

*US Patent and Trademark Office*

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

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***Deposition of:*  
Robert Valuck, Ph.D., R.Ph. - Vol. 1  
October 8, 2015**

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UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE PATENT TRIAL AND APPEAL BOARD  
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AMNEAL PHARMACEUTICALS LLC  
AND PAR PHARMACEUTICAL, INC.,

Petitioners,

v.  
JAZZ PHARMACEUTICALS, INC.,

Patent Owner.

Case IPR2015-00546  
Patent 7,765,106  
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DEPOSITION OF  
Robert Valuck, Ph.D., R.Ph. - Volume 1  
October 8, 2015  
Greenwood Village, Colorado  
Lead: Eric Stops, Esquire  
Firm: Quinn Emanuel

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APPEARANCES

ATTORNEY FOR PETITIONER AMNEAL  
Matthew C. Ruedy, Esquire  
MADDOX EDWARDS, PLLC  
1900 K Street, NW - Suite 725  
Washington, DC 20006  
202-830-0779  
mruedy@meiplaw.com

ATTORNEYS FOR PETITIONER PAR  
PHARMACEUTICAL, INC., AND THE  
WITNESS  
Aziz Burgy, Esquire  
Bradford C. Frese, Esquire  
ARENT FOX LLP  
1717 K Street, NW  
Washington, DC 20006-5344  
202-857-6000  
aziz.burgy@arentfox.com  
bradford.frese@arentfox.com

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ATTORNEYS FOR THE PATENT OWNER  
Eric Stops, Esquire  
Frank C. Calvosa, Esquire  
QUINN EMANUEL  
51 Madison Avenue, 22nd Floor  
New York, New York 10010  
212-849-7000  
ericstops@quinnemanuel.com  
frankcalvosa@quinnemanuel.com  
- and -  
John V. Biernacki, Esquire  
JONES DAY  
901 Lakeside Avenue  
Cleveland, Ohio 44114  
216-586-3939  
jvbiernacki@jonesday.com

ALSO PRESENT  
David Silverstein, Par Pharmaceutical

JANE ROSE REPORTING  
74 Fifth Avenue  
New York, New York 10011  
1-800-825-3341  
Margie Dauster, Court Reporter

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1                   \*   \*   \*  
2                   Greenwood Village, Colorado  
3                   8:58 a.m.  
4                   \*   \*   \*

5

6                   MR. STOPS: So this is Eric Stops for Jazz.  
7 For the record, I guess, do you guys want to introduce  
8 yourselves first?  
9                   MR. BURGY: Sure. Sure. My name is Aziz  
10 Burgy, I'm from the law firm of Arent Fox, and I  
11 represent Par Pharmaceutical, Inc., in this matter and  
12 also representing the witness here.  
13                   MR. FRESE: My name is Bradford Frese. I'm  
14 also from the firm of Arent Fox, and I also represent  
15 Par Pharmaceutical, Inc., in this matter and the  
16 witness.  
17                   MR. RUEDY: Matt Ruedy representing Amneal, and  
18 I also represent the witness in this proceeding.  
19                   MR. SILVERSTEIN: David Silverstein, in-house  
20 counsel at Par Pharmaceutical, Inc.  
21                   MR. STOPS: And for the record, also, with me  
22 for Jazz is Frank Calvosa from Quinn Emanuel and John  
23 Biernacki from Jones Day.  
24                   And for the record, this deposition is being  
25 taken regarding Dr. Valuck's declarations in several

