

US Patent and Trademark Office

Actavis, LLC v. Abraxis Bioscience, LLC

CONFIDENTIAL

Video Deposition of: Cory Berkland, Ph.D. November 30, 2017



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UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD

ACTAVIS LLC,

ABRAXIS BIOSCIENCE, LLC,

Patent Owner.

Case IPR2017-01101

Petitioner,

Case IPR2017-01103

Case IPR2017-01104

VIDEO DEPOSITION OF:

Cory J. Berkland, Ph.D.

November 30, 2017

Washington, DC

Lead: Andrew Chalson, Esquire Firm: Quinn Emanuel Urquhart

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Witness: Cory J. Berkland, Ph.D.

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ioia	VIS V. ADIANIS	1	Cory Bernand, Nov. 30, 2017
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1	VIDEO SPECIALIST: Here begins video	1	Apotex in two other proceedings involving the same
2	number 1, volume 1, in the deposition of Dr. Cory	2	patent; is that right?
3	Berkland, Ph.D., taken in the matter of Actavis LLC	3	A. Yes, that's my understanding.
4	v. Abraxis Bioscience LLC. Today's date is	4	Q. Are you represented by counsel today?
5	November 30th, 2017. The time on the video monitor	5	A. Yes. I believe that's correct.
6	is 8:19.	6	MR. KLEIN: Well, it's
7	This deposition is being taken at the office	7	A. I don't know the legal
8	of Winston & Strawn and was made at the request of	8	MR. KLEIN: We'll to the form.
9	representatives of the Patent Owner. I am Jason	9	I'm not sure we technically represent him.
10	Aqui, the videographer, and the court reporter is	10	Q. Do you know the answer to that,
11	Linda Kinkade from Jane Rose Reporting, New York,	11	Dr. Berkland?
12	New York.	12	A. It sounds like a legal argument. I don't
13	Counsel, please identify yourselves and	13	know.
14	state whom you represent.	14	Q. Okay. Do you know if you're represented
15	MR. CHALSON: Andrew Chalson from Quinn	15	by anyone else in the room today?
16	Emanuel on behalf of the Patent Owner. With me is	16	A. I don't know.
17	Daniel Wiesner, also from Quinn Emanuel; Chris	17	Q. You understand you're under oath?
18	Harnett from Jones Day; and Patrick Elsevier from	18	A. Yes, I do.
19	Celgene Corporation.	19	Q. Is there any reason you can't testify
20	MR. KLEIN: Chuck Klein with Winston &	20	truthfully and accurately?
21	Strawn for Actavis and the Petitioner, and with	21	A. No, there is not.
22	me is Sharon Lin.	22	Q. You've been deposed before, correct,
23	MR. PATEL: Anil Patel with K&L Gates for	23	Dr. Berkland?
24		24	A. Yes.
25	Cipla Limited. VIDEO SPECIALIST: Will the court	25	Q. About how many times?
			,
	Page 6		Page 8
1	reporter please swear in the witness.	1	A. I'd say around 15 probably.
2	CORY J. BERKLAND, Ph.D.,	2	Q. It's fair to say you understand the
3	having been first duly sworn, was	3	process?
4	thereafter examined and testified as follows:	4	A. Yes.
5	EXAMINATION	5	Q. Have you been deposed recently?
6	BY MR. CHALSON:	6	A. Yes, I think in the last six months.
7	Q. Good morning, Dr. Berkland.	7	Q. When was the most recent deposition you
8	A. Good morning.	8	did in a patent case?
9	Q. My name is Andrew Chalson. I'm here on	9	A. I think the most recent one, if I recall
10	behalf of the Patent Owner, and, as I'm sure you're	10	correctly, was an IPR proceeding on behalf of
11	aware, we're here to talk about patent products	11	Alkermes.
12	covering Abraxane. Do you understand that?	12	Q. Were you working with the Patent Owner or
13	A. Yes.	13	the challenger in that case?
14	Q. Can you state your full name and home	14	A. I was working with the Patent Owner.
15	address for the record?	15	Q. Was there a drug product at issue in that
16	A. Cory J. Berkland, 1117 East 1264 Road,	16	case?
17	Lawrence, Kansas 66047.	17	A. Yes.
18	Q. You're currently employed by the	18	Q. Do you recall which one?
19	University of Kansas?	19	A. Risperdal Consta.
20	A. That's correct.	20	Q. Do you know what dosage form that product
21	Q. Were you hired to participate in the	21	is?
22	matters that we're here for today by Actavis?	22	A. It's an injectable.
23	A. I was retained by counsel, but, yes, on	23	Q. Does it involve nanotechnology?
24	behalf of Actavis.	24	A. No.
25	O Varrana alas nataines de Cinda and	25	

