Page 1

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATIENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC, PAR PHARMACEUTICALS, INC. and WOCKHARDT BIO AG,

Petitioners,

v.

JAZZ PHARMACEUTICALS, INC.,

Patent Owner

Case IPR2015-00554 Patent 7,668,730

Oral deposition of DR. JOSEPH DIPIRO, taken at the offices of Quinn Emanuel Urquhart & Sullivan, LLP, 51 Madison Avenue, 22nd Floor, New York, New York 10010, on Wednesday, February 3, 2016, at 9:35 a.m., before Anthony Armstrong, a Realtime Systems Administrator, Certified Realtime Reporter, Certified Court Reporter and Notary Public of the State of New York.

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2/3/2016

1 APPE AR ANCES: 1 JOSEPH DIPIRO, Pharmal.D., a witness, having 2 MADDOX EDWARDS, PLC 3 MR.RUEDY: For the resord, we're 1000 K Street, NW, Suite 725 3 MR.RUEDY: For the resord, we're 2 Provide Wenchew com 6 4 BY, MATTHEW, C.RUEDY, ESQ., (200830-0779) 6 546, 547, 551, 554, and the related 7 ARENT FOX, LLP 7 8 MR.STOPS: Shall we do 17 RY KICHARD J BERNAN, ESQ., (200857-6000 6 546, 547, 551, 554, and the related 7 ARENT FOX, LLP 8 MR.STOPS: Shall we do 11 BY: ERG STOPS, ESQ., (200847-6000 10 MR.STOPS: Stall we do 12 SI Madison Avenue, 22nd Floor 11 MR.STOPS: Shall we do 13 BY: ERG STOPS, ESQ., (212)849-7501 13 MR.RUEDY: Sure. 14 erisstops@quintennanuel.com 14 Evangeline Shik, also from Quinn Emanaceuticals 15 erisstops@quintennanuel.com 16 For representing Ameae Pharmaceuticals 15 MR.STOPS, ESQ., (212)849-7000 17 MR.BREANN: Rick Bernan from Arent 14 erisstops@quintennanuel.com 16 For representing Ameae Pharmaceuticals 15 MR.STOPS, ESQ., (212)849-7000 17 MR.BERNAN: Rick Bernan from Arent
MADDOX EDWARDS, PLLC 2 first been duly svore, testified as follows: 1 100 K Street NW, suite 725 2 MR, RUEDY: For the record, we're Mathington, DC 20006 4 MR, RUEDY: For the record, we're MATTHEW C, RUEDY, ESQ, 2 MR, RUEDY: For the record, we're Attorneys for Annuel Pharmaceuticals 6 546, 547, 548, 551, 554, and the related Attorneys for Annuel Pharmaceuticals 6 546, 547, 548, 551, 554, and the related 7 Attorneys for Annuel Pharmaceuticals 6 MR, STOPS: Shall we do 8 WY: RICHARD, HERMAN, ESQ, 9 MR, STOPS: Shall we do 9 INT'R Street, NW, 2015-0054, 9 MR, STOPS: Shall we do 11 MR, STOPS: Shall we do introductions? MR, STOPS: Shall we do 12 S1 Matison Avenue, 22nd Floor MR, STOPS: This is Eric Stops from 13 Quinn Emanuel, for the patent owner Jazz 9 14 ericstops @quinnenanuel.com 16 Eavangeline Shih, also form Quinn Emanuel. 15 Cl218/49-7561 16 MR, BERMAN: Rich Berman from Arent 16 ericstops @quinnenanuel.com 17 MR, BERMAN: Rich Berman from Arent 17 Stops # 20 22 22 18 Fox representing Annual Pharmaceuticals.
3 1900 K Street KW, Suite 725 3 MR. RUEDY: For the record, we're Washington, DC 20006 BY: MATTHEW C, RUEDY, ESQ., (20)8300779 4 here today for a deposition in a series of enter parties versive IPR Nos. 2015-05454, 546, 547, 548, 551, 554, and the related joined cases. Good morning. 7 ARENT FOX, LLP 7 introductions? 8 Washington, DC 2003(57, 6000 10 MR. RUEDY: Sure. 9 QU20357, 6000 10 MR. RUEDY: Sure. 10 Attorneys for Par Pharmaceuticals 11 MR. STOPS: Shall we do 11 QUINN EMANUEL URQUHART & SULLIVAN, LLP 13 MR. STOPS: This is thic Stops from 12 Attorneys for Par Pharmaceuticals 13 MR. RUEDY: Sure. 13 QUINN EMANUEL URQUHART & SULLIVAN, LLP 13 Pharmaceuticals and the witness. With me is 14 ericstops équintemanuel.com 16 Edwards representing Anneel Pharmaceutical. 15 MR. BERMAN: Rich Berman from Arent evangelineshih@quinnemanuel.com 16 Edwards representing Par Pharmaceutical. 15 DIRECT EXAMINATION 2 1 DIRECT EXAMINATION 20 Page 2 Page 4 16 EV H1B IT S 1 DIRECT EXAMINATION 17 NUMBER DESCRIPTION PAGE 2 Q. Could you p
