

# EXHIBIT 1

Cords, Dr. Sven-Michael

5/30/2007

CONFIDENTIAL

Page 1

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS  
Civil Action No. 05-12237 WGY

AMGEN, INC.,	)	DEPOSITION OF:
	)	DR. SVEN-MICHAEL CORDS
	)	
Plaintiff,	)	
	)	
vs.	)	**CONFIDENTIAL**
	)	
	)	
F. HOFFMANN-LA ROCHE LTD., a	)	
Swiss Company, ROCHE	)	
DIAGNOSTICS GmbH, a German	)	
Company, and HOFFMANN-LA	)	
ROCHE, INC., A New Jersey	)	
Corporation,	)	
	)	
Defendants.	)	

TRANSCRIPT of the stenographic notes of the proceedings in the above-entitled matter, as taken by and before LISA FORLANO, RMR, CRR, CSR, CLNR, Notary Public, held at the offices of Duane, Morris, 1540 Broadway, New York, New York, on Wednesday, May 30, 2007, commencing at 9:03 a.m.

(This transcript has been designated CONFIDENTIAL as per Section 5(c) of the Amended Protective Order. Please treat the entire transcript in accordance with the Protective Order.)

CONFIDENTIAL

Page 36

1 rephrase the question?

2 BY MR. NIELSEN:

3 Q You had a protocol that you followed in  
4 performing your bioassay, correct?

5 A Yes.

6 Q And that protocol didn't include a step  
7 of normalizing data, did it?

8 A No, the whole calculation was not part  
9 of the protocol.

10 Q The calculation of normalization?

11 A That's correct.

12 Q You normalized the data simply for  
13 purposes of generating Figure 3 to appear in your  
14 expert report, is that right?

15 A I'm sorry, can you repeat?

16 Q Well, you explained just a moment  
17 ago --

18 A Yeah.

19 Q -- that normalizing the data was not  
20 part of your protocol, right?

21 A Correct.

22 Q Okay. But you did normalize the data  
23 for purposes of generating Figure 3, right?

24 A That's correct.

25 Q And was the purpose of normalizing the

Cords, Dr. Sven-Michael

5/30/2007

CONFIDENTIAL

Page 47

1 A Yes, it was my understanding.

2 Q You did not write Paragraph 10 of your  
3 report, correct?

4 A As I said, it was prepared by the  
5 attorneys of Roche.

6 Q The entire report?

7 A Yes.

8 Q Dr. Cords, if you will, please provide  
9 us today with the tutorial that you think you might  
10 give at trial in this case on the general aspects of  
11 the Normomouse bioassay.

12 A Yes. The general aspect of this  
13 protocol or the general aspect when you normally  
14 test erythropoietic stimulating agents for quality  
15 control purposes, for example?

16 Q Well, I want both out of you. I want  
17 to hear from you today everything that you think you  
18 might possibly tell the Court later on in this case  
19 as part of a tutorial. So let's start first with  
20 the protocol in this case.

21 A Yes. Maybe I start a little bit more  
22 general. It might be easier and then go into the  
23 detail.

24 Q Fair enough.

25 A The normocythaemic assay is a part of

CONFIDENTIAL

Page 48

1 the European Pharmacopoeia, so it's a validated test  
2 to test the activity of erythropoietic stimulating  
3 agents. In this test, you compare one or two  
4 samples of one distinct substance against its own  
5 standard. The difference to the protocol of this  
6 study is that instead of using one dosage, you use  
7 three dosages and instead of sampling four samples  
8 over a time period, you sample after four days after  
9 injection of the mice.

10 The activity is calculated by  
11 comparison, the reticulocyte response of the samples  
12 in comparison to the standard and it is analyzed by  
13 the so-called parallel line assay which compares  
14 parallelity and linearity and dosage effectiveness.

15 Instead of this in this protocol, we  
16 measured over different time points the samples  
17 using one dosage and comparing different substances  
18 and no deeper statistical analytical measurement was  
19 made.

