

# **EXHIBIT D**

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UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

--ooOoo--

AMGEN INC.,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	No. 05-CV-12237 WGY
	)	
F. HOFFMAN-LA ROCHE, LTD.,	)	
ROCHE DIAGNOSTICS, GmbH, and	)	
HOFFMAN-LA ROCHE, INC.,	)	
	)	
Defendants.	)	
_____	)	

Videotaped Deposition of  
RALPH BRADSHAW, Ph.D.  
TUESDAY, JUNE 19, 2007

(Contains Amgen Confidential and Roche Restricted  
Access Confidential Information BLA/IND Material  
Subject To Protective Order.) **REDACTED**

SHEILA CHASE & ASSOCIATES  
REPORTING ON BEHALF OF LIVENOTE WORLD SERVICE  
221 Main Street, Suite 1250  
San Francisco, CA 94105

Reported by:  
DIANA NOBRIGA, CSR, CRR  
LICENSE NO. 7071



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<p style="text-align: right;">Page 6</p> <p>1 VIDEOGRAPHER: Here begins the videotaped                  2 deposition of Ralph Bradshaw, tape one, Volume I, in the                  3 matter of Amgen, Inc. versus F. Hoffman-La Roche                  4 Limited, et al., in the United States District Court,                  5 District of Massachusetts, Case No. 05-12237 WGY.                  6 Today's date is June 19th, 2007 and the time on the                  7 video monitor is 9:06.                  8 The video operator today is Jake Krohn,                  9 representing LiveNote World Service, located at 221 Main                  10 Street, Suite 1250, San Francisco, California 94105,                  11 phone number 415 321-2300. The court reporter is Diane                  12 Nobriga of Sheila Chase, reporting on behalf of LiveNote                  13 World Service.                  14 Today's deposition is being taken on behalf of                  15 the defendant and is taking place at 221 Main Street,                  16 Suite 1250, San Francisco, California 94105.                  17 Counsel, please introduce yourselves and state                  18 whom you represent.                  19 MR. JAGOE: Christopher Jagoe from Kaye                  20 Scholer, representing the defendants.                  21 MS. CARTER: Krista Carter of Day Casebeer on                  22 behalf of Amgen and Dr. Bradshaw.                  23 VIDEOGRAPHER: Okay. You can swear the                  24 witness.                  25</p>	<p style="text-align: right;">Page 8</p> <p>1 this case, signed your first expert report in                  2 this case?)                  3 MR. JAGOE: Do you need clarification of that?                  4 MS. CARTER: Dr. Bradshaw is here as an                  5 independent expert. Day Casebeer represents Amgen.                  6 THE WITNESS: I'm trying to remember the                  7 chronology. My initial contact with this case was with                  8 Linda Baxley. At what point I also began to deal with                  9 counselor, I don't remember exactly. Sometime in the                  10 last two months, I would say.                  11 MR. JAGOE: Q. Did you make any arrangements                  12 with the Day Casebeer law firm where they would act as                  13 your attorneys during the pendency of this case?                  14 A. Day Casebeer contracted with me to be an                  15 expert witness in this case.                  16 Q. And are you acting as an expert on behalf of                  17 Amgen?                  18 MS. CARTER: Objection.                  19 THE WITNESS: I was contracted with Day                  20 Casebeer under the understanding that I am representing                  21 Amgen, yes.                  22 MR. JAGOE: Q. The testimony you are giving                  23 in this deposition is testimony on behalf of Amgen;                  24 correct?                  25 MS. CARTER: Objection; Dr. Bradshaw is an</p>
<p style="text-align: right;">Page 7</p> <p>1 RALPH BRADSHAW, Ph.D.,                  2 having been duly sworn, testified as follows:                  3 EXAMINATION BY MR. JAGOE                  4 MR. JAGOE: Q. Dr. Bradshaw, is Ms. Carter                  5 representing you today?                  6 A. Yes, she is.                  7 Q. Are you paying her for that representation?                  8 MS. CARTER: Objection.                  9 THE WITNESS: No, I'm not.                  10 MR. JAGOE: Q. When did you first understand                  11 that she was representing you?                  12 MS. CARTER: Objection; calls for a legal                  13 conclusion.                  14 THE WITNESS: I think about a month ago.                  15 MR. JAGOE: Q. Was that before you served                  16 your first expert report in this case, signed your first                  17 expert report in this case?                  18 MS. CARTER: Objection; I don't know that he                  19 understands the meaning of me representing him.                  20 THE WITNESS: Yes. Could you qualify the                  21 question.                  22 MR. JAGOE: What's the pending question that                  23 I'm qualifying?                  24 (Record read as follows: QUESTION: Was that                  25 before you served your first expert report in</p>	<p style="text-align: right;">Page 9</p> <p>1 independent expert.                  2 THE WITNESS: I'm giving an expert opinion                  3 based on the information that Day Casebeer asked me to                  4 opine on.                  5 MR. JAGOE: Q. And Day Casebeer is paying you                  6 to give the opinions that you're going to give; right?                  7 A. I'm being reimbursed for my services, yes.                  8 Q. You are being reimbursed by Day Casebeer; is                  9 that correct?                  10 A. Since I haven't been reimbursed, I'm not                  11 actually sure who is writing the checks.                  12 Q. You have an agreement with Day Casebeer that                  13 you will be reimbursed by them for giving your opinions                  14 in this case?                  15 MS. CARTER: Objection; he's not being                  16 reimbursed for his opinions. It's for his time.                  17 THE WITNESS: I'm being reimbursed for my time                  18 in this case, yes.                  19 MR. JAGOE: Q. By whom?                  20 A. Could you clarify the question, by whom?                  21 Q. By whom will you be reimbursed for the time                  22 spent giving opinions in this case?                  23 MS. CARTER: Asked and answered.                  24 THE WITNESS: I don't have any information who                  25 will write the actual check.</p>

