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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

Continued 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 Thursday, February 4, 2016, at 9:30 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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1	A P P E A R A N C E S:	¹ JOSEPH DIPIRO, Pharma.D., a witness, having
2		² been previously sworn, testifies as
3 4	MADDOX EDWARDS, PLLC	³ follows:
5	1900 K Street NW, Suite 725 Washington, DC 20006	4 CROSS-EXAMINATION (Cont'd)
5	BY: MATTHEW C. RUEDY, ESQ.,	⁵ BY MR. BERMAN:
6	(202)830-0779	DT MR. DEROM I.C.
7	mruedy@meiplaw.com	Q. Good monning, Di. Dii no. Eet s piek
8	Attorneys for Amneal Pharmaceuticals	⁷ up where we left off in your report, Exhibit 2046
9		⁸ on the '059 patent. And I'll refer you to
10	ARENT FOX, LLP	⁹ paragraph 55 of your report. That's page 21.
11	1717 K Street, NW	¹⁰ Are you there?
12	Washington, DC 20038	¹¹ A. Yes.
12	BY: RICHARD J. BERMAN, ESQ., (202)857-6000	¹² Q. Okay. You say in the first sentence,
13	richard.berman@arentfox.com	
14	Attorneys for Par Pharmaceuticals	it is my opinion that only those with skin
15		¹⁴ exceeding that of a POSA would have a need or
16	QUINN EMANUEL URQUHART & SULLIVAN, LLP	¹⁵ motivation to thoroughly read the federal
	51 Madison Avenue, 22nd Floor	¹⁶ register." Do you see that?
17	New York, New York 10010	¹⁷ A. Yes.
1.0	BY: ERIC STOPS, ESQ.,	¹⁸ Q. What do you mean by skill exceeding
18 19	(212)849-7561	¹⁹ that of a POSA?
17	ericstops@quinnemanuel.com BY: EVANGELINE SHIH, ESQ.,	
20	(212)849-7000	r. r don't define that in my statement.
21	evangelineshih@quinnemanuel.com	²¹ So we have talked before about the definition of
22	Attorneys for Jazz Pharmaceuticals	²² a POSA that we're using, so this is referring to
	Page 284	Page 286
1	INDEV	1 any and all other skill outside that I would
1	INDEX	¹ any and all other skill outside that I would
2		2 expect of a POSA.
	WITNESS PAGE	 ² expect of a POSA. ³ Q. So can you give me an example of what
2		2 expect of a POSA.
2 3	WITNESS PAGE	 ² expect of a POSA. ³ Q. So can you give me an example of what
2 3 4	WITNESS PAGE DR. JOSEPH DIPIRO	 expect of a POSA. Q. So can you give me an example of what that means?
2 3 4 5	WITNESS PAGE DR. JOSEPH DIPIRO By Mr. Berman 286, 424	 expect of a POSA. Q. So can you give me an example of what that means? A. I don't know where to start. That would could be any skill.
2 3 4 5 6 7	WITNESS PAGE DR. JOSEPH DIPIRO By Mr. Berman 286, 424 By Mr. Stops 417	 expect of a POSA. Q. So can you give me an example of what that means? A. I don't know where to start. That would could be any skill. Q. So you said only those with skill
2 4 5 7 8	WITNESS PAGE DR. JOSEPH DIPIRO By Mr. Berman 286, 424	 expect of a POSA. Q. So can you give me an example of what that means? A. I don't know where to start. That would could be any skill. Q. So you said only those with skill exceeding that of a POSA would have a need or
2 4 5 6 7 8 9	WITNESSPAGEDR. JOSEPH DIPIROBy Mr. BermanBy Mr. Berman286, 424By Mr. Stops417E X HIBITS	 expect of a POSA. Q. So can you give me an example of what that means? A. I don't know where to start. That would could be any skill. Q. So you said only those with skill exceeding that of a POSA would have a need or motivation to thoroughly read the federal
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	WITNESS PAGE DR. JOSEPH DIPIRO By Mr. Berman 286, 424 By Mr. Stops 417 E X H I B I T S F100 PAGE	 expect of a POSA. Q. So can you give me an example of what that means? A. I don't know where to start. That would could be any skill. Q. So you said only those with skill exceeding that of a POSA would have a need or motivation to thoroughly read the federal register, right? A. It is my opinion that only those with skills exceeding that of a POSA would have a need or motivation to thoroughly read the federal register, right? A. It is my opinion that only those with skills exceeding that of a POSA would have a need or motivation to thoroughly read the federal register, yes. Q. So when you say exceeding that of a POSA in this context, can you explain what you mean by that? A. No. I haven't considered that or defined that.