20 Q Is there anything else that you think  
21 will be part of your tutorial in this case?

22 MR. LEEMAN: Objection.

23 BY MR. NIELSEN:

24 Q Let me ask you a better question.

25 In addition to what you just explained

Cords, Dr. Sven-Michael

5/30/2007

CONFIDENTIAL

Page 49

1 to me, do you believe there are any other aspects or  
2 parts of a tutorial which you might explain later on  
3 at trial in this case?

4 MR. LEEMAN: Objection.

5 THE WITNESS: It's possible to go in  
6 very detail how the samples were diluted, for  
7 example, and then applicated to the mice, how the  
8 receiving of the blood of each animal was performed  
9 and then the calculation by flow cytometry of the  
10 reticulocytes.

11 BY MR. NIELSEN:

12 Q Do you think you may go into such  
13 detail at trial?

14 MR. LEEMAN: Objection.

15 THE WITNESS: I can do this. Of course  
16 this is in some -- to some extent privileged  
17 information, just keeping the way we are performing  
18 our assay in-house.

19 BY MR. NIELSEN:

20 Q How is it privileged?

21 A It's just a question of know how.

22 Q The know how of Bioassay GmbH?

23 A Yes, that's right.

24 Q And I assume that you don't plan on  
25 discussing the know how or the confidential know how

Cords, Dr. Sven-Michael  
CONFIDENTIAL

5/30/2007

Page 51

1 BY MR. NIELSEN:

2 Q I believe earlier, Dr. Cords, you said  
3 something to the effect, and please correct me if  
4 I'm wrong, I'm trying to be accurate here, that the  
5 difference between the protocol, the typical  
6 protocol for a Normomouse bioassay and the study you  
7 performed was that instead of one dosage, there were  
8 three dosages and instead of four samples --

9 A Four times.

10 Q Okay. Instead of testing at four  
11 times, there's only a test at one time?

12 A One time after four days, yes.

13 Q Okay. Which goes with the  
14 Normomouse -- strike that.

15 Which goes with the standard Normomouse  
16 bioassay and which goes with the version that you  
17 performed in this case?

18 A The standard Normomouse assay, we use  
19 three different dosages at one time point  
20 measurement after four days after injection.

21 Q And in the modified Normomouse bioassay  
22 that you performed in this case?

23 A You had four times measurements with  
24 only one dosage.

25 Q You never performed this modified

Cords, Dr. Sven-Michael

5/30/2007

CONFIDENTIAL

Page 73

1 mono-PEG-EPO were samples that were assayed in a  
2 Normomouse assay that generated the data shown in  
3 this document. Okay?

4 A I just recognize it, yes.

5 Q Okay. Let's also assume that all other  
6 parameters of the Normomouse bioassay that was  
7 performed that yielded these results were done in a  
8 manner consistent with the bioassay which you  
9 performed in this case, okay?

10 A You assume that these both results are  
11 consistent?

12 Q Not that the results are consistent,  
13 but I'm asking you to assume for purposes of looking  
14 at Cords Deposition Exhibit 3 that the other  
15 parameters of the Normomouse bioassay that was  
16 applied to yield these results were the same or  
17 comparable to the parameters of your bioassay.

18 A Yes. Apart from the parameter of the  
19 time collection, it seems that the four groups have  
20 the same parameters.

21 Q Your assay didn't measure reticulocyte  
22 formation at 144 hours, correct?

23 A Correct.

24 Q Why not?

25 A Sorry?



Cords, Dr. Sven-Michael

5/30/2007

CONFIDENTIAL

Page 74

1 Q Why not?

2 A Simply because we were not asked.

3 Q Roche asked you -- strike that.

4 The attorneys for Roche asked you to  
5 conduct a bioassay that measured reticulocyte  
6 formation through an ending at 120 hours, is that  
7 correct?

