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

NALOX-1 PHARMACEUTICALS, LLC,

Petitioner,

v.

ADAPT PHARMA OPERATIONS LTD., AND
OPIANT PHARMACEUTICALS, INC.

Patent Owners

CASE IPR2019-00685

U.S. Patent No. 9,211,253

Video deposition of STUART ALLEN JONES, Ph.D., held remotely via Zoom, on Friday, May 1, 2020, commencing at 8:06 a.m., before Kathleen McHugh, a Registered Professional Reporter, Certified Realtime Reporter, Certified Shorthand Reporter-NJ, License No. 30XI00180400, and Notary Public.

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ALSO PRESENT:
Martin Zinkel, Videographer (via Zoom)
Joshua Harris (via Zoom)

EXAMINATION INDEX

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VIDEOGRAPHER: We are now on the video record.
This is the video deposition of Dr. Stuart Allen Jones, taken by plaintiff -- petitioner, in the matter of Nalox-1 Pharmaceuticals, LLC v. Adapt Pharma Operations Ltd., et al., hearing remotely with the deponent in Watford, United Kingdom, on Friday, May 1st, 2020, at 8:06 a.m.
I am Martin Zinkel, the videographer. The court reporter is Kathy McHugh. We are from the firm of Advanced Depositions in Philadelphia, Pennsylvania.
Counsel will be noted on -- the appearances will be noted on the transcript, and the reporter will now swear in the witness.
STUART ALLEN JONES, Ph.D., having been duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. BERMAN:
Q. Hello again, Dr. Jones. My name again is Rich Berman. I'm counsel for petitioner, Nalox-1 Pharmaceuticals, LLC.
Let's turn to Exhibit 2300, your Supplemental Declaration, just the cover page,

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page 1.
And this is the declaration that you submitted for the '747 patent.
Do you see that?
A. Yes.
Q. And my understanding is that you submitted this same substantive declaration in all three IPRs; is that correct?
A. Yes, I believe they're identical.
Q. Okay. If we can go to paragraph 12. I don't have the page number in front of me.
Oh, there you go. Good.
It starts off --
You can just blow up that paragraph.
It starts off saying, Dr. Donovan limited the analysis in her second declaration to oxidative degradation of naloxone.
Do you see that?
A. Yes.
Q. So sitting here today, you don't know of any mechanism for degradation of naloxone other than oxidative degradation, correct?
A. I understand that the degradation of naloxone is a complex process, and it can occur by many different mechanisms. One of those mechanisms

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is oxidative degradation, but there are others. And I cited in my first report that also naloxone is prone to photoinstability issues, i.e., degradation under light.
Q. If we can go to Nalox 1201, the Donovan Supplemental Declaration, and paragraph 15.
And you can blow up up until the line there.
Great.
It says, Wyse discloses that formulations 7, 9, 14 and 14A contained, quote, an additional degradant, unquote, one that was not reported as being found in at least some of the other disclosed formulations. Since these formulations were pH adjusted, quote, to accelerate degradation, unquote, of the naloxone -- and there's a citation given there -- a Formulator POSA would have considered that, if the, quote, additional degradant, unquote, was a naloxone degradant, it would likely be an oxidation degradant.
Do you see that?
A. Yes.
MR. KRINSKY: And I'd just like to note, you only have part of the paragraph on the

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screen. I just wanted to make sure Dr. Jones knew that he could ask Martin to put up what he needs to put up if he'd like to look at something else.
BY MR. BERMAN:
Q. Do you agree with Dr. Donovan's opinion that a POSA would have considered it likely that the naloxone degradant was an oxidation degradant?
THE WITNESS: If you could just do -- Martin, I still have to look at the full page, please. (Witness reviews document.)
Could I just look at the next page of the document as well, please. (Witness reviews document.)
If you can go back to the previous page, please. (Witness reviews document.)
And can I have the question?
BY MR. BERMAN:
Q. Yes. Do you need me to repeat the question? Okay.
The question is, do you agree with Dr. Donovan's opinion that a POSA would have considered it likely that the naloxone degradant was an oxidation degradant?
A. The POSA would have read Wyse and

would have understood from Wyse that benzalkonium chloride caused the degradation of naloxone.

They would have read Wyse and understood Wyse in the wider context of the literature and understand this was a valid proposition from Wyse's data and what Wyse actually said.

Wyse identified an additional degradant of four formulations containing benzalkonium chloride. And, therefore, POSA would have read Wyse and understood that Wyse showed that benzalkonium chloride caused naloxone degradation.

The POSA would not need to understand the mechanism by which that would occur because they would have read Wyse and understood Wyse from what Wyse said and what Wyse did.

Wyse removed benzalkonium chloride in the formulations after finding it caused instability in the formulations with respect to naloxone, and, therefore, the POSA would have followed Wyse's teaching away from using benzalkonium chloride in the formulation and would not go on to think about the mechanism of degradation.

Q. But do you agree with Dr. Donovan's

opinion that a POSA would have considered it likely that the naloxone degradant was an oxidation degradant?

MR. KRINSKY: Objection. Asked and answered.

THE WITNESS: The POSA would have read Wyse and understood from Wyse that benzalkonium chloride caused naloxone degradation.

Wyse produced a series of experiments whereby he tested naloxone's compatibility in a series of different intranasal formulations, and he showed from that series of experiments that, indeed, benzalkonium chloride caused naloxone degradation.

He identified an additional naloxone degradation peak in four formulations which contained benzalkonium chloride and went on to state in a number of places in Wyse's patent that benzalkonium chloride caused the degradation of naloxone.

The POSA would have read this and read what Wyse did subsequent to defining this finding in that he removed benzalkonium chloride from his subsequent formulation testing and went on to make an intranasal formulation that was chemically

stable. The POSA would not go on to consider the mechanism by which that occurred.

MR. BERMAN: If we can go to Wyse -- that's Nalox 1007.

MR. KRINSKY: I believe you said Nalox 1007.

MR. BERMAN: Nalox 1007. That's just the exhibit number. Thanks.

PDF page 22, we're going to look at Example 5 on columns 26 and 27.

If you could zoom in on where it says Example 5 above where you are a bit. Right there. Yes.

No. Down. Down. Around line 20.

Yes, there you go. That's fine.

BY MR. BERMAN:

Q. Okay. So I'm looking at Wyse Example 5 and specifically at -- I'm going to just read from a couple of places and then ask you a couple of questions.

Around line 29, it says, The formulations were at pH 5.0 to accelerate degradation.

Do you see that?

A. Yes.

Q. And then going on -- if you can leave that up, and then go on to the next column, 27.

And then just go from the top down to about line 30.

Yep. Perfect.

And here around line 20, it says, Increasing the pH of the solution accelerated the degradation of naloxone HCL resulting in the formation of a major degradant at a relative retention time, RRT, of 0.52. However, it was found that decreasing the pH minimizes the formation of potential oxidative degradants.

Do you see that?

A. Yes.

Q. So in this Example 5 test, Wyse increased the pH of the solution to accelerate the degradation of naloxone, correct?

MR. KRINSKY: Object to the form of the question.

THE WITNESS: (Witness reviews document.)

Could you reask the question, please?

BY MR. BERMAN:

Q. Sure.

In this example, Wyse increased the pH

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