

Richard Dorin, M.D.

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

3 -----  
4 AMERIGEN PHARMACEUTICALS LIMITED,  
5 ARGENTUM PHARMACEUTICALS LLC,  
6 Petitioner

7 v.  
8 JANSSEN ONCOLOGY, INC.

9 Patent Owner

10 -----

11 Case IPR2016-00286  
12 Patent No. 8,822,438 B2

13 -----

14  
15 VIDEO DEPOSITION OF RICHARD DORIN, M.D.

16  
17 Akin Gump Strauss Hauer & Feld, LLP  
18 Robert E. Strauss Building  
19 1333 New Hampshire Avenue NW  
20 Washington, DC 20036

21 January 19, 2017 9:00 a.m.

22 Denise D. Vickery, CRR/RMR

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2

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22        **Also Present:**

23        Michael Gay, Videographer

24

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1                    **I N D E X**

2                    **EXAMINATION OF**

3        RICHARD DORIN, M.D.                    **PAGE**

4            BY MR. KRAUSE                            7

5            AFTERNOON SESSION                        95

6            BY MR. HARE                                    114

7                    **E X H I B I T S**

8        **PREVIOUSLY MARKED EXHIBITS            REFERENCED**

9        AMERIGEN 1093 Declaration of            9

10        Dr. Richard I. Dorin

11        AMERIGEN 1023 Selective blockade of    41

12        androgenic steroid synthesis by novel lyase

13        inhibitors as a therapeutic strategy for

14        treating metastatic prostate cancer,

15        Attard et al.

16        AMERIGEN 1005 U.S. Patent No. 5,604,213 41

17        Barrie et al.

18        AMERIGEN 1003 Hormonal impact of the   55

19        17a-hydroxylase/C17,20-lyase inhibitor

20        abiraterone acetate (CB7630) in patients with

21        prostate cancer, O'Donnell et al.

22        AMERIGEN 1154 17a-Hydroxylase/17,20-Lyase 66

23        Deficiency: From Clinical Investigation to

Page 4

1        **PREVIOUSLY MARKED EXHIBITS            REFERENCED**

2        AMERIGEN 1156 Deletion of a            70

3        Phenylalanine in the N-terminal Region of Human

4        Cytochrome P-45017a Results in Partial Combined

5        17a-Hydroxylase/17,20-Lyase Deficiency,

6        Yanase et al.

7        AMERIGEN 1027 Two Prevalent CYP17    71

8        Mutations and Genotype-Phenotype Correlations

9        in 24 Brazilian Patients with 17-Hydroxylase

10        Deficiency, Costa-Santos et al.

11        AMERIGEN 1167 Short Reports:            74

12        Female phenotype in a male child due to

13        17-a-hydroxylase deficiency

14        AMERIGEN 1179 A Novel Point Mutation in   76

15        P450c17 (CYP17) Causing Combined

16        17a-Hydroxylase/17,20-Lyase Deficiency,

17        Brooke et al.

18        AMERIGEN 1155 Differential Inhibition of

19        17a-Hydroxylase and 17,20-Lyase Activities by

20        Three Novel Missense CYP17 Mutations Identified

21        in Patients with P450c17 Deficiency,

22        Van Den Akker et al.

23

24

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1        **PREVIOUSLY MARKED EXHIBITS            REFERENCED**

2        AMERIGEN 1173 Use of Prednisone With    104

3        Abiraterone Acetate in Metastatic

4        Castration-Resistant Prostate Cancer,

5        Auchus et al.

6        JANSSEN 2014 Phase 1 Clinical Trial    105

7        of a Selective Inhibitor of CYP17, Abiraterone

8        Acetate, Confirms that Castration-Resistant

9        Prostate Cancer Commonly Remains Hormone Drive,

10        Attard et al.

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1 PROCEEDINGS  
 2 ---  
 3 THE VIDEOGRAPHER: We are on the  
 4 record. The time is 9:00 o'clock.  
 5 This marks the beginning of disk  
 6 No. 1 for the videotaped deposition  
 7 testimony of Richard Dorin in the matter  
 8 of Amerigen Pharmaceuticals Limited  
 9 versus Janssen Oncology, Inc. This case  
 10 is pending in the United States Patent  
 11 and Trademark Office, Case No. IPR  
 12 2016-00286.  
 13 Today's date is January 19, 2017.  
 14 This deposition is being conducted at  
 15 1333 New Hampshire Avenue, Northwest,  
 16 Washington, DC.  
 17 Will all attorneys present please  
 18 identify themselves and who they  
 19 represent.  
 20 MR. KRAUSE: Todd Krause of  
 21 Sidley Austin here representing Patent  
 22 Owner Janssen.  
 23 MR. HARE: I'm Bill Hare,  
 24 McNeely, Hare & War representing

