### Mark J. Ratain, M.D.

| 1  | UNITED STATES PATENT AND TRADEMARK OFFICE     |  |  |  |  |  |  |
|----|---|--|--|--|--|--|--|
| 2  |   |  |  |  |  |  |  |
| 3  | BEFORE THE PATENT TRIAL AND APPEAL BOARD      |  |  |  |  |  |  |
| 4  | · <del></del>                                 |  |  |  |  |  |  |
| 5  |   |  |  |  |  |  |  |
|    | Amerigen Pharmaceuticals Limited and          |  |  |  |  |  |  |
| 6  | Argentum Pharmaceuticals LLC                  |  |  |  |  |  |  |
| 7  | Petitioners                                   |  |  |  |  |  |  |
| 8  | V.  |  |  |  |  |  |  |
| 9  | Janssen Oncology, Inc.                        |  |  |  |  |  |  |
| 10 | Patent Owner                                  |  |  |  |  |  |  |
| 11 |   |  |  |  |  |  |  |
| 12 | Case IPR2016-00286                            |  |  |  |  |  |  |
|    | Patent 8,822,438 B2                           |  |  |  |  |  |  |
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| 16 |   |  |  |  |  |  |  |
| 17 | VIDEOTAPED DEPOSITION OF MARK J. RATAIN, M.D. |  |  |  |  |  |  |
| 18 | January 23, 2017                              |  |  |  |  |  |  |
| 19 | Chicago, Illinois                             |  |  |  |  |  |  |
| 20 |   |  |  |  |  |  |  |
| 21 |   |  |  |  |  |  |  |
| 22 |   |  |  |  |  |  |  |
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| 24 |   |  |  |  |  |  |  |



