

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 JOSEPH DIPIRO, Pharma.D., a witness, having
 2 been previously sworn, testifies as
 3 follows:
 4 CROSS-EXAMINATION (Cont'd)
 5 BY MR. BERMAN:
 6 Q. Good morning, Dr. DiPiro. Let's pick
 7 up where we left off in your report, Exhibit 2046
 8 on the '059 patent. And I'll refer you to
 9 paragraph 55 of your report. That's page 21.
 10 Are you there?
 11 A. Yes.
 12 Q. Okay. You say in the first sentence,
 13 "It is my opinion that only those with skill
 14 exceeding that of a POSA would have a need or
 15 motivation to thoroughly read the federal
 16 register." Do you see that?
 17 A. Yes.
 18 Q. What do you mean by skill exceeding
 19 that of a POSA?
 20 A. I don't define that in my statement.
 21 So we have talked before about the definition of
 22 a POSA that we're using, so this is referring to

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 3 WITNESS PAGE
 4 DR. JOSEPH DIPIRO
 5 By Mr. Berman 286, 424
 6 By Mr. Stops 417
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 8 EXHIBITS
 9
 10 NUMBER DESCRIPTION PAGE
 11
 12 DiPiro Exhibit 1052 Patent Owner Response 287
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1 any and all other skill outside that I would
 2 expect of a POSA.
 3 Q. So can you give me an example of what
 4 that means?
 5 A. I don't know where to start. That
 6 would -- could be any skill.
 7 Q. So you said only those with skill
 8 exceeding that of a POSA would have a need or
 9 motivation to thoroughly read the federal
 10 register, right?
 11 A. It is my opinion that only those with
 12 skills exceeding that of a POSA would have a need
 13 or motivation to thoroughly read the federal
 14 register, yes.
 15 Q. So when you say exceeding that of a
 16 POSA in this context, can you explain what you
 17 mean by that?
 18 A. No. I haven't considered that or
 19 defined that.
 20 (Whereupon, DiPiro Exhibit No.
 21 1052 was marked for identification.)
 22 *****

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<p>1 BY MR. BERMAN:</p> <p>2 Q. Showing you what's been marked as</p> <p>3 Exhibit 1052. This is paper entitled Patent</p> <p>4 Owner Response. Do you see that?</p> <p>5 A. Yes.</p> <p>6 Q. I'll submit to you this was filed by</p> <p>7 Jazz Pharmaceuticals in the '059 patent IPR.</p> <p>8 Let's go to page 18. And the first</p> <p>9 full paragraph there it says, "In Dr. DiPiro's</p> <p>10 opinion, only those whose skill exceeds that of a</p> <p>11 POSA such as a researcher focused on drug</p> <p>12 distribution, safety and abuse prevention or</p> <p>13 regulatory affairs would have had a reason to look</p> <p>14 to the federal register and to advisory committee</p> <p>15 meetings." Do you see that?</p> <p>16 A. Yes.</p> <p>17 Q. So is it your opinion that a skill</p> <p>18 exceeding that of a POSA includes a researcher</p> <p>19 focused on drug distribution, safety and abuse</p> <p>20 prevention or regulatory affairs?</p> <p>21 A. Before I can answer that, I need to</p> <p>22 be oriented to the document that we're speaking</p> <p style="text-align: right;">Page 288</p>	<p>1 another question or so. I see that it doesn't</p> <p>2 have my signature, so it is not my statement.</p> <p>3 But I understand then from your explanation, and</p> <p>4 I haven't seen this document before, that this is</p> <p>5 a document -- I'm assuming this is a document</p> <p>6 prepared by Jazz counsel in response to the</p> <p>7 petitioner's --</p> <p>8 Q. Correct, yes. So this was prepared</p> <p>9 by Jazz's attorneys, and so they are stating in</p> <p>10 this response certain statements. So one of the</p> <p>11 statement is the one that I directed you to.</p> <p>12 A. That should refer back to something</p> <p>13 in my declaration?</p> <p>14 Q. Correct. So, for example -- well,</p> <p>15 let's look at the sentence that I had just read.</p> <p>16 That refers to your report at paragraph 55, which</p> <p>17 is the section we have just been discussing in</p> <p>18 your report. Does that orient you as to the</p> <p>19 topic?</p> <p>20 A. I think so. I may have another</p> <p>21 question later. So then does this refer back to</p> <p>22 the paragraph in my statement?</p> <p style="text-align: right;">Page 290</p>
<p>1 about here.</p> <p>2 Q. Do you have a particular question</p> <p>3 regarding that document that I can potentially</p> <p>4 clarify?</p> <p>5 A. Well, at the moment I may recall, but</p> <p>6 I'm not recalling that I have seen this before.</p> <p>7 What this is to both, '059, '059 --</p> <p>8 MR. STOPS: You want to tell him what</p> <p>9 it is?</p> <p>10 BY MR. BERMAN:</p> <p>11 Q. I'll submit to you what this is --</p> <p>12 I'll just generally explain is that after your</p> <p>13 report was filed, your declaration, or</p> <p>14 concurrently with your declaration being filed,</p> <p>15 Jazz also filed this document, Exhibit 1052, in</p> <p>16 the patent office explaining to the patent office</p> <p>17 their response to the petitions that were filed</p> <p>18 in the IPR proceedings. Okay?</p> <p>19 A. I see.</p> <p>20 Q. Does that clarify what this document</p> <p>21 is?</p> <p>22 A. Yes. So this is -- I may have</p> <p style="text-align: right;">Page 289</p>	<p>1 Q. Yes. You see how it refers to</p> <p>2 Exhibit 2046, paragraph 55?</p> <p>3 A. I see.</p> <p>4 Q. So when you're ready, I'll repeat the</p> <p>5 question or rephrase.</p> <p>6 A. Sure. It will take me a minute or</p> <p>7 two to make sure I'm oriented.</p> <p>8 (Perusing.)</p> <p>9 I'm ready. Thank you.</p> <p>10 Q. On page 18 of 1052, Jazz's attorneys</p> <p>11 say, "In Dr. DiPiro's opinion, only those whose</p> <p>12 skill exceeds that of a POSA such as a researcher</p> <p>13 focused on drug distribution safety and abuse</p> <p>14 prevention or regulatory affairs would have had a</p> <p>15 reason to look to the federal register and to</p> <p>16 advisory committee meetings." Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. And that cites your exhibit -- your</p> <p>19 declaration at paragraph 55. Do you see that?</p> <p>20 A. I do.</p> <p>21 Q. And so what you said in paragraph 55</p> <p>22 is that it is your opinion that only those with</p> <p style="text-align: right;">Page 291</p>

