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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EXAMINATION INDEX

E X H I B I T S
(Attached to the Transcript)

EXHIBIT INDEX CONTINUED

P R O C E E D I N G S

April 14, 2020

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THE VIDEOGRAPHER: This is Video No. 1 in the video-recorded deposition of Dr. Günther Hochhaus, taken in the matters of Nalox-1 Pharmaceuticals, LLC versus Opiant Pharmaceuticals, Inc. It is pending before the United States Patent and Trademark Office before the Patent Trial and Appeal Board, with the following IPR numbers: 2019-00685, 00688, 00694.

This deposition is being recorded by remote video by Zoom, and the physical recording is being taken place in Culpeper, Virginia, on April 14th, 2020. The time on the video screen is 9:46 a.m.

My name is Daniel Holmstock, and I am the legal video specialist. Our court reporter today is Michele Eddy. Counsel for appearances will be noted on the stenographic record. At this point now the court reporter will administer the oath.

- - -

GÜNTHER HOCHHAUS,

having been duly sworn, testified as follows:

EXAMINATION BY COUNSEL FOR PATENT OWNER ADAPT PHARMA

BY MS. REYES:

Q Doctor, this is Ana Reyes. I'm an attorney at Williams & Connolly. Can you hear me?

A Yes.

Q Okay. Good morning, how are you?

A I'm doing fine.

Q All right.

You do not have clinical expertise in the administration of opioid antagonists to treat opioid overdoses, correct?

A No, I don't practice medicine.

Q You are not a medical practitioner with knowledge and experience relating to the treatment of opioid overdoses, correct?

A I'm not treating patients, no. I'm a clinical pharmacologist.

Q Right. And that's because you're not a medical practitioner at all, correct?

A That is correct.

Q You are not board certified in emergency medicine, correct?

A That's absolutely correct.

Q You are not board certified in any medical field, correct?

A That is correct.

Q You have never served as the medical director of any Department of Health, correct?

A Correct.

Q You have never treated a patient suffering from an opioid overdose, correct?

A Correct.

Q You have never administered any route of naloxone to any patient, correct?

A Correct.

Q You have never supervised others administering naloxone, correct?

A I did some animal experiments, actually. I delivered naloxone by myself, but that was more in a basic science environment --

Q And that was in the 1980s?

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A -- but just to be correct, not with patients.
Q That was in the 1980s?
A Yes.
Q Okay. Now, just let me rephrase my question, then.
You have never administered any route of naloxone to any human being, correct?
A Correct.
Q You have never supervised others administering naloxone to human beings, correct?
A Correct.
Q You have never had to make any decision as to what initial dose of naloxone to give a patient, correct?
A Correct.
Q You have never been asked to make a medical assessment as to the dose for administering naloxone sufficient to restore breathing in an overdosing patient, correct?
A Asked by whom?
Q By anyone.

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A I have to think about it. I might have had conversations with colleagues about that, and I would use then my knowledge that I obtained from the literature, reading medical articles, reading opinions of medical doctors and form opinions towards the correct dose.
Q That was -- that was in an -- I'm sorry, that was in connection with this litigation?
A Certainly, and also with respect to this litigation, of course, that one talked about it, but dose finding, more than I --
Q Let me rephrase the question, then.
You have never had to make a medical assessment as to the dose for administering naloxone sufficient to restore breathing in an overdosing patient, correct?
A Yes. As I said, I have never treated an overdose patient.
Q Okay. And you have never observed or treated the withdrawal and side effects of administering naloxone to an overdosing patient, correct?

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A I have never observed. Again, I've read literature from practitioners who have practical experience.
Q In connection with this litigation. I understand that we can all read, but I'm asking about your treatment or lack of treatment of any patient. You don't have any firsthand experience observing administering naloxone to an individual who is overdosing and then seeing what the withdrawal or side effects are, correct?
MR. BERMAN: Objection.
A I have not.
Q You have never handed out MAD kits to lay individuals and taught them how to use them, correct?
A What is a MAD kit?
Q You don't know what a MAD kit is?
MR. BERMAN: Object to form.
Q I'm sorry, sitting here today, do you know what a MAD kit is?
A Well, as I said, the audio is not very, very good so I understood kid as in child.

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Q No, I'm sorry, MAD kit, K-I-T.
A Okay, no.
Q Okay. You have never published any paper on the administration of naloxone, correct?
A Correct.
Q You have never been asked to and you have never served on an expert panel to conduct a review of the literature on naloxone administration and published the results and recommendation for that use, correct?
A Correct.
Q Throughout your report, you reference what a "pharmacologist POSA" would find obvious, correct?
A I was asked to serve as a pharmacologist POSA, correct.
Q Correct. And that's the perspective that you bring to the litigation.
A That's very, very clearly written in my declarations, yes.
Q Yes. We're in heated agreement about that.

