

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

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AMERIGEN PHARMACEUTICALS LIMITED, :

6 ARGENTUM PHARMACEUTICALS LLC, :

Petitioners :

7 :

VS :

8 :

JANSSEN ONCOLOGY, INC., :

9 Patent Owner :

- - - - -X

10 Case IPR2016-00286

Patent No. 8,822,438 B2

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14 Videotaped deposition of SCOTT R. SERELS,  
M.D. taken at the offices of Hilton Garden Inn, 560  
15 Main Avenue, Norwalk, Connecticut, before Clifford  
Edwards, LSR, Connecticut License No. SHR.407, a  
16 Professional Shorthand Reporter and Notary Public,  
in and for the State of Connecticut on January 21,  
17 2017, at 9:02 a.m.

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Page 2

1 APPEARANCES:  
 2  
 3 ON BEHALF OF THE PETITIONERS, AMERIGEN  
 4 PHARMACEUTICALS LIMITED, ARGENTUM  
 5 PHARMACEUTICALS LLC:  
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 14 ON BEHALF OF THE PATENT OWNER, JANSSEN ONCOLOGY:  
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 21  
 22  
 23 ALSO PRESENT: KEVIN MARTH, VIDEOGRAPHER  
 24

Page 3

1 THE VIDEOGRAPHER: Good morning. We  
 2 are now on the record. My name is Kevin  
 3 Marth. I'm the legal videographer today  
 4 representing Golkow Technologies.  
 5 Today's date is January 21, 2017 and  
 6 the time is approximately 9:01 a.m. The  
 7 video deposition today is being held in  
 8 Norwalk, Connecticut in the matter of  
 9 Amerigen Pharmaceuticals Limited,  
 10 Argentum Pharmaceuticals LLC vs Janssen  
 11 Oncology, Inc. for the United States  
 12 Patent and Trademark Office before the  
 13 patent trial and appeal board. Our  
 14 deponent today is Dr. Scott Serels.  
 15 At this time, would counsel please  
 16 identify themselves for the record.  
 17 MR. ZEGGER: Paul Zegger with Sidley  
 18 Austin for the patent owner Janssen  
 19 Oncology, Inc.  
 20 MR. CASIERI: Chris Casieri of  
 21 McNeely, Hare & War representing the  
 22 petitioner.  
 23 THE VIDEOGRAPHER: Our court

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1 will now swear in the witness and we may  
 2 proceed.  
 3  
 4 SCOTT R. SERELS, M.D.  
 5 residing at 12 Elmcrest Terrace, Norwalk,  
 6 Connecticut 06850, having first been duly sworn,  
 7 deposed and testified as follows:  
 8  
 9 DIRECT EXAMINATION  
 10  
 11 BY MR. ZEGGER:  
 12 Q Good morning.  
 13 A Good morning.  
 14 Q Sir, let me put before you a document  
 15 that bears exhibit Amerigen 1095.  
 16 And let me ask you whether you recognize  
 17 that as your reply declaration in the present IPR  
 18 proceeding?  
 19 A I do.  
 20 Q Now, is that your signature on the first  
 21 page?  
 22 A It is.  
 23 Q When did you actually sign it?  
 24 A The date says January 16.

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1 Q Is that when you signed?  
 2 A I believe that was when I signed.  
 3 Q That was this past Monday?  
 4 A Correct.  
 5 Q You signed a previous declaration in this  
 6 IPR back in December of 2015; do you recall that?  
 7 A I -- I do recall signing something  
 8 previously.  
 9 Q And do you recall having your deposition  
 10 taken back in August of last year?  
 11 A Yes.  
 12 Q Could you turn to paragraph four of your  
 13 declaration, the reply declaration?  
 14 A Yes.  
 15 Q Are you there?  
 16 A I am.  
 17 Q And does that list the materials that you  
 18 were asked to review for your reply declaration?  
 19 A Yes.  
 20 Q Okay. In particular, it's the expert  
 21 reports of Dr. Chodak, Dr. Auchus and Dr. Veltura?  
 22 A Correct.  
 23 Q And also the Amerigen expert declarations

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1 A Correct.

2 Q Did you look at any other expert  
3 declarations?

4 A Not that I recall.

5 Q Okay. Do you recall being provided the  
6 patent owner's response brief?

7 A Not in specifics, but yes.

8 Q Well, is that something you reviewed?

9 A I did, yes.

10 Q You didn't review -- is there any reason  
11 why that's not listed in your list of materials  
12 considered in paragraph four?

13 A I think this is something that perhaps  
14 was reviewed before this document was completed, so  
15 it wasn't included.

16 Q I'm sorry, do you know when the patent  
17 owner's response was dated?

18 A I don't. I don't recall.

19 Q Okay. That was a brief back in October  
20 of 2016? I'm just trying to find out whether you  
21 recall being provided with that document?

22 A I believe I was, but I don't recall the  
23 document specifically.

24 Q Okay. Were you provided a -- an expert

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1 declaration of a Dr. Rettig?