8 A Yes. The end point was 120 hours.

9 Q And that's what the attorneys for Roche  
10 instructed you to do, right?

11 A Yes. It was included in the protocol.

12 Q Did the attorneys for Roche or Roche  
13 itself send you a written protocol for the bioassay  
14 in this case?

15 A The protocol was sent by the attorneys.

16 Q When did they send it to you?

17 A It was at the end of March.

18 Q Do you remember who sent it?

19 A I'm not absolute sure. It could be  
20 Mr. Jungermann.

21 Q I'm sorry, what was the first name?

22 A The first name is Sebastian.

23 Q Is Mr. Jungermann an attorney for  
24 Roche?

25 A He's located in Frankfurt.

Cords, Dr. Sven-Michael  
CONFIDENTIAL

5/30/2007

Page 75

1 Q Does he work for Roche?

2 A I don't know, but he's an attorney for  
3 Kaye Scholer.

4 Q Do you recall roughly how many pages  
5 the protocol was that was sent to you?

6 A The protocol, I'm not absolute sure,  
7 but two sides I would suggest.

8 Q Two pages?

9 A Two pages, yes.

10 Q Do you know if that protocol has been  
11 produced to Amgen in this case?

12 MR. LEEMAN: Objection.

13 THE WITNESS: Can you specify or  
14 rephrase the question?

15 BY MR. NIELSEN:

16 Q Do you know if the protocol which you  
17 just referred to or a copy of it was produced or  
18 given to Amgen or Amgen attorneys in this case?

19 MR. LEEMAN: Objection.

20 THE WITNESS: I have no -- I don't know  
21 it, no.

22 BY MR. NIELSEN:

23 Q You don't have any knowledge of whether  
24 any particular documents were given to Amgen in this  
25 case, do you?

Cords, Dr. Sven-Michael

5/30/2007

CONFIDENTIAL

Page 125

1 in no other respect and, therefore, and maybe  
2 without the hand writing, so this document arguably  
3 has more information because of the handwriting than  
4 the -- any non-identical equivalent that might be  
5 out there without the handwriting, so I expect that  
6 there won't be need for additional questioning, if  
7 there is such an equivalent out there.

8 MR. NIELSEN: And you haven't seen this  
9 additional document, have you?

10 MR. LEEMAN: I'm unaware of the other  
11 document or its whereabouts.

12 MR. NIELSEN: Okay. Well, we can't  
13 agree to waive any rights we have to resume the  
14 deposition.

15 MR. LEEMAN: I understand your  
16 position, Matt.

17 BY MR. NIELSEN:

18 Q Dr. Cords, counsel for Roche just  
19 provided an explanation of what he believes to be  
20 the, you know, facts and circumstances surrounding  
21 the non-identical version of this document which you  
22 referred to, but I haven't heard from you yet as to  
23 what you think about what he said. I'm a little  
24 surprised, I have to admit, that now it seems like  
25 things have changed, so do you now recognize the

Cords, Dr. Sven-Michael

5/30/2007

CONFIDENTIAL

Page 126

1 document bearing Bates numbers 8890792 through 93?

2 A Yes. The emphasis was that I've never  
3 seen this particular document with the Roche emblem  
4 and the handwriting and -- except from the head of  
5 this first page, the protocol was identical of which  
6 was sent to us.

7 Q And when you say the head of the page,  
8 can you please make it clear for the record,  
9 beginning where and ending where you're referring  
10 to?

11 A From my remembering the protocol starts  
12 with the sentence protocol of sample preparation for  
13 the comparison study for epoetin beta and MIRCERA.

14 Q What was it that jogged your memory, if  
15 you will, as to as to you having seen that remaining  
16 portion of this document before?

17 MR. LEEMAN: Objection.

18 THE WITNESS: I didn't understand it.

19 BY MR. NIELSEN:

20 Q Why is it that you're coming back now  
21 after having been off the record for a substantial  
22 amount of time, I believe with counsel for Roche,  
23 and telling me that now there are parts of this  
24 document which look familiar to you?

25 A Yes, but the first question you rise is

Cords, Dr. Sven-Michael  
CONFIDENTIAL

5/30/2007

Page 135

1 role?

