (Exh. B).

<sup>9</sup> 3/28/07 Lin Tr. 198:19-199:3 (Exh. B).

Further, Dr. Lin has already testified that he did not conduct, oversee or observe the radioimmunoassay of the culture media from COS cells described in example 8 of the patents:

Q And now let's get back to example 8. Who did that work?

A (Examining document) I believe this is done by Joan Egrie's group.

Q Okay. And did you tell her how to do this work that's in example 8?

A Molecular biology for doing the radioimmunoassay, they would know how to carry out radioimmunoassay. I don't have to tell her how to do it, unless she have problem, come to me, or have problem arise -- any problem raise.

Q Did you say "raise"?

A Yes.

Q "Raise." Sorry.

A So for doing the immunoassay, any associate or scientist can do it.<sup>10</sup>

Finally, Lin testified that Dr. Egrie conducted the radioimmunoassay work described in example 10 of the Amgen EPO patents.

Q For this paragraph that we just looked at, column 27, line 62 through column 28, line 23, who did that work?

A The assay aspect was carried out by Joan Egrie's groups.<sup>11</sup>

### III. CONCLUSION

For the foregoing reasons, Roche respectfully requests that this Court preclude Amgen's fact witness Dr. Lin from testifying about the procedures and results of any in vivo assay, in vitro assay, or radioimmunoassay.

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<sup>10</sup> 3/28/07 Lin Tr. 238:18-239:11 (Exh. B).

<sup>11</sup> 3/28/07 Lin Tr. 246:21-25 (Exh. B).

Dated: September 27, 2007  
Boston, Massachusetts

Respectfully submitted,

F. HOFFMANN-LA ROCHE LTD,  
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**CERTIFICATE OF SERVICE**

I hereby certify that this document filed on the above date through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

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