

Page 1

1 UNITED STATES PATENT AND TRADEMARK OFFICE  
-----X  
2 AMERIGEN PHARMACEUTICALS LIMITED,  
3                   Petitioner,  
4       -against-  
5 JANSSEN ONCOLOGY, INC.,  
6                   Patent Owner.  
7 Case IPR2016-00286  
-----X  
8  
9                               787 Seventh Avenue  
                                  New York, New York  
10  
11                               August 22, 2016  
                                  9:23 a.m.  
12  
13                   DEPOSITION of SCOTT SERELS, M.D., taken  
14 before Sadie L. Herbert, a Registered  
15 Professional Reporter and Notary Public of the  
16 States of New York and New Jersey.  
17  
18  
19  
20  
21  
22                               THE MCS GROUP, INC.  
23                   1601 Market Street, 8th Floor  
24                               Philadelphia, PA 19103  
25                               (215) 405-8178

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1                   **A P P E A R A N C E S:**  
2  
3                   **MCNEELY, HARE & WAR LLP**  
4                   **ON BEHALF OF PETITIONER**  
5                   12 Roszel Road, Suite C104  
6                   Princeton, New Jersey 08540  
7                   **BY: GABRIELA MATERASSI, ESQ.**  
8                   Materassi@miplaw.com  
9                   Phone 347.400.1154  
10                   **WILLIAM D. HARE, ESQ.**  
11                   Bill@miplaw.com  
12  
13                   **SIDLEY AUSTIN LLP**  
14                   **ON BEHALF OF PATENT OWNER**  
15                   787 Seventh Avenue  
16                   New York, New York 10019  
17                   **BY: BINDU DONOVAN, ESQ.**  
18                   Bdonovan@sidley.com  
19                   Phone 212.839.5696  
20                   **ALYSSA B. MONSEN, ESQ.**  
21                   Amonsens@sidley.com  
22  
23                   **ALSO PRESENT:**  
24                   **JENNIFER REDA, Johnson & Johnson**  
25                   **TOM DEVINE, Videographer**

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1                   ----- I N D E X -----  
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9                   Exhibit 2028   Patent Owner's Notice of  
10   Deposition of Scott R.  
11   Serels, M.D.           5  
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6   (EXHIBITS TO BE PRODUCED)  
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1 PROCEEDINGS  
2 (Janssen Exhibit 2028, Patent  
3 Owner's Notice of Deposition of  
4 Scott R. Serels, M.D., was  
5 marked for identification.)  
6 (Janssen Exhibit 2029,  
7 Curriculum Vitae, was marked  
8 for identification.)  
9 THE VIDEOGRAPHER: Good  
10 morning. We are now on the record.  
11 Today's date is August 22nd, 2016,  
12 and the time is approximately  
13 9:23 a.m.  
14 We are located at the offices  
15 of Sidley Austin LLP located at 787  
16 7th Avenue, New York, New York.  
17 We are taking the deposition of  
18 Dr. Scott Serels for an inter  
19 partes review proceeding in the  
20 matter of Amerigen Pharmaceuticals  
21 Limited V Janssen Oncology --  
22 Oncology, Incorporated before the  
23 U.S. Patent and Trademark Office  
24 before the Patent Trial and Appeal  
25 Board, case number IPR 2016-00286.

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1 My name is Thomas Devine and I  
2 am the legal video specialist with  
3 Deitz Reporting. The court  
4 reporter is Sadie Herbert, also  
5 with Deitz Reporting.  
6 At this time, I would like to  
7 ask the attorneys present to please  
8 introduce themselves for the video  
9 record, please state your name, the  
10 firm with which you are affiliated  
11 and whom you represent, after which  
12 the court reporter will swear in  
13 the witness and we may proceed.  
14 MS. DONOVAN: Bindu Donovan  
15 with Sidley Austin representing  
16 patent owner, Janssen Oncology Inc.  
17 And with me is my colleague, Alyssa  
18 Monsen.  
19 MS. MATERASSI: Gabriela  
20 Materassi of McNeely, Hare & War  
21 LLP representing petitioner,  
22 Amerigen Pharmaceuticals Limited.  
23 With me is my colleague, William  
24 Hare.  
25 MS. REDA: Jennifer Reda with

