1 UNITED STATES PATENT AND TRADEMARK OFFICE 2 BEFORE THE PATENT TRIAL AND APPEAL BOARD 3 4 5 - - -X AMERIGEN PHARMACEUTICALS LIMITED, : ARGENTUM PHARMACEUTICALS LLC, 6 : Petitioners : 7 VS • 8 JANSSEN ONCOLOGY, INC., : 9 Patent Owner : - - - -X Case IPR2016-00286 10 Patent No. 8,822,438 B2 11 12 13 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. 18 19 20 GOLKOW TECHNOLOGIES, INC. 21 877.370.3377 ph | 917.591.5672 fax deps@golkow.com 22 23 24

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	_	Page 2		Page 4
	1 2	A P P E A R A N C E S:	1	will now swear in the witness and we may
	2	ON BEHALF OF THE PETITIONERS, AMERIGEN	2	proceed.
	3	PHARMACEUTICALS LIMITED, ARGENTUM	3	
	4	PHARMACEUTICALS LLC: CHRISTOPHER CASIERI, ESQ.	4	SCOTT R. SERELS, M.D.
	т	MCNEELY, HARE & WAR LLP	5	residing at 12 Elmcrest Terrace, Norwalk,
	5	12 Roszel Road, Suite C104	6	Connecticut 06850, having first been duly sworn,
	c	Princeton, NJ 08540 609.731.3668	7	deposed and testified as follows:
	0	chris@miplaw.com	8	
	7		9	DIRECT EXAMINATION
	8	ON BEHALF OF THE PATENT OWNER, JANSSEN ONCOLOGY:	10	
	9	PAUL J. ZEGGER, ESQ.	11	BY MR. ZEGGER:
		SIDLEY AUSTIN LLP	12	Q Good morning.
	10	1501 K STREET, NW Washington, DC 20005	13	A Good morning.
	11	202.736.8060	14	Q Sir, let me put before you a document
		pzegger@sidley.com	15	that bears exhibit Amerigen 1095.
	12 13		16	And let me ask you whether you recognize
	13 14	ALSO PRESENT: KEVIN MARTH, VIDEOGRAPHER	17	that as your reply declaration in the present IPR
	15		18	proceeding?
	16 17		19	A I do.
	18		20	Q Now, is that your signature on the first
	19		21	
	20 21		22	A It is.
	21 22		23	
	23		24	Q When did you actually sign it?
	24		21	A The date says January 16.
		Page 3		Page 5
	1	THE VIDEOGRAPHER: Good morning. We	1	Q Is that when you signed?
	2	are now on the record. My name is Kevin	2	A I believe that was when I signed.
		Marth. I'm the legal videographer today	3	Q That was this past Monday?
	4	representing Golkow Technologies.	4	A Correct.
	5	Today's date is January 21, 2017 and	5	Q You signed a previous declaration in this
	6	the time is approximately 9:01 a.m. The	6	IPR back in December of 2015; do you recall that?
		video deposition today is being held in	7	A I I do recall signing something
	8	Norwalk, Connecticut in the matter of	8	previously.
	9	Amerigen Pharmaceuticals Limited,	9	Q And do you recall having your deposition
	10	Argentum Pharmaceuticals LLC vs Janssen	10	taken back in August of last year?
	11	Oncology, Inc. for the United States	11	A Yes.
	12	Patent and Trademark Office before the	12	Q Could you turn to paragraph four of your
	13	patent trial and appeal board. Our	13	declaration, the reply declaration?
	14	deponent today is Dr. Scott Serels.	14	A Yes.
	15	At this time, would counsel please	15	Q Are you there?
	16	identify themselves for the record.	16	A I am.
	17	MR. ZEGGER: Paul Zegger with Sidley	17	Q And does that list the materials that you
	18	Austin for the patent owner Janssen	18	were asked to review for your reply declaration?
	19	Oncology, Inc.	19	A Yes.
	20	MR. CASIERI: Chris Casieri of	20	Q Okay. In particular, it's the expert
	21	McNeely, Hare & War representing the	21	reports of Dr. Chodak, Dr. Auchus and Dr. Velltura?
		petitioner.	22	A Correct.
	23	THE VIDEOGRAPHER: Our court	23	Q And also the Amerigen expert declarations
-	-			