4 BY: MATTHEW C. RUEDY, ESQ., (202)/S00779 1 here today for a deposition in a sense of (202)/S00779 5 minedy @meiplaw.com 5 enter parties review IPR Nos. 2015-00545, 546, 547, 548, 551, 554, and the related joined cases. Good morning. 6 ARENT FOX, LLP 7 1717 K Street, NW 8 MR. STOPS: Shall we do introductions? 9 Washingon, DC 2008 9 9 Y. RUCHARD, J. BERMAN, ESQ., (202)/S7-6000 9 9 SI Madion Avene, 2: 2016 9 10 MR. STOPS: Shall we do introductions? 9 11 MR. STOPS: Shall we do 9 12 QUINN FMANUEL URQUHART & SULLIVAN, ILP 13 13 Pharmaceuticals and the wintess. With me is Evangeline Shih, also from Quinn Emanuel. 14 14 erictstops@quinnemanuel.com 16 15 MR. RUEDY: Marthere Ruedy from Maddox 16 erictstops@quinnemanuel.com 16 17 RVE, BERMAN: Rich Bernan fron Arent evangelineshih@quinnemanuel.com 16 18 FURLSTOP, Shall we do 16 19 DIRECT EXAMINATION 17 20 Page 2 Page 4 1 INDEX 1 DIRECT EXAMINATION 21 page.) 22 22
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¹⁵ transcribing your verbal answers. So no head ¹⁶ nods, no yes, no shaking of the head, if that
¹⁶ nods, no yes, no shaking of the head, if that
17 works.
¹⁸ A. I may slip from time to time, but I
¹⁹ will do my best. I would not mind a reminder.
20 Q. Sure. If you don't understand one of
²¹ my questions, please ask for clarification. If
²² you do answer, that means that you understood the
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		1	
1	question. Okay?	1	was?
2	A. Yes.	2	A. The one that I referred to first
3	Q. And if you need a break at any time,	3	occurred about 10 years ago was Skelaxin.
4	just please let me know. All I ask is if there	4	Q. And then the other one?
5	is a question pending, that the question be	5	A. I don't recall.
6	answered prior to us taking a break.	6	Q. Was either one of those cases Elan v.
7	A. Sure.	7	Corepharma?
8	Q. Is there any reason that you cannot	8	A. That could be. That sounds right.
9	give full and complete answers today?	9	Q. And was that the Skelaxin case?
10	A. No.	10	A. I believe so. Again, it's I have
11	Q. Have you ever been deposed before?	11	not refreshed my memory on this, so it's going
12	A. Yes.	12	back 10 years.
13	Q. How many times?	13	Q. And then the second case, was that
14	A. Twice.	14	King Pharma versus Eon?
15	Q. What did each of those cases involve?	15	A. That sounds right, yes, to the best
16	A. The most recent was about three years	16	of my memory.
17	ago, and was a personal property dispute related	17	Q. And Quinn Emanuel was your counsel
18	to my family.	18	for that case, correct?
19	Q. And the second?	19	MR. STOPS: Objection. Foundation.
20	A. Was a approximately 10 years ago,	20	A. I was working with lawyers at Jones
21	with some followup in a year or two after, a	21	Day.
22	patent case that I was working with Jones Day	22	Q. Okay. How many cases have you worked
	Page 6		Page 8
1	from.	1	on how many patent cases have you worked with
2	Q. And do you remember the name of that	2	Jones Day on?
3	case?	3	A. So the only ones that I was involved
4	A. I remember some points about it, the	4	with so 10 years ago one involved report and
5	particular drug involved in the patent, and I	5	deposition with Skelaxin. Within the next year
6	probably couldn't recall all the parties involved	6	or two, there were followup reports; no further
7	in the litigation.	7	depositions. And then a couple of years prior to
8	Q. But from your general recollection,	8	that, a report with Jones Day. And those are the
9	what was the drug involved?	9	only ones related to patents that I have been
10	A. Skelaxin.	10	involved with.
11	Q. How many patent cases have you been	11	Q. Have you ever testified in a district
12	involved with?	12	court case?
13	A. I know so prior to that I was	13	A. I once provided testimony for a
14	involved in another report without deposition	14	malpractice case. I'm not sure what the
15	with Jones Day. It may have been a couple of	15	jurisdiction was. And this would have been
16	years earlier. And between that experience and	16	almost a decade ago.
17	the first one that I related to, I'm not clear	17	Q. But not a patent case?
18	how many patents were involved there. To my way	18	A. Not a patent case.
19	of thinking, there were two cases that I don't	19	Q. Are you represented by counsel today?
20	recall that they were related.	20	A. I'm working in conjunction with the
		1	73. Thi working in conjunction with the
21		21	legal counsel for Quinn Emanuel
21 22	Q. Okay. And in that second case with	21	legal counsel for Quinn Emanuel.
21 22		21 22	legal counsel for Quinn Emanuel. Q. What did you do to prepare for
	Q. Okay. And in that second case with		-

