

# **EXHIBIT 1**

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UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

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AMGEN INC. )

Plaintiff(s), )

VS ) Civil Action No.

) 05-12237 WGY

F.HOFFMANN-LA ROCHE, LTD. ) (This transcript contains Confidential  
a Swiss Company, ) BLA/IND information. Please treat the  
ROCHE DIAGNOSTICS GmbH, ) entire transcript in accordance with the  
a German Company and ) Amended Protective Order in this matter)  
HOFFMANN-LA ROCHE INC., )

a New Jersey Corporation )

Defendant(s). )

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DEPOSITION Of: RICHARD A. FLAVELL, Ph.D

DATE: June 26, 2007

HELD AT: Omni Hotel

Goffe Room

New Haven, Connecticut

Reporter: JENNY C. EBNER, RPR, LSR 00030.

BRANDON SMITH REPORTING SERVICES, LLC

44 Capitol Avenue

Hartford, CT. 06106

(860) 549-1850

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1 and so that is cumulative in what my opinion is.

2 Q How does Roche insert the DNA sequencing  
3 coding human EPO into itself?

4 MR. FLEMING: Objection;  
5 mischaracterizes his opinions, ambiguous  
6 as to term insert human EPO DNA,  
7 misstates the opinions in this report.

8 THE WITNESS: So, as I said, I  
9 described this completely in this report  
10 here. If you would like to refer to a  
11 particular paragraph.

12 BY MS. BAXLEY:

13 Q No, well, you just referred to a number  
14 of paragraphs --

15 A Uh-huh.

16 Q -- as to explain your opinion, and I am  
17 trying to understand from these paragraphs  
18 whether you can tell me what is the basis for  
19 your opinion that Roche does not transform or  
20 transfect with isolated DNA sequence in coding  
21 human EPO itself?

22 A I am sorry, you'll have to repeat that.

23 Q I am trying to understand the basis for  
24 your opinion that Roche does not transform or  
25 transfect with an isolated DNA in coding human

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1 THE WITNESS: I am not sure I

2 understand the question.

3 BY MS. BAXLEY:

4 Q I am asking you which of the four

5 methods that you -- would you -- you would agree

6 with me, wouldn't you, that Roche's cells have

7 EPO DNA inserted into it; is that correct?

8 MR. FLEMING: Objection; vague as to

9 EPO DNA, mischaracterizes the testimony,

10 calls for a legal conclusion.

11 THE WITNESS: Yes, I don't want -- I

12 am not quite sure what you mean by EPO

13 DNA. Do you want --

14 BY MS. BAXLEY:

15 Q Do you have any understanding as to

16 whether Roche uses CHO cells, Chinese hamster

17 ovary cells, to manufacture the epoetin beta

18 starting material used to make CERA?

19 MR. FLEMING: Objection; vague,

20 mischaracterizes the record,

21 mischaracterizes his opinions.

22 THE WITNESS: If we go to the right

23 part of the report I think we will find

24 the statement I make on that. If you

25 would like to go to that.

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1 cell; is that correct?

2 MR. FLEMING: Objection;  
3 mischaracterizes his testimony, his  
4 opinion is what it is, vague as to the  
5 term.

6 THE WITNESS: Well, what I just read  
7 was the DNA contents of the bacterial  
8 protoplasts are incorporated into the  
9 host cell. In the event that it is akin  
10 to a somatic cell hybridization the  
11 bacterial chromosome, and I think this  
12 is the relevant part for you, is  
13 transferred into the host cells and  
14 therefore there is a real possibility  
15 that some bacterial DNA sequences are  
16 incorporated into the transformed cells.

17 BY MS. BAXLEY:

18 Q Do you know whether Roche used bacterial  
19 protoplast fusion to introduce genetic material  
20 into their host cells?

21 MR. FLEMING: Objection; vague,  
22 beyond the scope of his expert report.

23 THE WITNESS: I don't think  
24 that's -- I actually asked that  
25 question, but as I sit here now, I don't

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1 recall exactly. It's beyond the scope  
2 of the report.

3 BY MS. BAXLEY:

4 Q So you have no opinion as to how Roche  
5 introduces its genetic material into its host  
6 cells?

7 MR. FLEMING: Objection;  
8 mischaracterizes his testimony. He says  
9 he doesn't recall, vague.

10 THE WITNESS: I don't recall. What  
11 I do recall is what they do not do which  
12 is what I described. I described  
13 several times now.

