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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
MAUREEN DONOVAN, Ph.D., Volume 2
Swisher, Iowa
April 17, 2020, 9:39 a.m.

Reported by: Michele E. Eddy, RPR, CRR, CLR

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1 ATTENDANCE, Continued
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E X H I B I T S

(None marked)

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1 PROCEEDINGS
2 April 17, 2020
3 ---
4 THE VIDEOGRAPHER: The time is
5 9:39 a.m., Central Time, on April 17th, 2020.
6 This is video 1 of volume 2 of the continued video
7 deposition of Dr. Maureen Donovan.
8 Will the court reporter please
9 readminister the oath, and counsel for appearances
10 will be noted on the stenographic record.
11 ---
12 MAUREEN DONOVAN, Ph.D.,
13 having been duly sworn, testified as follows:
14 EXAMINATION BY COUNSEL FOR PATENT OWNER ADAPT PHARMA
15 BY MS. BERNIKER:
16 Q Good morning, Doctor.
17 A Good morning.
18 Q How are you today?
19 A I'm fine, thanks.
20 Q Great, great.
21 So you understand that you're under oath
22 this morning, right?

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1 A Yes, I do.
2 Q And just like you were the last time you
3 testified in this proceeding?
4 A Yes.
5 Q And just like you were when you
6 submitted the declarations that you submitted in
7 this proceeding?
8 A Yes, that's my understanding.
9 Q Okay. And I believe you testified to
10 this earlier, but you do not have clinical
11 expertise in the administration of opioid
12 antagonists to treat opioid overdoses, right?
13 A I don't have a license to practice as a
14 physician. I have -- I was licensed as a
15 pharmacist at one point in time in my career.
16 Q You don't hold yourself out as having
17 clinical expertise, right, Doctor?
18 A I have -- I don't have a license to
19 practice medicine, but I had a license to practice
20 pharmacy.
21 Q Do you hold yourself out as a clinical
22 expert?

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1 A I have knowledge of clinical treatments,
2 but I don't have a license to practice medicine.
3 Q And you wouldn't call yourself a
4 clinician, right?
5 A No, I don't have a license to practice.
6 Q Okay. And in your first declaration you
7 characterized yourself as testifying from the
8 perspective of the formulator POSA; is that right?
9 A That most of my opinions are involved or
10 are focused on formulation aspects of these
11 patents. I have other expertise, but, again, as
12 part of the POSA team that I proposed, most of my
13 opinions are focused on the formulation aspects.
14 Q Well, why don't we look at paragraph 28
15 of your original report, then, because my
16 understanding was that you were holding yourself
17 out as the formulator part of the POSA. If you
18 could turn to paragraph 28 of Exhibit 1002,
19 please.
20 If we could turn to paragraph 28 on page
21 13. It says numbered page 13. Great.
22 Do you see in paragraph 28, you say, "I

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1 have at least the ordinary skill of the
2 'formulator' who forms part of the POSA team
3 (i.e., the 'Formulator POSA')"?
4 Do you see that?
5 A I see that.
6 Q Okay. And you didn't take the position
7 in your declaration that you were speaking from
8 the perspective of somebody other than the
9 formulator POSA as you defined it, right?
10 A Well, again, the POSA is a -- is a team.
11 The people on that team, or the individuals as
12 part of that team, bring multitudes of information
13 into the team. But, again, yes, I am -- my
14 opinions are focused or are primarily specific to
15 a formulator on the POSA team.
16 Q Okay. You didn't purport to represent
17 the entire POSA team, right?
18 A No, I don't.
19 Q Okay. And -- and let's take a look at
20 the Jones declaration, please, Exhibit 2201.
21 THE VIDEOGRAPHER: That just got sent to
22 me now. Hang on.

