Amgen Inc. v. F. Hoffmann-LaRoche LTD et al

Case 1:05-cv-12237-WGY

Document 1175-3 Filed 09/27/2007

Page 1 of 4

Doc. 1175 Att. 2

## **EXHIBIT B**

	Page 533			
1	UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS			
2	Civil Action			
3 4	No. 97-10814-WGY * * * * * * * * * * * * * * * * * * *			
5	AMGEN, INC., *			
6	Plaintiff, * TRANSCRIPT OF			
7	* TRANSCRIPT OF  v. * PROCEEDINGS ON REMAND  * (Volume 5)			
8	HOECHST MARION ROUSSEL, INC. * and *			
9	TRANSKARYOTIC THERAPIES, INC., *			
10	Defendants. *			
11	* * * * * * * * * * * * * * * *			
12	BEFORE: The Honorable William G. Young, District Judge			
13	APPEARANCES:			
14	DAY CASEBEER MADRID & BATCHELDER, LLP (By Lloyd R.			
15	Day, Jr., Esq., David M. Madrid, Esq., Jonathan Loeb, Esq., and Robert M. Galvin, Esq.) 20400 Stevens Creek			
16	Blvd., Suite 750, Cupertino, California 95014			
17	HOWREY, SIMON, ARNOLD & WHITE, LLP (By Edward M. O'Toole, Esq.), 321 North Clark Street, Chicago,			
18	Illinois 60610-4714  - and -			
19	DUANE MORRIS, LLP (By D. Dennis Allegretti, Esq.), 470 Atlantic Avenue, Suite 500, Boston, Massachusetts			
20	02210			
21	- and - STUART L. WATT, ESQ. and MONIQUE L. CORDRAY, ESQ.,			
22	Amgen, Inc., One Amgen Center Drive, Thousand Oaks, California 91320-1799, on behalf of the Plaintiff			
23 24 25	1 Courthouse Way Boston, Massachusetts October 17, 2003			

AM670068519 AM-ITC 00853186

	Odsc 1.05 cv 12257 vvG1 Bocument		73 Thea 03/21/2007 Tage 3 01 4
	Page 562		Page 56 <sup>-</sup>
1	A. Tab 5 is, again is a memo I wrote on March 23rd, 1983.	1	THE COURT: Well, do you know what tests were
2	It summarized the results related to the EPO research goals	2	used?
3	in Item No. 5.	3	THE WITNESS: Yes, of course.
4	Q. At the bottom of the first page?	4	THE COURT: Do you know yourself?
5	A. That's correct.	5	THE WITNESS: Yes, of course.
6	Q. What does it summarize here?	6	THE COURT: You may testify.
7	A. It says human polycythemic renal tumor was transplanted	7	MR. HALEY: Your Honor, may I be heard?
8	into seven nude mice in kidney capsule and subcutaneously.	8	THE COURT: Yes.
9	Two of them might be bearing tumors. And three renal tumor	9	MR. HALEY: I believe Dr. Lin may be getting ready
10	cells and one liver tumor cell, those are not making	10	to testify about tests that others did, not that he did.
11	measurable amount of EPO. This renal tumor cell line and	11	THE COURT: So long as he himself knows well,
12	liver tumor cell lines are the cells that I obtained from	12	by knows it means you either did the experiments or you
13	ATCC.	13	observed them being done, not that your people came and
14	Q. Okay. So you also implanted those in mice as well?	14	told you about them.
15	A. Those were injected into nude mice.	15	Do you understand the difference?
16	Q. And in any of those experiments were you able to	16	THE WITNESS: Only the in vivo experiment that was
17	succeed in getting the cells or the tissue to produce EPO?	17	not done in house; all other experiments I know
18	A. No.	18	THE COURT: And you
19	Q. Dr. Lin, prior to cloning the EPO gene were you or any	19	THE WITNESS: were not, that is done in house,
20	members of your team at Amgen ever successful in obtaining	20	yes.
21	EPO producing human cells or tissue sources?	21	THE COURT: But what Mr. Haley's pressing, and
22	A. No.	22	he's right to press it, how do you know that these
23	Q. Prior to cloning the EPO gene were you or your team	23	experiments, the in-house ones, were done?
24	ever successful in obtaining human cells or tissue sources	24	THE WITNESS: I know how they were done.
25	that could be induced to produce	25	THE COURT: How?
	Page 563		Page 565
1	A. No.	1	THE WITNESS: Carried out by the people,
2	Q EPO?	2	procedure-wise, I know.
3	Dr. Lin, were you or your team ever successful in	3	THE COURT: But how do you know?
4	obtaining human cells or tissue sources that could be used	4	THE WITNESS: Because they are part of the EPO,
5	to generate a cDNA library?	5	the EPO team.
6	A. No.	6	THE COURT: Well, various things get done in this
7	Q. Now, in this litigation HMR/TKT have asserted that EPO	7	courthouse that I don't see get done
8	producing human cells and tissues were readily available	8	THE WITNESS: I understand.
9	before 1983. In your experience, before you cloned the EPO	9	THE COURT: because they're part of my team.
10	gene were EPO producing human cells publicly available?	10	THE WITNESS: Sure.
11	A. No.	11	THE COURT: But I don't see them being done.
12	Q. I want to ask you about the methods described in your	12	THE WITNESS: Oh, I see. I have interaction with
13	patents for detecting EPO protein. And please take a look	13	the people that working on these assays.
14	at Tab 6, which is Trial Exhibit 1.	14	THE COURT: And they will you what they've done?
15	Do you see that?	15	THE WITNESS: That's right. The result will
16	A. Yes.	16	THE COURT: Did you do the assays?
17	Q. In general, and I just would like a brief and general	17	THE WITNESS: No, I don't personally do all these
18	answer for the Court, in the patents what tests did you use	18	assays, no.
1	to determine whether you had produced human EPO?	19	THE COURT: How are you going to deal with that,
19	· · · · · · · · · · · · · · · · · · ·	20	Mr. Day?
l .	MR. HALEY: Object, your Honor; hearsay.		
20	MR. HALEY: Object, your Honor; hearsay. THE COURT: What tests did he use. Did he use,		
20 21	THE COURT: What tests did he use. Did he use,	21	MR. DAY: Well, let me ask some questions, if I
20 21 22	THE COURT: What tests did he use. Did he use, that imports that he did them himself, if he knows.	21 22	MR. DAY: Well, let me ask some questions, if I may.
20 21 22 23	THE COURT: What tests did he use. Did he use, that imports that he did them himself, if he knows.  Is that how you understand how	21 22 23	MR. DAY: Well, let me ask some questions, if I may. $ \label{eq:THECOURT:PROBLEM}        $ THE COURT: Fine.
20 21 22	THE COURT: What tests did he use. Did he use, that imports that he did them himself, if he knows.	21 22	MR. DAY: Well, let me ask some questions, if I may.