## Mark J. Ratain, M.D.

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|--|--|----------------------------------|--|
| 1  | rage 2   | 1                                | INDEX  |
| 2  |  | 2                                | MARK J. RATAIN, M.D. EXAMINATION   |
| 3  |  | 3                                | BY MR. KRAUSE 6  |
|  |  | 5                                | EXHIBITS   |
| 4  |  | 6                                | REFERENCED EXHIBIT FIRST REFERRED TO   |
| 5  |  | 7                                | Amerigen Article by O'Donnell, 51  |
| 6  | The videotaped deposition of MARK J. RATAIN, M.D.,                                       |                                  | Exhibit 1003 et al., "Hormonal   |
| 7  | called by the Patent Owner for examination, taken  | 8                                | impact," etc.  |
| 8  | before CORINNE T. MARUT, C.S.R. No. 84-1968,   | 9                                | Amerigen Article by Tannock, et 90<br>Exhibit 1006 al., "Chemotherapy with   |
| 9  | Registered Professional Reporter and a Certified   | 10                               | Mitoxantrone," etc.  |
| 10   | Shorthand Reporter of the State of Illinois, at the                                      | 11                               | Amerigen Article by Tannock, et 88   |
| 11   | offices of Sidley Austin LLP, Suite 3800, One South                                      | 12                               | Exhibit 1022 al., "Docetaxel plus  |
| 12   | Dearborn Street, Chicago, Illinois, on   | 13                               | Prednisone," etc. Amerigen Declaration of Dr. Mark 7   |
| 13   | January 23, 2017, commencing at 8:57 a.m.  |                                  | Exhibit 1091 J. Ratain   |
| 14   |  | 14                               |  |
| 15   |  | 1 -                              | Amerigen Article by Richards, et 109   |
| 16   |  | 15                               | Exhibit 1136 al., "Interactions of Abiraterone, Eplerenone,  |
| 17   |  | 16                               | and Prednisolone," etc.  |
| 18   |  | 17                               | Janssen Article by Krishnan, et 84   |
|  |  | 1.0                              | Exhibit 2024 al., "A Glucocorticoid-<br>Responsive Mutant  |
| 19   |  | 18                               | Androgen Receptor," etc.   |
| 20   |  | 19                               | imarogen receptor, etc.  |
| 21   |  | 20                               |  |
| 22   |  | 21 22                            |  |
| 23   |  | 23                               |  |
| 24   |  | 24                               |  |
|  | Page 3   |                                  | Page 5   |
| 1  | APPEARANCES:   | 1                                | THE VIDEOGRAPHER: We are now on the record   |
| 2  | ON BEHALF OF THE PETITIONERS:  | 2                                | My name is Terry Kupperman. I am a   |
| 3  | McNEELY, HARE & WAR LLP  | 3                                | videographer for Golkow Technologies.  |
|  | 5335 Wisconsin Avenue, NW, Suite 440   | 4                                | Today's date is January 23, 2017. The  |
| 4  | Washington, DC 20015   | 5                                | time is now 8:57 a.m.  |
| 5  | 202-640-1801<br>BY: WILLIAM D. HARE, ESQ.  | 6                                | This video deposition is being held in   |
|  | bill@miplaw.com  | 7                                | Chicago, Illinois in the matter of Amerigen  |
| 6  | CHRISTOPHER CASIERI, ESQ.  | 8                                | Pharmaceuticals Limited vs. Janssen Oncology, Inc.,  |
| 7  | chris@miplaw.com   | 9                                | for the United States Patent and Trademark Office.   |
| 8  |  | 10                               | The deponent's name is   |
| 9  | ON DELIVER OF THE RESTRICTION  | 11                               | Dr. Mark J. Ratain.  |
| 10   | ON BEHALF OF THE PATENT OWNER:<br>SIDLEY AUSTIN LLP                                      | 12                               |  |
| - 0  | 787 Seventh Avenue   |                                  | Will counsel please identify yourselves  |
|  | Novy Vork Novy Vork 10010  | 13                               | for the record.  MR. KRAUSE: Todd Krause of Sidley Austin  |
| 11   | New York, New York 10019   | 1 1 1                            | INTER PROPERTY OF TOTAL PROPERTY AND A TRAINING TOTAL PROPERTY OF THE PROPERTY |
|  | 212-839-5696   | 14                               |  |
| 12   | · · · · · · · · · · · · · · · · · · ·  | 15                               | representing Patent Owner, Janssen.  |
| 12   | 212-839-5696<br>BY: TODD L. KRAUSE, ESQ.   | 15<br>16                         | representing Patent Owner, Janssen.  MR. CASIERI: Chris Casieri of McNeely, Hare &   |
| 12<br>13<br>14                               | 212-839-5696<br>BY: TODD L. KRAUSE, ESQ.   | 15<br>16<br>17                   | representing Patent Owner, Janssen.  MR. CASIERI: Chris Casieri of McNeely, Hare & War representing the Petitioners and with me is   |
| 12   | 212-839-5696<br>BY: TODD L. KRAUSE, ESQ.   | 15<br>16                         | representing Patent Owner, Janssen.  MR. CASIERI: Chris Casieri of McNeely, Hare & War representing the Petitioners and with me is William Hare.   |
| 12<br>13<br>14<br>15<br>16<br>17             | 212-839-5696<br>BY: TODD L. KRAUSE, ESQ.<br>tkrause@sidley.com                           | 15<br>16<br>17                   | representing Patent Owner, Janssen.  MR. CASIERI: Chris Casieri of McNeely, Hare & War representing the Petitioners and with me is   |
| 12<br>13<br>14<br>15<br>16<br>17<br>18       | 212-839-5696 BY: TODD L. KRAUSE, ESQ. tkrause@sidley.com  VIDEOTAPED BY: TERRY KUPPERMAN | 15<br>16<br>17<br>18             | representing Patent Owner, Janssen.  MR. CASIERI: Chris Casieri of McNeely, Hare & War representing the Petitioners and with me is William Hare.   |
| 12<br>13<br>14<br>15<br>16<br>17             | 212-839-5696<br>BY: TODD L. KRAUSE, ESQ.<br>tkrause@sidley.com                           | 15<br>16<br>17<br>18<br>19       | representing Patent Owner, Janssen.  MR. CASIERI: Chris Casieri of McNeely, Hare & War representing the Petitioners and with me is  William Hare.  THE VIDEOGRAPHER: Will the Court Reporter   |
| 12<br>13<br>14<br>15<br>16<br>17<br>18<br>19 | 212-839-5696 BY: TODD L. KRAUSE, ESQ. tkrause@sidley.com  VIDEOTAPED BY: TERRY KUPPERMAN | 15<br>16<br>17<br>18<br>19<br>20 | representing Patent Owner, Janssen.  MR. CASIERI: Chris Casieri of McNeely, Hare & War representing the Petitioners and with me is William Hare.  THE VIDEOGRAPHER: Will the Court Reporter please identify yourself and swear in the witness.   |