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<p>1 MS. CARTER: Objection; outside the scope of                  2 his expert report.                  3 THE WITNESS: I just don't have an opinion.                  4 MR. JAGOE: Q. Do you agree with the                  5 statement that treatment of urinary EPO with phenol will                  6 reduce the number of branches of each of the asparagine                  7 type sugar chains?                  8 MS. CARTER: Objection; outside the scope of                  9 his expert report, incomplete hypothetical.                  10 THE WITNESS: I have no personal knowledge                  11 about that. I couldn't answer that question.                  12 MR. JAGOE: Q. Do you have any expert opinion                  13 about that?                  14 A. Beyond the scope of anything I've ever done.                  15 I may be an expert, but it doesn't mean I have done                  16 everything there is to do, including chemistry. And                  17 I've never used a phenol extraction to make a protein                  18 cell. I really have no idea whether phenol affects                  19 glycoproteins.                  20 Q. But you are offering an opinion about the                  21 Miyake procedure which used a phenol extraction method?                  22 A. The opinion I offered, I believe, if you check                  23 what I said, was that Dr. Goldwasser felt that's what                  24 phenol did.                  25 Q. Do you have an opinion whether phenol will</p>	<p>1 time. I can't give you a specific example of another                  2 application of this type.                  3 Q. So before forming your opinion that the                  4 statement in the Lin patent that a C4 column could be                  5 used to purify EPO, you never checked the prior art                  6 literature on the use of C4 columns to purify proteins?                  7 A. I didn't need to. C4 columns were used to                  8 purify proteins. Just because I can't cite you an                  9 example doesn't mean I'm not aware they were used.                  10 Q. Did you cite any articles in your expert                  11 report where a protein was purified by a C4 column?                  12 A. I don't believe I did, no.                  13 Q. Would you agree with the statement that prior                  14 to 1985 only a single reference is known to exist                  15 disclosing the elution of a protein with ethanol from a                  16 C4 column?                  17 MS. CARTER: Objection. Could you read the                  18 question again.                  19 MR. JAGOE: Can you read it, please.                  (Record read as follows: QUESTION: Would you                  20 agree with the statement that prior to 1985                  21 only a single reference is known to exist                  22 disclosing the elution of a protein with                  23 ethanol from a C4 column?)                  24 MS. CARTER: Objection; outside the scope of                  25</p>
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<p>1 cause a reduction in the number of branches of the                  2 asparagine type sugar chains on the erythropoietin?                  3 MS. CARTER: Objection; outside the scope of                  4 his expert report.                  5 THE WITNESS: I don't have any opinion at all.                  6 I'm not familiar with phenol and glycoprotein stability,                  7 so I don't know what the effect of phenol is on                  8 glycoprotein stability of N-linked glycosylation.                  9 MR. JAGOE: Q. So you don't know whether or                  10 not when someone applies the Miyake method they are                  11 actually changing the carbohydrate structure of the                  12 carbohydrates on erythropoietin?                  13 MS. CARTER: Objection; outside the scope of                  14 his expert report, asked and answered.                  15 THE WITNESS: I do not have any notion whether                  16 phenol changes glyco portions of N-linked carbohydrates                  17 on a protein if used in a purification procedure.                  18 MR. JAGOE: Q. Prior to 1984, prior to                  19 November 30th of 1984, are you aware of any literature                  20 references where a protein has been purified on a C4                  21 column using an ethanol gradient?                  22 A. I can't cite any personal experience. I never                  23 bothered to look in the literature. Whether or not that                  24 was done, C4 columns were certainly well known at this                  25 time, ethanol gradients were certainly known at this</p>	<p>1 the expert report and lacks foundation.                  2 THE WITNESS: I can't comment on the                  3 statement, because I have no knowledge to know whether                  4 the statement is true or not.                  5 MR. JAGOE: Q. You just submitted a                  6 declaration about the Lai '016 patent; right?                  7 A. Yes, that's correct.                  8 Q. Did you read the Lai '016 patent before you                  9 submitted the declaration?                  10 A. Yes, I did.                  11 Q. Did the Lai '016 patent say anything about the                  12 state of the art of eluting proteins from C4 columns                  13 with ethanol gradients?                  14 MS. CARTER: Objection. I don't think Dr.                  15 Bradshaw was required to memorize the materials he                  16 reviewed.                  17 THE WITNESS: I did not read the Lai patent                  18 with respect to the previous literature. He cites some                  19 previous literature, he cites the Lin patents. But I                  20 did not bother to read the backgrounds with respect to                  21 other possible applications of C4 prior to the Lai or                  22 Lin patents.                  23 MR. JAGOE: Q. So you formed the opinion that                  24 the Lai patent was a novel, nonobvious method, and you                  25 didn't review what prior art existed about purification</p>