2 A Dr. Rettig? Yes, I do believe I saw a  
3 document from Dr. Rettig.

4 Q Okay. Is there any reason why that  
5 wasn't listed in your list of materials considered  
6 in paragraph four of your reply declaration?

7 A I thought these were most specific to the  
8 declaration.

9 Q Okay. Do you know who Dr. Rettig is?

10 A I believe he's a physician, urologist.  
11 But, again, I don't recall the specifics of his  
12 report.

13 Q Okay. Were you asked to review it  
14 specifically?

15 A I've seen -- you know, I've a lot of  
16 different papers and different, you know, reports  
17 pertaining to this case. So I recognize the name,  
18 but I don't recognize the -- or remember the -- or  
19 recall the specifics of what he was describing.

20 Q Did you know that he's a medical  
21 oncologist?

22 A I knew he was a physician. I wasn't sure  
23 exactly what his title was.

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1 THE VIDEOGRAPHER: Excuse me,  
2 counsel.

3 Doctor, could I can you to scooch  
4 your microphone up --

5 THE WITNESS: Oh, absolutely.

6 THE VIDEOGRAPHER: -- just a little  
7 bit?

8 THE WITNESS: Absolutely.

9 THE VIDEOGRAPHER: Thank you, sir.

10 BY MR. ZEGGER:

11 Q In any event, you weren't, for purposes  
12 of your reply declaration, asked to respond to  
13 Dr. Rettig?

14 A Correct.

15 Q Now, in paragraph six of your reply  
16 declaration, you discuss a definition of a person of  
17 ordinary skill in the art or a PHOSITA, for short?

18 A Correct.

19 Q And do you agree that a PHOSITA is a  
20 urologist or oncologist with access to  
21 endocrinologist to the extent needed?

22 A I agree.

23 Q And do you agree that a urologist is  
24 generally not an expert in endocrinology?

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1 A Correct.

2 MR. CASIERI: Object to form.

3 BY MR. ZEGGER:

4 Q And do you agree that an oncologist is  
5 generally not an expert in endocrinology?

6 MR. CASIERI: Object to form.

7 A Correct.

8 BY MR. ZEGGER:

9 Q Are you an expert in oncology -- in  
10 endocrinology?

11 A No.

12 Q Prior to your work in connection with  
13 this case, had you ever heard of a condition called  
14 CYP17 deficiency?

15 A Yes.

16 Q And that was prior to your work in  
17 connection with this case?

18 A Correct.

19 Q But in terms of your own work, if you  
20 have the need of expertise in endocrinology, you  
21 would consult a physician that has some expertise in  
22 that area; correct?

23 A Correct.

<p style="text-align: right;">Page 10</p> <p>1 declaration, you did not fully consider the various 2 mechanisms by which ketoconazole was known to 3 inhibit adrenal steroid synthesis beyond inhibiting 4 CYP17 enzyme synthesis; correct? 5 MR. CASIERI: Object to form. 6 A Correct. 7 BY MR. ZEGGER: 8 Q Okay. And particularly, you were 9 focusing on one particular mechanism of action; is 10 that right? 11 A As it pertained to abiraterone, which was 12 the compound that we were most interested in. 13 Q You agree that ketoconazole has 14 mechanisms of action other than inhibiting CYP17 15 enzyme synthesis? 16 A I do agree. 17 MR. CASIERI: Object to form. 18 BY MR. ZEGGER: 19 Q Now, in defending the approach that you 20 took in this case, you cite to an article authored 21 by a Vidal and a Dr. De bono; is that right? 22 A Correct. 23 Q Let me show you Amerigen Exhibit 1147. 24 And is this the article that you relied</p>	<p style="text-align: right;">Page 12</p> <p>1 it says on the front page. 2 Q Okay. Does that refresh any recollection 3 that you have as to when you were first provided the 4 Vidal paper? 5 A You know, I've seen so many papers, I 6 don't recall exactly when. But if that's when he 7 downloaded it, I -- I really just don't know. I 8 mean whether his downloading pertains to when I saw 9 the paper, I just don't know. 10 Q Okay. No, I'm just trying to find out 11 how many hours or days before you signed your reply 12 declaration on January 16th, you had the Vidal 13 paper? 14 A I'm not sure. 15 MR. CASIERI: Object to form. 16 BY MR. ZEGGER: 17 Q All right. You cite a portion of the 18 Vidal paper in your reply declaration, paragraph 19 nine; is that right? 20 I'm sorry, paragraph eight? 21 A Correct. 22 Q Now, is there any indication in the 23 portion that you cite indicating that ketoconazole 24 is a CYP17 inhibitor?</p>
<p style="text-align: right;">Page 11</p> <p>1 upon? 2 A Yes. 3 Q When did you first see it? 4 A This article? I couldn't specifically 5 say. 6 Q All right. Do you see at the bottom of 7 the cover page there is a notation, "Download by 8 Mr. William Hare." And there's a date, "January 12, 9 2017." 10 Do you see that? 11 A I don't. 12 It's on the bottom of the first page? 13 Q The very first page. 14 A I do. 15 Q Do you have an understanding as to 16 whether Mr. William Hare is Amerigen's counsel in 17 the present IPR? 18 A He is. I know -- I know Mr. Hare. 19 Q Okay. And do you see that this indicates 20 that this particular paper by Vidal was downloaded 21 by Mr. Hare on January 12th -- 22 A Yes. 23 Q -- 2017?</p>	<p style="text-align: right;">Page 13</p> <p>1 A Sorry. Can you repeat the -- 2 Q Sure. 3 Is there any portion of the Vidal paper 4 that you cite that indicates that ketoconazole is a 5 CYP17 inhibitor? 6 A Yes. I couldn't exactly find it for you, 7 but yes. 8 I think that, you know, the purpose was 9 that it was describing similarities between it and 10 the compound that we are most concerned with, 11 abiraterone, in terms of its mechanism of action, 12 inhibiting the adrenal gland. 13 Q Okay. In -- well, let's take it step by 14 step here. 15 A Uh-huh. 16 Q Could you look at paragraph eight of your 17 reply declaration? 18 A Sure. 19 Q Are you there? 20 A I am. 21 Q Okay. And the portion that you cite from 22 the Vidal paper states that both ketoconazole and 23 abiraterone acetate as treating prostate cancer by</p>

