

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.

1 APPEARANCES:

2 ARENT FOX LLP

3 BY: RICHARD J. BERMAN, ESQUIRE (via Zoom)

4 Richard.berman@arentfox.com

5 BY: YELEE Y. KIM, ESQUIRE (via Zoom)

6 Yelee.kim@arentfox.com

7 1717 K Street, NW

8 Washington, DC 20006

9 202-857-6000

10 Counsel for Petitioner, Nalox-1

11 Pharmaceuticals, LLC

12 WILLIAMS & CONNOLLY LLP

13 BY: DAVID M. KRINSKY, ESQUIRE (via Zoom)

14 dkrinsky@wc.com

15 BY: JESSAMYN S. BERNIKER, ESQUIRE (via Zoom)

16 jberniker@wc.com

17 BY: ANA C. REYES, ESQUIRE (via Zoom)

18 areyes@wc.com

19 BY: ANTHONY H. SHEH, ESQUIRE (via Zoom)

20 asheh@wc.com

21 BY: YOULIN YUAN, ESQUIRE (via Zoom)

22 Yyuan@wc.com

23 725 Twelfth Street, NW

24 Washington, DC 20005

25 202-434-5000

Counsel for Patent Owner Adapt

Pharma Operations Limited

GREEN, GRIFFITH & BORG-BREEN LLP

BY: JESSICA TYRUS MACKAY, ESQUIRE (via Zoom)

jmackay@greengriffith.com

676 North Michigan Avenue, Suite 3900

Chicago, Illinois 60611

313-883-8000

Counsel for Patent Owners Adapt

Pharma Operations Ltd., and

Opiant Pharmaceuticals, Inc.

ALSO PRESENT:

Martin Zinkel, Videographer (via Zoom)

Joshua Harris (via Zoom)

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EXAMINATION INDEX

Dr. Stuart Allen Jones

BY MR. BERMAN . . . . . 4

4	<p>1 VIDEOGRAPHER: We are now on the video                  2 record.                  3 This is the video deposition of                  4 Dr. Stuart Allen Jones, taken by plaintiff --                  5 petitioner, in the matter of Nalox-1                  6 Pharmaceuticals, LLC v. Adapt Pharma Operations                  7 Ltd., et al., hearing remotely with the deponent in                  8 Watford, United Kingdom, on Friday, May 1st, 2020,                  9 at 8:06 a.m.                  10 I am Martin Zinkel, the videographer.                  11 The court reporter is Kathy McHugh. We are from                  12 the firm of Advanced Depositions in Philadelphia,                  13 Pennsylvania.                  14 Counsel will be noted on -- the                  15 appearances will be noted on the transcript, and                  16 the reporter will now swear in the witness.                  17 STUART ALLEN JONES, Ph.D., having been                  18 duly sworn, was examined and testified as follows:                  19 EXAMINATION                  20 BY MR. BERMAN:                  21 Q. Hello again, Dr. Jones. My name again                  22 is Rich Berman. I'm counsel for petitioner,                  23 Nalox-1 Pharmaceuticals, LLC.                  24 Let's turn to Exhibit 2300, your                  25 Supplemental Declaration, just the cover page,</p>	6	<p>1 is oxidative degradation, but there are others.                  2 And I cited in my first report that also naloxone                  3 is prone to photoinstability issues, i.e.,                  4 degradation under light.                  5 Q. If we can go to Nalox 1201, the                  6 Donovan Supplemental Declaration, and paragraph 15.                  7 And you can blow up up until the line                  8 there.                  9 Great.                  10 It says, Wyse discloses that                  11 formulations 7, 9, 14 and 14A contained, quote, an                  12 additional degradant, unquote, one that was not                  13 reported as being found in at least some of the                  14 other disclosed formulations. Since these                  15 formulations were pH adjusted, quote, to accelerate                  16 degradation, unquote, of the naloxone -- and                  17 there's a citation given there -- a Formulator POSA                  18 would have considered that, if the, quote,                  19 additional degradant, unquote, was a naloxone                  20 degradant, it would likely be an oxidation                  21 degradant.                  22 Do you see that?                  23 A. Yes.                  24 MR. KRINSKY: And I'd just like to                  25 note, you only have part of the paragraph on the</p>
5	<p>1 page 1.                  2 And this is the declaration that you                  3 submitted for the '747 patent.                  4 Do you see that?                  5 A. Yes.                  6 Q. And my understanding is that you                  7 submitted this same substantive declaration in all                  8 three IPRs; is that correct?                  9 A. Yes, I believe they're identical.                  10 Q. Okay. If we can go to paragraph 12.                  11 I don't have the page number in front of me.                  12 Oh, there you go. Good.                  13 It starts off --                  14 You can just blow up that paragraph.                  15 It starts off saying, Dr. Donovan                  16 limited the analysis in her second declaration to                  17 oxidative degradation of naloxone.                  18 Do you see that?                  19 A. Yes.                  20 Q. So sitting here today, you don't know                  21 of any mechanism for degradation of naloxone other                  22 than oxidative degradation, correct?                  23 A. I understand that the degradation of                  24 naloxone is a complex process, and it can occur by                  25 many different mechanisms. One of those mechanisms</p>	7	<p>1 screen. I just wanted to make sure Dr. Jones knew                  2 that he could ask Martin to put up what he needs to                  3 put up if he'd like to look at something else.                  4 BY MR. BERMAN:                  5 Q. Do you agree with Dr. Donovan's                  6 opinion that a POSA would have considered it likely                  7 that the naloxone degradant was an oxidation                  8 degradant?                  9 THE WITNESS: If you could just do --                  10 Martin, I still have to look at the full page,                  11 please. (Witness reviews document.)                  12 Could I just look at the next page of                  13 the document as well, please. (Witness reviews                  14 document.)                  15 If you can go back to the previous                  16 page, please. (Witness reviews document.)                  17 And can I have the question?                  18 BY MR. BERMAN:                  19 Q. Yes. Do you need me to repeat the                  20 question? Okay.                  21 The question is, do you agree with                  22 Dr. Donovan's opinion that a POSA would have                  23 considered it likely that the naloxone degradant                  24 was an oxidation degradant?                  25 A. The POSA would have read Wyse and</p>