2 A No, that's all.

3 Q What other people -- pardon me, strike  
4 that.

5 What other individuals at Bioassay GmbH  
6 had a role in the bioassay that was performed in  
7 this case other than yourself?

8 A I have my predecessor who is also my  
9 backup and he's also our scientific advisor.

10 Q And his name is?

11 A Professor Sponer.

12 Q Can you spell that, please?

13 A S-P-O-N-E-R.

14 Q Were there any other individuals who  
15 had a role in the bioassay performed in this case?

16 A The lab head as already mentioned,  
17 Eckart Pahlke.

18 Q I'm sorry, what was the name?

19 A Pahlke.

20 Q Okay. Anyone else?

21 A And a technician and a second  
22 technician.

23 Q What was that technician's name, the  
24 first technician?

25 A I know that Mrs. Hach, H-A-C-H, was

Cords, Dr. Sven-Michael

5/30/2007

CONFIDENTIAL

Page 136

1 involved and a second, I cannot remember. I have to  
2 look at the protocols.

3 Q Did you observe each of the procedures  
4 or measurements that were a part of the bioassay  
5 that your company performed?

6 A No, I did not see the experiment.

7 Q If I could direct your attention to  
8 Exhibit 2 to your expert report, Doctor, your  
9 publication list. Are there any publications which  
10 you're an author or co-author of regarding work with  
11 erythropoietin?

12 A No, I'm not.

13 Q Any publications which you're an author  
14 or co-author of involving experiments with any  
15 erythropoietic stimulating agent?

16 A No.

17 Q Are there any publications which you're  
18 listed as an author or co-author on which involve  
19 experiments with the Normomouse bioassay?

20 A No.

21 Q And I take it the answer would be the  
22 same for a modified Normomouse bioassay?

23 A That's correct.

24 Q If I could direct your attention to  
25 Paragraph 4 of your expert report.

CONFIDENTIAL

Page 137

1 Do you see the last sentence which  
2 says: "I have tested approximately 1,000 samples,  
3 measuring the biological activity of erythropoietin  
4 samples in the parallel line assay according to the  
5 European Pharmacopoeia."?

6 A Yeah, that's correct.

7 Q What biological activity of  
8 erythropoietin have you measured prior to this case?

9 A It's a standard protocol, as I already  
10 mentioned, as part of the quality control of these  
11 agents to confirm the biological activity.

12 Q Have those tests been efforts to  
13 determine the potency of a sample?

14 A Yes, correct, it's a potency assay.

15 Q Than was that done by measuring  
16 reticulocytes?

17 A That's correct, yes.

18 Q Is there any other biological activity  
19 that -- of erythropoietin that that sentence is  
20 referring to or is that it, what you just said?

21 A That's what we do in our lab.

22 Q Your lab measures the potency of  
23 erythropoietin samples?

24 A That's correct, just by the  
25 normocythaemic mouse assay.

Cords, Dr. Sven-Michael

5/30/2007

CONFIDENTIAL

Page 138

1 Q If I could direct your attention to  
2 Paragraph 15, Dr. Cords.

3 Please take as much time as you'd like  
4 to look at that paragraph, but my question to you is  
5 are the assays that you refer to in Paragraph 15 the  
6 potency assays that you were referring to a moment  
7 ago?

8 A You asked me whether these assay that I  
9 mentioned here are referring to the potency assay?

10 Q Yes.

11 A Yes, that's correct.

12 Q And just so the record is clear, here  
13 is Paragraph 15 of your report, correct?

14 A Yes.

15 Q Forgive me if we've covered this  
16 earlier, but is it correct that prior to your work  
17 in this case, you had not previously had experience  
18 with a modified version of the Normomouse bioassay?

19 A That's correct, yes.

20 Q And is it also correct that prior to  
21 your work in this case, your company, Bioassay GmbH,  
22 had not previously had experience with a modified  
23 Normomouse bioassay?

