

## **EXHIBIT 11**

Shouval, Dr. Daniel

5/24/2007

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UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

Civil Action No. 95-12237 WGY

AMGEN, INC.,	)	DEPOSITION OF:
	)	
Plaintiff,	)	DR. DANIEL SHOUVAL
	)	
vs.	)	**HIGHLY 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 proceedings  
in the above-entitled matter, as taken by and  
before CATHERINE M. DONAHUE, CSR, Notary Public,  
held at the offices of Duane Morris, 1540  
Broadway, New York, New York, on Thursday, May 24,  
2007, commencing at 8:15 a.m.

(This transcript contains testimony  
designated as per the protective order in  
this matter. Please treat each segment of  
designated testimony in accordance with the  
protective order.)

Shouval, Dr. Daniel

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1 Dr. Daniel Shouval - May 24, 2007

2 A. Because in science you usually try 11:54

3 to get the maximum proof when you make a 11:54

4 statement about EPO or, for instance, EPO 11:54

5 production. 11:54

6 Q. Did you have the maximum proof in 11:54

7 Exhibit 2 when you submitted that? 11:54

8 MR. DROZDOFF: Objection. 11:54

9 Objection. Vague. Asked and answered. 11:54

10 A. I don't know what you call maximum 11:54

11 proof. Can you define it? 11:54

12 Q. You just used the phrase "maximum 11:54

13 proof," and I'm asking you in science whether or 11:54

14 not you felt when you submitted Exhibit 2, it 11:54

15 was published in March of '83, it set forth the 11:54

16 maximum proof for the proposition that the RC-1 11:54

17 cells were producing erythropoietin? 11:54

18 A. Let me put it this way: I was 11:54

19 absolutely convinced that these cells produced 11:54

20 erythropoietin when the abstract was submitted. 11:54

21 There was no doubt in my mind. One has to be 11:54

22 totally blind -- 11:54

23 Q. But I'm not asking about that. 11:55

24 A. -- to exclude the option that this 11:55

25 is not erythropoietin, knowing everything we 11:55

Shouval, Dr. Daniel

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1 Dr. Daniel Shouval - May 24, 2007  
2 know about erythropoietin. 11:55  
3 However, there were -- the 11:55  
4 methodology to strengthen these statements used 11:55  
5 a number of assays or a number of methods which 11:55  
6 included, which, first of all, represented by 11:55  
7 Dr. Sherwood at this meeting initially, but 11:55  
8 there are more specified in detail in this 11:55  
9 paper. And this includes the ultrastructure 11:55  
10 analysis in more detail, the chromosome 11:55  
11 analysis, the tumors immortalized and the CFU-E 11:55  
12 assays. 11:55  
13 Q. Were you present at the presentation 11:55  
14 that occurred with respect to the abstract? 11:55  
15 A. No. 11:55  
16 Q. Why weren't you there? 11:56  
17 A. I was already back in Israel. I 11:56  
18 didn't think we both have to be there. 11:56  
19 Q. So you weren't there to obtain what 11:56  
20 Dr. Sherwood said at that presentation, correct? 11:56  
21 A. She discussed it with me. 11:56  
22 Q. Okay. 11:56  
23 But you weren't there to hear what 11:56  
24 she said? 11:56  
25 A. I was not. It was not necessary. 11:56

Shouval, Dr. Daniel

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1 Dr. Daniel Shouval - May 24, 2007

2 Q. So you don't know on the basis of 11:56  
3 having been what she said at the presentation, 11:56  
4 correct? 11:56

5 MR. DROZDOFF: Objection. 11:56

6 Q. Because you weren't there? 11:56

7 A. Well, I wasn't there, but I -- she 11:56  
8 discussed the presentation with me before. 11:56

9 Q. Directing your attention to 11:56  
10 Exhibit 2, and with respect to the line 11:56  
11 regarding the radioimmunoassay, do you see where 11:56  
12 it says, "As measured by radioimmunoassay 11:56  
13 increasing from 7 million of erythropoietin per 11:56  
14 ml." 11:57

15 Do you see that? 11:57

16 A. Yes. 11:57

17 Q. Now, reading your abstract in 1983, 11:57  
18 would the person of ordinary skill in the art 11:57  
19 have been able to understand what was meant with 11:57  
20 reference to units of erythropoietin as measured 11:57  
21 by radioimmunoassay? 11:57

22 MR. DROZDOFF: Objection. 11:57

23 Outside the scope of the report. 11:57

24 A. It meant that the cells produced 11:57  
25 erythropoietin and that it can be measured by 11:57

**Shouval, Dr. Daniel** **5/24/2007**  
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1           Dr. Daniel Shouval - May 24, 2007