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<p>1 of proteins?</p> <p>2 MS. CARTER: Objection; mischaracterizes his</p> <p>3 testimony.</p> <p>4 THE WITNESS: I did not review all the prior</p> <p>5 art for the Lai patent. But in my experience, the urea,</p> <p>6 acid urea treatment was unique. I did not do a</p> <p>7 literature search, but I had never encountered that</p> <p>8 before.</p> <p>9 Whereas, I certainly had encountered use of C4</p> <p>10 columns. We use C4 columns in my laboratory to purify</p> <p>11 proteins. Even though we may never have published it,</p> <p>12 we certainly did. So I was well familiar with C4</p> <p>13 columns.</p> <p>14 I was not familiar with a urea DEAE column, so</p> <p>15 in my opinion this was a novel step. I wasn't a patent</p> <p>16 examiner and I didn't look at the prior art.</p> <p>17 MR. JAGOE: Q. Did you read the discussion of</p> <p>18 the prior art in the Lai patent before you formed your</p> <p>19 opinion about its novelty or nonobviousness?</p> <p>20 A. I read it very briefly, yes.</p> <p>21 Q. Do you recall anything in there that you</p> <p>22 disagreed with?</p> <p>23 MS. CARTER: Objection. I don't think he can</p> <p>24 answer it without looking at the document.</p> <p>25 THE WITNESS: I would have to look at the Lai</p>	<p>1 pharmaceutical composition?</p> <p>2 MS. CARTER: Objection; outside the scope of</p> <p>3 his expert report.</p> <p>4 MR. JAGOE: Q. In 1985.</p> <p>5 A. Once again, that requires me to know something</p> <p>6 about a pharmaceutical composition. If I simply focus</p> <p>7 on your ability to get urinary EPO, based on the</p> <p>8 relative scarcity of starting material, the complexity</p> <p>9 of the Miyake procedure, the statement probably</p> <p>10 certainly has some validity, to the extent that the</p> <p>11 statement would have to be analyzed in the context for</p> <p>12 which it is written.</p> <p>13 Q. In the 1985 time frame, was it true that there</p> <p>14 continues to exist a need in the art for rapid and</p> <p>15 efficient preparatory procedures suitable for recovery</p> <p>16 of biologically active proteins from recombinant</p> <p>17 sources?</p> <p>18 MS. CARTER: Objection; outside the scope of</p> <p>19 his expert report.</p> <p>20 THE WITNESS: That's clearly somebody's</p> <p>21 assessment of a situation. And taken out of context,</p> <p>22 how could I possibly answer the question?</p> <p>23 Furthermore, it requires knowledge that I</p> <p>24 didn't have in 1985, nor do I have now with respect to</p> <p>25 preparing an economically viable erythropoietin</p>
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<p>1 patent before answering that question. If you want me</p> <p>2 to look at the Lai patent, I will be happy to do it.</p> <p>3 MR. JAGOE: Q. Would you agree with the</p> <p>4 statement that recovery procedures for erythropoietin</p> <p>5 from urinary fluid sources have generally been very</p> <p>6 complex, costly and labor intensive?</p> <p>7 MS. CARTER: Objection; outside the scope of</p> <p>8 his expert report, vague as to time.</p> <p>9 MR. JAGOE: Q. Prior to 1985.</p> <p>10 MS. CARTER: Incomplete hypothetical, that is</p> <p>11 taken out of context.</p> <p>12 THE WITNESS: It is a statement taken out of</p> <p>13 context.</p> <p>14 And things like efficiency and so forth all</p> <p>15 have to do relative to what it is you're trying to</p> <p>16 accomplish. I would have to know what that statement</p> <p>17 was in reference to and the context before I could tell</p> <p>18 whether I agreed with it or not. You've taken it out of</p> <p>19 context and I have no idea where it came from.</p> <p>20 MR. JAGOE: Q. But to make a pharmaceutical</p> <p>21 composition?</p> <p>22 MS. CARTER: What is the question?</p> <p>23 MR. JAGOE: Q. The procedures for isolating</p> <p>24 erythropoietin for urinary fluids is very complex,</p> <p>25 costly and labor intensive if you want to make it into a</p>	<p>1 pharmaceutical composition. And so I can't answer that</p> <p>2 question.</p> <p>3 MR. JAGOE: Q. Is it fair to say you don't</p> <p>4 know the state of the art of preparing pure preparations</p> <p>5 of human erythropoietin as of 1985?</p> <p>6 MS. CARTER: Objection; mischaracterizes his</p> <p>7 testimony.</p> <p>8 THE WITNESS: I have no idea what that</p> <p>9 question is supposed to mean, so you will have to</p> <p>10 rephrase it.</p> <p>11 MR. JAGOE: Q. Do you know what the state of</p> <p>12 the art was in terms of efforts to purify human</p> <p>13 erythropoietin from recombinant cells as of 1985?</p> <p>14 A. My knowledge of this is based on the Lin</p> <p>15 patents, and I have really no other information as of</p> <p>16 1985 for purifying recombinant erythropoietin from</p> <p>17 anybody else.</p> <p>18 MR. JAGOE: I will give you a copy of the</p> <p>19 Lai/Strickland patent.</p> <p>20 (Exhibit 4 marked for</p> <p>21 identification.)</p> <p>22 MR. JAGOE: Q. I would like you to look at</p> <p>23 Claim 10 of the '016 patent. Is Claim 10 something you</p> <p>24 are offering opinions about in your declaration that you</p> <p>25 submitted recently?</p>