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1 skill exceeding that of a POSA would have a need
 2 or motivation to thoroughly read the federal
 3 register. Do you see that?
 4 A. Yes.
 5 Q. Well, you see that the attorneys did
 6 not quote your statement on paragraph 55,
 7 correct? They didn't use quotation marks?
 8 A. I'm not agreeing other than I don't
 9 see the exact text from my declaration statement
 10 55 in this portion of the document. I have not
 11 had an opportunity to review other parts of this
 12 document.
 13 Q. Right. So they are paraphrasing your
 14 paragraph 55 in the statement on page 18 of
 15 Exhibit 1052, correct?
 16 MR. STOPS: Objection, foundation.
 17 A. I'm not seeing it that way. There's
 18 additional information that isn't in paragraph
 19 55.
 20 BY MR. BERMAN:
 21 Q. Okay. So let's talk about that
 22 additional information.

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1 Is it your opinion that a researcher
 2 focused on drug distribution, safety and abuse
 3 prevention or regulatory affairs is someone whose
 4 skill exceeds that of a POSA?
 5 A. I posed those as examples of someone
 6 whose skill exceeds that of a POSA.
 7 Q. So that's a yes?
 8 A. I posed those as examples of someone
 9 whose -- exactly that. Their skill exceeds of a
 10 POSA.
 11 Q. So there could be other skills that
 12 exceed that of a POSA?
 13 A. And I have not considered what those
 14 skills would be. It's not part of my testimony,
 15 not anything I'm offering. I'm not offering an
 16 opinion about the skills exceeding a POSA other
 17 than these examples.
 18 Q. So is it your opinion that a person
 19 of ordinary skill in the art would not be focused
 20 on drug distribution, safety and abuse prevention
 21 or regulatory affairs?
 22 MR. STOPS: Objection, form.

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1 A. Well, I have to go back to the
 2 definition that we're using. We have defined it,
 3 we have talked about that, we have gone over it.
 4 And we're using and accepting the definition that
 5 Dr. Valuck has posed, and I have not defined POSA
 6 any further than that and Dr. Valuck has gone
 7 with it.
 8 Q. Let's look at page 23 of your
 9 opinion -- I mean declaration, excuse me, at
 10 paragraph 58.
 11 A. We're still on Exhibit 2046?
 12 Q. Yes. And I want to -- it's the top
 13 of page 23. And the last sentence says, "In my
 14 opinion, the reasons a Pharmacist POSA would have
 15 looked to the federal register are extremely
 16 limited. For example, to look for information
 17 regarding requests for proposals to undertake
 18 contract work for various federal agencies." Do
 19 you see that?
 20 A. Yes.
 21 Q. What's the basis for your opinion?
 22 MR. STOPS: Objection. The question

