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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NALOX-1 PHARMACEUTICALS, LLC
Petitioner
v.
ADAPT PHARMA OPERATIONS LIMITED, and
OPIANT PHARMACEUTICALS, INC.,
Patent owners

Case No. IPR2019-00685
Case No. IPR2019-00688
Case No. IPR2019-00694

REMOTE VIDEO CONFERENCE
CONTINUED VIDEOTAPED DEPOSITION OF
GUNTHER HOCHHAUS, Ph.D. Volume 2
Gainesville, Florida
April 14, 2020, 9:46 a.m.

Reported by: Michele E. Eddy, RPR, CRR, CLR

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1 ATTENDANCE, Continued
2
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1 EXAMINATION INDEX
2 PAGE
3 EXAMINATION BY MS. REYES 344
4
5 E X H I B I T S
6 (Attached to the Transcript)
7 DEPOSITION EXHIBIT PAGE
8 Exhibit 1 "San Francisco EMS Agency Protocol 381
9 Manual" dated January 30, 2017
10
11 Exhibit 2 "Naloxone Distribution and 392
12 Cardiopulmonary Resuscitation
13 Training for Injection Drug Users
14 to Prevent Heroin Overdose Death:
15 A Pilot Intervention Study" by
16 Karen H. Seal, Robert Thawley
17
18 Exhibit 3 "Basic Principles of Dose 540
19 Optimization"; PHA 5127
20 Simulations; Excel Pharmacokinetic
21 Simulations
22

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1 EXHIBIT INDEX CONTINUED

2

3 DEPOSITION EXHIBIT PAGE

4 Exhibit 4 Skoog|West "Fundamentals of 606

5 Analytical Chemistry 9E"

6

7 Exhibit 5 Propagated absolute SD formula 618

8

9 Exhibit 6 Wyse Spreadsheet with Cmax and SD 667

10 figures

11

12 Exhibit 7 "Standard deviations and standard 668

13 errors" by Douglas G. Altman and

14 J. Martin Bland

15

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18

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20

21

22

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1 ---

2 GÜNTHER HOCHHAUS,

3 having been duly sworn, testified as follows:

4 EXAMINATION BY COUNSEL FOR PATENT OWNER ADAPT PHARMA

5 BY MS. REYES:

6 Q Doctor, this is Ana Reyes. I'm an

7 attorney at Williams & Connolly. Can you hear me?

8 A Yes.

9 Q Okay. Good morning, how are you?

10 A I'm doing fine.

11 Q All right.

12 You do not have clinical expertise in

13 the administration of opioid antagonists to treat

14 opioid overdoses, correct?

15 A No, I don't practice medicine.

16 Q You are not a medical practitioner with

17 knowledge and experience relating to the treatment

18 of opioid overdoses, correct?

19 A I'm not treating patients, no. I'm a

20 clinical pharmacologist.

21 Q Right. And that's because you're not a

22 medical practitioner at all, correct?

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1 PROCEEDINGS

2 April 14, 2020

3 ---

4 THE VIDEOGRAPHER: This is Video No. 1

5 in the video-recorded deposition of Dr. Günther

6 Hochhaus, taken in the matters of Nalox-1

7 Pharmaceuticals, LLC versus Opiant

8 Pharmaceuticals, Inc. It is pending before the

9 United States Patent and Trademark Office before

10 the Patent Trial and Appeal Board, with the

11 following IPR numbers: 2019-00685, 00688, 00694.

12 This deposition is being recorded by

13 remote video by Zoom, and the physical recording

14 is being taken place in Culpeper, Virginia, on

15 April 14th, 2020. The time on the video screen is

16 9:46 a.m.

17 My name is Daniel Holmstock, and I am

18 the legal video specialist. Our court reporter

19 today is Michele Eddy. Counsel for appearances

20 will be noted on the stenographic record. At this

21 point now the court reporter will administer the

22 oath.

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1 A That is correct.

2 Q You are not board certified in emergency

3 medicine, correct?

4 A That's absolutely correct.

5 Q You are not board certified in any

6 medical field, correct?

7 A That is correct.

8 Q You have never served as the medical

9 director of any Department of Health, correct?

10 A Correct.

11 Q You have never treated a patient

12 suffering from an opioid overdose, correct?

13 A Correct.

14 Q You have never administered any route of

15 naloxone to any patient, correct?

16 A Correct.

17 Q You have never supervised others

18 administering naloxone, correct?