2 (Pages 356 to 359)

<p style="text-align: right;">Page 360</p> <p>1 MS. BERNIKER: Okay.</p> <p>2 BY MS. BERNIKER:</p> <p>3 Q You're familiar with Dr. Jones'</p> <p>4 definition of a POSA, right, Doctor?</p> <p>5 A I have seen Dr. Jones' definition of a</p> <p>6 POSA. I'm going to need to refamiliarize myself</p> <p>7 with it.</p> <p>8 Q Sure. And before I -- before I get to</p> <p>9 the details, let me ask you this. You understand</p> <p>10 that Dr. Jones also set forth a definition of a</p> <p>11 POSA, which is a team of individuals, right?</p> <p>12 A Again, I need to see it. I don't have</p> <p>13 enough recollection of his definition to opine on</p> <p>14 it right now.</p> <p>15 Q Okay. Why don't we take a look at</p> <p>16 Dr. Jones' paragraphs 38 through 40.</p> <p>17 THE VIDEOGRAPHER: It's importing right</p> <p>18 now. It's scanning all the pages.</p> <p>19 MS. BERNIKER: Absolutely.</p> <p>20 My apologies, Dan, for missing that one.</p> <p>21 THE VIDEOGRAPHER: No, it's quite all</p> <p>22 right. Thank you for letting me get a head start</p>	<p style="text-align: right;">Page 362</p> <p>1 BY MS. BERNIKER:</p> <p>2 Q Certainly.</p> <p>3 Just like the Nalox-1 POSA definition,</p> <p>4 Dr. Jones' definition is also of a POSA team,</p> <p>5 right?</p> <p>6 A Yes.</p> <p>7 Q And you possess some of the</p> <p>8 qualifications of the team, but you don't purport</p> <p>9 to possess the qualifications of the entire team,</p> <p>10 right?</p> <p>11 A I don't possess the -- I am a member of</p> <p>12 the POSA team proposed in my -- under my</p> <p>13 definition of POSA, and I would be a member of the</p> <p>14 POSA team as defined by Dr. Jones.</p> <p>15 Q You don't represent the complete POSA</p> <p>16 team defined by Dr. Jones, right?</p> <p>17 A Again, that's why we -- why the POSA is</p> <p>18 defined as a team, so that there can be multiple</p> <p>19 members. But I represent a member of the POSA</p> <p>20 team based on my definition of a POSA and I would</p> <p>21 meet the definition of a member of the POSA team</p> <p>22 in Dr. Jones' definition.</p>
<p style="text-align: right;">Page 361</p> <p>1 with that. Okay. So, there's Jones, 2201. Let's</p> <p>2 pull this up. Okay. Let's exit out of this.</p> <p>3 Pull this up now, which everybody should be able</p> <p>4 to see this. Okay. That's what we have here.</p> <p>5 Okay. What page, counsel?</p> <p>6 MS. BERNIKER: Pages 20 to 21, please.</p> <p>7 Not -- I believe they're --</p> <p>8 THE VIDEOGRAPHER: So 20 and 21, okay.</p> <p>9 Doctor, let me --</p> <p>10 MS. BERNIKER: If you could just give</p> <p>11 the doctor the opportunity to take a look at</p> <p>12 paragraphs 38 through 40.</p> <p>13 THE VIDEOGRAPHER: Doctor, let me know</p> <p>14 when to flip the page.</p> <p>15 THE WITNESS: Okay. Thank you.</p> <p>16 (Document review.)</p> <p>17 Okay. Can you flip the page?</p> <p>18 THE VIDEOGRAPHER: Sure.</p> <p>19 THE WITNESS: (Document review.)</p> <p>20 Okay. I've read that and recalled what</p> <p>21 the -- Dr. Jones' definition of a POSA is. Is</p> <p>22 there a question that you would like me to answer?</p>	<p style="text-align: right;">Page 363</p> <p>1 Q Okay. But to be clear, Doctor, you</p> <p>2 don't represent the complete POSA team in</p> <p>3 Dr. Jones' definition, right?</p> <p>4 A I represent a member of the POSA team.</p> <p>5 Q So that's a yes?</p> <p>6 A I stand by my statement. I represent a</p> <p>7 member of the POSA team described by Dr. Jones.</p> <p>8 Q But not the complete team, right?</p> <p>9 A You know, POSAs are -- are imaginary</p> <p>10 compilations of expertise based on -- and then we</p> <p>11 try to overlay individuals on them. I'm a member</p> <p>12 of the POSA team as defined by Dr. Jones.</p> <p>13 Q Are you having trouble with my question?</p> <p>14 My question is, you're only part of the team,</p> <p>15 right?</p> <p>16 MR. BERMAN: Objection to form.</p> <p>17 Q It's a yes or no question. You're part</p> <p>18 of the team, not the complete team, right?</p> <p>19 A By definition of "team," there would be</p> <p>20 multiple human members. I would be one of those</p> <p>21 human members.</p> <p>22 Q Because you don't have all of the</p>