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Q. You were also retained by Cipla and

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Q. I think you said you've been deposed



25

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1	about 50 times; is that right?	1	ANDA cases, but I I'm not positive.
2	MR. KLEIN: Fifty?	2	Q. Do you expect to provide trial testimony
3	A. Fifteen.	3	in this case?
4	Q. Fifteen. Of those 15, how many were	4	A. If called upon, I guess.
5	patent cases?	5	Q. You don't have an expectation one way or
6	A. I think all but one.	6	another sitting here today?
7	Q. Do you recall what the other one was	7	A. My experience has been a lot of these
8	about?	8	matters settle, so I don't know.
9	A. Yeah. Thanks for jogging my memory. So	9	Q. You understand that we're here today in
10	I have been deposed recently in a dispute between	10	connection with proceedings before the Patent
11	the University of Kansas and a former graduate	11	Office relating to the validity of patents relating
12	student.	12	to Abraxane?
13	Q. Not a patent case.	13	A. Yes.
14	A. Not a patent case.	14	Q. You're also involved in pending
15	Q. Other than the Risperdal case, have you	15	litigation in federal court between the same
16	been involved in any other IPRs?	16	parties regarding the same patents; is that right?
17	A. Perhaps. I can't remember.	17	A. I think that's correct, but
18	Q. Nothing comes to mind?	18	Q. Do you know whether or not you signed a
19	A. Nothing comes to mind. Sometimes I don't	19	declaration and your name was disclosed in
20	even know or understand if it's an IPR. I mean,	20	connection with the District Court litigation I
21	I'm asked for a legal I'm asked for an opinion	21	just referred to?
22	on a technical matter, and sometimes the	22	 A. I'll take your representation that that's
23	proceedings get twisted up in my mind whether it's	23	true.
24	an IPR or a patent dispute.	24	Q. You just don't have a specific
25	Q. Were the other patent cases that you were	25	recollection one way or the other today?
	Page 10		Page 12
1	involved in cases involving drug products?	1	A. I can't remember if that was signed early
2	A. Not always.	2	tal at 188
3		_	on and then the IPR representation was later. I
	Q. About how many times have you been or	3	on and then the IPR representation was later. I can't recall.
4	have you provided written opinion in a case		
	have you provided written opinion in a case involving a patent dispute?	3	can't recall. Q. What did you do to prepare for today's deposition?
4 5 6	have you provided written opinion in a case involving a patent dispute? A. Like a declaration or an expert report?	3 4 5 6	can't recall. Q. What did you do to prepare for today's deposition? MR. KLEIN: We caution the witness not to
4 5 6 7	have you provided written opinion in a case involving a patent dispute? A. Like a declaration or an expert report? Q. Any kind of written opinion.	3 4 5 6 7	can't recall. Q. What did you do to prepare for today's deposition? MR. KLEIN: We caution the witness not to reveal the contents of any communications with
4 5 6 7 8	have you provided written opinion in a case involving a patent dispute? A. Like a declaration or an expert report? Q. Any kind of written opinion. A. The number of cases would probably be a	3 4 5 6 7 8	can't recall. Q. What did you do to prepare for today's deposition? MR. KLEIN: We caution the witness not to reveal the contents of any communications with counsel.
4 5 6 7 8 9	have you provided written opinion in a case involving a patent dispute? A. Like a declaration or an expert report? Q. Any kind of written opinion. A. The number of cases would probably be a little fewer than 15 because there were times I was	3 4 5 6 7 8 9	can't recall. Q. What did you do to prepare for today's deposition? MR. KLEIN: We caution the witness not to reveal the contents of any communications with counsel. A. Sure. I arrived Tuesday, early in the
