Document 567-3 Filed 06/29/2007

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### **EXHIBIT B**

Baxley Decl. in Support of Amgen's Opposition To Roche's Motion for Summary Judgment that Claim 1 Of '422 Patent is Invalid Under 35 USC S. 112

6/6/2007

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS
----X
AMGEN, INC.,

Plaintiff,

v.

Civil Action No. 05 Civ. 12237 WGY

F. HOFFMANN-LA ROCHE LTD., ROCHE DIAGNOSTICS GmbH, and HOFFMANN-LA ROCHE, INC.,

Defendants.

CONFIDENTIAL

DEPOSITION OF CAROLYN BERTOZZI, Ph.D.,

New York, New York

Wednesday, June 6, 2007

REPORTED BY: BARBARA R. ZELTMAN

Professional Shorthand Reporter

Job Number: 12691

6/6/2007

June 6, 2007 9:10 a.m. Deposition of CAROLYN BERTOZZI, Ph.D. taken by Plaintiff, pursuant to Notice, at the offices of DUANE MORRIS LLP, 380 Lexington Avenue, New York, New York, before BARBARA R. ZELTMAN, a Professional Shorthand Reporter and Notary Public within and for the State of New York. 

6/6/2007

1	
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3	
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21	ALSO PRESENT: Douglas Smith, Paralegal
22	Marcelo Rivera, Videographer
23	
24	
25	

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1	CAROLYN BERTOZZI, Ph.D CONFIDENTIAL	11:14:45
2	I have seen that.	11:14:47
3	Q So that would be yes, there	11:14:49
4	is erythropoietin protein which is not	11:14:50
5	a glycoprotein?	11:14:52
6	A It's referred to that way in	11:14:53
7	the literature.	11:15:01
8	In my mind these are molecules	11:15:02
9	and structures. And the terminology is	11:15:05
10	in the literature but all of these have	11:15:09
11	molecular structures.	11:15:12
12	You could ascribe any name to	11:15:13
13	those molecular structures. It's a	11:15:15
14	discrete structure and a discrete name.	11:15:21
15	Q I confess I am one of those	11:15:23
16	people who use "erythropoietin" or	11:15:25
17	"EPO" more as a noun than an adjective.	11:15:30
18	So you'll have to forgive me for that.	11:15:31
19	Can we agree that if I say	11:15:33
20	"erythropoietin" I am referring to the	11:15:35
21	erythropoietin protein irrespective of	11:15:40
22	its glycosylation state.	11:15:43
23	Is that acceptable to you?	11:15:45
24	A Okay.	11:15:46
25	So for you erythropoietin just	
		E.

1	CAROLYN BERTOZZI, Ph.D CONFIDENTIAL	11:15:50
2	equals linkages of amino acids? That's	11:15:55
3	your definition?	11:15:57
4	Q Irrespective whether it's	11:15:58
5	glycosylated or not.	11:16:00
6	So erythropoietin could be	11:16:02
7	glycosylated or non-glycosylated?	11:16:09
8	A So you are referring to many	11:16:10
9	structures using the same term?	11:16:12
10	Q Right. Is that okay with	11:16:13
11	you?	11:16:14
12	A Well, it's confusing.	11:16:19
13	Because they are different molecules,	11:16:21
14	but as long as I know what you are	11:16:23
15	referring to.	11:16:23
16	Q Okay.	11:16:24
17	If I use it in a way you don't	11:16:26
18	understand, please let me know and	11:16:29
19	let's clarify it right then and there.	11:16:35
20	What do you understand the	11:16:36
21	phrase "recombinant erythropoietin	11:16:41
22	protein" to mean?	11:16:43
23	A Erythropoietin protein?	11:16:45
24	Recombinant erythropoietin protein?	11:16:48
25	Q Yes.	

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1	CAROLYN BERTOZZI, Ph.D CONFIDENTIAL	11:16:50
2	A Well, "recombinant" is the	11:16:53
3	term that's used to describe basically	11:16:59
4	making artificial DNAs; for example,	11:17:07
5	taking DNA sequence from some source,	11:17:11
6	amplifying it from the source and	11:17:15
7	integrating it into a plasmid that can	11:17:20
8	then be introduced into a host cell to	11:17:25
9	drive the translational machinery or	11:17:31
10	transcriptional and translational	11:17:32
11	machinery of that cell.	11:17:36
12	So recombinant erythropoietin	11:17:39
13	protein would be the erythropoietin	11:17:43
14	protein that was produced by a cell	11:17:46
15	that had this recombinant DNA inserted	11:17:52
16	into that cell.	11:17:56
17	Q What do you understand the	11:17:57
18	phrase "urinary erythropoietin protein"	11:18:01
19	to mean?	11:18:07
20	A Again erythropoietin protein,	11:18:10
21	and I don't know that there is such a	11:18:11
22	thing in urine. Because when you say	11:18:17
23	"erythropoietin protein" you include	11:18:18
24	all the different glycosylated forms.	11:18:22
25	Q Right.	