9 (Pages 562 to 565)

AM670068527 AM-ITC 00853194

Page 566 Page 568 Q. How many people worked on this project during this time history. Maybe you need more evidence. 1 1 2 2 period? It's not much of a jump, an inferential jump to 3 A. Oh, a lot of people. Ten, twenty. I don't know. I 3 infer that the experiments were in fact done and they came 4 4 cannot count all them. up with conclusions that are set forth in the patent. Of Q. Okay. Physically where were they located? course there is an error in the patent which you called it 5 5 6 A. They all located at Amgen. 6 to my attention that things are not perfect. 7 7 Q. In what building? But strictly speaking, on evidence, not an 8 8 adequate foundation. Sustained. A. In Thousand Oaks. At the time I think we probably have a total of maybe six buildings or so, something like that. 9 Q. Dr. Lin, in the course of your work as a project leader 9 10 Q. Okay. And the people working on the EPO project team, 10 for the EPO team, did you make decisions about what assays where were they all located? 11 would be performed to characterize the product? 11 12 12 A. Mainly in Building 2. A. Yes. 13 Q. Okay. And where were you located? 13 MR. HALEY: Objection; leading. A. Building 2 and 1. I think Building 2 and 1. 14 THE COURT: Did he make -- I'm going to let it 14 15 Q. And where were you located? 15 stand. 16 A. In Building 2. 16 Q. And who was the, who was the individual that was 17 Q. Okay. And did you interact with members of the team on 17 responsible for deciding what set of tests or assays would be performed in order to characterize whether or not the 18 a daily basis? 18 19 A. Yeah, regular basis. Yes, we had regular meetings. 19 product that you were obtaining was in fact human EPO? 20 Yes. 20 A. Yes. 21 21 Q. Who was the person responsible? Q. Did you assist in the design of the experiments that 22 22 A. Iam. Iam. they all performed? 23 23 A. This is, some of it is designed by others, some Q. Now, in the patents there are a set of tests. designed by myself because -- you know. 24 24 Well, let me just ask the foundational question. 25 25 Q. Did you review the design? What experiments are recorded in your patent that deal with Page 567 Page 569 A. Depends. Depends. Those that I have to review myself, 1 the identification of the EPO protein? 1 2 2 I reviewed. If not, then it would be the scientists who MR. HALEY: Your Honor, I object. The patent were in charge of project who would review the design. 3 speaks for itself. 3 4 Q. Okay. And did you supervise the performance of the 4 THE COURT: It does. So I don't think you need a 5 5 experiments that are reflected in the patents that you foundation. Sustained. The patent says what it says. 6 filed? 6 Q. Well, in your opinion as the project leader, if you 7 A. The performance of experiments actually carried out by 7 were managing the project or making decisions, which of the 8 individual, under individual's authority, whoever that, 8 tests reported in the patent were needed to confirm the 9 that clinician work for or whatever the scientist is 9 identity of the protein you produced? 10 supposed to be doing. 10 A. The identity of erythropoietin that we produced had to 11 Q. And were you supervising the scientists? 11 be done by RIA, by SDS-PAGE, then followed by width and A. Yes. In a way we had a coordinator for the whole 12 12 run, and then N-terminal sequence analysis of the protein 13 research project. 13 that express. And we also check for the in vitro/in vivo 14 Q. Okay. 14 activity of the protein expressed so that we know if this A. Yes. 15 15 protein have activity --16 MR. DAY: Your Honor, I think on that basis I've 16 MR. HALEY: Object, your Honor; move to strike. 17 laid an adequate foundation to establish that he knows what 17 A. -- in vivo or in vitro. experiments were done. 18 THE COURT: Wait one second. Grounds? 18 19 THE COURT: Do you press the objection? 19 MR. HALEY: It's hearsay again saying we did such 20 MR. HALEY: Yes, your Honor, I do. 20 and so. The question is --THE COURT: Sustained. I don't think that's an 21 THE COURT: The way I heard him say we had to 21 22 adequate foundation. We're going to need the people who 22 check. I'm going to let it stand. 23 did them, if you want them for the truth. After all, these 23 Q. And, Dr. Lin, which of the tests reported in your 24 things are in the patent from which one can infer, and I 24 specification were needed to confirm the activity of the 25 25 have gone over in some great detail the prosecution protein produced?

10 (Pages 566 to 569)

AM670068528 AM-ITC 00853195