4 5 6 7 8 9	have you provided written opinion in a case involving a patent dispute? A. Like a declaration or an expert report? Q. Any kind of written opinion. A. The number of cases would probably be a little fewer than 15 because there were times I was retained and didn't provide a written opinion, and	3 4 5 6 7 8 9	can't recall. Q. What did you do to prepare for today's deposition? MR. KLEIN: We caution the witness not to reveal the contents of any communications with counsel. A. Sure. I arrived Tuesday, early in the morning, and spent the better half of Tuesday and
4 5 6 7 8 9 10	have you provided written opinion in a case involving a patent dispute? A. Like a declaration or an expert report? Q. Any kind of written opinion. A. The number of cases would probably be a little fewer than 15 because there were times I was retained and didn't provide a written opinion, and there were times I was retained and provided	3 4 5 6 7 8 9 10	can't recall. Q. What did you do to prepare for today's deposition? MR. KLEIN: We caution the witness not to reveal the contents of any communications with counsel. A. Sure. I arrived Tuesday, early in the morning, and spent the better half of Tuesday and yesterday preparing with counsel.
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4 5 6 7 8 9 10 11 12	have you provided written opinion in a case involving a patent dispute? A. Like a declaration or an expert report? Q. Any kind of written opinion. A. The number of cases would probably be a little fewer than 15 because there were times I was retained and didn't provide a written opinion, and there were times I was retained and provided multiple written opinions in a single case matter. Q. You're familiar with the Hatch-Waxman Act	3 4 5 6 7 8 9 10 11 12 13	can't recall. Q. What did you do to prepare for today's deposition? MR. KLEIN: We caution the witness not to reveal the contents of any communications with counsel. A. Sure. I arrived Tuesday, early in the morning, and spent the better half of Tuesday and yesterday preparing with counsel. Q. When you say "preparing with counsel," are you referring to Mr. Klein and Ms. Lin?
4 5 6 7 8 9 10 11 12 13 14	have you provided written opinion in a case involving a patent dispute? A. Like a declaration or an expert report? Q. Any kind of written opinion. A. The number of cases would probably be a little fewer than 15 because there were times I was retained and didn't provide a written opinion, and there were times I was retained and provided multiple written opinions in a single case matter. Q. You're familiar with the Hatch-Waxman Act generally?	3 4 5 6 7 8 9 10 11 12 13 14	can't recall. Q. What did you do to prepare for today's deposition? MR. KLEIN: We caution the witness not to reveal the contents of any communications with counsel. A. Sure. I arrived Tuesday, early in the morning, and spent the better half of Tuesday and yesterday preparing with counsel. Q. When you say "preparing with counsel," are you referring to Mr. Klein and Ms. Lin? A. Yes.
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4 5 6 7 8 9 10 11 12 13 14 15 16 17	have you provided written opinion in a case involving a patent dispute? A. Like a declaration or an expert report? Q. Any kind of written opinion. A. The number of cases would probably be a little fewer than 15 because there were times I was retained and didn't provide a written opinion, and there were times I was retained and provided multiple written opinions in a single case matter. Q. You're familiar with the Hatch-Waxman Act generally? A. Generally speaking. Q. Do you know what an Abbreviated New Drug Application is? A. Yes.	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	can't recall. Q. What did you do to prepare for today's deposition? MR. KLEIN: We caution the witness not to reveal the contents of any communications with counsel. A. Sure. I arrived Tuesday, early in the morning, and spent the better half of Tuesday and yesterday preparing with counsel. Q. When you say "preparing with counsel," are you referring to Mr. Klein and Ms. Lin? A. Yes. Q. Was anyone else present? A. I was joined by our third member here on the second day. We also had shared a video connection with counsel representing Apotex. I
