## **CONFIDENTIAL TESTIMONY**





## Transcript of Stuart Allen Jones

Friday, February 21, 2020

Nalox-1 Pharmaceuticals, LLC v. Adapt Pharma Operations Ltd.

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1	UNITED STATES PATENT AND TRADEMARK OFFICE			
2	BEFORE THE PATENT TRIAL AND APPEAL BOARD			
3	x			
4	NALOX-1 PHARMACEUTICALS, LLC :			
5	Petitioner, : Case No.			
6	v. : IPR2019-00685			
7	ADAPT PHARMA OPERATIONS LTD., and : IPR2019-00688			
8	OPIANT PHARMACEUTICALS, INC., : IPR2019-00694			
9	Patent Owners. :			
10	X			
11	Friday, February 21, 2020			
12	Washington, DC			
12	Washington, DC CONFIDENTIAL TESTIMONY			
13	CONFIDENTIAL TESTIMONY			
13	CONFIDENTIAL TESTIMONY  Deposition of STUART ALLEN JONES, a			
13 14 15	CONFIDENTIAL TESTIMONY  Deposition of STUART ALLEN JONES, a witness herein, called for examination by the			
13 14 15 16	CONFIDENTIAL TESTIMONY  Deposition of STUART ALLEN JONES, a  witness herein, called for examination by the  Petitioner in the above-entitled matter, pursuant to			
13 14 15 16 17	CONFIDENTIAL TESTIMONY  Deposition of STUART ALLEN JONES, a  witness herein, called for examination by the  Petitioner in the above-entitled matter, pursuant to notice, the witness being duly sworn by Desirae S.			
13 14 15 16 17	CONFIDENTIAL TESTIMONY  Deposition of STUART ALLEN JONES, a  witness herein, called for examination by the  Petitioner in the above-entitled matter, pursuant to notice, the witness being duly sworn by Desirae S.  Jura, a Notary Public in and for the District of			
13 14 15 16 17 18	CONFIDENTIAL TESTIMONY  Deposition of STUART ALLEN JONES, a  witness herein, called for examination by the  Petitioner in the above-entitled matter, pursuant to  notice, the witness being duly sworn by Desirae S.  Jura, a Notary Public in and for the District of  Columbia, taken at Williams & Connolly LLP, at 9:33			



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5	YELEE Y. KIM, ESQUIRE	5 DI WK. BEKWAN	O		
6	Arent Fox LLP	6 Afternoon session Page 92			
7		Afternoon session - Page 83			
8	1717 K Street, NW	8			
9	Washington, DC 20006				
10	(202) 857-6000	ЕХПІВІІЗ	DACE		
11	richard.berman@arentfox.com	LAHIDH NO.	PAGE		
12	yelee.kim@arentfox.com	11 1 - Pharmacokinetic Properties and Human 12 Use Characteristics of an FDA-Approved			
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17	JOSHUA H. HARRIS				
18	Burford Capital	18			
19	350 Madison Avenue	19			
20	New York, New York 10017	20			
21	(646) 849-6410	21			
22	jharris@burfordcapital.com	22			



Page 8 PROCEEDINGS <sup>1</sup> with certain IPRs, correct? <sup>2</sup> Whereupon, A. Yes. STUART ALLEN JONES Q. I'm showing you what's been previously 4 was called as a witness by counsel for the marked as Exhibit 2201 for the IPRs in the '253, <sup>5</sup> Defendants, and having been duly sworn, was examined <sup>5</sup> '747, and '965 patent matters. 6 and testified as follows: Do you see that? EXAMINATION BY COUNSEL FOR THE PETITIONER MR. KRINSKY: And I'd like to note for the 8 BY MR. BERMAN: record that you've passed out copies marked Q. Good morning, Dr. Jones. My name is Rich <sup>9</sup> Protective Order Material. We can sort out <sup>10</sup> Berman. I'm counsel for petitioner Nalox-1 <sup>10</sup> confidentiality designations afterwards, but at least <sup>11</sup> Pharmaceuticals, LLC. on an interim basis, let's mark the transcript 12 <sup>12</sup> confidential. Can you recite your full name and home <sup>13</sup> address for the record. 13 MR. BERMAN: Sure. A. Stuart Allen Jones. 42 Fairlawns Langley <sup>14</sup> BY MR. BERMAN: <sup>15</sup> Road, Watford, United Kingdom. Q. Do you see that? Q. We'll go over some ground rules. Let me 16 A. Yes. 17 <sup>17</sup> know if you don't hear or understand the question. Q. I am going to use for questioning today 18 If you answer, we'll assume you heard and understood <sup>18</sup> the '253 IPR. Okay? 19 the question. Okay? A. Okay. A. Okay. Q. And if any answer you give today would be <sup>21</sup> different for either of the other two IPRs, the '747 Q. Let me know if you don't know or can't <sup>22</sup> remember the information sought by the question. If <sup>22</sup> or '965, will you let me know that? Page 9 <sup>1</sup> you answer, we will assume that you know and remember MR. KRINSKY: Objection to form. <sup>2</sup> the information sought. Okay? THE WITNESS: Can you repeat the question, A. Okay. 3 please? Q. We have a court reporter who is making a <sup>4</sup> BY MR. BERMAN: <sup>5</sup> transcript, so be sure to answer in a way that the Q. Sure. I'm going to use the '253 as the <sup>6</sup> court reporter can record in the transcript. And <sup>6</sup> basis of going through and asking you some questions. <sup>7</sup> you'll need to answer out loud. The court reporter <sup>7</sup> But if, in the context of answering those questions, <sup>8</sup> cannot record nodding or shaking of the head. Also, <sup>8</sup> if your answer would be different depending on which <sup>9</sup> please say yes rather than uh-huh. Okay? <sup>9</sup> of the three patents we're talking about, can you let A. Yes. <sup>10</sup> me know the difference? 11 Q. And let me know if you want to take a MR. KRINSKY: If I could just state for <sup>12</sup> break for any reason. Okay? 12 the record, I believe these are all the same exact 13 A. Yes. <sup>13</sup> documents under the cover sheet. 14 Q. And let me know if you realize that an MR. BERMAN: Right. I understand that. <sup>15</sup> answer you previously gave is inaccurate or <sup>15</sup> BY MR. BERMAN: 16 incomplete. Just say that you want to correct or Q. What I'm saying is, inartfully, if an <sup>17</sup> supplement a previous answer. Okay? <sup>17</sup> answer you're going to give would be different if we 18 <sup>18</sup> were talking about the '253 patent declaration versus A. Okay. 19 the '747 or the '965 patent, will you let me know if Q. Is there any reason why you cannot give <sup>20</sup> full and complete answers today? <sup>20</sup> there's any difference in your answer? 21 21 A. No. MR. KRINSKY: Object to the form of the <sup>22</sup> question. Vague. Q. You submitted declarations in connection