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1 Johnson & Johnson representing  
2 Janssen Oncology.  
3  
4 SCOTT SERELS, M.D., the witness herein, having  
5 first been duly sworn by a Notary Public  
6 of the State of New York, was examined and  
7 testified as follows:  
8 MS. DONOVAN: Just before we  
9 start, I'd just like to state on  
10 the record, I've marked Dr. Hare --  
11 the notice of deposition that we  
12 served for Dr. Hare as Janssen  
13 Exhibit 2028.  
14 MR. HARE: Serels.  
15 MS. DONOVAN: Okay. Serels.  
16 THE WITNESS: Serels.  
17 MS. DONOVAN: I apologize. I'm  
18 not going to ask any questions, but  
19 I just wanted it on the record.  
20 MR. HARE: Sure.  
21 CROSS-EXAMINATION  
22 BY MS. DONOVAN:  
23 **Q Dr. Serels, please could you state**  
24 **your full name for the record.**  
25 **A** Scott Serels.

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1 **Q And what is your home address?**  
2 **A** 9 North Ridge Road in Westford,  
3 Connecticut.  
4 **Q Okay. And have you had your**  
5 **deposition taken before today, sir?**  
6 **A** Yes, not in this case, but other  
7 cases.  
8 **Q Have you had it taken previously in**  
9 **a patent infringement proceeding?**  
10 **A** Yes.  
11 **Q Could you tell me which proceeding**  
12 **that was?**  
13 **A** I don't have the exact docket  
14 number, but it was a case involving an  
15 overactive bladder medication, used to treat  
16 problems with urinary incontinence.  
17 **Q And were you testifying as an**  
18 **expert witness in that case?**  
19 **A** I was.  
20 **Q And other than that case, have you**  
21 **testified in any other patent infringement**  
22 **proceeding?**  
23 **A** No.  
24 **Q And did -- in that patent**  
25 **infringement case that you mentioned, did**

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1 you also testify at trial?  
2 A I did.  
3 Q Do you remember the name of the  
4 medication?  
5 A I believe it was tolterodine.  
6 Q Okay. And other than this patent  
7 infringement case, can you just describe,  
8 have you been deposed in other matters?  
9 A Yes.  
10 Q How many times?  
11 A To give you a rough number,  
12 probably four or five times a year.  
13 Q And could you generally describe  
14 the nature of those matters?  
15 A Those matters are usually related  
16 to medical devices or medical malpractice.  
17 Q And have you also previously, other  
18 than this patent case, testified at trial?  
19 A No.  
20 Q Okay. So you're generally familiar  
21 with the deposition procedure. I'll just  
22 remind you, if you don't understand a  
23 question, please let me know and I will  
24 rephrase it for you. And if you don't ask  
25 me to rephrase a question, I'm going to

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1 assume that you understand the question,  
2 okay, sir?  
3 A Fine.  
4 Q All right. I'm going to show the  
5 witness what's been previously marked as  
6 Amerigen Exhibit 1002.  
7 (Amerigen Exhibit 1002,  
8 Declaration of Scott R. Serels,  
9 M.D., having been previously  
10 marked, was introduced into the  
11 record.)  
12 Q Sir, do you recognize this  
13 document?  
14 A I do.  
15 Q This is your December 4th, 2015  
16 declaration in this matter; is that correct?  
17 A That's correct.  
18 Q When did you last review your  
19 declaration?  
20 A Yesterday.  
21 Q And when were you first approached  
22 to get involved in this matter?  
23 MS. MATERASSI: Objection to  
24 form.  
25 A It was probably six to eight months

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1 ago.  
2 Q And who approached you?  
3 A Bill Hare.  
4 Q Okay. And about how many in-person  
5 meetings did you have with your attorneys  
6 related to the preparation of your  
7 declaration?  
8 A In person, before today, none.  
9 Q Did you have teleconferences with  
10 them?  
11 A We had some phone conversations,  
12 yes.  
13 Q About how -- how many times did you  
14 talk on the phone?  
15 A Once or twice.  
16 Q And did you write the declaration  
17 yourself?  
18 A I had the aid of some attorneys and  
19 others.  
20 Q About how much time in total did  
21 you spend in the preparation of your  
22 declaration?  
23 A I would say, five hours, maybe, six  
24 hours.  
25 Q And how much, in total, in expert