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4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	have you provided written opinion in a case involving a patent dispute? A. Like a declaration or an expert report? Q. Any kind of written opinion. A. The number of cases would probably be a little fewer than 15 because there were times I was retained and didn't provide a written opinion, and there were times I was retained and provided multiple written opinions in a single case matter. Q. You're familiar with the Hatch-Waxman Act generally? A. Generally speaking. Q. Do you know what an Abbreviated New Drug Application is? A. Yes. Q. If I say an ANDA, you'll understand that's what I'm referring to? A. I will. Q. Have you ever testified at trial in an	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	can't recall. Q. What did you do to prepare for today's deposition? MR. KLEIN: We caution the witness not to reveal the contents of any communications with counsel. A. Sure. I arrived Tuesday, early in the morning, and spent the better half of Tuesday and yesterday preparing with counsel. Q. When you say "preparing with counsel," are you referring to Mr. Klein and Ms. Lin? A. Yes. Q. Was anyone else present? A. I was joined by our third member here on the second day. We also had shared a video connection with counsel representing Apotex. I think that's correct. Q. Do you recall specifically who the attorneys were for Apotex? A. No, I can't recall their names.
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	have you provided written opinion in a case involving a patent dispute? A. Like a declaration or an expert report? Q. Any kind of written opinion. A. The number of cases would probably be a little fewer than 15 because there were times I was retained and didn't provide a written opinion, and there were times I was retained and provided multiple written opinions in a single case matter. Q. You're familiar with the Hatch-Waxman Act generally? A. Generally speaking. Q. Do you know what an Abbreviated New Drug Application is? A. Yes. Q. If I say an ANDA, you'll understand that's what I'm referring to? A. I will. Q. Have you ever testified at trial in an ANDA case?	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	can't recall. Q. What did you do to prepare for today's deposition? MR. KLEIN: We caution the witness not to reveal the contents of any communications with counsel. A. Sure. I arrived Tuesday, early in the morning, and spent the better half of Tuesday and yesterday preparing with counsel. Q. When you say "preparing with counsel," are you referring to Mr. Klein and Ms. Lin? A. Yes. Q. Was anyone else present? A. I was joined by our third member here on the second day. We also had shared a video connection with counsel representing Apotex. I think that's correct. Q. Do you recall specifically who the attorneys were for Apotex? A. No, I can't recall their names. Q. Were there more than one person?
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	have you provided written opinion in a case involving a patent dispute? A. Like a declaration or an expert report? Q. Any kind of written opinion. A. The number of cases would probably be a little fewer than 15 because there were times I was retained and didn't provide a written opinion, and there were times I was retained and provided multiple written opinions in a single case matter. Q. You're familiar with the Hatch-Waxman Act generally? A. Generally speaking. Q. Do you know what an Abbreviated New Drug Application is? A. Yes. Q. If I say an ANDA, you'll understand that's what I'm referring to? A. I will. Q. Have you ever testified at trial in an	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	can't recall. Q. What did you do to prepare for today's deposition? MR. KLEIN: We caution the witness not to reveal the contents of any communications with counsel. A. Sure. I arrived Tuesday, early in the morning, and spent the better half of Tuesday and yesterday preparing with counsel. Q. When you say "preparing with counsel," are you referring to Mr. Klein and Ms. Lin? A. Yes. Q. Was anyone else present? A. I was joined by our third member here on the second day. We also had shared a video connection with counsel representing Apotex. I think that's correct. Q. Do you recall specifically who the attorneys were for Apotex? A. No, I can't recall their names.