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1 IPRs. The numbers are IPR-2015-545, -546, -547, -548,  
2 -551, and -554.  
3                   This deposition also applies to several IPRs  
4 that are in the process of being joined. Those numbers  
5 are 2015-1810, -1813, -1814, -1815, -1816, -1817, -1818,  
6 and -1820.  
7                   And we've discussed these multiple IPRs being  
8 addressed simultaneously with counsel for Par and  
9 Amneal, and they have consented.  
10                   MR. BURGY: That's fine. This is Aziz Burgy.  
11 And we've also discussed the issue of objections for  
12 this deposition. I will be making the primary  
13 objections on behalf of both Par and Amneal. Certainly,  
14 if I miss an objection and my colleague, Mr. Ruedy,  
15 wants to interject an objection, he's free to do so. I  
16 assume you guys have no objections to that, Eric.  
17                   MR. STOPS: Correct.  
18                   MR. BURGY: Great. Thank you.  
19 ROBERT VALUCK, PhD, RPH,  
20                   having been duly sworn, was examined  
21                   and testified as follows:  
22 EXAMINATION  
23 BY MR. STOPS:  
24                   **Q. Good morning again, Dr. Valuck.**  
25                   A. Good morning.

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1                   **Q. Would you please state your full name for the**  
2 **record and your home address.**  
3                   A. Yes. My name is Robert James Valuck. Last  
4 name is spelled V-a-l-u-c-k. My home address is  
5 7059 South Magnolia Circle, Centennial, Colorado 80112.  
6                   **Q. And just a few instructions before we get**  
7 **started. I need your answers orally. The court**  
8 **reporter cannot record nods of your head. Do you**  
9 **understand?**  
10                   A. Yes.  
11                   **Q. If you don't understand a question, I need you**  
12 **to ask for clarification before you answer. If you do**  
13 **answer, that means you understood the question. Is that**  
14 **okay?**  
15                   A. Yes.  
16                   **Q. And are you represented by counsel today?**  
17                   A. Yes, I am.  
18                   **Q. Who is representing you?**  
19                   A. Both Mr. Burgy, Mr. Frese, and Mr. Ruedy.  
20                   **Q. How many times have you been deposed?**  
21                   A. I don't know the exact number.  
22                   **Q. Approximately.**  
23                   A. Approximately half a dozen times.  
24                   **Q. Have you been deposed in any patent cases**  
25 **before?**

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1                   A. No, I have not.  
2                   **Q. Do you have any patents in your name?**  
3                   A. No, I do not.  
4                   **Q. You've filed a patent application; correct?**  
5                   A. I was associated with the filing of a patent  
6 application.  
7                   **Q. What do you mean by "associated"?**  
8                   A. It was filed by another -- another individual.  
9                   **Q. You were a named vendor on that application,**  
10 **though?**  
11                   A. I believe so, yes.  
12                   **Q. Okay.**  
13                   A. I don't recall the -- the paper. I don't have  
14 that with me.  
15                   **Q. Do you know what that patent application was**  
16 **for?**  
17                   A. I would have to review that -- that  
18 application.  
19                   **Q. You don't remember the subject matter of the**  
20 **application?**  
21                   A. Only generally. Again, I don't have the  
22 application with me, so I don't have the --  
23                   **Q. What's your general recollection?**  
24                   MR. BURGY: Objection. Relevance.  
25                   A. Yeah, I was not asked to opine on it for this

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1 matter, so I don't have any recollection or opinion  
2 about it at this time.  
3 **Q. (By Mr. Stops) It was not about restricted**  
4 **distribution systems --**  
5 MR. BURG: Same --  
6 **Q. (By Mr. Stops) -- is that correct?**  
7 MR. BURG: I'm sorry. Same objection.  
8 A. Again, I don't have any opinion on it at this  
9 time. No recollection.  
10 **Q. (By Mr. Stops) Okay. Do you know if it's --**  
11 **that application is still pending?**  
12 MR. BURG: Same objection.  
13 A. I don't know.  
14 **Q. (By Mr. Stops) Okay. But through your**  
15 **experience in the application, are you generally**  
16 **familiar with what patents are?**  
17 A. General familiarity with what patents are.  
18 **Q. Okay. Have you read -- have you ever read a**  
19 **patent?**  
20 A. Yes.  
21 **Q. Have you ever read a patent before this case?**  
22 A. Yes.  
23 **Q. Okay. Now, you understand that this deposition**  
24 **concerns declarations that you've submitted in**  
25 **connection with six separate IPRs on six patents owned**

