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GUNTHER HOCHHAUS

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

-----)
 NALOX-1 PHARMACEUTICALS, LLC,)
 Petitioner,) IPR No.
 vs.) 2019-00688
 OPIANT PHARMACEUTICALS, INC.,)
 Patent Owner.)
 -----)

DEPOSITION OF GUNTHER HOCHHAUS

Washington, D.C.

December 6, 2019

REPORTED BY: Tina Alfaro, RPR, CRR, RMR

Job No. 172401

GUNTHER HOCHHAUS
Deposition of GUNTHER HOCHHAUS, held at the
offices of:

Arent Fox
1717 K Street, NW
Washington, D.C. 20006

Taken pursuant to notice before Tina M.
Alfaro, a Notary Public within and for the District
of Columbia.

GUNTHER HOCHHAUS
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for inclusion with transcript

GUNTHER HOCHHAUS

(Witness sworn.)

WHEREUPON:

GUNTHER HOCHHAUS,

called as a witness herein, having been first duly sworn, was examined and testified as follows:

EXAMINATION

BY MS. BERNIKER:

Q. Good morning, Doctor. My name is Jessamyn Berniker, and I represent the Patent Owner in this case. Nice to meet you.

A. Hello.

Q. I understand that you've been deposed before?

A. A few times, yes.

Q. And you understand that you're under oath today?

A. Yes.

Q. And you understand that you're testifying under penalty of perjury; is that right?

A. Yes.

Q. And you have to provide the most complete and truthful answers; is that right?

A. Yes.

Q. They need to be both truthful and complete;

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do you understand that?

A. I understand.

Q. I thought you might say that. You understand that the testimony that you provided by way of declaration, which you have in front of you, to the Patent Office was also under penalty of perjury, right?

A. Yes.

Q. And that you also had an obligation to provide complete and truthful answers there; is that right?

A. Yes.

Q. And you understood that when you signed it?

A. Yes.

Q. And did you review your declaration carefully to confirm that you believed that everything you said in there was complete and truthful?

A. Yes.

Q. Okay. Well, I'd like to direct your attention -- I'm going to work off of the '747 Patent, Case No. IPR 2019-0688 version of your declaration for today. So you're welcome to reference the other ones if you want, but that's the

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one that I'm going to be referring to when we talk about paragraph numbers.

MS. BERNIKER: Counsel, did you want a copy?

MR. BERMAN: I'll take one, please.

BY MS. BERNIKER:

Q. Okay. Can I refer you, please, to paragraph 64 -- I'm sorry -- yes, paragraph 64 of your declaration in that case. Did you draft the declaration, sir?

A. We did it together. So I found my opinion and then I got, of course, help.

Q. Is it your view the words in here are your own?

A. Yeah.

Q. You stand by them?

A. Yeah.

Q. You stand by the choices of what you cited and what you didn't cite?

A. Yeah.

Q. And you stand by what you reviewed in preparing these opinions?

A. Yeah. I tried my best, yes.

Q. Do you believe that you reviewed any

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materials that would have been -- a reasonable person would have reviewed in preparing the opinions that you submitted here?

A. I believe so.

Q. Did you go out of your way to try to make sure that you reviewed everything that you think would have been relevant to your opinions?

A. Yeah. I mean, I did quite a bit of Google searches. I did some literature searches by myself.

Q. You did independent research beyond what the attorneys provided to you?

A. Yes.

Q. Okay. So I want to direct your attention to paragraph 64 and something that you say in paragraph 64, and you said -- in 64 you're talking about your position that "In emergency situations in general and in naloxone therapy" --

A. Where are you?

Q. Paragraph 64. You say "As I mentioned above" --

A. Yes.

Q. -- "in emergency situations in general, and in naloxone therapy in particular, rapid onset of action and high drug exposure are desired to get the

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overdose victim breathing normally as quickly as possible"; do you see that?

A. I see that.

Q. And when you talk about overdose victim, you're talking about opioid overdose victims, right?

A. Let me just read through the sentence again. You're pretty fast.

Q. Sorry.

(Witness reviewing document.)

A. That sentence says that "In emergency situations in general" --

Q. Yes.

A. -- "and in naloxone therapy in particular, rapid onset of action and high drug exposure" --

THE REPORTER: I'm sorry.

THE WITNESS: Sorry.

A. It says that "In emergency situations in general" -- so it's not totally focused alone on the therapy -- "and naloxone therapy in particular, rapid onset of action and high drug exposure are desired to get the overdose victim breathing normally as quickly as possible."

Q. And with respect to naloxone, the overdose victim has overdosed on what?

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A. In this case opioids.

Q. Okay. You're talking about people who have overdosed on opioids, right?

A. That would include people with opioid overdose.

Q. With respect to naloxone, the drug is being used to treat people who have opioid overdose, not some other kind of overdose, right, sir?

A. The overdose would be included, yes.

Q. Right. I'm asking now a separate question from your sentence. When we're talking about the use of naloxone to reverse overdose, that is about reversing opioid overdose, right?

A. If you only say overdose, that would include -- that would not specify it. If you say that naloxone is being used for a very, very specific situation, then it would include the very, very specific situation.