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Actav	vis v. Abraxis	Cory Berkland, Nov. 30, 2017		
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1	A. A man and a woman. I'm sorry. I can't	1	MR. KLEIN: You can I'll object on	
2	recall their names.	2	work product grounds, but you can answer the	
3	Q. Did you talk to anyone else in	3	question generally.	
4	preparation for your deposition?	4	A. Yeah, I reviewed my declarations as well	
5	A. No.	5	as responses. I reviewed the exhibits associated	
6	Q. Do you know if there's any kind of joint	6	with those documents. I think that's about it.	
7	defense agreement or any other formal cooperation	7	Q. Did you review anything that was	
8	between Actavis and Apotex or Cipla?	8	exchanged by the parties or the Patent Office in	
9	MR. KLEIN: Objection, foundation.	9	this proceeding after you put your declaration in	
10	A. I don't even know what that means from a	10	back in April?	
11	legal perspective.	11	A. Are you are you asking if I reviewed	
12	Q. Fair enough. Who has engaged you in	12	any new material that wasn't part of the	
13	connection with any analysis you've done of the	13	declaration as filed?	
14	patents at issue in these proceedings?	14	Q. Yes.	
15	A. I was first engaged by Winston Strawn,	15	A. I can't recall.	
16	and then over the week and a half leading up to	16	Q. So, for example, you understand that	
17	this deposition was engaged by counsels	17	• • • •	
18		18	after you put your declaration in the Patent Owner	
	representing Apotex and Cipla or no I get the	19	put in a preliminary response in each of the four	
19	legal terms mixed up with the company, the		proceedings? Are you aware of that?	
20	pharmaceutical companies sometimes. Hopefully	20	A. Yes.	
21	that's correct.	21	Q. Did you review that preliminary response?	
22	Q. Sure. So not going to hold you to any	22	A. I think they were provided to me, if I	
23	specifics -	23	remember correctly, but I don't remember reading	
24	A. Okay.	24	them in detail.	
25	Q. – as to who retained you, but in terms	25	Q. And subsequent to that, the Patent Office	
	Page 14		Page 16	
1	of the companies, correct me if this is wrong, but	1	issued rulings in all four of the cases in which	
2	you were first retained by Actavis, right?	2	you put in declarations. Are you aware of that?	
3	A. Correct.	3	A. Yes.	
4	Q. Through counsel?	4	Q. Have you reviewed those four rulings from	
5	A. Yes.	5	the Patent Office?	
6	Q. And then you were subsequently retained	6	A. Again, I think they might have been	
7	by both Cipla and Apotex?	7	provided to me. Actually I recall them being	
8	A. That's correct.	8	provided to me except for maybe the 260. I don't	
9	Q. So sitting here today, you are currently	9	know if I saw that one or not since it wasn't	
10	retained by all three of those companies in	10	instituted, but I had the documents. I don't	
11	connection with analyzing the patents that we're	11	know that I read them certainly didn't read them	
12	here to talk about today.	12	in detail.	
13	A. That's my understanding.	13	Q. And that's true even including your	
14	Q. I think you said you were retained within	14	deposition prep over the last two days; you didn't	
15	the week or week and a half leading up to this	15	review the preliminary responses or the Patent	
16	deposition by Apotex and Cipla; is that right?	16	Office decisions in detail?	
17	A. Yeah. I can't recall when the latest	17	A. That's true.	
18	declarations were filed on behalf of Apotex and	18	Q. Let's just take a step back and talk	
19	Cipla, but it was roughly a week or so before those	19	generally about your education.	
20	Oipia, but it was roughly a week of so before those	20	yenerally about your education.	

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A. Yes.

documents?

Q. Understood. Did you review any documents

during preparation for your deposition?

Q. Do you recall reviewing any specific

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You have a Bachelor of Science in chemical

Q. Did any of your coursework leading up to

engineering from Iowa State in 1998; is that right?

A. I certainly was exposed to colloids in

that degree focus on nanotechnology?

A. That's correct.



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