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1 **by Jazz; correct?**  
2 A. Yes.  
3 **Q. For the purpose of the -- of this deposition,**  
4 **I'm going to refer to the patents by their last three**  
5 **numbers. So, for example, for Patent Number 7,668,730,**  
6 **I'll refer to that as the '730 patent. Is that okay**  
7 **with you?**  
8 A. Yes, that's fine.  
9 **Q. And I'm going to refer to the patents about**  
10 **which you've submitted declarations collectively as "the**  
11 **Jazz patents." Is that clear?**  
12 A. Yes.  
13 **Q. You're a registered pharmacist; correct?**  
14 A. Yes.  
15 **Q. Is your license still -- still current?**  
16 A. My license is active in Colorado.  
17 **Q. And, actually, let me mark -- or hand you your**  
18 **CV that was attached to -- well, I'll hand you your CV**  
19 **which is designated as PAR1008 which was attached to the**  
20 **IPR for the '988 patent.**  
21 **And for the record, this is -- this is your CV;**  
22 **correct?**  
23 A. Yes.  
24 **Q. And going back to your previous answer, you**  
25 **said your license is still current in Colorado. It's no**

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1 **longer current in the state of Illinois; is that**  
2 **correct?**  
3 A. It is on a -- I don't know the term that is  
4 used in Illinois, but it is on the -- the equivalent of  
5 a dormant status, which I could apply for that to become  
6 active again. But it has not lapsed in the sense that  
7 there is no license in Illinois.  
8 **Q. You don't currently act in a dispensing**  
9 **capacity; is that correct?**  
10 A. That's correct.  
11 **Q. And the last time you did act in a dispensing**  
12 **capacity was in 1994; correct?**  
13 A. Yes, that's correct.  
14 **Q. Let's talk about your experience with drugs**  
15 **that are subject to restricted distribution systems or**  
16 **risk management systems. You've never dispensed Xyrem;**  
17 **correct?**  
18 MR. BURG: Objection. Lack of foundation.  
19 A. That's correct.  
20 **Q. (By Mr. Stops) You've also never dispensed**  
21 **Revlimid; correct?**  
22 A. That's correct.  
23 **Q. You've also never dispensed Thalomid; correct?**  
24 MR. BURG: Objection. Form.  
25 A. No, I have not. I don't believe -- I'm not

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1 sure that's a product.  
2 **Q. (By Mr. Stops) Okay. You've also never**  
3 **dispensed a drug that was the subject of an FDA-approved**  
4 **risk evaluation and mitigation strategies, or REMS;**  
5 **correct?**  
6 MR. BURG: Objection. Form.  
7 A. No. I don't believe so, no.  
8 **Q. (By Mr. Stops) And you've never dispensed a**  
9 **drug that was subject to an FDA-approved risk**  
10 **minimization action plan, or RiskMAP; correct?**  
11 MR. BURG: Objection. Form. Foundation.  
12 A. I don't know.  
13 **Q. (By Mr. Stops) Okay. Now, in your**  
14 **declarations, you stated you've dispensed Accutane and**  
15 **Clozaril; correct?**  
16 A. I would have to refer to those -- those  
17 declarations to verify any statements I made in them.  
18 **Q. Sure. To your knowledge, have you previously**  
19 **dispensed Accutane and Clozaril?**  
20 A. Again, I would have to refer to my declarations  
21 where I stated my -- my recollection -- recollections  
22 clearly.  
23 **Q. Okay. If you had dispensed either of those**  
24 **drugs, the last time you would have had the opportunity**  
25 **to do so would have been in 1994; correct?**