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1 was asked yesterday.
 2 A. So the full statement here in
 3 paragraph 58, in the off chance that a Pharmacist
 4 POSA would have been motivated to look to the
 5 federal register, it is my opinion that the POSA
 6 still would not look to find meeting
 7 announcements regarding the history of an
 8 approved drug's distribution system. So instead,
 9 in my opinion the reasons a Pharmacist POSA would
 10 have looked to the federal register are extremely
 11 limited, for example, to look for information
 12 regarding requests for proposals to undertake
 13 contract work for various federal agencies.
 14 So what is the basis of that opinion
 15 in --
 16 Q. In 58, yes.
 17 A. So it goes to my experience, as I
 18 indicated yesterday, of 38 years that the only
 19 time I can recall someone, Pharmacist POSA,
 20 including myself, looking at the federal register
 21 would have been before 1981. And in that
 22 specific instance, I was working in a pharmacy

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<p>1 system that was doing contracts for federal 2 agencies and would look specifically to federal 3 documents, one of which is the federal register. 4 I have a vague recollection of all of the 5 materials because it was so long ago, Commerce 6 Business Daily, to become alerted to contracts 7 for research projects.</p> <p>8 Q. Besides your own experience, did you 9 do any other research regarding the statement you 10 made in paragraph 58?</p> <p>11 A. No.</p> <p>12 Q. What other reasons besides the ones 13 you listed -- are there other reasons a 14 pharmacist would look to the federal register?</p> <p>15 A. Could I add to my response to the 16 last question?</p> <p>17 In that instance, I was involved in 18 activity -- it was a mix of activity, some of 19 which was within the realm of a POSA. The purpose 20 for looking at the federal register was my 21 research activity which was outside of that scope. 22 This was something that was just not common or</p> <p style="text-align: right;">Page 296</p>	<p>1 Q. Do you agree with that statement?</p> <p>2 A. Yes.</p> <p>3 Q. So if we can go back to your report 4 at page 21, paragraph 56. And yesterday we were 5 discussing the interest level of a Pharmacist 6 POSA in drug distribution, safety and abuse or 7 regulatory affairs. Do you recall that?</p> <p>8 A. I do.</p> <p>9 Q. And you said that a Pharmacist POSA, 10 depending on the requirements of their job, may 11 be interested in learning about these areas as it 12 applies to their job and keeping up with the 13 field. Do you recall that?</p> <p>14 MR. STOPS: Objection. 15 Mischaracterizes. Form.</p> <p>16 A. Are you suggesting that's my exact 17 words?</p> <p>18 Q. I'm just paraphrasing what you said 19 to orient you to my next question.</p> <p>20 A. Well, I'd like to go back to my exact 21 words from yesterday then.</p> <p>22 Q. Sure. But you recall the substance</p> <p style="text-align: right;">Page 298</p>
<p>1 typical for a POSA. So these were concurrent but 2 not within my function as a POSA at that time.</p> <p>3 Q. Okay. Thank you.</p> <p>4 So are there any other reasons a 5 Pharmacist POSA would look to the federal register 6 besides the ones you listed?</p> <p>7 A. Not that I'm aware of. That's a no.</p> <p>8 Q. Let's go back to Exhibit 105, to page 9 18 again. And there's say statement above the 10 one we were focused on the last time. It says, 11 "In Dr. DiPiro's opinion, the only reason a 12 Pharmacist POSA would look to the federal 13 register would be for information regarding 14 requests for proposals to undertake contract work 15 for federal agencies." Do you see that?</p> <p>16 A. Not yet, no.</p> <p>17 Q. It's the third line from the top.</p> <p>18 A. Where it begins instead?</p> <p>19 Q. Yes.</p> <p>20 A. I do see that now.</p> <p>21 Q. Do you see that?</p> <p>22 A. Yes.</p> <p style="text-align: right;">Page 297</p>	<p>1 of what I'm talking about, right?</p> <p>2 A. I recall the question. But again, as 3 to recharacterizing my words, I would go back to 4 the way that I answered that yesterday.</p> <p>5 Q. I understand. That's fine. I don't 6 mean to at all alter your testimony in that 7 regard. But I wanted to orient you to that group 8 of POSAs, the ones that may be interested in 9 learning about drug distribution, safety and 10 abuse or regulatory affairs. Okay?</p> <p>11 MR. STOPS: Objection, foundation.</p> <p>12 A. Not necessarily. And I don't know 13 where you are headed. But I haven't defined that 14 group of POSAs -- I'm using Valuck's definition 15 of a POSA. That's the limit of my consideration.</p> <p>16 Q. Okay. So yesterday we were 17 discussing the interest level of a Pharmacist 18 POSA in drug distribution, safety abuse or 19 regulatory affairs. You recall that, correct?</p> <p>20 A. The general discussion. Again, not 21 the exact words.</p> <p>22 Q. Right. And generally, it was your</p> <p style="text-align: right;">Page 299</p>

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