

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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1	A P P E A R A N C E S	1	PREVIOUSLY MARKED EXHIBITS REFERENCED
2		2	AMERIGEN 1156 Deletion of a 70
3	Attorneys for Petitioner:	3	Phenylalanine in the N-terminal Region of Human
4	McNEELY, HARE & WAR LLP	4	Cytochrome P-45017a Results in Partial Combined
5	5335 Wisconsin Avenue NW	5	17a-Hydroxylase/17,20-Lyase Deficiency,
6	Suite 440	6	Yanase et al.
7	Washington, DC 20015	7	AMERIGEN 1027 Two Prevalent CYP17 71
8	202.640.1801	8	Mutations and Genotype-Phenotype Correlations
9	BY: WILLIAM HARE, ESQ.	9	in 24 Brazilian Patients with 17-Hydroxylase
10	bill@miplaw.com	10	Deficiency, Costa-Santos et al.
11		11	AMERIGEN 1167 Short Reports: 74
12		12	Female phenotype in a male child due to
13	Attorneys for Patent Owner:	13	17-a-hydroxylase deficiency
14	SIDLEY AUSTIN LLP	14	AMERIGEN 1179 A Novel Point Mutation in 76
15	787 Seventh Avenue	15	P450c17 (CYP17) Causing Combined
16	New York, NY 10019	16	17a-Hydroxylase/17,20-Lyase Deficiency,
17	212.839.5696	17	Brooke et al.
18	BY: TODD L. KRAUSE, ESQ.	18	AMERIGEN 1155 Differential Inhibition of
19	tkrause@sidley.com	19	17a-Hydroxylase and 17,20-Lyase Activities by
20		20	Three Novel Missense CYP17 Mutations Identified
21		21	in Patients with P450c17 Deficiency,
22	Also Present:	22	Van Den Akker et al.
23	Michael Gay, Videographer	23	
24		24	
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3	RICHARD DORIN, M.D. PAGE	3	Abiraterone Acetate in Metastatic
4	BY MR. KRAUSE 7	4	Castration-Resistant Prostate Cancer,
5	AFTERNOON SESSION 95	5	Auchus et al.
6	BY MR. HARE 114	6	JANSSEN 2014 Phase 1 Clinical Trial 105
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8	PREVIOUSLY MARKED EXHIBITS REFERENCED	8	Acetate, Confirms that Castration-Resistant
9	AMERIGEN 1093 Declaration of 9	9	Prostate Cancer Commonly Remains Hormone Drive,
10	Dr. Richard I. Dorin	10	Attard et al.
11	AMERIGEN 1023 Selective blockade of 41	11	
12	androgenic steroid synthesis by novel lyase	12	
13	inhibitors as a therapeutic strategy for	13	
14	treating metastatic prostate cancer,	14	
15	Attard et al.	15	
16	AMERIGEN 1005 U.S. Patent No. 5,604,213 41	16	
17	Barrie et al.	17	
18	AMERIGEN 1003 Hormonal impact of the 55	18	
19	17a-hydroxylase/C17,20-lyase inhibitor	19	
20	abiraterone acetate (CB7630) in patients with	20	
21	prostate cancer, O'Donnell et al.	21	
22	AMERIGEN 1154 17a-Hydroxylase/17,20-Lyase 66	22	
23	Deficiency: From Clinical Investigation to	23	

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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

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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?

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

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

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?

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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