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1 MR. BURG: Objection. Form.  
2 A. I couldn't speculate on the last opportunity.  
3 I'm currently licensed to practice in Colorado.  
4 **Q. (By Mr. Stops) Okay.**  
5 A. So I couldn't speculate on when that would be.  
6 **Q. But you haven't dispensed any drugs since 1994,**  
7 **though; correct?**  
8 A. That's correct.  
9 **Q. You don't have any experience designing a risk**  
10 **management program; correct?**  
11 A. I have experience --  
12 MR. BURG: Sorry. Just slow down just a  
13 little bit.  
14 Objection. Foundation.  
15 A. I have experience with consulting with  
16 pharmaceutical companies who design and implement risk  
17 management and risk evaluation and mitigation programs.  
18 I have familiarity with the FDA and their processes and,  
19 if justified, at FDA hearings about product risk.  
20 I have practiced pharmacy in various settings  
21 to be aware of which products I can dispense and under  
22 which circumstances, and so I have awareness of the  
23 RiskMAP and REMS programs that way.  
24 I've been educated about them in my education  
25 and training. I have in turn educated future

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1 practitioners about them in their education and training  
2 in my career as an academic.  
3 **Q. (By Mr. Stops) Okay. But you have not**  
4 **designed a risk management program; correct?**  
5 MR. BURG: Objection. Form.  
6 A. I believe I just answered.  
7 **Q. (By Mr. Stops) No. You told me a bunch of**  
8 **things that you did do. I'm asking, have you actually**  
9 **designed a risk management program?**  
10 MR. BURG: Objection. Form.  
11 A. I guess I'm not clear on what you mean by  
12 "design a program."  
13 **Q. (By Mr. Stops) Sure. Is there any risk**  
14 **management programs that you had a hand in creating?**  
15 MR. BURG: Objection. Form.  
16 A. I'm not quite sure, you know, what you mean by  
17 "had a hand in creating."  
18 **Q. (By Mr. Stops) Any involvement in creating a**  
19 **risk management program?**  
20 MR. BURG: Same objection.  
21 A. Again, my -- I had stated my -- my involvement  
22 with pharmaceutical companies in advising and consulting  
23 on matters related to risk management, RiskMAP, and REMS  
24 programs.  
25 **Q. (By Mr. Stops) That's actually what I'm asking**

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1 about.  
2 **For the consulting that you've done with**  
3 **pharmaceutical companies, what risk management programs**  
4 **have you consulted on?**  
5 MR. BURG: Objection. Form.  
6 A. Again, I've provided advice to them on product  
7 drug, product risk, and possible strategies for risk  
8 mitigation of the -- of those risks.  
9 **Q. (By Mr. Stops) Was that consulting in**  
10 **connection with a particular drug, or was it just**  
11 **general consulting?**  
12 MR. BURG: Objection. Form.  
13 A. It was with respect to a specific drug.  
14 **Q. (By Mr. Stops) Can you name any specific drugs**  
15 **that you have consulted with on the development of a**  
16 **risk management program?**  
17 A. Under prior agreement under my -- terms of my  
18 consulting agreement, I can't disclose the names of the  
19 products or the companies in that instance.  
20 **Q. Okay. And do you recall what category of**  
21 **drugs -- well, let me ask this -- sorry -- a preliminary**  
22 **question.**  
23 **How many drugs were you involved with in that**  
24 **capacity?**  
25 A. I don't recall the exact number. I don't want

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1 to misspeak.  
2 **Q. Do you know -- do you recall generally?**  
3 A. I believe it was -- again, I don't want to  
4 misspeak, but I believe it was two or three. I don't  
5 have the exact number.  
6 **Q. Do you know what therapeutic category those**  
7 **drugs fell in?**  
8 MR. BURG: Objection. Form.  
9 A. Yes.  
10 **Q. (By Mr. Stops) Can you disclose that**  
11 **information?**  
12 A. No. Under the terms of my consulting  
13 agreement, I can't disclose the product information.  
14 **Q. Was there a specific category of risk that you**  
15 **were trying to minimize in your consulting?**  
16 MR. BURG: Objection. Foundation.  
17 A. I don't believe I can disclose that per the  
18 terms of my consulting agreement. I'd rather not rather  
19 than risk violating that agreement.  
20 **Q. (By Mr. Stops) Sure. You also mentioned some**  
21 **FDA testimony. When was that?**  
22 MR. BURG: Objection. Form.  
23 A. I don't recall the exact date. It would have  
24 been in the fall of 2004. I do not recall the exact  
25 date, however.

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