<p style="text-align: right;">Page 14</p> <p>1 quote from Vidal "Through the inhibition of key 2 enzymes in the adrenal steroid biosynthesis pathways 3 with agents such as ketoconazole or the CYP17 4 inhibitor, abiraterone acetate." 5 Do you see that? 6 A I do. 7 Q In the quoted portion that you take from 8 Vidal, is there any indication that ketoconazole is 9 a CYP17 inhibitor? 10 A Yes. To my recollection, yes. 11 Q Well, either the quoted material refers 12 to ketoconazole as a -- 13 A Uh-huh. 14 Q -- CYP17 inhibitor or it doesn't. 15 Right? 16 A Correct. 17 Q Okay. Now, that's referring to 18 abiraterone acetate as a CYP17 inhibitor; correct? 19 A Correct. 20 Q Okay. But it doesn't state that 21 ketoconazole is a CYP17 inhibitor. 22 Correct? 23 MR. CASIERI: Object to form. 24 A You are saying that quote doesn't? I</p>	<p style="text-align: right;">Page 16</p> <p>1 something being a CYP17 inhibitor is referring to 2 the abiraterone acetate not ketoconazole. 3 Correct? 4 MR. CASIERI: Object to form. 5 A I think it's subject to interpretation. 6 BY MR. ZEGGER: 7 Q Well, do you see any express statement in 8 the Vidal paper referring to ketoconazole as a CYP17 9 inhibitor? 10 A It's -- it's more a descriptive of 11 adrenal inhibition. I'd have to reread the article 12 to be certain if there's anything specifically 13 saying, CYP17. 14 Q Okay. Well, I don't want you to -- 15 A Yup. 16 Q -- to guess. If you could take some time 17 looking at the Vidal article -- 18 A Sure. 19 Q -- that you cite and if you could let us 20 know whether you find any express statement in that 21 article that ketoconazole is a CYP17 inhibitor? 22 A Yeah. I think -- you know, I think what 23 you quoted what I quoted on page eight of the 24 article is the inference that ketoconazole inhibits</p>
<p style="text-align: right;">Page 15</p> <p>1 mean, it's subject to interpretation. 2 And, you know, ketoconazole affects the 3 adrenal production, the adrenal glands production 4 and CYP17 inhibitors is one of the functions of the 5 adrenal gland. 6 BY MR. ZEGGER: 7 Q Well, my question doesn't go to whether 8 ketoconazole -- 9 A Yup. 10 Q -- is a CYP17 inhibitor. 11 A Sure. 12 Q My question goes to whether Vidal -- 13 A Yes. 14 Q -- that publication is referring to 15 ketoconazole as a CYP17 inhibitor. 16 Do you understand? 17 A I -- I do. It's a subtle difference. 18 And I think, you know, that it seems to be fairly 19 clear from the article that ketoconazole can inhibit 20 the adrenal gland which would encompass the CYP17 21 enzymes. So my inference would be that, yes, it 22 does suggest that ketoconazole would inhibit the 23 CYP17.</p>	<p style="text-align: right;">Page 17</p> <p>1 adrenal steroid biosynthesis. And it compares it to 2 abiraterone in terms of being a CYP17 inhibitor. 3 And I think that's where that quote comes from, the 4 specific line within page eight which describes it 5 as being this inhibitor of biosynthesis and it 6 compares it to abiraterone. 7 Q Okay. So is there any express statement 8 in the Vidal paper that ketoconazole is a CYP17 9 inhibitor? 10 MR. CASIERI: Object to form. 11 A Yeah. Other than the quote that states 12 it comparing it to the other CYP17 inhibitor, there 13 isn't. But that's where the quote comes from, their 14 direct description. 15 BY MR. ZEGGER: 16 Q Now, could you look at paragraph nine of 17 your declaration? 18 A Sure. 19 Q And there you refer to a rebuttal opinion 20 of Dr. Doran? 21 A Uh-huh. 22 Q That's Amerigen's expert? 23 A Uh-huh.</p>

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