


Scott Serels, M.D.
August 22, 2016

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<p>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 12 9:23 a.m. 13 14 DEPOSITION of SCOTT SERELS, M.D., taken 15 before Sadie L. Herbert, a Registered 16 Professional Reporter and Notary Public of the 17 States of New York and New Jersey. 18 19 20 21 22 THE MCS GROUP, INC. 23 1601 Market Street, 8th Floor 24 Philadelphia, PA 19103 25 (215) 405-8178</p>	<p>1 ----- INDEX ----- 2 WITNESS EXAMINATION BY PAGE 3 SCOTT SERELS, M.D. MS. DONOVAN 7, 215 4 MS. MATERASSI 195 5 6 7 ----- EXHIBITS ----- 8 JANSSEN DESCRIPTION FOR I.D. 9 Exhibit 2028 Patent Owner's Notice of 10 Deposition of Scott R. 11 Serels, M.D. 5 12 Exhibit 2029 Curriculum Vitae 5 13 Exhibit 2030 Jubelirer Article 137 14 Exhibit 2031 O'Donnell Article with 15 handwritten notations 154 16 ----- PREVIOUSLY MARKED EXHIBITS ----- 17 AMERIGEN 18 Exhibit 1001 US Patent 8.822,438 41 19 Exhibit 1002 Declaration of Scott R. 20 Serels, M.D. 10 21 Exhibit 1003 O'Donnell Article 72 22 Exhibit 1004 Gerber Article 156 23 Exhibit 1005 US Patent 5,604,213 148 24 Exhibit 1020 Harris Article 119 25 Exhibit 1021 Oh Article 140</p>
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<p>1 APPEARANCES: 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</p>	<p>1 ----- PREVIOUSLY MARKED EXHIBITS (Cont'd) ----- 2 AMERIGEN DESCRIPTION FOR I.D. 3 Exhibit 1028 Jubelirer Abstract 132 4 5 6 (EXHIBITS TO BE PRODUCED) 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p> 

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<p>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.</p>	<p>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.</p>
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<p>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</p>	<p>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</p>

<p style="text-align: right;">Page 9</p> <p>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</p>	<p style="text-align: right;">Page 11</p> <p>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</p>
<p style="text-align: right;">Page 10</p> <p>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</p>	<p style="text-align: right;">Page 12</p> <p>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</p>

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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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<p>1 A Yes.</p> <p>2 Q Have you been involved in the</p> <p>3 design of any clinical trials relating to</p> <p>4 prostate cancer?</p> <p>5 A No.</p> <p>6 Q Have you been involved in any</p> <p>7 medicinal chemistry research relating to the</p> <p>8 discovery of drugs?</p> <p>9 A Explain, explain a little more</p> <p>10 clearly what you mean by that.</p> <p>11 Q Have you -- have you been involved</p> <p>12 in any medicinal chemistry research?</p> <p>13 A So actually doing the chemistry?</p> <p>14 Q Yes.</p> <p>15 A All my research has been clinical</p> <p>16 recently.</p> <p>17 Q Why don't -- can you explain to me</p> <p>18 the type of clinical research that you do.</p> <p>19 A Yeah. Essentially, once a compound</p> <p>20 has been created and either it has FDA</p> <p>21 approval or it's going to get -- or looking</p> <p>22 to get FDA approval, I'll be involved in the</p> <p>23 clinical trials to bring that medication or</p> <p>24 drug to market.</p> <p>25 Q And you just confirmed none of</p>	<p>1 Q Do you agree replacing one drug for</p> <p>2 another in a drug combination can have</p> <p>3 unpredictable results?</p> <p>4 A Depending on how far along you are,</p> <p>5 yes, you could be surprised by things.</p> <p>6 Q So replacing one drug for another</p> <p>7 in a drug combination can have unpredictable</p> <p>8 results; correct?</p> <p>9 A I imagine it could, yes.</p> <p>10 Q Okay. And you agree it's not</p> <p>11 possible to know in advance whether therapy</p> <p>12 will be safe and effective without</p> <p>13 conducting a clinical trial; correct?</p> <p>14 A Yes.</p> <p>15 Q And you have never developed any</p> <p>16 drug combinations for prostate cancer;</p> <p>17 correct?</p> <p>18 A Correct.</p> <p>19 Q All right, sir, if you could look</p> <p>20 at your declaration, please.</p> <p>21 Could you please turn to</p> <p>22 Paragraph 8 of your declaration, sir. And</p> <p>23 in Paragraph 8, you provide an opinion</p> <p>24 concerning the person of ordinary skill in</p> <p>25 the art at the time of the filing of the</p>
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<p>1 these clinical trials have concerned</p> <p>2 prostate cancer drugs?</p> <p>3 A Correct.</p> <p>4 Q Other than this clinical trial</p> <p>5 research, have you been involved in any</p> <p>6 other type of research relating to the</p> <p>7 discovery or development of a drug?</p> <p>8 A No.</p> <p>9 Q Can you describe for me, just</p> <p>10 generally, the clinical trials that you have</p> <p>11 been involved with, the type of medications?</p> <p>12 A They've all been related to</p> <p>13 urologic care regarding either prostate</p> <p>14 problems or prostatitic problems.</p> <p>15 Q Do you agree drug discovery is</p> <p>16 unpredictable?</p> <p>17 MS. MATERASSI: Objection to</p> <p>18 form.</p> <p>19 A I'm not sure -- can you elaborate</p> <p>20 on the question.</p> <p>21 Q That's my question.</p> <p>22 Do you agree drug discovery is</p> <p>23 unpredictable, sir, is that a correct</p> <p>24 statement?</p> <p>25 A Yes.</p>	<p>1 '438 patent.</p> <p>2 A Mm-hmm.</p> <p>3 Q Correct?</p> <p>4 A Mm-hmm, correct.</p> <p>5 Q And there, you say that the person</p> <p>6 of ordinary skill in the art at the time of</p> <p>7 filing of this patent is, "A physician</p> <p>8 specializing in urology or oncology or holds</p> <p>9 a Ph.D. in pharmacology, biochemistry or a</p> <p>10 related discipline."</p> <p>11 Do you see that, sir?</p> <p>12 A Yes, I do.</p> <p>13 Q Do you agree, sir, that in actual</p> <p>14 practice, not all urologists treat prostate</p> <p>15 cancer?</p> <p>16 MS. MATERASSI: Objection.</p> <p>17 Form.</p> <p>18 A I mean, I'm sure there are some</p> <p>19 that don't, but urologists tend to treat a</p> <p>20 broad, a group of different conditions and</p> <p>21 usually prostate cancer is one of them.</p> <p>22 Q But you'd agree that there may be</p> <p>23 some urologists that don't treat prostate</p> <p>24 cancer; is that true?</p> <p>25 A I'm sure there are some.</p>

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