19 A I did some animal experiments, actually.

20 I delivered naloxone by myself, but that was more

21 in a basic science environment --

22 Q And that was in the 1980s?

| | |
|--|---|
| <p style="text-align: right;">Page 346</p> <p>1 A -- but just to be correct, not with 2 patients.</p> <p>3 Q That was in the 1980s?</p> <p>4 A Yes.</p> <p>5 Q Okay. Now, just let me rephrase my 6 question, then.</p> <p>7 You have never administered any route of 8 naloxone to any human being, correct?</p> <p>9 A Correct.</p> <p>10 Q You have never supervised others 11 administering naloxone to human beings, correct?</p> <p>12 A Correct.</p> <p>13 Q You have never had to make any decision 14 as to what initial dose of naloxone to give a 15 patient, correct?</p> <p>16 A Correct.</p> <p>17 Q You have never been asked to make a 18 medical assessment as to the dose for 19 administering naloxone sufficient to restore 20 breathing in an overdosing patient, correct?</p> <p>21 A Asked by whom?</p> <p>22 Q By anyone.</p> | <p style="text-align: right;">Page 348</p> <p>1 A I have never observed. Again, I've read 2 literature from practitioners who have practical 3 experience.</p> <p>4 Q In connection with this litigation. I 5 understand that we can all read, but I'm asking 6 about your treatment or lack of treatment of any 7 patient. You don't have any firsthand experience 8 observing administering naloxone to an individual 9 who is overdosing and then seeing what the 10 withdrawal or side effects are, correct?</p> <p>11 MR. BERMAN: Objection.</p> <p>12 A I have not.</p> <p>13 Q You have never handed out MAD kits to 14 lay individuals and taught them how to use them, 15 correct?</p> <p>16 A What is a MAD kit?</p> <p>17 Q You don't know what a MAD kit is?</p> <p>18 MR. BERMAN: Object to form.</p> <p>19 Q I'm sorry, sitting here today, do you 20 know what a MAD kit is?</p> <p>21 A Well, as I said, the audio is not very, 22 very good so I understood kid as in child.</p> |
| <p style="text-align: right;">Page 347</p> <p>1 A I have to think about it. I might have 2 had conversations with colleagues about that, and 3 I would use then my knowledge that I obtained from 4 the literature, reading medical articles, reading 5 opinions of medical doctors and form opinions 6 towards the correct dose.</p> <p>7 Q That was -- that was in an -- I'm sorry, 8 that was in connection with this litigation?</p> <p>9 A Certainly, and also with respect to this 10 litigation, of course, that one talked about it, 11 but dose finding, more than I --</p> <p>12 Q Let me rephrase the question, then.</p> <p>13 You have never had to make a medical 14 assessment as to the dose for administering 15 naloxone sufficient to restore breathing in an 16 overdosing patient, correct?</p> <p>17 A Yes. As I said, I have never treated an 18 overdose patient.</p> <p>19 Q Okay. And you have never observed or 20 treated the withdrawal and side effects of 21 administering naloxone to an overdosing patient, 22 correct?</p> | <p style="text-align: right;">Page 349</p> <p>1 Q No, I'm sorry, MAD kit, K-I-T.</p> <p>2 A Okay, no.</p> <p>3 Q Okay. You have never published any 4 paper on the administration of naloxone, correct?</p> <p>5 A Correct.</p> <p>6 Q You have never been asked to and you 7 have never served on an expert panel to conduct a 8 review of the literature on naloxone 9 administration and published the results and 10 recommendation for that use, correct?</p> <p>11 A Correct.</p> <p>12 Q Throughout your report, you reference 13 what a "pharmacologist POSA" would find obvious, 14 correct?</p> <p>15 A I was asked to serve as a pharmacologist 16 POSA, correct.</p> <p>17 Q Correct. And that's the perspective 18 that you bring to the litigation.</p> <p>19 A That's very, very clearly written in my 20 declarations, yes.</p> <p>21 Q Yes. We're in heated agreement about 22 that.</p> |

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1 A Yes.

2 Q Of the available experts in this case,
3 if the Board wanted the viewpoints of a clinician
4 POSA as opposed to a pharmacologist POSA, they
5 would have to go to Dr. Williams, right, not you?

6 MR. BERMAN: Objection to form.

7 A I'm sure that the Board could go to
8 somebody else, too.

9 Q Well, they would not be able to go to
10 you, right, because you are not a clinician POSA?

11 MR. BERMAN: Objection.

12 A I am not a clinician POSA, no, but there
13 are lots of clinician POSAs besides Dr. Williams.

14 Q Of the experts in this litigation,
15 Dr. Williams is the only clinician POSA, correct?

16 A As far as I know, yes.

17 Q And, in your view, the clinical
18 pharmacologist generally serves as a link between
19 formulators and clinicians, correct?

20 A That's written in my first declaration.

21 Q Okay. And, in your view, for this case
22 the POSA team would include a clinician, correct?

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1 A I don't think that I said in my
2 declaration the POSA team. And we might want to
3 take a look exactly at the section that deals with
4 that. Maybe you can help me find that section.

5 Q Let me withdraw that question, and let
6 me go back to the previous question.

7 You agree that the clinical
8 pharmacologist generally serves as a link between
9 formulators and clinicians, correct?

10 A During drug development, yes.

11 Q Okay. And you are not a formulator and
12 you are not a clinician, correct?

13 A I made that very, very clear in my
14 declaration, yes.

15 Q Okay. And you are just the link between
16 the two.

17 A I would probably not say "just."

18 Q But you are the link between the two.

19 A That sounds much better.

20 Q Okay. And as the link between the two,
21 a clinical pharmacologist would routinely
22 collaborate with others, such as formulators and

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1 clinicians, to achieve a target pharmaceutical
2 profile, correct?