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1 Amerigen.  
 2 THE VIDEOGRAPHER: My name is  
 3 Michael Gay. I'm with Golkow  
 4 Technologies. Our court reporter today  
 5 is Denise Vickery also with Golkow  
 6 Technologies and will now swear in our  
 7 witness.  
 8 ---  
 9 RICHARD DORIN, M.D.,  
 10 called for examination, and, after having been  
 11 duly sworn, was examined and testified as  
 12 follows:  
 13 EXAMINATION  
 14 THE VIDEOGRAPHER: You may  
 15 proceed.  
 16 BY MR. KRAUSE:  
 17 Q. Good morning, Dr. Dorin. Can you  
 18 please state your name and home address for the  
 19 record?  
 20 A. Richard Ira Dorin.  
 21 Q. Have you ever -- I'm sorry?  
 22 A. 2526 Elfego Road -- one word --  
 23 E-l-f-e-g-o Road, Northwest, Albuquerque, New

Page 8

1 Q. Have you ever been deposed  
 2 before?  
 3 A. I have never been deposed before.  
 4 Q. There are a few points that I'd  
 5 like to review before we get started.  
 6 If I ask a question that's not  
 7 clear or you don't hear me, please let me know  
 8 so I can ask the question again. If you answer,  
 9 I'll assume that you understand and heard my  
 10 question. Okay?  
 11 A. Yes.  
 12 Q. And we have a court reporter  
 13 taking down your answers to my questions. So  
 14 please try to give verbal answers to my  
 15 questions. Okay?  
 16 A. Yes.  
 17 Q. And we'll try to take breaks  
 18 about every hour or so, but please let me know  
 19 if you need a break.  
 20 A. Thank you.  
 21 Q. I'll finish whatever question I'm  
 22 asking and then we can take a break. Okay?  
 23 A. Great.  
 24 Q. Is there any reason you cannot

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1 give complete and accurate testimony here today?  
 2 A. No.  
 3 Q. (Handing document).  
 4 A. Thank you.  
 5 MR. HARE: Thank you.  
 6 MR. KRAUSE: Certainly.  
 7 BY MR. KRAUSE:  
 8 Q. Dr. Dorin, I've handed you a  
 9 document that's been marked Amerigen Exhibit  
 10 1093.  
 11 Is this your declaration?  
 12 A. It is.  
 13 Q. And is the declaration an  
 14 accurate statement of the opinions that you've  
 15 reached in this case?  
 16 A. Yes.  
 17 Q. And are there any errors in the  
 18 declaration or the exhibits that you're aware  
 19 of?  
 20 A. No.  
 21 Q. When were you first asked to  
 22 provide opinions on the subject matter in your  
 23 declaration?

Page 10

1 Q. And around that time is that when  
2 you began working on the opinions that you have  
3 expressed in your declaration?  
4 A. Yes.  
5 Q. And how many hours did you spend  
6 working on the opinions that you've expressed in  
7 your declaration?  
8 A. Oh, perhaps 40 hours.  
9 Q. How did you gather the  
10 information that you relied on in your  
11 declaration?  
12 A. I -- I reviewed Dr. Auchus's  
13 statement, and I searched the literature that I  
14 thought was relevant in the usual fashion  
15 through PubMed and references in the articles I  
16 had read and looked at all the primary  
17 literature.  
18 Q. And about how many -- how much  
19 time did you spend searching the literature?  
20 A. Long time.  
21 Q. Can you give me a ballpark in  
22 hours?  
23 A. 20 or 30 hours.  
24 Q. And do you recall what topics you

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1 searched in PubMed when you were trying to get  
2 an understanding of the literature?  
3 A. Yes. A variety of topics, but  
4 including the syndrome of  
5 17-hydroxylase/17,20-lyase deficiency, the topic  
6 of prostate cancer, some of the treatments for  
7 prostate cancer, and of course specifically any  
8 papers related to abiraterone, both basic  
9 science and clinical science related to  
10 abiraterone and including the original as well  
11 as current literature.  
12 Q. Were you provided any references  
13 that are cited in your declaration?  
14 A. I was given the references that  
15 were already submitted in -- I guess in previous  
16 depositions. So whatever was in your files  
17 already I was given.  
18 Q. And so did you identify on your  
19 own all of the other references that are cited  
20 in your declaration?  
21 A. Correct.  
22 Q. How much time did you spend  
23 reading the information that's cited in your

Page 12

1 A. Again, I'll give you a number of  
2 like 20 or 30 hours, but it's quite -- quite an  
3 intense area to explore, yes.  
4 Q. And did you thoroughly read each  
5 reference cover to cover?  
6 A. Yes.  
7 Q. Now, did you speak with anyone  
8 other than Petitioner's counsel in preparing the  
9 opinions that you've expressed in your  
10 declaration?  
11 A. I'm not sure what you mean speak  
12 to someone.  
13 Q. Well, did you -- did you talk to  
14 anybody other than Petitioner's counsel in  
15 preparing -- in trying to understand the  
16 information or come to the opinions that you've  
17 expressed in your declaration?  
18 Did you ask colleagues, for  
19 example? Did you talk to other experts in this  
20 case?  
21 A. Not about the endocrine aspects.  
22 I did talk to oncologists and urologists.  
23 Q. And about how many oncologists  
24 did you speak with?