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1 fees have you billed?  
2 A I do not have the exact amount.  
3 I'd have to get that for you.  
4 Q Do you have an estimate?  
5 A Maybe \$3,000.  
6 Q And I asked you about the total  
7 time you spent in preparation of your  
8 declaration, you said five, maybe six hours?  
9 A Correct.  
10 Q Does that include reviewing  
11 literature or --  
12 A Yes.  
13 Q -- just --  
14 A Yes.  
15 Q So in total, the drafting of the  
16 declaration and review of literature, you  
17 spent about five to six hours?  
18 A Correct.  
19 Q I'm going to show the witness what  
20 has been previously marked as Janssen  
21 Exhibit 2029.  
22 MS. MATERASSI: So just a  
23 question, Counsel, are we marking  
24 these exhibits in numerical order,  
25 is this Exhibit 3 or are we

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1 following the original designation  
2 of the exhibit number?  
3 MS. DONOVAN: We are not  
4 marking what's previously been  
5 marked, we're following the  
6 Amerigen exhibit number. What I've  
7 given you right now is Dr. Serels'  
8 CV, this was not previously part of  
9 the record, so I've given it the  
10 next Janssen exhibit number.  
11 So we've -- the last paper that  
12 was filed was the pro hac  
13 submission for Isaac Olson, that  
14 was 2027, we've now started the  
15 notice of deposition as 2028 and  
16 Dr. Serels' CV is 2029.  
17 MS. MATERASSI: Okay. Thank  
18 you.  
19 BY MS. DONOVAN:  
20 **Q Sir, do you recognize Janssen**  
21 **Exhibit 2029?**  
22 A I do.  
23 **Q Okay. And that's your CV; correct?**  
24 A Correct.  
25 **Q And when did you last update your**

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1 **CV?**  
2 A I want to say, probably September  
3 of last year.  
4 **Q Do you consider it to be up to date**  
5 **and generally reflective of your**  
6 **professional background?**  
7 A Yes.  
8 **Q Now, your current position is**  
9 **director of daily operations at the Bladder**  
10 **Control Center of Norwalk; correct?**  
11 A Correct.  
12 **Q And there, you state on your CV,**  
13 **you're director of daily operations which**  
14 **involve urodynamics, female urology and**  
15 **neurourology; is that right?**  
16 A Neurourology, correct.  
17 **Q So you don't specialize in prostate**  
18 **cancer; right, sir?**  
19 A Correct.  
20 **Q Did you treat men who have been**  
21 **diagnosed with prostate cancer?**  
22 A Yes.  
23 **Q What percentage of your practice**  
24 **involves the treatment of men who have been**  
25 **diagnosed with prostate cancer?**

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1 A Probably about 20 percent.  
2 **Q And what percentage of your**  
3 **practice involves the treatment of men with**  
4 **metastatic castration-resistant prostate**  
5 **cancer?**  
6 A Probably somewhere between 5 to  
7 8 percent.  
8 **Q Now, with regard to the prostate**  
9 **cancer patients that you treat, what**  
10 **percentage of your practice involves**  
11 **actually treating the cancer?**  
12 MS. MATERASSI: Objection.  
13 A I would say the 20 percent.  
14 **Q Have you administered ADT?**  
15 A I have.  
16 **Q And what about second-line hormonal**  
17 **therapy?**  
18 A I have.  
19 **Q Your CV lists one publication dated**  
20 **1997 that concerns prostate cancer; is that**  
21 **correct?**  
22 A Correct.  
23 **Q So you haven't published an article**  
24 **concerning prostate cancer in about**  
25 **20 years; is that right?**

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1 A Correct.  
2 **Q And your CV also lists one**  
3 **presentation concerning prostate cancer**  
4 **dated 1996; is that right?**  
5 A Correct.  
6 **Q So you haven't made any**  
7 **presentations concerning prostate cancer in**  
8 **about 20 years; is that right?**  
9 A Correct.  
10 **Q So you're not an expert in the**  
11 **treatment of prostate cancer; is that**  
12 **correct?**  
13 A I'm a urologist who treats prostate  
14 cancer.  
15 **Q Do you consider yourself an expert**  
16 **in the treatment of prostate cancer?**  
17 A No.  
18 **Q Do you have any drug discovery**  
19 **experience, sir?**  
20 A Drug discovery --  
21 **Q Discovery.**  
22 A Could you elaborate on the  
23 question.  
24 **Q Have you been involved in the**  
25 **design of any clinical trials?**