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<p style="text-align: right;">Page 298</p> <p>1 expert reports are, just the two expert reports.  2 (Whereupon, at 5:40 p.m. the deposition of  3 RALPH BRADSHAW, Ph.D. was adjourned.)  4  5  6 I declare under penalty of perjury that the  7 foregoing is true and correct.  8  9  10  11  12 Dated: _____  13 RALPH BRADSHAW, Ph.D.  14  15  16  17  18  19  20  21  22  23  24  25</p>	
<p style="text-align: right;">Page 299</p> <p>1 STATE OF CALIFORNIA )  2 )  3 COUNTY OF ALAMEDA )  4 I, DIANA NOBRIGA, hereby certify that the  5 witness in the foregoing deposition was by me duly sworn  6 to testify to the truth, the whole truth, and nothing  7 but the truth in the within-entitled cause; that said  8 deposition was taken at the time and place therein  9 stated; that the testimony of said witness was reported  10 by me, a Certified Shorthand Reporter and disinterested  11 person, and was thereafter transcribed into typewriting,  12 and that the pertinent provisions of the applicable code  13 or rules of civil procedure relating to the notification  14 of the witness and counsel for the parties hereto of the  15 availability of the original transcript of the  16 deposition for reading, correcting and signing have been  17 met.  18 And I further certify that I am not of counsel  19 or attorney for either or any of the parties to said  20 deposition, nor in any way interested in the outcome of  21 the cause named in said action.  22 DATED: _____  23  24 _____  25 DIANA NOBRIGA, CSR NO. 7071</p>	