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	WITNESS PAGE DR. JOSEPH DIPIRO By Mr. Berman 286, 424 By Mr. Stops 417 E X H I B I T S F100 PAGE	 expect of a POSA. Q. So can you give me an example of what that means? A. I don't know where to start. That would could be any skill. Q. So you said only those with skill exceeding that of a POSA would have a need or motivation to thoroughly read the federal register, right? A. It is my opinion that only those with skills exceeding that of a POSA would have a need or motivation to thoroughly read the federal register, right? A. It is my opinion that only those with skills exceeding that of a POSA would have a need or motivation to thoroughly read the federal register, yes. Q. So when you say exceeding that of a POSA in this context, can you explain what you mean by that? A. No. I haven't considered that or defined that. (Whereupon, DiPiro Exhibit No.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	WITNESS PAGE DR. JOSEPH DIPIRO By Mr. Berman 286, 424 By Mr. Stops 417 E X H I B I T S F100 PAGE	 expect of a POSA. Q. So can you give me an example of what that means? A. I don't know where to start. That would could be any skill. Q. So you said only those with skill exceeding that of a POSA would have a need or motivation to thoroughly read the federal register, right? A. It is my opinion that only those with skills exceeding that of a POSA would have a need or motivation to thoroughly read the federal register, right? A. It is my opinion that only those with skills exceeding that of a POSA would have a need or motivation to thoroughly read the federal register, yes. Q. So when you say exceeding that of a POSA in this context, can you explain what you mean by that? A. No. I haven't considered that or defined that. (Whereupon, DiPiro Exhibit No. 1052 was marked for identification.)
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	WITNESS PAGE DR. JOSEPH DIPIRO By Mr. Berman 286, 424 By Mr. Stops 417 E X H I B I T S F100 PAGE	 expect of a POSA. Q. So can you give me an example of what that means? A. I don't know where to start. That would could be any skill. Q. So you said only those with skill exceeding that of a POSA would have a need or motivation to thoroughly read the federal register, right? A. It is my opinion that only those with skills exceeding that of a POSA would have a need or motivation to thoroughly read the federal register, right? A. It is my opinion that only those with skills exceeding that of a POSA would have a need or motivation to thoroughly read the federal register, yes. Q. So when you say exceeding that of a POSA in this context, can you explain what you mean by that? A. No. I haven't considered that or defined that. (Whereupon, DiPiro Exhibit No. 1052 was marked for identification.)

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1	BY MR. BERMAN:	1	another question or so. I see that it doesn't
2	Q. Showing you what's been marked as	2	have my signature, so it is not my statement.
3	Exhibit 1052. This is paper entitled Patent	3	But I understand then from your explanation, and
4	Owner Response. Do you see that?	4	I haven't seen this document before, that this is
5	A. Yes.	5	a document I'm assuming this is a document
6	Q. I'll submit to you this was filed by	6	prepared by Jazz counsel in response to the
7	Jazz Pharmaceuticals in the '059 patent IPR.	7	petitioner's
8	Let's go to page 18. And the first	8	Q. Correct, yes. So this was prepared
9	full paragraph there it says, "In Dr. DiPiro's	9	by Jazz's attorneys, and so they are stating in
10	opinion, only those whose skill exceeds that of a	10	this response certain statements. So one of the
11	POSA such as a researcher focused on drug	11	statement is the one that I directed you to.
12	distribution, safety and abuse prevention or	12	A. That should refer back to something
13	regulatory affairs would have had a reason to look	13	in my declaration?
14	to the federal register and to advisory committee	14	Q. Correct. So, for example well,
15	meetings." Do you see that?	15	let's look at the sentence that I had just read.
16	A. Yes.	16	That refers to your report at paragraph 55, which
17	Q. So is it your opinion that a skill	17	is the section we have just been discussing in
18	exceeding that of a POSA includes a researcher	18	your report. Does that orient you as to the
19	focused on drug distribution, safety and abuse	19	topic?
20	prevention or regulatory affairs?	20	A. I think so. I may have another
21	A. Before I can answer that, I need to	21	question later. So then does this refer back to
22	be oriented to the document that we're speaking	22	the paragraph in my statement?
	Page 288		Page 290
1	about here.	1	Q. Yes. You see how it refers to
2	Q. Do you have a particular question	2	Exhibit 2046, paragraph 55?
3	regarding that document that I can potentially	3	A. I see.