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1 A Yes.  
2 **Q Have you been involved in the**  
3 **design of any clinical trials relating to**  
4 **prostate cancer?**  
5 A No.  
6 **Q Have you been involved in any**  
7 **medicinal chemistry research relating to the**  
8 **discovery of drugs?**  
9 A Explain, explain a little more  
10 clearly what you mean by that.  
11 **Q Have you -- have you been involved**  
12 **in any medicinal chemistry research?**  
13 A So actually doing the chemistry?  
14 **Q Yes.**  
15 A All my research has been clinical  
16 recently.  
17 **Q Why don't -- can you explain to me**  
18 **the type of clinical research that you do.**  
19 A Yeah. Essentially, once a compound  
20 has been created and either it has FDA  
21 approval or it's going to get -- or looking  
22 to get FDA approval, I'll be involved in the  
23 clinical trials to bring that medication or  
24 drug to market.  
25 **Q And you just confirmed none of**

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1 **these clinical trials have concerned**  
2 **prostate cancer drugs?**  
3 A Correct.  
4 **Q Other than this clinical trial**  
5 **research, have you been involved in any**  
6 **other type of research relating to the**  
7 **discovery or development of a drug?**  
8 A No.  
9 **Q Can you describe for me, just**  
10 **generally, the clinical trials that you have**  
11 **been involved with, the type of medications?**  
12 A They've all been related to  
13 urologic care regarding either prostate  
14 problems or prostatic problems.  
15 **Q Do you agree drug discovery is**  
16 **unpredictable?**  
17 MS. MATERASSI: Objection to  
18 form.  
19 A I'm not sure -- can you elaborate  
20 on the question.  
21 **Q That's my question.**  
22 **Do you agree drug discovery is**  
23 **unpredictable, sir, is that a correct**  
24 **statement?**  
25 A Yes.

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1 **Q Do you agree replacing one drug for**  
2 **another in a drug combination can have**  
3 **unpredictable results?**  
4 A Depending on how far along you are,  
5 yes, you could be surprised by things.  
6 **Q So replacing one drug for another**  
7 **in a drug combination can have unpredictable**  
8 **results; correct?**  
9 A I imagine it could, yes.  
10 **Q Okay. And you agree it's not**  
11 **possible to know in advance whether therapy**  
12 **will be safe and effective without**  
13 **conducting a clinical trial; correct?**  
14 A Yes.  
15 **Q And you have never developed any**  
16 **drug combinations for prostate cancer;**  
17 **correct?**  
18 A Correct.  
19 **Q All right, sir, if you could look**  
20 **at your declaration, please.**  
21 **Could you please turn to**  
22 **Paragraph 8 of your declaration, sir. And**  
23 **in Paragraph 8, you provide an opinion**  
24 **concerning the person of ordinary skill in**  
25 **the art at the time of the filing of the**

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1 **'438 patent.**  
2 A Mm-hmm.  
3 **Q Correct?**  
4 A Mm-hmm, correct.  
5 **Q And there, you say that the person**  
6 **of ordinary skill in the art at the time of**  
7 **filing of this patent is, "A physician**  
8 **specializing in urology or oncology or holds**  
9 **a Ph.D. in pharmacology, biochemistry or a**  
10 **related discipline."**  
11 **Do you see that, sir?**  
12 A Yes, I do.  
13 **Q Do you agree, sir, that in actual**  
14 **practice, not all urologists treat prostate**  
15 **cancer?**  
16 MS. MATERASSI: Objection.  
17 Form.  
18 A I mean, I'm sure there are some  
19 that don't, but urologists tend to treat a  
20 broad, a group of different conditions and  
21 usually prostate cancer is one of them.  
22 **Q But you'd agree that there may be**  
23 **some urologists that don't treat prostate**  
24 **cancer; is that true?**  
25 A I'm sure there are some.

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