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A Yes.
Q Of the available experts in this case, if the Board wanted the viewpoints of a clinician POSA as opposed to a pharmacologist POSA, they would have to go to Dr. Williams, right, not you?
MR. BERMAN: Objection to form.
A I'm sure that the Board could go to somebody else, too.
Q Well, they would not be able to go to you, right, because you are not a clinician POSA?
MR. BERMAN: Objection.
A I am not a clinician POSA, no, but there are lots of clinician POSAs besides Dr. Williams.
Q Of the experts in this litigation, Dr. Williams is the only clinician POSA, correct?
A As far as I know, yes.
Q And, in your view, the clinical pharmacologist generally serves as a link between formulators and clinicians, correct?
A That's written in my first declaration.
Q Okay. And, in your view, for this case the POSA team would include a clinician, correct?

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A I don't think that I said in my declaration the POSA team. And we might want to take a look exactly at the section that deals with that. Maybe you can help me find that section.
Q Let me withdraw that question, and let me go back to the previous question.
You agree that the clinical pharmacologist generally serves as a link between formulators and clinicians, correct?
A During drug development, yes.
Q Okay. And you are not a formulator and you are not a clinician, correct?
A I made that very, very clear in my declaration, yes.
Q Okay. And you are just the link between the two.
A I would probably not say "just."
Q But you are the link between the two.
A That sounds much better.
Q Okay. And as the link between the two, a clinical pharmacologist would routinely collaborate with others, such as formulators and

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clinicians, to achieve a target pharmaceutical profile, correct?
A If you -- as I said, I really would like to see what I have written in the declaration.
Q Well, I don't -- I'm not -- I have your declaration. I'm not here for you to read your declaration to me. I'm here for you to answer my questions.
A Yes, but I would --
Q I have -- I have a question that's not dependent on his declaration.
MR. BERMAN: Hang on, please.
Q It's dependent on his experience. So let me ask the question again.
MR. BERMAN: Excuse me, hang on. Dr. Hochhaus, can you please slow down your answers and allow me to object.
THE WITNESS: Yes.
MR. BERMAN: Okay. Thank you.
BY MS. REYES:
Q All right. As the link between the formulator and the clinician, the clinical

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pharmacologist would routinely collaborate with others, such as formulators and clinicians, to achieve a target pharmaceutical profile, correct?
A Yes.
Q And here you collaborated with a formulator, Dr. Donovan, correct?
A Can you define collaboration?
Q Well, how do you define collaboration?
A It depends on what area. If I collaborate within research, then I work together with other research groups to answer a question.
Q Okay. And so in that terminology, here you collaborated with Dr. Donovan, who's a formulator, correct?
MR. BERMAN: Objection to form.
A I never talked to Dr. Donovan.
Q You never talked to Dr. Donovan?
A Correct.
Q Okay. And you never talked to any clinician either, right?
A I read --
Q No, I'm not asking about reading. We

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can all read, sir. I'm asking if you talked to any clinician in forming your opinions.

MR. BERMAN: Objection to form.

A As I said, I did not talk, but I -- I have to object a little bit. Reading literature from medical people is truly time to learn from them and trying to see their viewpoint, which I then can use with my clinical pharmacological background to come up with my own opinion. My opinions --

Q Sorry, sir. I'm not going to let you just talk on and on. I appreciate that viewpoint, but I am asking you a very specific question and I would like an answer to my specific question.

That is, as part of this work that you did on this case, you did not consult with or talk to any live clinician, correct?

MR. BERMAN: Objection.

A I did not.

Q Correct?

A I did not talk to any clinician, correct.

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Q Thank you.

Now, as between you and Dr. Williams, Dr. Williams has more experience in assessing the lowest effective dose of naloxone to treat a patient suffering from an opioid overdose, correct?

MR. BERMAN: Objection to form.

A He treats patients. As I said, I don't.

Q Right. So the answer to my question is yes, Dr. Williams has lots more experience because you have never done it, right?

MR. BERMAN: Objection to form.

A I've never treated a patient.

Q And so, therefore, Dr. Williams, who has treated patients on narcotics for decades, has more experience than you do treating patients with naloxone, right?

A Yes.

MR. BERMAN: Objection to form.

Q Right?

A Yes.

Q Thank you.

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And as between you and Dr. Williams, Dr. Williams has more experience in observing and dealing with withdrawal and side effects in patients given naloxone, right?

MR. BERMAN: Objection to form.

A He has more firsthand experience seeing patients, yes.

Q And that's because he has decades of experience and you have none, right?

MR. BERMAN: Objection to form.

A I don't know that he has decades of experience. I assume. He has certainly been treating -- he is certainly treating patients.

Q Okay.

Now, in your report, you reference a number of pharmacokinetic studies and you do some modeling based on those studies, correct?

A What report?

Q Good point, thank you.

In your first supplemental report.

A Yes.

Q And those pK studies were conducted on

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opioid-naive individuals, correct?

A Yes.

Q And naloxone does not generate withdrawal effects on opioid-naive individuals, correct?

A Correct.

Q And the pK studies do not reflect what withdrawal symptoms an opioid overdose individual will experience or at what dose of the naloxone they will experience those, correct?

A pK studies have a very, very clear goal. They want to look at the concentration time profiles of naloxone after a given administration. The goal of pK studies is not to investigate potential side effects in patients.

Q And they can't tell you anything about the potential side effects in patients for that reason, right? That's not what they're designed to do.

A That's -- that's -- yeah, those studies are not interested in evaluating that.

Q Now, the priority date for this matter

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