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CAROLYN BERTOZZI, Ph.D CONFIDENTIAL	11:18:24
A So human urinary	11:18:29
erythropoietin protein in your	11:18:30
vernacular would be the collection of	11:18:34
molecules in the human urine that have	11:18:45
a common linkage of amino acids that	11:18:49
being encoded by the DNA.	11:18:55
Q Encoded by the erythropoietin	11:18:57
gene?	11:18:57
A The erythropoietin gene.	11:18:58
In other words, the linkage of	11:19:01
amino acids that's specified by the	11:19:05
sequence of the gene which in the case	11:19:08
of the human urinary erythropoietin	11:19:13
would not be a recombinant gene. It	11:19:15
would be the gene as it exists in the	11:19:21
human chromosomes.	11:19:29
Q Where in the body is human	11:19:31
urinary erythropoietin synthesized?	11:19:39
MR. HECKEL: Objection.	11:19:49
A I am not a physiologist;	11:19:50
preface with that.	11:19:55
But my understanding from	11:19:56
reading the literature is that all	11:20:00
human erythropoietin is originally	
	erythropoietin protein in your vernacular would be the collection of molecules in the human urine that have a common linkage of amino acids that being encoded by the DNA.  Q Encoded by the erythropoietin gene?  A The erythropoietin gene.  In other words, the linkage of amino acids that's specified by the sequence of the gene which in the case of the human urinary erythropoietin would not be a recombinant gene. It would be the gene as it exists in the human chromosomes.  Q Where in the body is human urinary erythropoietin synthesized?  MR. HECKEL: Objection.  A I am not a physiologist; preface with that.  But my understanding from reading the literature is that all

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1	CAROLYN BERTOZZI, Ph.D CONFIDENTIAL	11:20:07
2	produced in the kidney and some of that	11:20:15
3	material is released into the serum,	11:20:20
4	into the plasma of the blood, and then	11:20:27
5	eventually the material is processed	11:20:31
6	for excretion. So some subset appears	11:20:42
7	in the urine.	11:20:42
8	So my understanding is that	11:20:45
9	erythropoietin glycoproteins in the	11:20:50
10	urine would have prior to that	11:20:54
11	originated from blood and prior to that	11:21:00
12	from kidney.	11:21:02
13	I believe that's the order of	11:21:03
14	events that's proposed. And that's the	11:21:08
15	extent of my understanding of the	11:21:09
16	physiology.	11:21:11
17	Q So you are not an expert in	11:21:12
18	the physiology of erythropoietin?	11:21:15
19	MR. HECKEL: Objection.	11:21:17
20	A I am not an expert in the	11:21:21
21	pharmaco-dynamics, I should say, which	11:21:30
22	describes the sort of physiological	11:21:38
23	events by which molecules traffic from,	11:21:45
24	you know, kidney to other organs.	11:21:50
25	MR. LOEB: Sorry to interrupt	

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1	CAROLYN BERTOZZI, Ph.D CONFIDENTIAL	11:21:50
2	you. We need to change the tape.	11:21:52
3	So if we can go off the record,	11:21:55
4	please.	11:21:55
5	THE VIDEOGRAPHER: Time is	11:21:56
6	11:18 a.m. This completes Tape 1,	11:21:58
7	Volume 1 of the videotaped	11:22:00
8	deposition of Dr. Carolyn Bertozzi.	11:29:36
9	(A brief recess was	11:29:36
10	taken.)	11:29:37
11	THE VIDEOGRAPHER: Time is	11:29:37
12	11:26 a.m. This is Tape 2, Volume 1	11:29:41
13	of the continued videotaped	11:29:43
14	deposition of Dr. Carolyn Bertozzi.	11:29:46
15	Q Dr. Bertozzi, a moment ago	11:29:47
16	you gave me a definition of urinary	11:29:52
17	erythropoietin and you gave you a	11:29:53
18	definition of recombinant	11:29:54
19	erythropoietin.	11:29:56
20	You can assume going forward	11:29:57
21	that if I use those two phrases I'm	11:30:01
22	just adopting your definitions.	11:30:03
23	Is that okay?	11:30:05
24	A Can you read back my	11:30:05
25	definitions? Just want to make sure	

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CAROLINA DEDECATE DE CONSTRUMENTAT	05:43:18
CAROLYN BERTOZZI, Ph.D CONFIDENTIAL	05:43:18
THE VIDEOGRAPHER: Time is	05:43:20
5:39 p.m. This completes Tape 4,	05:43:24
Volume 1 of the videotaped	05:43:26
deposition of Dr. Carolyn Bertozzi.	
(The deposition was concluded	
at 5:39 p.m.)	
GAROLINA DEDEGGET DE D	
Subscribed and sworn	
to before me this	·
day of, 2007	
Notary Dublic	
Notary rubire	
	Volume 1 of the videotaped deposition of Dr. Carolyn Bertozzi.  (The deposition was concluded at 5:39 p.m.)  CAROLYN BERTOZZI, Ph.D.  Subscribed and sworn to before me this

6/6/2007

1	
2	STATE OF NEW YORK ) PAGE of
3	) ss: COUNTY OF NEW YORK )
4	I wish to make the following
5	changes, for the following reasons:
6	PAGE LINE
7	CHANGE:
8	REASON:
9	CHANGE:
10	REASON:
11	CHANGE:
12	REASON:
13	CHANGE:
14	REASON:
15	CHANGE:
16	REASON:
17	CHANGE:
18	REASON:
19	CHANGE:
20	REASON:
21	
22	Witness's signature Date
23	
24	
25	

				291
1				
2	CERTIFICATE STATE OF NEW YORK )			
3 4	: ss. COUNTY OF NEW YORK ) I, BARBARA R. ZELTMAN,			
5	Shorthand Reporter and Notary			
6	Public, within and for the State of			
7	New York, do hereby certify:			
8	That CAROLYN BERTOZZI, Ph.D.,			
9	the witness whose deposition is			
10	hereinbefore set forth, was duly	-	•	
11	sworn by me and that such deposition			
12	is a true record of the testimony			
13	given by the witness.			·
14	I further certify that I am			
15	not related to any of the parties			
16	to this action by blood or marriage,			
17	and that I am in no way interested			
18	in the outcome of this matter.			
19	IN WITNESS WHEREOF, I have			
20	hereunto set my hand this 8th day of			
21	June, 2007.			
22	206			
23				
24	BARBARA R. ZELTMAN Court Reporter and Notary Public			
25	court keporter and notary rubitc			