24 MR. LEEMAN: Objection.

25 THE WITNESS: That's hard for me to



Cords, Dr. Sven-Michael  
CONFIDENTIAL

5/30/2007

Page 160

1 protein content.

2 Q That wasn't something that was  
3 performed by you or your company?

4 A No.

5 Q If you could move on to pages three and  
6 four of Cords Exhibit 11. I believe counsel earlier  
7 characterized those two pages as essentially  
8 identical or virtually identical to documents that  
9 we've already looked at today.

10 Do you agree with that?

11 A Yes, I do.

12 Q Counsel for Roche also referred to  
13 there potentially being something additionally in  
14 this document regarding modifications that were made  
15 to the standard Normomouse protocol, is that  
16 correct?

17 MR. LEEMAN: Objection.

18 THE WITNESS: I don't think so. No, I  
19 don't think so.

20 BY MR. NIELSEN:

21 Q Is it your testimony that Cords Exhibit  
22 11 doesn't -- strike that.

23 Is it your testimony that pages three  
24 and four of Cords Exhibit 11 don't provide any  
25 additional comment about any modifications to the

Cords, Dr. Sven-Michael  
CONFIDENTIAL

5/30/2007

Page 161

1 standard Normomouse protocol?

2 A Yes, as already stated --

3 MR. LEEMAN: Objection.

4 THE WITNESS: -- this is true. Apart  
5 from number one on the third page, examples to be  
6 included in the study you can see or you can  
7 conclude that it is not the standard protocol.

8 BY MR. NIELSEN:

9 Q There are no other comments on pages  
10 three and four of this document regarding any  
11 modifications to be made to the standard Normomouse  
12 protocol?

13 MR. LEEMAN: Objection.

14 THE WITNESS: They're reflecting all  
15 kinds we are not responsible for. So it's hardly to  
16 say that we can make any commands on it if this is  
17 the same procedure as is done in the standard  
18 protocol or not.

19 BY MR. NIELSEN:

20 Q Is there anything else in Cords Exhibit  
21 11, other than what we've talked about already, that  
22 relates to any actual or potential modifications for  
23 a standard Normomouse bioassay?

24 A Yes, it's on the page two, the last  
25 sentence, reticulocyte counting after two, three,

Cords, Dr. Sven-Michael

5/30/2007

CONFIDENTIAL

Page 162

1 four and five days, five mice per group each.

2 Q Is there anything else in this document  
3 about any potential or actual modifications to the  
4 standard assay?

5 A No.

6 Q If you take a look at Page 4 under 2.4,  
7 Analytics. See where it says: "Normomouse bioassay,  
8 (see memo from Wolf Pahlke, P-A-H-L-K-E)"

9 Do you see that, Dr. Cords?

10 A Yes, I see it.

11 Q Was there a memo from Wolf Pahlke  
12 regarding the Normomouse bioassay that was ever  
13 considered by you in this case?

14 A No. As already stated, we did not  
15 receive any memo.

16 Q What is this referring to, then?

17 A That's -- I can't judge about it.

18 Q Is it your testimony, Dr. Cords, that  
19 Cords Exhibit 11 is the protocol that was sent to  
20 you by Kaye Scholer which you were to follow in  
21 performing the assay that was conducted in this  
22 case?

23 A Yes, that's correct.

24 Q Maybe I'm missing something, but it  
25 just doesn't seem to me that there is much in here

Cords, Dr. Sven-Michael

5/30/2007

CONFIDENTIAL

Page 163

1 about the conditions to perform the Normomouse  
2 bioassay, so how did you know the parameters of the  
3 assay?

4 A What we need for the dilution is the  
5 protein concentration. It's given. What we need to  
6 know how much we have to inject is given on the  
7 second page, this 100-milligram per mouse. All we  
8 have to evaluate then is the dilution protocol. And  
9 the rest is I think quite clear. We have to count  
10 reticulocytes after two, three, four and five days.