2           radioimmunoassay, which has a standard curve.           11:57

3           And there was a reference which was a relative           11:57

4           reference which suggests how much -- I mean,           11:57

5           which gives you a semi-quantitative idea           11:57

6           regarding the units of EPO as decided at that           11:57

7           time by those who developed the assay.           11:57

8           Q.    So is it your view the person of           11:57

9           ordinary skill in the art would have understood           11:57

10          that language that I just pointed to?           11:57

11          A.    Easily.           11:57

12          MR. DROZDOFF: Objection.           11:57

13          Objection. Misstates --           11:57

14          Q.    Why easy, easily?           11:57

15          A.    Can you repeat the question?           11:58

16          Q.    Why would the person of ordinary           11:58

17          skill in the art have easily understood the           11:58

18          measure as measured by radioimmunoassay           11:58

19          increasing from 7 units of erythropoietin per ml           11:58

20          of cultured medium as of March of '83 when this           11:58

21          abstract became available?           11:58

22          MR. DROZDOFF: Objection.           11:58

23          Misstates the document. Outside the           11:58

24          scope of the expert report.           11:58

25          A.    I don't understand the question. It           11:58

Shouval, Dr. Daniel

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1 Dr. Daniel Shouval - May 24, 2007  
2 is so obvious, this sentence. 11:58  
3 Q. Your report -- your report attempts 11:58  
4 to say what the person of ordinary skill in the 11:58  
5 art would have thought -- 11:58  
6 A. Yes. 11:58  
7 Q. -- before October of '83. 11:58  
8 A. Yes. 11:58  
9 Q. Agreed? 11:58  
10 MR. DROZDOFF: Objection. 11:58  
11 Q. Yes? 11:58  
12 MR. DROZDOFF: Misstates -- 11:58  
13 Q. Do you agree? 11:58  
14 MR. DROZDOFF: Mischaracterizes. 11:58  
15 Q. Stay with me on this. 11:58  
16 A. I don't understand the question. 11:58  
17 Q. Does your report, Doctor, does your 11:58  
18 expert report attempt to state what you think 11:58  
19 the person of ordinary skill in the art would 11:58  
20 have thought before October of 1983? 11:58  
21 MR. DROZDOFF: Objection. Vague. 11:59  
22 A. I did it in the context of my expert 11:59  
23 report, my total expert report. 11:59  
24 Q. Correct? 11:59  
25 A. Yes. 11:59

Shouval, Dr. Daniel

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1 Dr. Daniel Shouval - May 24, 2007

2 Q. Now, I want, because in your expert 11:59

3 report you refer to Exhibit No. 2, don't you? 11:59

4 A. One of the things I refer to. 11:59

5 Q. Right. 11:59

6 A. This is just one of a number of 11:59

7 things. 11:59

8 Q. One of the things that a person in 11:59

9 the ordinary skill in the art would have known 11:59

10 about according to your report. 11:59

11 A. A number of documents. This is one 11:59

12 of them. 11:59

13 Q. You tell me if a person of ordinary 11:59

14 skill in the art in March of '83 when this 11:59

15 abstract became available, as measured by 11:59

16 radioimmunoassay increasing from 7 million units 11:59

17 of erythropoietin per ml of culture medium, you 11:59

18 tell me if they would have understood? 11:59

19 MR. DROZDOFF: Objection. You're 11:59

20 mischaracterizing the document. 11:59

21 MR. MADRID: I'm not. 11:59

22 MR. DROZDOFF: There is a 11:59

23 parenthetical after that. 11:59

24 MR. MADRID: I'm happy to read 11:59

25 that. 11:59



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1	Dr. Daniel Shouval - May 24, 2007	
2	MR. DROZDOFF: Let's read the	11:59
3	whole sentence.	12:00
4	Q. As measured by radioimmunoassay	12:00
5	increasing 7 million of erythropoietin per ml of	12:00
6	culture medium, open paren, 2.2 million units	12:00
7	per milligram of cells for the first passage to	12:00
8	23 million units per milliliter, and then I	12:00
9	think -- I can't make out that number.	12:00
10	A. 23.	12:00
11	Q. Well, there's 23 there. But then is	12:00
12	it 16.9 million units per ml of cells for the	12:00
13	33rd passage, is the best I can make that out.	12:00
14	I'm asking you whether a person of	12:00
15	ordinary skill in the art in March of '83 would	12:00
16	have easily understood what that language meant?	12:00
17	MR. DROZDOFF: And objection.	12:00
18	Calls for a legal conclusion. And	12:00
19	vague.	12:00
20	Q. Go ahead.	12:00
21	A. I think that it is self-explanatory.	12:00
22	It does not need any more. It is evident. It	12:01
23	is obvious, and I don't see what -- I don't	12:01
24	understand the question.	12:01
25	Q. So you agree with a person of	12:01