|    | TIGITI 6: IKG                                       |    | ·   |
|----|---|----|---|
|    | Page 6  |    | Page 8  |
| 1  | MARK J. RATAIN, M.D.,                               | 1  | Q. Are there any errors in your declaration         |
| 2  | called as a witness herein, having been first duly  | 2  | that you're aware of?                               |
| 3  | sworn, was examined and testified as follows:       | 3  | A. Well, I was reviewing it in preparation          |
| 4  | EXAMINATION   | 4  | for this. I note that Exhibit A is missing and      |
| 5  | BY MR. KRAUSE:                                      | 5  | never was apparently I thought counsel was doing    |
| 6  | Q. Good morning, Dr. Ratain.                        | 6  | that. That's my error. And I there is some          |
| 7  | A. Good morning.                                    | 7  | parentheses missing in some places but nothing      |
| 8  | Q. Can you please state your name and home          | 8  | no substantive errors.                              |
| 9  | address for the record.                             | 9  | Q. When were you first asked to provide             |
| 10 | A. Sure. Mark Jeffrey Ratain. 1040 West             | 10 | opinions on the subject matter in your declaration? |
| 11 | Oakdale, Chicago, 60657.                            | 11 | A. It would have been sometime in the fall.         |
| 12 | Q. Have you ever been deposed before?               | 12 | Q. Can you a month maybe, November,                 |
| 13 | A. Yes.   | 13 | December, early fall, late?                         |
| 14 | Q. There are a few points I'd like to               | 14 | A. It would have been October or November.          |
| 15 | review before we get started.                       | 15 | Q. Okay. When did you begin working on the          |
| 16 | If I ask a question that's not clear or             | 16 | opinions that you have expressed in your            |
| 17 | you didn't hear me, please let me know so I can ask | 17 | declaration?  |
| 18 | the question again. If you answer, I'll assume you  | 18 | A. That was probably in November.                   |
| 19 | understood and heard my question. Okay?             | 19 | Q. About how many hours total did you spend         |
| 20 | A. Okay.  | 20 | working on the declaration from the very beginning  |
| 21 | Q. We have a Court Reporter taking down             | 21 | of the time until you signed it?                    |
| 22 | your answers to my questions. So, please try to     | 22 | A. Until? I'm sorry.                                |
| 23 | give verbal answers to my questions. Okay?          | 23 | Q. Until you signed it.                             |
| 24 | A. Yes.   | 24 | A. Well, let's see. I've invoiced about 40          |
|    | 11. 105.  |    | 71. Wen, let's see. I've involced about 40          |
|    | Page 7  |    | Page 9  |
| 1  | Q. We'll try to take breaks about every             | 1  | hours so far, but I haven't invoiced for my recent  |
| 2  | hour or so, but please let me know if you need a    | 2  | work. So, and that's recently it's been at          |
| 3  | break. I'll finish whatever question I'm on and we  | 3  | least a day a week. So, I don't know. A lot of      |
| 4  | can take a break.                                   | 4  | time.   |
| 5  | Is there any reason you can't give                  | 5  | Q. A day a week since when?                         |
| 6  | complete and accurate testimony here today?         | 6  | A. I would have last invoiced sometime in           |
| 7  | A. No.  | 7  | December. I don't I just don't remember.            |
| 8  | Q. I've handed you a document that's been           | 8  | Q. Sure.  |
| 9  | previously marked Amerigen Exhibit DX 1091.         | 9  | A. I've obviously put in time since I've            |
| 10 | Do you recognize this document?                     | 10 | signed it as well.                                  |
| 11 | A. Yes.   | 11 | Q. Do you regularly invoice in the                  |
| 12 | Q. And is this your declaration in this             | 12 | beginning of the month or the end of the month?     |
| 13 | matter?   | 13 | A. There is no regularity to that.                  |
| 14 | A. Yes.   | 14 | Q. Okay. How did you gather the                     |
| 15 | Q. And is that your signature on the first          | 15 | information that you relied on in your declaration? |
| 16 | page of the declaration?                            | 16 | A. First of all, I knew a lot of it and,            |
| 17 | A. Yes.   | 17 | second of all, I was asked to primarily respond to  |
| 18 | Q. Is this declaration an accurate                  | 18 | Dr. Rettig. So, I reviewed his declaration. I       |
| 19 | statement of the opinions that you've reached in    | 19 | reviewed his deposition transcript.                 |
|    | statement of the opinions that you've reached in    |    |   |
| 20 | this case?  | 20 | And then I did my own independent review            |