Page 10 THE WITNESS: I believe the three <sup>1</sup> administration of an opioid antagonist - in <sup>2</sup> documents are identical. <sup>2</sup> particular, naloxone; (2) claims directed to <sup>3</sup> BY MR. BERMAN: <sup>3</sup> single-use, pre-primed devices adapted for nasal Q. Okay. Let's go to paragraph 7 of your <sup>4</sup> delivery of such pharmaceutical formulations; and, <sup>5</sup> (3) methods of treating opioid overdose and symptoms <sup>5</sup> declaration. And you see, there is a summary of the <sup>6</sup> asserted grounds of obviousness for all three of the <sup>6</sup> thereof by nasally administering naloxone using <sup>7</sup> IPRs? <sup>7</sup> those" -- and it continues on the next page --MR. KRINSKY: Counsel, did you mean page <sup>8</sup> "devices and formulations." Yes. 9 7? O. And in paragraph 28, you recite what the 10 <sup>10</sup> formulations in the Adapt patents generally comprise. MR. BERMAN: Paragraph 7. 11 11 Do you see that? MR. KRINSKY: Thank you. 12 12 THE WITNESS: In paragraph 7, it says, "I A. Yes. <sup>13</sup> understand that each proceeding Nalox-1 argues that 13 Q. In your opinion, which of the features 14 the challenged claims of the Adapt patents are <sup>14</sup> distinguish the Adapt patents from the prior art? 15 obvious over a combination of references, as set MR. KRINSKY: Object to the form of the 16 forth in the charts below." <sup>16</sup> question. Vague. 17 And the charts below mention asserted THE WITNESS: Can you explain what you 18 mean by the word "distinct"? 18 grounds of obviousness. Yes. <sup>19</sup> BY MR. BERMAN: <sup>19</sup> BY MR. BERMAN: Q. And you see the main reference is the Wyse Q. What features, in your opinion, are <sup>21</sup> reference? <sup>21</sup> different between the Adapt patents and the prior <sup>22</sup> art? A. Can you explain what you mean by "main"? Q. Well, under the asserted grounds of MR. KRINSKY: Object to the form of the <sup>2</sup> obviousness, it says Wyse and HPE, Wyse, Djupesland, question. Vague. <sup>3</sup> and HPE, and so on and so forth. Do you see that? THE WITNESS: Can you explain what you A. I can see there's four references <sup>4</sup> mean by "features," please? <sup>5</sup> mentioned in those tables. <sup>5</sup> BY MR. BERMAN: Q. You're familiar with the Wyse patent, are Q. Let's do it this way. I'm showing you <sup>7</sup> you not? <sup>7</sup> what's been previously marked as Exhibit Nalox 1007. A. Yes. <sup>8</sup> This is the Wyse '570 patent. Do you see that? Q. Can you turn to paragraph 22 on page 13. A. Yes, I see that. <sup>10</sup> And the last sentence there says, "The Adapt patents O. You're familiar with this reference? <sup>11</sup> disclose formulations, devices, and methods for nasal <sup>11</sup> You've seen it before? <sup>12</sup> delivery of pharmaceutical compositions comprising A. Yes, I believe I've seen it before. 13 naloxone." Do you see that? 13 Q. So Wyse discloses intranasal 14 <sup>14</sup> administration of a composition to reverse opioid A. I see those words at the bottom of the <sup>15</sup> page 13, yes. <sup>15</sup> overdose, correct? Q. And turning onto paragraph 27, here you A. Yes. That's correct. 17 <sup>17</sup> recite three categories of claims covered by the Q. And Wyse discloses an aqueous solution <sup>18</sup> Adapt patents. Do you see that? <sup>18</sup> containing naloxone hydrochloride, correct? A. At the bottom of page 15, I note, "In A. Yes. That's correct. 20 general, the claims of the Adapt patents fall into Q. And Wyse discloses sodium chloride as an <sup>21</sup> three categories: (1) claims directed to <sup>21</sup> isotonicity agent, correct? <sup>22</sup> pharmaceutical formulations for intranasal A. Wyse uses sodium chloride, but I can't



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