11 Q Did you follow the protocol that is  
12 provided in Cords Exhibit 11?

13 A Yes, we did.

14 Q In following the protocol, you ignored  
15 the reference on Page 4 to a memo from Wolf Pahlke?

16 MR. LEEMAN: Objection.

17 THE WITNESS: This memo was for us  
18 absolutely not relevant because we had all the  
19 information on the first two pages.

20 BY MR. NIELSEN:

21 Q But you don't know -- well, do you know  
22 what the subject of that memo is about?

23 A No, I don't.

24 Q Cords Exhibit 14 -- strike that.

25 Cords Exhibit 11 does not say anything

Cords, Dr. Sven-Michael

5/30/2007

CONFIDENTIAL

Page 167

1 analyzes on the samples.

2 Q So you don't know, Dr. Cords, whether  
3 the samples were still in the same condition when  
4 you began to assay them as they were when you  
5 received them, is that correct?

6 A It's out of my scope to judge about  
7 this. I just can tell you the way -- the way we  
8 handled the samples. Analytical parts we cannot  
9 conclude.

10 Q If you can go to Page 4 of Cords  
11 Exhibit 11 and go to the second to the last bullet  
12 point -- I'm sorry, third to the last under  
13 risks/issues. Do you see where it says: "The  
14 experiment has not been performed since 1999, there  
15 is no possibility for training and test experiments  
16 (only one shot!)."

17 Do you see that, Dr. Cords?

18 A Yes, I see this.

19 Q You didn't receive any training for  
20 performing the modified Normomouse bioassay that you  
21 performed in this case, is that correct?

22 A We did not received any training  
23 because all our staff members are well trained with  
24 Normomouse, the standard of Normomouse assay, and  
25 especially the handling is exactly the same.

Cords, Dr. Sven-Michael

5/30/2007

CONFIDENTIAL

Page 168

1 Q No one had received -- strike that.

2 No one at your company received any  
3 special training for the -- strike that again.

4 No one at your company received any  
5 special training for the modified Normomouse  
6 bioassay that was actually performed in this case,  
7 though, is that correct?

8 A That's correct.

9 MR. NIELSEN: Subject to my comments  
10 earlier on the record, we have no further questions  
11 at this time. That said, we do reserve our rights  
12 to resume the deposition and continue it and we  
13 consider it to still be an open deposition, but at  
14 this time, considering the circumstances that we're  
15 in, we have no further questions.

16 MR. LEEMAN: Okay, Matt, we obviously  
17 disagree on that. We consider the deposition to be  
18 at an end or soon to be, but let me ask a few  
19 questions myself.

20 BY MR. LEEMAN:

21 Q Did you receive a draft of your expert  
22 report before you signed it?

23 A Yes.

24 Q Did you have a chance to make some  
25 edits for purposes of accuracy?

Cords, Dr. Sven-Michael  
CONFIDENTIAL

5/30/2007

Page 173

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J U R A T

I, DR. SVEN-MICHAEL CORDS, the witness herein,  
the foregoing testimony of the pages of this  
deposition, do hereby certify it to be a true  
and correct transcript, subject to the corrections, if  
any, shown on the attached page.

\_\_\_\_\_  
DR. SVEN-MICHAEL CORDS

Subscribed and Sworn to before me  
this \_\_\_\_\_ day of \_\_\_\_\_ 2007.

\_\_\_\_\_  
Notary Public

CONFIDENTIAL

Page 174

C E R T I F I C A T I O N

I, LISA FORLANO, a Certified Realtime Reporter, Certified Court Reporter and Notary Public, do hereby certify that I reported the deposition in the above-captioned matter, that the said witness was duly sworn by me; that the foregoing is a true and correct transcript of the stenographic notes of testimony taken by me in the above-captioned matters.

I further certify that I am not an attorney or counsel for any of the parties, not a relative or employee of any attorney or counsel connected with the action, nor financially interested in the action.

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LISA FORLANO, CRR, CCR #XI01143

DATED: May 31, 2007