3 A If you -- as I said, I really would like
4 to see what I have written in the declaration.

5 Q Well, I don't -- I'm not -- I have your
6 declaration. I'm not here for you to read your
7 declaration to me. I'm here for you to answer my
8 questions.

9 A Yes, but I would --

10 Q I have -- I have a question that's not
11 dependent on his declaration.

12 MR. BERMAN: Hang on, please.

13 Q It's dependent on his experience. So
14 let me ask the question again.

15 MR. BERMAN: Excuse me, hang on.
16 Dr. Hochhaus, can you please slow down your
17 answers and allow me to object.

18 THE WITNESS: Yes.

19 MR. BERMAN: Okay. Thank you.

20 BY MS. REYES:

21 Q All right. As the link between the
22 formulator and the clinician, the clinical

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1 pharmacologist would routinely collaborate with
2 others, such as formulators and clinicians, to
3 achieve a target pharmaceutical profile, correct?

4 A Yes.

5 Q And here you collaborated with a
6 formulator, Dr. Donovan, correct?

7 A Can you define collaboration?

8 Q Well, how do you define collaboration?

9 A It depends on what area. If I
10 collaborate within research, then I work together
11 with other research groups to answer a question.

12 Q Okay. And so in that terminology, here
13 you collaborated with Dr. Donovan, who's a
14 formulator, correct?

15 MR. BERMAN: Objection to form.

16 A I never talked to Dr. Donovan.

17 Q You never talked to Dr. Donovan?

18 A Correct.

19 Q Okay. And you never talked to any
20 clinician either, right?

21 A I read --

22 Q No, I'm not asking about reading. We

4 (Pages 350 to 353)

| | |
|---|--|
| <p style="text-align: right;">Page 354</p> <p>1 can all read, sir. I'm asking if you talked to 2 any clinician in forming your opinions. 3 MR. BERMAN: Objection to form. 4 A As I said, I did not talk, but I -- I 5 have to object a little bit. Reading literature 6 from medical people is truly time to learn from 7 them and trying to see their viewpoint, which I 8 then can use with my clinical pharmacological 9 background to come up with my own opinion. My 10 opinions -- 11 Q Sorry, sir. I'm not going to let you 12 just talk on and on. I appreciate that viewpoint, 13 but I am asking you a very specific question and I 14 would like an answer to my specific question. 15 That is, as part of this work that you 16 did on this case, you did not consult with or talk 17 to any live clinician, correct? 18 MR. BERMAN: Objection. 19 A I did not. 20 Q Correct? 21 A I did not talk to any clinician, 22 correct.</p> | <p style="text-align: right;">Page 356</p> <p>1 And as between you and Dr. Williams, 2 Dr. Williams has more experience in observing and 3 dealing with withdrawal and side effects in 4 patients given naloxone, right? 5 MR. BERMAN: Objection to form. 6 A He has more firsthand experience seeing 7 patients, yes. 8 Q And that's because he has decades of 9 experience and you have none, right? 10 MR. BERMAN: Objection to form. 11 A I don't know that he has decades of 12 experience. I assume. He has certainly been 13 treating -- he is certainly treating patients. 14 Q Okay. 15 Now, in your report, you reference a 16 number of pharmacokinetic studies and you do some 17 modeling based on those studies, correct? 18 A What report? 19 Q Good point, thank you. 20 In your first supplemental report. 21 A Yes. 22 Q And those pK studies were conducted on</p> |
| <p style="text-align: right;">Page 355</p> <p>1 Q Thank you. 2 Now, as between you and Dr. Williams, 3 Dr. Williams has more experience in assessing the 4 lowest effective dose of naloxone to treat a 5 patient suffering from an opioid overdose, 6 correct? 7 MR. BERMAN: Objection to form. 8 A He treats patients. As I said, I don't. 9 Q Right. So the answer to my question is 10 yes, Dr. Williams has lots more experience because 11 you have never done it, right? 12 MR. BERMAN: Objection to form. 13 A I've never treated a patient. 14 Q And so, therefore, Dr. Williams, who has 15 treated patients on narcotics for decades, has 16 more experience than you do treating patients with 17 naloxone, right? 18 A Yes. 19 MR. BERMAN: Objection to form. 20 Q Right? 21 A Yes. 22 Q Thank you.</p> | <p style="text-align: right;">Page 357</p> <p>1 opioid-naive individuals, correct? 2 A Yes. 3 Q And naloxone does not generate 4 withdrawal effects on opioid-naive individuals, 5 correct? 6 A Correct. 7 Q And the pK studies do not reflect what 8 withdrawal symptoms an opioid overdose individual 9 will experience or at what dose of the naloxone 10 they will experience those, correct? 11 A pK studies have a very, very clear 12 goal. They want to look at the concentration time 13 profiles of naloxone after a given administration. 14 The goal of pK studies is not to investigate 15 potential side effects in patients. 16 Q And they can't tell you anything about 17 the potential side effects in patients for that 18 reason, right? That's not what they're designed 19 to do. 20 A That's -- that's -- yeah, those studies 21 are not interested in evaluating that. 22 Q Now, the priority date for this matter</p> |

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