21

22

missing pages.

Q. Sure.

A. Checking to make sure there is no

of what I as a physician and professor call the

22 literature but you in the law call the prior art.

<sup>23</sup> So, I looked at both literature before the filing

Page 10

- 1 and expectation of success and then I looked at
- more recent literature in the context of his
- opinions regarding unexpected results.
- And I used the standard approach I use
- in my daily professional work as a professor,
- physician and investigator and used searches with
- PubMed and Google Scholar.
- 8 Q. And how did you decide which references
- you would identify in your declaration based on the
- 10 searches that you performed?
- 11 A. Well, as I said, I was asked to respond
- 12 to Dr. Rettig and so, you know, I cited references
- that -- that supported my opinions.
- 14 Q. Did you read every page of every
- 15 reference that you cite in your declaration?
- 16 A. I think so. It's conceivable there is a
- 17 book cited that I didn't read every page of, but I
- 18 read every page of any article or book chapter that
- 19 was relevant.
- 20 Q. Did you speak with anyone other than
- Petitioner's counsel in preparing the opinions that
- you've expressed in your declaration?
- 23 A. No.
- 24 You didn't speak with any other

- 1 relied on in your declaration that you did not
- identify in your declaration?
- A. I would have to go through and sit here
- and go through it word by word to make sure there
- is nothing else missing.
- Q. Was there ever a draft Exhibit A?
  - A. Not that I saw.
- 8 Q. Did you keep a list of the references
- that you were reviewing in the preparation of your declaration?
- 11 A. Not -- not in a formal way, no. I was
- 12 relying on counsel for -- to legalize my
- declaration, so to speak.
- 14 Q. What do you mean by that?
- 15 A. To get the references in the proper
- 16 legal format.

17

- Q. Did you actually draft your declaration?
- 18 A. Yes.
- 19 Q. About how many hours did you spend
- 20 drafting your declaration?
- 21 A. I can't tell you that because I spend a
- lot of time reviewing the literature and
- formulating my opinions and communicating my
- opinions with counsel and making sure they

#### Page 11

- colleagues?
- A. No.
- 3 Q. No other experts?
- 4 A. No.
- 5 Q. And I believe you mentioned that you
- 6 read Dr. Rettig's deposition transcript, is that
- 7 right?

2

11

- 8 A. Yes.
- 9 Q. You don't identify Dr. Rettig's
- 10 deposition transcript in your declaration, do you?
  - A. Well, in theory it would have been in
- 12 Exhibit A because I certainly reviewed it. I do
- 13 note -- I guess it's not cited as specifically, but
- 14 there are certainly, you know, for example,
- 15 paragraph 29, I say, "I first note that Dr. Rettig
- admitted in his deposition that he did not perform
- 17 a review of any literature other than that provided
- 18 to him by counsel for Janssen."
- 19 So, you are technically correct in that
- my declaration doesn't cite the exhibit number that would be associated with his deposition transcript,
- but I presume that the basis for that sentence
- would be clear to the Board.