	Page 6		Page 8
1	A Correct.	1	THE VIDEOGRAPHER: Excuse me,
2	Q Did you look at any other expert	2	counsel.
3	declarations?	3	Doctor, could I can you to scooch
4	A Not that I recall.	4	your microphone up
5	Q Okay. Do you recall being provided the	5	THE WITNESS: Oh, absolutely.
6	patent owner's response brief?	6	THE VIDEOGRAPHER: just a little
7	A Not in specifics, but yes.	7	bit?
8	Q Well, is that something you reviewed?	8	THE WITNESS: Absolutely.
9	A I did, yes.	9	THE VIDEOGRAPHER: Thank you, sir.
10	Q You didn't review is there any reason	10	BY MR. ZEGGER:
	why that's not listed in your list of materials	11	Q In any event, you weren't, for purposes
12	considered in paragraph four?	12	of your reply declaration, asked to respond to
13	A I think this is something that perhaps	13	Dr. Rettig?
	was reviewed before this document was completed, so	14	A Correct.
15	it wasn't included.	15	Q Now, in paragraph six of your reply
16	Q I'm sorry, do you know when the patent	16	declaration, you discuss a definition of a person of
17	I I I I I I I I I I I I I I I I I I I	17	ordinary skill in the art or a PHOSITA, for short?
18	A I don't. I don't recall.	18	A Correct.
19	Q Okay. That was a brief back in October	19	Q And do you agree that a PHOSITA is a
20	of 2016? I'm just trying to find out whether you	20	urologist or oncologist with access to
	recall being provided with that document?	21	endocrinologist to the extent needed?
22	A I believe I was, but I don't recall the	22	A I agree.
23	document specifically.	23	Q And do you agree that a urologist is
24	Q Okay. Were you provided a an expert	24	generally not an expert in endocrinology?
	Page 7		Page 9
	declaration of a Dr. Rettig?		A Correct.
2	A Dr. Rettig? Yes, I do believe I saw a	2	MR. CASIERI: Object to form.
3	e	3	BY MR. ZEGGER:
4	Q Okay. Is there any reason why that		Q And do you agree that an oncologist is
	wasn't listed in your list of materials considered	5	generally not an expert in endocrinology?
6	in paragraph four of your reply declaration?	7	MR. CASIERI: Object to form.
8	A I thought these were most specific to the	8	A Correct. BY MR. ZEGGER:
9	declaration.	9	
10	Q Okay. Do you know who Dr. Rettig is?	10	Q Are you an expert in oncology in endocrinology?
11	A I believe he's a physician, urologist. But, again, I don't recall the specifics of his	11	A No.
12	report.	12	Q Prior to your work in connection with
13	Q Okay. Were you asked to review it	13	this case, had you ever heard of a condition called
14	specifically?		CYP17 deficiency?
15	A I've seen you know, I've a lot of	15	A Yes.
16	different papers and different, you know, reports	16	Q And that was prior to your work in
17	pertaining to this case. So I recognize the name,	17	connection with this case?
18	but I don't recognize the or remember the or	18	A Correct.
19	recall the specifics of what he was describing.	19	Q But in terms of your own work, if you
20	Q Did you know that he's a medical	20	have the need of expertise in endocrinology, you
21	oncologist?	21	would consult a physician that has some expertise in
22	A I knew he was a physician. I wasn't sure		that area; correct?
23	exactly what his title was.	23	A Correct.
1	-	1	

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	Page 10	Page 12
	declaration, you did not fully consider the various	1 it says on the front page.
2	mechanisms by which ketoconazole was known to	<sup>2</sup> Q Okay. Does that refresh any recollection
3	inhibit adrenal steroid synthesis beyond inhibiting	<sup>3</sup> that you have as to when you were first provided the
4	,, _,, _	4 Vidal paper?
5	MR. CASIERI: Object to form.	<sup>5</sup> A You know, I've seen so many papers, I
6	A Correct.	<sup>6</sup> don't recall exactly when. But if that's when he
7	BY MR. ZEGGER:	<sup>7</sup> downloaded it, I I really just don't know. I
8	Q Okay. And particularly, you were	<sup>8</sup> mean whether his downloading pertains to when I saw
9	focusing on one particular mechanism of action; is	<sup>9</sup> the paper, I just don't know.
10	that right?	<sup>10</sup> Q Okay. No, I'm just trying to find out
11	A As it pertained to abiraterone, which was	11 how many hours or days before you signed your reply
12	the compound that we were most interested in.	<sup>12</sup> declaration on January 16th, you had the Vidal
13	Q You agree that ketoconazole has	13 paper?
14	mechanisms of action other than inhibiting CYP17	14 A I'm not sure.
15	enzyme synthesis?	<sup>15</sup> MR. CASIERI: Object to form.
16	A I do agree.	<sup>16</sup> BY MR. ZEGGER:
17	MR. CASIERI: Object to form.	<sup>17</sup> Q All right. You cite a portion of the
18	BY MR. ZEGGER:	<sup>18</sup> Vidal paper in your reply declaration, paragraph
19	Q Now, in defending the approach that you	19 nine; is that right?
20	took in this case, you cite to an article authored	<sup>20</sup> I'm sorry, paragraph eight?
21	by a Vidal and a Dr. De bono; is that right?	21 A Correct.
22	A Correct.	<sup>22</sup> Q Now, is there any indication in the
23	Q Let me show you Amerigen Exhibit 1147.	<sup>23</sup> portion that you cite indicating that ketoconazole
24	And is this the article that you relied	<sup>24</sup> is a CYP17 inhibitor?
-	Dage 11	
	Page 11	Page 13
	upon?	<sup>1</sup> A Sorry. Can you repeat the
2	upon? A Yes.	1ASorry. Can you repeat the2QSure.
2 3	upon? A Yes. Q When did you first see it?	<ol> <li>A Sorry. Can you repeat the</li> <li>Q Sure.</li> <li>3 Is there any portion of the Vidal paper</li> </ol>
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Page 16Page 161quote from Vidal "Through the inhibition of key2enzymes in the adrenal steroid biosynthesis pathways3with agents such as ketoconazole or the CYP174inhibitor, altriatrone acetate."5Do you see that?6A7Q7Q9a CYP17 inhibitor?10A9a CYP17 inhibitor?11Q9a CYP17 inhibitor?12A13Q14Q15R Idea15R Idea16Y CyP17 inhibitor?17Q18A19A19A10Correct.19A10Correct.19A10Correct.10Q11Correct.12Correct.13MR.CASIERI: Object to form.14A15A Correct.16A17O Ckay, Neu, that's referring to18abiraterone acetate as a CYP17 inhibitor.19Q10CArrect.11mean, it's subject to interpretation.11mean, it's subject to interpretation.12MR.CASIERI: Object to form.13MR.CASIERI: Object to form.14A15atrenal gend16A17Matta attage attage attage attage attage attage attage attag			
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## DOCKET A L A R M



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