## US Patent and Trademark Office

Amneal Pharmaceuticals LLC and Par Pharmaceutical, Inc., v.
Jazz Pharmaceuticals, Inc.,

## **CONFIDENTIAL**

Deposition of: Robert Valuck, Ph.D., R.Ph. - Vol. 2 October 9, 2015



Page 223

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

AMNEAL PHARMACEUTICALS LLC AND PAR PHARMACEUTICAL, INC.,

Petitioners.

JAZZ PHARMACEUTICALS, INC.,

Patent Owner.

Case IPR2015-00546 Patent 7,765,106

**DEPOSITION OF** 

Robert Valuck, Ph.D., R.Ph. - Volume 2

October 9, 2015

Greenwood Village, Colorado

Lead: Eric Stops, Esquire

Firm: Quinn Emanuel

FINAL COPY - CONFIDENTIAL

JANE ROSE REPORTING 1-800-825-3341

Page 225

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Page 224

Page 226

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**TABLE OF CONTENTS** 

Witness:

Robert Valuck, Ph.D., R.Ph. - Volume 2

Examination

By Mr. Burgy.....Page 227 By Mr. Stops.....Page 314

Begin Confidential Portion......Page 232/Line 15 End Confidential Portion......Page 236/Line 2 Phone Conference with Board......Page 300 - 314

Reporter Certificate.....Page 345

Notice to Read and Sign.....Page 347

Index of Exhibits......Page 349

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	Da 207		Daga 220
	Page 227		Page 229
1	* * *	1	V7, 0 to 16 seconds. There and I believe there may
2	Greenwood Village, Colorado	2	be other instances there may be another one at page
3	9:29 a.m.	3	34 similarly.
4	* * *	4	The places I refer to that that particular
5		5	instance from the video, I believe it's should be
6	ROBERT VALUCK, Phd, RPh,	6	segment Video Segment 8 rather than Video Segment 7
7	having been previously sworn, was examined	7	that I was referring to.
8	and testified as follows:	8	Q. And how did you come about to learn that that
9	EXAMINATION	9	was an error in the citation?
10	BY MR. BURGY:	10	A. In in reviewing the rewatching the video
11	Q. Good morning, Dr. Valuck.	11	for prep myself the last couple of weeks. I rewatched
12	A. Good morning.	12	the video and reread this. And the videos submitted to
13	Q. Welcome back to day 2 of your deposition.	13	the as far as the backing up the references are in
14	As you know, my name is Aziz Burgy. I	14	little pieces. And reviewing them, looked at Video 7,
15	represent Par Pharmaceutical, Inc., in this matter. And	15	and it wasn't wasn't what I expected to be for that
16	I'm going to be questioning you on redirect on some of	16	step. It was really Video Segment 8 that I'm really
17	the topics that counsel, Mr. Eric Stops, asked you about	17	referring to.
18	yesterday.	18	So that's a typo in any instance. And those
19	Do you understand that?	19	are the two that I see from having looking back at
20	A. Yes.	20	this yesterday. Those are the two that I noticed. If
21	Q. Okay. And you understand that you're still	21	there's other instances where I refer to that entry
22	under oath today?	22	pharmacy staff receives and enters into a computer
23	A. Yes.	23	referring to Video Segment 7, any instance of that
24	Q. Before we get started today, I wanted to ask	24	should be 8. And I and those are the two that I know
25	you whether you had any discussions with counsel between	25	of. But if there's others, it would be the same
-			
	Page 228		Page 230
1	•	1	-
1 2	yesterday's cross-examination and today's redirect	1 2	correction.
1 2 3	yesterday's cross-examination and today's redirect questioning by me about your testimony today.		correction.  Q. Okay. So just so the record is clear, if
2	yesterday's cross-examination and today's redirect questioning by me about your testimony today.  A. No.	2	correction.  Q. Okay. So just so the record is clear, if you're citing PAR1006, V7 from time stamp 0 to 16
2	yesterday's cross-examination and today's redirect questioning by me about your testimony today.  A. No.  Q. And did you do anything to prepare for your	2 3	correction.  Q. Okay. So just so the record is clear, if you're citing PAR1006, V7 from time stamp 0 to 16 seconds, that citation should be changed to Video 8 for
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2 3 4 5 6	yesterday's cross-examination and today's redirect questioning by me about your testimony today.  A. No.  Q. And did you do anything to prepare for your deposition testimony today?  A. No.  Q. Counsel yesterday asked you about your	2 3 4 5 6	correction.  Q. Okay. So just so the record is clear, if you're citing PAR1006, V7 from time stamp 0 to 16 seconds, that citation should be changed to Video 8 for all applicable citations for all your declarations?  A. Yes.  Q. Okay.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	yesterday's cross-examination and today's redirect questioning by me about your testimony today.  A. No.  Q. And did you do anything to prepare for your deposition testimony today?  A. No.  Q. Counsel yesterday asked you about your declarations that you submitted in the IPR proceedings that are related to the Jazz patents. Do you recall that?  A. Yes.  Q. Okay. Do you have any corrections to make to your declarations that you know of? And there are several declarations from yesterday, so feel free to take a look.  A. If you don't mind. There's one thing that I believe is a typo. As we were looking at the '730 declaration yesterday, we were talking about  Q. Can you tell me what page you're on?  A. Yes. I'm talking about page 40. There's an instance in the claim chart that refers to the the video and transcript. And I refer in the middle of that	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	correction.  Q. Okay. So just so the record is clear, if you're citing PAR1006, V7 from time stamp 0 to 16 seconds, that citation should be changed to Video 8 for all applicable citations for all your declarations?  A. Yes.  Q. Okay.  A. That's the only one that I that I noticed as a as a correction for my declarations.  Q. Okay. Let's move on, Dr. Valuck.  Counsel asked you yesterday whether you have been paid for your work on the six IPR declarations that are the subject of the deposition. Do you recall that?  A. Yes.  Q. You testified that you have not been compensated for your work.  A. Yes.  Q. And why have you not been compensated for your work?  A. I just haven't submitted invoices yet.  Q. Are Par Pharmaceutical, Inc., and Amneal aware that you have not submitted any invoices for your work