4	clarify?	4	Q. So when you're ready, I'll repeat the
5	A. Well, at the moment I may recall, but	5	question or rephrase.
6	I'm not recalling that I have seen this before.	6	A. Sure. It will take me a minute or
7	What this is to both, '059, '059	7	two to make sure I'm oriented.
8	MR. STOPS: You want to tell him what	8	(Perusing.)
9	it is?	9	I'm ready. Thank you.
10	BY MR. BERMAN:	10	Q. On page 18 of 1052, Jazz's attorneys
11	Q. I'll submit to you what this is	11	say, "In Dr. DiPiro's opinion, only those whose
12	I'll just generally explain is that after your	12	skill exceeds that of a POSA such as a researcher
13	report was filed, your declaration, or	13	focused on drug distribution safety and abuse
14	concurrently with your declaration being filed,	14	prevention or regulatory affairs would have had a
15	Jazz also filed this document, Exhibit 1052, in	15	reason to look to the federal register and to
16	the patent office explaining to the patent office	16	advisory committee meetings." Do you see that?
17	their response to the petitions that were filed	17	A. Yes.
18	in the IPR proceedings. Okay?	18	Q. And that cites your exhibit your
19	A. I see.	19	declaration at paragraph 55. Do you see that?
20	Q. Does that clarify what this document	20	A. I do.
21	is?	21	Q. And so what you said in paragraph 55
22	A. Yes. So this is I may have	22	is that it is your opinion that only those with
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1	skill exceeding that of a POSA would have a need	1	A. Well, I have to go back to the
2	or motivation to thoroughly read the federal	2	definition that we're using. We have defined it,
3	register. Do you see that?	3	we have talked about that, we have gone over it.
4	A. Yes.	4	And we're using and accepting the definition that
5	Q. Well, you see that the attorneys did	5	Dr. Valuck has posed, and I have not defined POSA
6	not quote your statement on paragraph 55,	6	any further than that and Dr. Valuck has gone
7	correct? They didn't use quotation marks?	7	with it.
8	A. I'm not agreeing other than I don't	8	Q. Let's look at page 23 of your
9	see the exact text from my declaration statement	9	opinion I mean declaration, excuse me, at
10	55 in this portion of the document. I have not	10	paragraph 58.
11	had an opportunity to review other parts of this	11	A. We're still on Exhibit 2046?
12	document.	12	Q. Yes. And I want to it's the top
13	Q. Right. So they are paraphrasing your	13	of page 23. And the last sentence says, "In my
14	paragraph 55 in the statement on page 18 of	14	opinion, the reasons a Pharmacist POSA would have
15	Exhibit 1052, correct?	15	looked to the federal register are extremely
16	MR. STOPS: Objection, foundation.	16	limited. For example, to look for information
17	A. I'm not seeing it that way. There's	17	regarding requests for proposals to undertake
18	additional information that isn't in paragraph	18	contract work for various federal agencies." Do
19	55.	19	you see that?
20	BY MR. BERMAN:	20	A. Yes.
21	Q. Okay. So let's talk about that	21	Q. What's the basis for your opinion?
22	additional information.	22	MR. STOPS: Objection. The question
	5 000		5 004
	Page 292		Page 294
1	Is it your opinion that a researcher	1	was asked yesterday.
2	focused on drug distribution, safety and abuse	2	A. So the full statement here in
3	prevention or regulatory affairs is someone whose	3	paragraph 58, in the off chance that a Pharmacist
4	skill exceeds that of a POSA?	4	POSA would have been motivated to look to the
5	A. I posed those as examples of someone	5	federal register, it is my opinion that the POSA
6	whose skill exceeds that of a POSA.	6	still would not look to find meeting
7	Q. So that's a yes?	7	announcements regarding the history of an
8	A. I posed those as examples of someone	8	approved drug's distribution system. So instead,
9	whose exactly that. Their skill exceeds of a	9	in my opinion the reasons a Pharmacist POSA would
10	POSA.	10	have looked to the federal register are extremely
11	Q. So there could be other skills that	11	limited, for example, to look for information
12	exceed that of a POSA?	12	regarding requests for proposals to undertake
13	A. And I have not considered what those	13	contract work for various federal agencies.
14	skills would be. It's not part of my testimony,	14	So what is the basis of that opinion
15	not anything I'm offering. I'm not offering an	15	in
16	opinion about the skills exceeding a POSA other	16	Q. In 58, yes.