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1 qualifications. You have some of them, right?
 2 A Well, as defined, the POSA is defined as
 3 a team, a grouping of individuals who have
 4 expertise. I'm a member of the POSA team as
 5 defined by both Dr. Jones and by me.
 6 Q Let's try this again. You have some but
 7 not all of the qualifications of the POSA team as
 8 defined by Dr. Jones, right? This should not be a
 9 hard question.
 10 MR. BERMAN: Objection to form.
 11 A Well, again, I'm -- I'm a member of the
 12 POSA team and I bring my expertise to the POSA
 13 team. And I recognize that there are other people
 14 who would bring additional expertise to the team.
 15 Q Do you or do you not have all of the
 16 qualifications of the POSA team that Dr. Jones
 17 sets forth in his declaration?
 18 A Dr. Jones defines a team, and he chooses
 19 to pull out specific characteristics of that -- of
 20 that -- of those team members and separate them
 21 into individual paragraphs. That's, you know, an
 22 artificial manner of defining the team, and I,

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1 again, represent a member of the team who can
 2 contribute to the POSA team regarding this matter.
 3 Q Is there some reason you're not
 4 comfortable testifying that you don't have every
 5 single one of the qualifications of his POSA team
 6 even if you just told me five minutes ago that you
 7 don't have all of the qualifications of your POSA
 8 team?
 9 MR. BERMAN: Objection to form.
 10 A Is there a specific aspect that you want
 11 to ask about? Again, the POSA team members
 12 have --
 13 Q I don't think this is a hard question.
 14 You've seen the POSA team description. Do you or
 15 do you not have all of the qualifications of that
 16 team?
 17 A I have the qualifications.
 18 Q You personally.
 19 A I have the qualifications to be a member
 20 of the POSA team.
 21 Q But you don't represent the entire POSA,
 22 in terms of experience, right?

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1 A Well, the POSA has already been defined
 2 as a team.
 3 Q So why can't you just answer me yes, I
 4 do not?
 5 A There's multiple individuals who are
 6 part of that team who contribute aspects to the
 7 team.
 8 Q This is going to be a really long day if
 9 I can't get a clean answer to a very basic
 10 question so let's make it simpler.
 11 Look at paragraph 40 in front of you.
 12 Among the things in Dr. Jones' definition, "the
 13 POSA team would include a medical practitioner
 14 and, thus, would have had knowledge regarding the
 15 administration of opioid antagonists to treat
 16 opioid overdoses by medically trained personnel,
 17 first responders, and others in the community, and
 18 would have had clinical experience with
 19 administering opioid antagonists to overdose
 20 patients."
 21 Do you see that?
 22 A I see that.