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<b>~</b> !!!!!	ear and r ar v. Jazz		Nobelt values, Fil.D., N.I II Vol.
	Page 231		Page 233
1	in prior to the deposition I made them aware of that.	1	A. By Par Pharmaceutical, Inc.
2	Q. (By Mr. Burgy) And why had you not why have	2	Q. Okay. And with respect to PAR 1042, you
3	you not submitted invoices yet?	3	testified that these are the engagement letters that
4	A. I just hadn't gotten around to it yet.	4	encompass your work regarding the IPRs in this case?
5	Q. So the client should expect a pretty hefty bill	5	A. Yes.
6	from you at some point.	6	Q. And is this document this engagement letter
7	A. Yeah, I suppose that may may cause a little	7	at PAR 1042 specific to any of the specific Jazz
8	bit of angst for accounting maybe. But I just hadn't	8	patents?
9	I just hadn't done it yet and will be doing so.	9	A. Yes.
10	(Par Exhibit Numbers 1042, 1043, and 1044 were	10	Q. Which? And which patents are those?
11	marked.)	11	A. This is specific to the '059 patent and the
12	Q. Dr. Valuck, I've handed you three documents	12	'988 patent.
13	that have been marked as Exhibits PAR 1042, 1043, and	13	Q. Okay. Let's move on to the next document,
14	1044. Do you see that?	14	which is PAR 1043. Are you there, sir?
15	MR. STOPS: Which one is which?	15	A. Yes.
16	MR. BURGY: Sorry. And I was just going to get	16	Q. And briefly, what is this document?
17	to that.	17	A. This, similarly, is another retainer agreement
18	MR. STOPS: Sorry.	18	letter between law firms and myself related to some of
19	Q. (By Mr. Burgy) So Xyrem the document that	19	the IPR work that I've done here.
20	has the Bates Number Xyrem IPR 1 through 4 is has	20	Q. And who are the retaining parties?
21	been marked PAR 1042. And Xyrem IPR 5 through 8 has	21	A. Here it's Amneal Pharmaceuticals, LLC, and Par
22	been marked PAR 1043. And Xyrem IPR 9 through 11 has	22	Pharmaceutical, Inc. Hang on. There's a typo. This
23	been marked 1044.	23	one
24	Can you please confirm that that is correct on	24	Q. Where is that?
25	the documents that you have before you.	25	A. The first line. It says "Amneal
	Page 232		Page 234
1	A. Yes.	1	Pharmaceuticals, LLC (Amneal) and Par Pharmaceutical
2	Q. Do you recognize these three documents,	2	(Par)," which should be "Par Pharmaceutical, Inc.
3	Dr. Valuck?	3	(Par)"
4	A. Yes, I do.	4	Q. Oh, okay. Thank you.
5	Q. And what are these three documents?	5	A "collectively have authorized" and such.
6	A. These are the retainer agreement letters	6	Q. Okay. And so Amneal and Par are the retaining
7	between the law firm or firms and myself related to	7	parties; is that correct?
8	these six IPRs that I prepared in this matter.	8	A. Yes.
9	Q. And if we could take the first one, PAR 1042.	9	Q. And this engagement letter pertains to which
10	Do you see that?	10	Jazz patent?
11	A. Yes.	11	A. This letter specifically pertains to the '730
12	MR. BURGY: And just for the record, I'd like	12	patent.
13	to designate this portion of the transcript as	13	Q. All right. And this letter encompasses your
14	confidential under the protective order.	14	work with respect to the IPR declarations that you've
15	(The following portion is designated	15	submitted with respect to the '730 patent; is that
16	confidential.)	16	correct?
17	Q. (By Mr. Burgy) Dr. Valuck, do you see in the	17	MR. STOPS: Objection. Form.
18	first sentence it says Par Pharmaceutical, Inc., the	18	A. Yes.
19	retaining party, has authorized you to retain has	19	Q. (By Mr. Burgy) If we can move on to the last
20	authorized us to retain you to provide consulting and	20	document, which is PAR 1044. Do you see that?
21	expert witness services to Arent Fox on behalf of the	21	A. Yes.
22	retaining party? Do you see that?	22	Q. And what is this document?
23	A. Yes.	23	A. Similarly, this is a retainer agreement letter
24	Q. And so who are you retained by with respect to	24	between law firms and myself related to some of the IPR
25	these IDDs?	25	declarations that I've prepared for this matter

these IPRs?