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1 A. One.  
2 Q. And who was that?  
3 A. Dr. James Lin at my institution,  
4 the Albuquerque VA Medical Center.  
5 Q. Okay. And what did Dr. Lin tell  
6 you?  
7 A. He told me that they used the  
8 drug abiraterone in the setting of metastatic  
9 castration-resistant prostate cancer.  
10 Q. Did he tell you anything else?  
11 A. I really wanted to understand  
12 what they took from the endocrinology and how  
13 sophisticated they were about what the drug  
14 does, and I can tell you my conclusion about  
15 that if you'd like.  
16 Q. Yes.  
17 A. That they're not so  
18 sophisticated. They -- they think of it as  
19 something that blocks cortisol and, therefore,  
20 prednisone is prescribed with it.  
21 Q. Okay. Did Dr. Lin tell you  
22 anything else?  
23 A. No, that was the gist of it.

1 spoke to a urologist?

2 A. Yes.

3 Q. And who was that?

4 A. Dr. Anthony Smith.

5 Q. And what did Dr. Smith tell you?

6 A. He told me about the life of  
7 patients who have a diagnosis of metastatic  
8 castration-resistant prostate cancer.

9 Q. And what do you mean telling you  
10 about the life of those patients?

11 A. What happens between the time of  
12 diagnosis and the time that they die in the  
13 course of a typical patient's life, what they  
14 experience and what sort of complications are  
15 encountered.

16 Q. And can you tell me what you  
17 recall about what he told you with respect to  
18 those activities?

19 A. Well, it's -- I came away with  
20 the impression that it's a very unpleasant  
21 wrap-up to a life and that there can be a lot of  
22 bone pain, and there can be complications of  
23 urinary obstruction, and there can be  
24 complications of infectious problems and that

1 problems of -- we use the word inanition  
2 sometimes. So wasting away due to lack of  
3 appetite and weight loss are common in the  
4 course of this disease.

5 Q. Anything else?

6 A. No.

7 Q. And did you speak with anybody  
8 other than Drs. Lin and Smith in preparing the  
9 opinions that you've expressed in your  
10 declaration?

11 A. No.

12 Q. And you didn't disclose the fact  
13 that you had conversations with Drs. Lin and  
14 Smith in your declaration, did you?

15 A. I did not. They were informal.

16 Q. How did you prepare your  
17 declaration?

18 MR. HARE: And I'll object to the  
19 extent that you shouldn't give, you know,  
20 attorney-client communications. You  
21 can't disclose that, but you can answer  
22 other than that.

23 THE WITNESS: Okay. I prepared

1 manuscript of data. So I analyzed the  
2 data and then wrote it up and edited what  
3 I wrote and came up with a final  
4 declaration. I -- I focused the  
5 declaration on the statement of  
6 Dr. Auchus.

7 BY MR. KRAUSE:

8 Q. Okay. So you actually put pen to  
9 paper or fingers to the -- to the keyboard in  
10 typing it up then; is that correct?

11 A. Oh, yes.

12 Q. About how many hours did you  
13 spend drafting your declaration?

14 A. Around 12 hours.

15 Q. And about how many hours did you  
16 spend editing your declaration?

17 A. 12 hours.

18 Q. And when was your declaration  
19 completed?

20 A. Same day you received it.  
21 January 16, 2017.

22 Q. Okay. If I could ask you to turn  
23 to paragraph 7 of your declaration.

24 Are you with me?

1 A. Yes.

2 Q. Okay. In paragraph 7, you  
3 indicate that you relied on your knowledge,  
4 training, expertise, and the documents cited in  
5 the declaration, as well as materials discussed  
6 in the Auchus declaration; is that correct?

7 A. Yes.

8 Q. Did you rely on any other  
9 materials?

10 A. There's -- there's a body of  
11 literature that I'm familiar with through my  
12 research and teaching and that sort of general  
13 information was applied, of course.

14 Q. Okay. And did you review all of  
15 the materials that were cited by Dr. Auchus?

16 A. Yes.

17 Q. And about how much time did you  
18 spend doing that?

19 A. I'm going to estimate --

20 Q. Sure.

21 A. -- at 12 hours.

22 Q. Okay. If I could ask you to turn  
23 to page 48 of your declaration. The page is

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