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1	today's deposition?	1	correct?
2	A. I worked in conjunction with legal	2	A. I'm not clear which documents you're
3	counsel to review the relevant documents that are	3	referring to.
4	cited in my statement and prepare the my	4	Q. I'm just referring to the
5	statement.	5	petitioner's on the IPRs. I'll submit to you
6	Q. So as far as preparing for today's	6	that each of these IPRs were filed initially by
7	deposition, did you meet with counsel?	7	Par Pharmaceutical and or Amneal pharmaceuticals
8	A. Yes.	8	LLC.
9	Q. Who did you meet with?	9	Just to make things easier, I'm
10	A. With the counsel that you see here,	10	referring to the entities that filed the IPRs as
11	and Frank Calvosa.	11	the petitioners, if that's okay with you.
12	Q. How many days did you meet?	12	A. Well, you know, I don't have an
13	A. Two days.	13	opinion about that because I'm not familiar with
14	Q. And you mentioned that you reviewed	14	the legal process, who files what.
15	documents to prepare for your deposition.	15	If you're asking me is that the way it
16	What did you review specifically?	16	happened
17	A. They're all stated in my and	17	Q. I'm just asking you so that we have
18	listed in my statement. It includes the ACA	18	an understanding of what I am referring to when I
19	materials and the patent documents and the	19	say petitioner. I'm referring to the parties
20	declaration of Dr. Valuck among those that I	20	that filed the IPRs in front of the patent
21	reviewed.	21	office. That's all.
22	Q. Okay. So referring to your expert	22	A. Okay. Yes.
	Page 10		Page 12
1	declarations, you submitted six of them for six	1	Q. So the six different patents in these
2	different inter partes reviews proceedings,	2	IPRs are owned by Jazz Pharmaceuticals, right?
3	correct?	3	A. That's my understanding.
4	A. Yes.	4	Q. And these six patents generally deal
5	Q. I'm just going to shortcut and say	5	with restricted drug distribution systems, right?
6	IPR, if that's okay with you, for inter partes	6	A. Yes.
7	review.	7	Q. Are you okay with that general
8	A. I know we have used that term, but	8	description? I'm not going to hold you to it
9	remind me what that acronym	9	necessarily, but I just want something that we
10	Q. Inter partes review?	10	can agree on that the patents generally cover.
11	A. Yes.	11	A. Yes.
12	Q. I'm just referring to the general	12	Q. Have you read each of the six
13	type of case that we're here for today, if that's	13	patents?
14	okay with your understanding.	14	A. Yes.
15	A. Right. I don't have a working	15	Q. Did you read the entirety of each of
16	definition of that term, but I thank you for the	16	them?
17	explanation.	17	A. Yes. And I recognize that much of
18	Q. Okay. It just saves me from having	18	that is the same or very similar from one to the
19	to repeat inter partes review.	19	next.
20	A. Sure.	20	Q. When were you first contacted about
21	Q. Each of these IPRs were filed either	21	this case?
22	by Par Pharmaceutical or Amneal Pharmaceuticals,	22	A. I don't recall the exact date, but it
	Page 11		Page 13