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1 Dr. Daniel Shouval - May 24, 2007  
2 ordinary skill in the art would have understood 12:01  
3 this language in March of 1983, yes or no? 12:01  
4 MR. DROZDOFF: Objection. Vague. 12:01  
5 Outside the scope of the report. 12:01  
6 A. Would have understood it in the 12:01  
7 context of the entire abstract, not as a single 12:01  
8 sentence. 12:01  
9 Q. But they would have understood it? 12:01  
10 A. Yes. 12:01  
11 MR. DROZDOFF: Objection. 12:01  
12 Q. Okay. 12:01  
13 Now, would they have understood the 12:01  
14 information I have read to you to indicate that 12:01  
15 the erythropoietin was biologically active? 12:01  
16 MR. DROZDOFF: Objection. Vague. 12:01  
17 And what information are you talking 12:01  
18 about? I will not let you mislead -- 12:01  
19 MR. MADRID: What I just read. 12:01  
20 MR. DROZDOFF: I will not have 12:02  
21 misleading questions put on the record. 12:02  
22 A. I would like to repeat what I have 12:02  
23 said before, that reading this abstract suggests 12:02  
24 that this erythropoietin was biologically 12:02  
25 active. 12:02

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1 Dr. Daniel Shouval - May 24, 2007

2 Q. Now, would the ordinary skilled 12:02

3 person as of March of '83 have had the ability 12:02

4 to repeat this radioimmunoassay that you 12:02

5 referred to here to confirm these results? 12:02

6 A. Yes. 12:02

7 MR. DROZDOFF: Objection. Excuse 12:02

8 me. Objection. Hypothetical. 12:02

9 Q. Would they have had all the reagents 12:02

10 they would need in order to practice this 12:02

11 radioimmunoassay in March of 1983? 12:02

12 MR. DROZDOFF: Objection. 12:02

13 A. I'm guessing. I don't know the 12:03

14 details, but the radioimmunoassay that time was 12:03

15 also performed at the NIH. NIH is a federal 12:03

16 organization that provides, with this respect, 12:03

17 assistance to a lot of laboratories interested 12:03

18 in specific methods or systems. And from what I 12:03

19 remember, those who were interested in 12:03

20 establishing such an assay could have been 12:03

21 supported by a particular laboratory, I don't 12:04

22 remember the name, at the NIH. 12:04

23 Q. Could the person of ordinary skill 12:04

24 in 1983, March of '83, reading this abstract, 12:04

25 conclude exclusively from the basis of the RIA 12:04

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1 Dr. Daniel Shouval - May 24, 2007  
2 result that's reported here in your Exhibit 12:04  
3 No. 2, could they have concluded exclusively 12:04  
4 from that information that the erythropoietin 12:04  
5 was biologically active? 12:04  
6 MR. DROZDOFF: Objection. 12:04  
7 Mischaracterizes the testimony. 12:04  
8 A. I repeat what I have said before. 12:04  
9 That you cannot isolate this particular sentence 12:04  
10 from the rest of the abstract. You have to look 12:04  
11 at it as one entity. And when you look at it, 12:04  
12 you can deduct that this erythropoietin was 12:04  
13 biologically active. 12:05  
14 Q. Could the RIA data taken alone tell 12:05  
15 you whether or not the erythropoietin was 12:05  
16 biologically active? 12:05  
17 MR. DROZDOFF: Objection. Asked 12:05  
18 and answered. 12:05  
19 Q. I'm trying to understand from a 12:05  
20 scientific standpoint what the limits are. 12:05  
21 A. I repeat what I said. 12:05  
22 Q. Of the methodology used here, RIA in 12:05  
23 terms of biological activity? 12:05  
24 MR. DROZDOFF: Objection. 12:05  
25 Outside the scope of the report and 12:05

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1 Dr. Daniel Shouval - May 24, 2007  
2 asked and answered. 12:05  
3 A. This is out of scope for this 12:05  
4 opinion. I mean, you cannot expect an abstract 12:05  
5 to go and explain the limits and neither the 12:05  
6 benefits. 12:05  
7 Q. Doctor -- Doctor, a radioimmunoassay 12:05  
8 is based on interaction with an antibody, 12:05  
9 correct? 12:05  
10 A. Competition, yes. 12:05  
11 Q. A competition. 12:05  
12 And there is antigenicity that's 12:05  
13 involved, correct? 12:06  
14 MR. DROZDOFF: Objection. Vague. 12:06  
15 Hypothetical. 12:06  
16 Q. Correct? 12:06  
17 A. Okay. 12:06  
18 Q. And the radioimmunoassay here made 12:06  
19 use of a polyclonal antibody, right? 12:06  
20 A. It doesn't say. 12:06  
21 Q. So you don't know whether or not the 12:06  
22 antibody that was used here, you don't know 12:06  
23 whether the antibody that was used here was 12:06  
24 monoclonal or polyclonal in Exhibit 2? 12:06  
25 MR. DROZDOFF: Objection. 12:06