8	<p>1 would have understood from Wyse that benzalkonium 2 chloride caused the degradation of naloxone. 3 They would have read Wyse and 4 understood Wyse in the wider context of the 5 literature and understand this was a valid 6 proposition from Wyse's data and what Wyse actually 7 said. 8 Wyse identified an additional 9 degradant of four formulations containing 10 benzalkonium chloride. And, therefore, POSA would 11 have read Wyse and understood that Wyse showed that 12 benzalkonium chloride caused naloxone degradation. 13 The POSA would not need to understand 14 the mechanism by which that would occur because 15 they would have read Wyse and understood Wyse from 16 what Wyse said and what Wyse did. 17 Wyse removed benzalkonium chloride in 18 the formulations after finding it caused 19 instability in the formulations with respect to 20 naloxone, and, therefore, the POSA would have 21 followed Wyse's teaching away from using 22 benzalkonium chloride in the formulation and would 23 not go on to think about the mechanism of 24 degradation. 25 Q. But do you agree with Dr. Donovan's</p>	10	<p>1 stable. The POSA would not go on to consider the 2 mechanism by which that occurred. 3 MR. BERMAN: If we can go to Wyse -- 4 that's Nalox 1007. 5 MR. KRINSKY: I believe you said Nalox 6 1007. 7 MR. BERMAN: Nalox 1007. That's just 8 the exhibit number. Thanks. 9 PDF page 22, we're going to look at 10 Example 5 on columns 26 and 27. 11 If you could zoom in on where it says 12 Example 5 above where you are a bit. Right there. 13 Yes. 14 No. Down. Down. Around line 20. 15 Yes, there you go. That's fine. 16 BY MR. BERMAN: 17 Q. Okay. So I'm looking at Wyse Example 18 5 and specifically at -- I'm going to just read 19 from a couple of places and then ask you a couple 20 of questions. 21 Around line 29, it says, The 22 formulations were at pH 5.0 to accelerate 23 degradation. 24 Do you see that? 25 A. Yes.</p>
9	<p>1 opinion that a POSA would have considered it likely 2 that the naloxone degradant was an oxidation 3 degradant? 4 MR. KRINSKY: Objection. Asked and 5 answered. 6 THE WITNESS: The POSA would have read 7 Wyse and understood from Wyse that benzalkonium 8 chloride caused naloxone degradation. 9 Wyse produced a series of experiments 10 whereby he tested naloxone's compatibility in a 11 series of different intranasal formulations, and he 12 showed from that series of experiments that, 13 indeed, benzalkonium chloride caused naloxone 14 degradation. 15 He identified an additional naloxone 16 degradation peak in four formulations which 17 contained benzalkonium chloride and went on to 18 state in a number of places in Wyse's patent that 19 benzalkonium chloride caused the degradation of 20 naloxone. 21 The POSA would have read this and read 22 what Wyse did subsequent to defining this finding 23 in that he removed benzalkonium chloride from his 24 subsequent formulation testing and went on to make 25 an intranasal formulation that was chemically</p>	11	<p>1 Q. And then going on -- if you can leave 2 that up, and then go on to the next column, 27. 3 And then just go from the top down to 4 about line 30. 5 Yep. Perfect. 6 And here around line 20, it says, 7 Increasing the pH of the solution accelerated the 8 degradation of naloxone HCL resulting in the 9 formation of a major degradant at a relative 10 retention time, RRT, of 0.52. However, it was 11 found that decreasing the pH minimizes the 12 formation of potential oxidative degradants. 13 Do you see that? 14 A. Yes. 15 Q. So in this Example 5 test, Wyse 16 increased the pH of the solution to accelerate the 17 degradation of naloxone, correct? 18 MR. KRINSKY: Object to the form of 19 the question. 20 THE WITNESS: (Witness reviews 21 document.) 22 Could you reask the question, please? 23 BY MR. BERMAN: 24 Q. Sure. 25 In this example, Wyse increased the pH</p>

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