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1	may have been in October in the middle of the	1	Q. The subject matter of the patents,
2	fall this past year, 2015.	2	the restricted drug distribution system.
3	Q. Who contacted you?	3	A. Well, I relied on what was supplied
4	A. Would have been Angela Chi.	4	by counsel in terms of the materials that are
5	Q. When you were contacted about this	5	cited in my report. I did not obtain those
6	case, what were you asked to do?	6	independently.
7	MR. STOPS: Objection, to the extent	7	Q. So my question is, did you do any
8	the question calls for attorney/client	8	other research beyond the materials provided by
9	communications. Maybe there's a way you can	9	counsel?
10	ask that question without getting to	10	A. Minimal.
11	MR. RUEDY: I'm not looking for	11	Q. What do you mean by minimal?
12	protected information.	12	A. I spent a small amount of time
13	BY MR. RUEDY:	13	reading about Xyrem and the manufacturers'
14	Q. I'm just looking in general what were	14	restricted distribution system, the material that
15	you asked to do.	15	was on their website.
16	MR. STOPS: That question still may	16	Q. Was all the materials that you
17	call for attorney/client communications.	17	reviewed on the Xyrem website?
18	You can answer generally to the extent	18	MR. STOPS: Objection, form.
19	you can without revealing attorney/client	19	A. I'm trying to recall what I looked
20	compilations.	20	at. I really didn't spend a minimal amount of
21	THE WITNESS: Repeat the question.	21	time outside the documents that were provided,
22	MR. RUEDY: If you can read it back,	22	and so I do recall specifically that I looked up
	5 14		
	Page 14		Page 16
1	please.	1	about Xyrem to become more familiar with it and
2	(The record was read.)	2	redistricted distribution system. I don't recall
3	*****	3	spending time doing other types of research at
4	A. Well, I was asked if I would be	4	that point time. You've directed me to this
5	willing to provide an opinion about the case and	5	initial contact and that time period.
6	the issues at hand.	6	Q. When you say a minimal amount of
7	BY MR. RUEDY:	7	time, can you quantify that at all?
8	Q. After you were contacted, were you	8	A. Probably 30 minutes.
9	asked to do any research for this case?		
9	asked to do any research for this case?	9	Q. Prior to being contacted in this
10	A. So it depends on what you mean by	9 10	Q. Prior to being contacted in this case, had you heard of Xyrem previously?
	-		
10	A. So it depends on what you mean by	10	case, had you heard of Xyrem previously?
10 11	A. So it depends on what you mean by research. I would say yes, in that I then went	10 11	case, had you heard of Xyrem previously? A. I had heard of it, yes.
10 11 12	A. So it depends on what you mean by research. I would say yes, in that I then went through the relevant documents in the case to	10 11 12	case, had you heard of Xyrem previously?A. I had heard of it, yes.Q. In what capacity?
10 11 12 13	A. So it depends on what you mean by research. I would say yes, in that I then went through the relevant documents in the case to gain a better understanding of all the issues.	10 11 12 13	case, had you heard of Xyrem previously?A. I had heard of it, yes.Q. In what capacity?A. I don't recall from what source the
10 11 12 13 14	A. So it depends on what you mean by research. I would say yes, in that I then went through the relevant documents in the case to gain a better understanding of all the issues.Q. Did you do your own independent	10 11 12 13 14	case, had you heard of Xyrem previously?A. I had heard of it, yes.Q. In what capacity?A. I don't recall from what source the information came from. It may have been one of a
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10 11 12 13 14 15 16 17 18	A. So it depends on what you mean by research. I would say yes, in that I then went through the relevant documents in the case to gain a better understanding of all the issues.Q. Did you do your own independent literature search?A. I do literature searches for a lot of things all the time. So specifically for what purpose?	10 11 12 13 14 15 16 17 18	 case, had you heard of Xyrem previously? A. I had heard of it, yes. Q. In what capacity? A. I don't recall from what source the information came from. It may have been one of a number of news feeds that we routinely receive. So I don't recall where it came from, but I was aware of the name. Q. Do you recall when you first heard of
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10 11 12 13 14 15 16 17 18 19 20 21	 A. So it depends on what you mean by research. I would say yes, in that I then went through the relevant documents in the case to gain a better understanding of all the issues. Q. Did you do your own independent literature search? A. I do literature searches for a lot of things all the time. So specifically for what purpose? Q. I'm just asking generally if once you were contacted about this case whether you chose to research the subject matter on your own? 	10 11 12 13 14 15 16 17 18 19 20 21	 case, had you heard of Xyrem previously? A. I had heard of it, yes. Q. In what capacity? A. I don't recall from what source the information came from. It may have been one of a number of news feeds that we routinely receive. So I don't recall where it came from, but I was aware of the name. Q. Do you recall when you first heard of Xyrem? A. No. Q. Prior to being contacted in this

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