Page 13

Page 12

- understood what my opinions were and making sure
- that my -- that we were on the same page as how my
- opinions would fit into the case legally.
- And I was not asked to provide any
- opinions on primary obviousness, only to respond to
- Dr. Rettig, and that's therefore the scope of my
- declaration.
- 8 Q. And when was your declaration completed?
- A. It was completed on January 16.
- 10 Q. Did you read any deposition transcripts
- 11 other than Dr. Rettig's?
  - Yes. A.
- 13 Q. What other deposition transcripts did
  - you read?

12

- A. I read Dr. Auchus' deposition. I read
- <sup>16</sup> Dr. Chodak's deposition. I read Dr. Serels'
- deposition. I read Dr. McDuff I believe, is the
- economist, his deposition. I don't remember if I
- reviewed the other economist's, the one that your
- client has retained. And then I've reviewed the
- deposition transcripts that have been obtained
- 22 since I filed this declaration.
- 23 Q. And what transcripts are those?



Page 14 Page 16 1 reviewed the various petitions, the original 1 substantive facts in the case. Isn't that fair to 2 petition I reviewed, the response, the reply. I've say? 3 reviewed the declarations of the various experts. A. I would say it was more for my curiosity Q. And your declaration doesn't identify than as being -- my opinions would be no different. My declaration would be no different if I had never that you reviewed any of those deposition transcripts, isn't that correct? seen Dr. Auchus' declaration or Dr. Auchus' A. That would have been in Exhibit A. deposition transcript, for example. 8 O. Which doesn't exist? Q. And how would you know that? 9 Which does not exist. A. I'm just telling you now that I -- I 10 Actually, my declaration does address know a lot of things that -- you could ask me if I the deposition transcripts. I'm sorry. It didn't have a particular piece of prior art, how 11 12 addresses the declarations, paragraph 16 where I would that change my opinion. I could give you an note that I reviewed the declaration or at least I answer to that. 14 14 note that the materials discussed in the So, I can -- I can say here under oath declarations, which would imply that I reviewed the that if I had never seen Dr. Auchus' deposition 16 declarations. transcript it wouldn't impact my -- my opinions. 17 17 Q. Why would saying the materials discussed Q. You were referring to paragraph 16 in 18 in the declarations would imply that you read the your declaration, and this paragraph identifies at 19 least a portion of what you considered in deposition transcripts? 20 20 A. No. The declaration. No, you're formulating your opinion. 21 21 This paragraph is the only mention of correct. 22 Q. Oh, I'm sorry. the Chodak declaration, is that correct? 23 23 A. Yeah. No. A. Yes. 24 And, you know, my understanding was that 24 Q. And your declaration provides no Page 15 Page 17 also that I reviewed these other documents, but I 1 opinions with respect to the opinions expressed by haven't cited them with the exception of Rettig's Dr. Chodak's declaration, is that right? 3 A. That's correct. deposition. 4 In other words, they're not -- they --Q. And Dr. Auchus' declaration is also it was of interest to me to understand what mentioned in paragraph 16. It's also mentioned in 6 everybody was saying, but it doesn't impact my own paragraph 19 of your declaration when you refer to 7 opinions. the standard for a person of ordinary skill that he 8 Q. But it informs your understanding of the applied, and then paragraph 35 where you say 9 issues in the case, correct? Dr. Dorin will address Dr. Auchus' opinions, is 10 A. It informs my understanding of the legal 10 that right? 11 11 That's a pretty loaded question. issues, yes. 12 So, Dr. Auchus is mentioned in paragraph Q. And the factual issues, correct? 13 MR. CASIERI: Object to form. 13 16, his declaration. He's also mentioned in 19 and 14 BY THE WITNESS: 15 15 A. I think the factual issues I can -- I But I guess my question is: Is there can form my opinions regarding the factual issues, any other mention of Dr. Auchus in your 16 the scientific medical issues, without reviewing, 17 declaration? 18 18 for example, the deposition transcript of the A. Now I'm going to have -- if you're going 19 endocrinologists, I mean, because I'm -- I'm not 19 to ask me a question like "Is there any other," I'm providing opinions, you know, from their going to have to go through and read it. So, if 21 perspective. you want to represent to me that there isn't,

22

BY MR. KRAUSE:

Q. But it gave you a better understanding

22

23

that's fine. Otherwise --

Q. I'm not aware of any. Are you aware of

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