14 BY MS. BAXLEY:

15 Q In bacterial protoplast fusion is  
16 that -- let me represent to you that Roche  
17 actually uses bacterial protoplast fusion to  
18 introduce the EPO DNA in coding epoetin beta into  
19 its host cell. How does that EPO -- when it does  
20 that, does any human DNA, other than the DNA in  
21 coding the epoetin beta, get introduced into the  
22 host cell?

23 MR. FLEMING: Objection; assumes  
24 facts not in evidence, mischaracterizes  
25 the record.

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1 Q So, using the protoplast, bacterial  
2 protoplast fusion technique that you describe in  
3 paragraph 65, other than epoetin beta DNA, the  
4 DNA in coding epoetin beta, is any other human  
5 DNA introduced into Roche's host cells?

6 MR. FLEMING: Objection; assumes  
7 facts not in evidence, mischaracterizes  
8 the record because he doesn't, he  
9 never opined in paragraph 65 as Roche's  
10 process. He's never opined in paragraph  
11 65 as Roche's process. That is what you  
12 tried to interject into the question,  
13 and it's been asked and answered.

14 MS. BAXLEY: But Dr. Flavell,  
15 doesn't have a recollection as to how  
16 the DNA in coding epoetin beta is  
17 introduced in cells. I will represent  
18 to you that it is introduced by  
19 bacterial protoplast fusion.

20 MR. FLEMING: He doesn't have to  
21 accept your representations.

22 BY MS. BAXLEY:

23 Q So if -- assuming that that is how it is  
24 done, is any human DNA, other than the DNA in  
25 coding epoetin beta, introduced into the host

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1 cells?

2 A What I am --

3 MR. FLEMING: Objection; incomplete

4 hypothetical, mischaracterizes the

5 record, assumes facts not in evidence,

6 beyond the scope of his report.

7 THE WITNESS: So the problem is you,

8 I would be extremely surprised if you

9 know Roche's production processes. We

10 do not have the information here. I

11 certainly haven't got that information

12 in front of me. And I am not going to

13 respond to a speculative question. I

14 just don't know what the answer is.

15 BY MS. BAXLEY:

16 Q Okay. So then when you refer to Amgen's

17 process for introducing genetic material into the

18 host cell as described in Amgen's patent

19 specification. You describe that at paragraph 67

20 of your report. Is it your opinion that only EPO

21 DNA is introduced or described to be introduced

22 in the host cells by Dr. Lin?

23 MR. FLEMING: Objection.

24 THE WITNESS: What I am saying is

25 that --



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1 Q Dr. Flavell, paragraph 73 of your  
2 report, Flavell Exhibit 3, again you say --

3 A My third report.

4 Q Third report, Flavell Exhibit 3,  
5 paragraph 73. You say that Roche has not  
6 infringed claims one or two of the 868 patent  
7 because the cells Roche uses to create epoetin  
8 beta reagent are not, quote, transformed or  
9 transvected with an isolated DNA sequence in  
10 coding human epoetin, closed quote.

11 So Roche's cells, what type of DNA was  
12 used to transform or transfect Roche's cells?

13 MR. FLEMING: Objection.

14 Mischaracterizes the testimony;  
15 mischaracterizes his report; asked and  
16 answered.

17 THE WITNESS: I think you asked this  
18 question before lunch.

19 BY MS. BAXLEY:

20 Q And you said you didn't know how Roche  
21 transformed or transvected its cells; is that  
22 correct?

23 MR. FLEMING: Objection.

24 Mischaracterizes his testimony. He said  
25 he doesn't recall.

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1 And to that end what I am asking is:  
2 How does Roche introduce DNA sequence in coding  
3 human epoetin into their cells?

4 MR. FLEMING: Objection.  
5 Mischaracterizes his testimony;  
6 ambiguous as to introducing human  
7 epoetin; lacks foundation, if that is  
8 even done, and asked and answered.

9 BY MS. BAXLEY:

10 Q If you know.

11 A So, I don't know what they do. I don't  
12 remember -- I don't recall, as I sit here now.

13 The basic reason for this is that I have  
14 a vast volume of paperwork here. I don't have  
15 any material in front of me now that tells me or  
16 refreshes my memory of what they do.

17 Q Okay. So can I have you turn to Flavell  
18 Exhibit 2, which is your second report?

19 Specifically, if you can go to paragraph  
20 10 of that report -- sorry -- make sure I have  
21 the right one.

22 MR. FLEMING: Do you want Exhibit 2?

23 Exhibit 2 is the May 8 --

24 MS. BAXLEY: I think the one -- I am  
25 sorry. It is actually Flavell Exhibit