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1 Q You're not a medical practitioner who
 2 has had clinical experience administering opioid
 3 overdoses -- opioid antagonists to overdose
 4 patients, right, Doctor?
 5 A As stated in that paragraph, there are
 6 aspects of the definition in that paragraph that I
 7 do not have -- I'm not a medically -- well, I --
 8 I'm a biomedically trained person, but, again, I
 9 have stated I do not have a license to practice
 10 medicine so I have not had the ability to directly
 11 treat patients, but I have many of the other
 12 understandings of the POSA being defined in this
 13 paragraph.
 14 Q One of the things that's required here
 15 is clinical experience with administering opioid
 16 antagonists to overdose patients, right?
 17 A I have not had clinical experience
 18 administering opioid antagonists to overdose
 19 patients.
 20 Q Okay. So it is not fair to say that you
 21 have all of the qualifications of a POSA under
 22 Dr. Jones' definition, right?

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1 MR. BERMAN: Objection to form.

2 A Again, I -- I have said repeatedly, I
3 don't have a license to practice medicine. I have
4 agreed that I don't have clinical experience with
5 administering opioid antagonists to overdose
6 patients, but I am qualified to be a member of the
7 POSA team as defined by Dr. Jones.

8 Q Okay. I would like you to direct your
9 attention, please, to your supplemental
10 declaration, Exhibit 1201, please. And if we
11 could take a look at footnote 1 on page 6.

12 THE VIDEOGRAPHER: Okay. One second.
13 1201, supplemental.

14 MS. BERNIKER: If we could pull up
15 footnote 1, please.

16 BY MS. BERNIKER:

17 Q This is your supplemental declaration
18 that you submitted in this case, right, Doctor?

19 A It appears to be, yes.

20 Q I want to look at the very last sentence
21 of this footnote. You say, "Nevertheless, I have
22 the qualifications of a POSA under Dr. Jones' and

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1 that team.

2 Q Even when you're referring to the
3 qualifications that you possess among that team?

4 MR. BERMAN: Objection to form.

5 A Again, I am a member of the POSA team.

6 Q Were you trying to represent to the
7 patent office here that you had all of the -- all
8 of the qualifications of Dr. Jones' POSA?

9 A In -- in my earlier statements, and even
10 in Dr. Jones' definition, he describes a POSA
11 team, and I meet the qualifications of a member of
12 the POSA team.

13 Q Were you trying to represent to the
14 patent office that you met all of the
15 qualifications of the POSA team under Dr. Jones'
16 definition?

17 A The statement as given in this footnote
18 is that I have the qualifications of a member of a
19 POSA team.

20 Q I don't see the word "member" --

21 A Dr. Jones --

22 Q -- or "team."

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1 Dr. Williams' definitions."

2 Do you see that?

3 A I see that.

4 Q Do you believe that's a fully accurate
5 sentence, Doctor?

6 A I -- I expect in the same way the term
7 "POSA" has been used throughout my report, yes,
8 that I'm a member of the POSA team. We -- I did
9 not write "POSA team" in all of the references to
10 "POSA" in my reports, and so I stand by that. I
11 have the qualifications as a member of the POSA
12 team under Dr. Jones' and Dr. Williams'
13 definitions.

14 Q You don't think it would have been more
15 accurate to say I have some of the qualifications
16 of a POSA team under Dr. Jones' and Dr. Williams'
17 definitions?

18 A There -- there may have been other ways
19 of stating this when I -- but, typically, when I
20 am writing reports, the POSA is, in general,
21 defined as a team, and it's been my general habit
22 to just use the term "POSA" when I'm referring to

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1 A -- defined it -- defined the POSA as a
2 team.

3 Q Where does it say member and team in the
4 sentence?

5 A It does not say member and team in the
6 sentence.

7 Q What it says is "I have the
8 qualifications of a POSA," not part of the POSA or
9 a member of the POSA, right?

10 A The POSA is defined as a team --

11 Q Do you think --

12 A -- and --

13 Q Do you think that it was irrelevant for
14 purposes of this footnote whether or not you had
15 clinical experience in administering opioid
16 overdose -- I'm sorry, in administering naloxone
17 to opioid overdose patients?

18 A I'm going to have to read the section of
19 my report that this footnote refers to.

20 Q Sure. Go ahead.

21 If we could just zoom out so the doctor
22 can see the entire source for the footnote.

5 (Pages 368 to 371)

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