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25

declarations that I've prepared for this matter.

25

Page 235 Page 237 1 Q. And who are the retaining parties? 1 PhD degree is doctor of philosophy in pharmacy. It's 2 2 A. On this letter, the retaining parties are also in the field. It's an advanced degree beyond 3 Amneal Pharmaceuticals (Amneal) and Par Pharmaceutical, 3 the -- what we call the entry-level practice degree. 4 Inc. -- same -- sorry -- same typo --4 And the entry-level practice degrees are either 5 5 Q. Okay. a bachelor's degree in pharmacy or a PharmD degree. 6 A. -- as on the last letter. The first one should 6 Those two degrees -- one of them is a requirement for 7 7 be Par Pharmaceutical, Inc., in the first line. And practice and licensure. Master's and PhD degrees are 8 8 between Sterne, Kessler, Goldstein & Fox -- Locke Lord additional training in research and different aspects of 9 9 is a typo as well. Locke Lord is not involved in this pharmacy, specific aspects. 10 10 one. A PharmD degree is advanced training in certain 11 Q. Okay. 11 aspects, clinical aspects. Each is advanced training A. It's just Sterne, Kessler, Goldstein & Fox and 12 12 beyond the entry-level training. It's a very -- it's a 13 13 small thing. But doctor of pharmacy versus doctorate in Arent Fox. 14 Q. And what patents does this engagement letter 14 pharmacy, there are slight differences but both of those 15 refer to? 15 exist. So it can be confusing to someone who doesn't 16 16 A. And this letter refers to the '182 patent, the know those various degrees exist. 17 '106 patent, and the '107 patent. 17 Q. Do you consider yourself to be a person of 18 ordinary skill in the art with respect to this case? 18 Q. And does this engagement letter encompass your work with respect to the IPR declarations that you've 19 19 A. Yes. 20 submitted with respect to the '182, '106, and '107 20 Q. How so? 21 21 A. I have a -- what I believe a POSA would have, patents? 22 MR. STOPS: Objection. Form. 22 is one of the entry-level practice degrees in pharmacy 23 23 A. Yes, it does. as -- one version. So I have a bachelor's degree in 24 24 Q. (By Mr. Burgy) Okay. You can put that aside. pharmacy. I have three to five years of work 25 MR. BURGY: And we can go off the confidential 25 experience. I have experience in a variety of practice Page 236 Page 238 1 settings. So I consider myself a POSA. 1 record. 2 2 Q. I'd like to turn to your declaration with (End of confidential portion.) 3 respect to the '730 patent. You have a pile of exhibits 3 Q. (By Mr. Burgy) Dr. Valuck, yesterday you --4 that we used yesterday. If you could pull that up. 4 5 Yesterday counsel asked you about a person of 5 A. Yes. 6 ordinary skill in the art. Do you recall that? 6 Q. Do you have that? 7 7 A. Yes. A. Yes. 8 Q. And specifically counsel asked you about the 8 Q. Do you recall that Jazz's counsel asked you 9 qualifications related to a person of ordinary skill in 9 about your expertise in this case yesterday? Do you recall that? 10 the art? 10 11 11 A. Yes. A. Yes. 12 Q. And specifically you testified that a PharmD 12 Q. And, specifically, if you would turn to page 6 13 was the only doctor of pharmacy degree, I believe is 13 of your declaration at paragraph 9. Do you see that? 14 what you said. Do you recall that? 14 A. Yes. 15 Q. I'm at the second sentence at paragraph 9 where 15 A. Yes. 16 Q. What educational background do you have in 16 you state, "I am an expert in the fields of drug safety, 17 17 drug abuse prevention, and prescription drug 18 18 A. I have a bachelor's degree in pharmacy, a distribution." 19 master's degree in pharmacy, and a PhD degree in 19 Do you see that? 20 20 A. Yes. Q. How is a PhD in pharmacy different from a 21 Q. If we could take each of these in turn. What 21 22 22 PharmD, if any? is the basis of your expertise in drug safety? 23 23 A. They're -- they're both doctorate degrees, but A. Well, it comes from a variety of different 24 it -- the doctor of pharmacy degree is a very specific 24 areas. I have specific education and training. I have



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degree. The PharmD is called doctor of pharmacy. The

work experience. I have research experience. I have

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