17	than these examples.	17	A. So it goes to my experience, as I
18	Q. So is it your opinion that a person	18	indicated yesterday, of 38 years that the only
19	of ordinary skill in the art would not be focused	19	time I can recall someone, Pharmacist POSA,
20	on drug distribution, safety and abuse prevention	20	including myself, looking at the federal register
21	or regulatory affairs?	21	would have been before 1981. And in that
22	MR. STOPS: Objection, form.	22	specific instance, I was working in a pharmacy
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1 System that was doing contracts for federal 1 Q. Do you agree with that statement? 2 agencies and would look specifically to federal 2 A. Yes. 3 documents, one of which is the federal registere. 3 Q. So if we can go back to your report 4 Have a vague ecollection of all of the 4 at page 21, prargnph 56. And yesterholy we were 5 Business Daily, to become altered to corracts 6 POSA in drug distribution, safety and havasis 7 for research projects. 7 regulatory affairs. Do you recall that? 8 ow any other research negaring the statement you A Ido. 9 O. Mad ous asid that a Pharmacist POSA, depending on the requirements of their job, may depending that statement? 13 pharmacist would hock to federal register? 14 Ms. STOPS: Objection. 14 hast question. 15 A. Crould Lad to my response to the 15 15 A. Could I add to my response to the				
a documentsNo.Proceedinga documentsa documentsa documentsa documentsa documentsa documentsb materials because it was so long ago, Commerceb documentsb documentsb materials because it was so long ago, Commerceb documentsb documentsc materials because it was so long ago, Commerceb documentsb documentsc materials because it was so long ago, Commercec documentsb documentsc materials because it was so long ago, Commercec documentsc documentsd do any other research regarding the startement youa A i do.c documentsc materials besides the onesc documentsc documentsdocumentsyou listed - are there other reasons ain that instance. I was involved inin that instance. I was involved ind doring at the federal register.in that instance. I was involved indocumentsist question?in that instance. I was involved indocumentsdocumentsist question?in that instance.in that instance.documentsist question?in that instance.in that instance.documentsist question?in that instance.in that instance.documentsist question?in that instance.in that instance.documents </td <td>1</td> <td>system that was doing contracts for federal</td> <td>1</td> <td>Q. Do you agree with that statement?</td>	1	system that was doing contracts for federal	1	Q. Do you agree with that statement?
4I have a vague recollection of all of the materials because it was so long age, Commerce4at puge 21, paragraph 56. And yesterday we were discussing the interest level of a Phramacist POSA in drug distribution, safety and abuse or regulatory affairs. Do you recall that?70. Resides your own experience, did you do any other research regulating the statement you made in paragraph 58?7720. What other reasons hesides the ones you listed – are there other reasons hesides the ones planmacist would look to the folderal register?11No.3120. What other reasons hesides the ones planmacist would look to the folderal register?14MR. STOPS: Objection.320. What other reasons housdown or planmacist would look to the folderal register?14MR. STOPS: Objection.4160. are you suggesting that's my exact words?10No.No.716In that instature, I was involved in research activity which was outside of that scope.12O. May other activity would be oblication.717In that instature, I was involved in research activity which was outside of that scope.12Of what I'm talking about, right?718typical for a POSA. So these were cocurrent but to ork within my function as a POSA at that time.12of what I'm talking about, right?718squita. That sa no.7regad. But I wanted to orient you to that group regad. But I wanted to orient you to that group or for POSA. So these were focused on the last time. It says, 1311of what I'm talking about, right?7 <td>2</td> <td>agencies and would look specifically to federal</td> <td>2</td> <td>A. Yes.</td>	2	agencies and would look specifically to federal	2	A. Yes.
5 materials because it was so long ago, Commerce 5 discussing the interest level of a Pharmacist 6 Business Daily, to become alterted to contracts 6 7 for research projects. 7 8 Q. Besides your own experience, did you 8 A. I do. 9 do any other research regarding the statement you 9 Q. And you said that a Pharmacist POSA. 11 be interested in learning about these areas as it applies to their job and keeping up with the 12 Q. What other reasons beides the ones 12 13 you listed – are there other reasons a 13 14 n. No. 15 Mc StoPS: Objection. 15 A. Could I add to ny response to the 15 Mischaracterizas. Form. 16 Ind thi instarce, I was involved in 17 work? 17 In that instarce, I was involved in 18 Q. Tm just paraphrasing what you said 19 which was within the realm of a POSA. The purpose 19 A. Nell, Td like to go back to my exact 21 research activity which was outside of that scope. 21 O. Sure. But you recall the substance 22 This was something that was just not common or 22 Q. Sure. But you recall the substance 23 typical for a POSA. So these were concurrent but not	3	documents, one of which is the federal register.	3	Q. So if we can go back to your report
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