Q. Is naloxone used to treat different kinds of overdose apart from opioid overdose?

A. I would have to think about it.

Q. Sitting here today, you're not aware of that right, sir?

A. I would have to think about it.

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Q. I'm asking are you aware today about whether naloxone -- how about this. Is naloxone indicated for the use of reversing any kind of overdose aside from opioid overdose?

A. I would have to look into the label directly.

Q. You haven't considered that question in forming your opinions today?

A. Not yet. I would -- I would have -- right now I would need to look at the label.

Q. Okay. Well, here's my question for you. In the 65 or so pages of your expert report were they based on the premise that naloxone is being used to treat opioid overdose?

A. That would include it, yes.

Q. Were they based on the premise that naloxone was being used for some other purpose?

A. Can you slow down?

Q. Sure. Were they based on the premise that naloxone was being used for some other purpose?

A. I would need to clearly read very, very much through my declaration and see whether there was something else in it.

Q. When's the last time you read your

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declaration?

A. Fully? A long time ago.

Q. You did not read your declaration fully before coming for a deposition about your declaration that is all of 65 pages, sir?

MR. BERMAN: Objection to form.

MS. BERNIKER: In preparing for coming here to testify today, is it your testimony that you didn't bother to read your 65-page declaration?

MR. BERMAN: Objection to form.

MS. BERNIKER: You can answer.

A. Huh?

Q. You can answer even though he objects.

A. I certainly read significant portions of it.

Q. Okay.

A. But it's 65 pages. It's a lot. So -- and I'm getting older. So I would need to go through it and clearly see whether other things were included or not.

Q. I assume that you're not suggesting that your age prevents you from being able to digest the information in your 65-page declaration, right?

MR. BERMAN: Objection to form.

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2 A. No.

3 Q. Okay. You have the mental capacity to
4 understand what you said here?

5 A. Absolutely.

6 Q. And you plan to defend it today, right?

7 A. Yes.

8 Q. Okay. So my question to you, sir, is is
9 your declaration about what a person of skill in the
10 art would have done in connection with using
11 naloxone to treat opioid overdose, or is it in
12 connection with something else?

13 A. It includes opioid overdose.

14 Q. Okay. Is there any other type of overdose
15 that you intended to include by your declaration?

16 A. It certainly includes the overdose,
17 absolutely.

18 Q. You're not answering my question. Is there
19 another kind of overdose that you intended to
20 include in terms of what the person of skill in the
21 art would have been focused on in connection with
22 your declaration?

23 A. To just be on the safe side I would need to
24 see the label.

25 Q. Okay. I'm not sure we have the label. We

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2 have the PDR. Let's hold on that question. We'll
3 come back to it.

4 A. Okay.

5 Q. In selecting -- in the comments that you
6 make about the appropriate dose of intranasal
7 naloxone, sir, was there some particular clinical
8 effect that you thought the person of skill in the
9 art would be trying to achieve?

10 A. I don't understand what you mean. Can you
11 rephrase?

12 Q. Okay. You have a bunch of opinions in here
13 about the dose of intranasal naloxone that a person
14 of skill in the art would have considered; is that
15 fair?

16 A. Yeah. Can you direct me to those?

17 Q. It's your entire report, isn't it?

18 MR. BERMAN: Objection to form.

19 A. You are asking me a very specific question,
20 and I would like to know what section of my report
21 you are referring to.

22 Q. Okay. Let's try another question. What
23 are the opinions in your report about generally?

24 A. About the things that are in here. Let's
25 go through them. It's the table of contents. So it

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2 covers the background and qualifications, it talks
3 about certain legal standards, it describes the
4 state-of-the-art. I then discuss the motivation to
5 design a nasal formulation having high
6 bioavailability with a reasonable expectation of
7 success, and it goes through --

8 Q. Is your expert -- is your declaration about
9 what a person of skill in the art as of March of
10 2015 would be thinking in connection with the
11 development of an intranasal naloxone product?

12 A. Certainly not in the entirety. I mean,
13 that probably would not be able to be captured in 65
14 pages.

15 Q. It wouldn't, would it?

16 A. No.

17 Q. Okay. Well, which aspects of that were you
18 intending to capture in your 65 pages?

19 A. As I said, I talk about the motivation to
20 design a naloxone nasal formulation having high
21 bioavailability with a reasonable expectation of
22 success. I talk about claim construction, I talk
23 about some other things, but the main portion
24 certainly deals with the prior art patent
25 application disclosure. It talks about the known

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2 physico-chemical and biopharmaceutical and
3 pharmacological properties of naloxone --

4 Q. Okay. I don't need you to read the entire
5 table of contents into the record.

6 A. You were asking me what my declaration is
7 about.

8 Q. What would a person of skill in the art be
9 trying to achieve in 2015?

10 A. That's a very, very -- I can't really --
11 you need to be more specific.

12 Q. Okay. It's your testimony that the person
13 of skill in the art would be trying to achieve
14 something in doing whatever it is that you say that
15 they need to do, right?

16 MR. BERMAN: Objection to form.

17 A. You need to be -- a person -- a POSA --
18 there are lots of POSA's. So you need to be more
19 specific.

20 Q. Is it your view that there are different
21 POSA's for the same obviousness analysis so that you
22 could have one POSA doing one thing and another POSA
23 doing something else and another POSA doing
24 something else?

25 A. Well, as I -- as I stated in my

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