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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NALOX-1 PHARMACEUTICALS, LLC

Petitioner,

v.

OPIANT PHARMACEUTICALS, INC.,

Patent Owner.

Case No. IPR2019-000685

Patent No. 9,211,253

DEPOSITION OF MAUREEN DONOVAN, PH.D.

Washington, D.C.

Friday , November 22, 2019

Reported by:

MATTHEW GOLDSTEIN, RPR

JOB NO. 172400

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November 22, 2019
9:01 a.m.

Deposition of MAUREEN DONOVAN, PH.D.,
held at the offices of Arent Fox LLP 1717 K
Street, NW, Washington, D.C. 20006, pursuant to
notice, before Matthew Goldstein, a Registered
Professional Reporter and Notary Public of the
District of Columbia.

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A P P E A R A N C E S (CONT'D):

GREEN GRIFFITH & BORG-BREEN LLP
Attorneys for Plaintiffs
676 N Michigan Avenue
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Chicago, Illinois 60611
312.882.8000
BY: JESSICA TYRUS MACKAY, ESQ.

ALSO PRESENT:
JOSHUA H. HARRIS - BURFORD

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A P P E A R A N C E S:

ARENT FOX
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BY: ANA REYES, ESQ.
KEVIN HOAGLAND-HANSON, ESQ.
JESSAMYN BERNIKER, ESQ.

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M. DONOVAN, PH.D.
MS. REYES: Do you want to state
appearances?
Ana Reyes for the respondents.
MS. BERNIKER: Jessamyn Berniker and
Kevin Hoagland-Hanson, also for the respondents,
patent owners.
MS. MACKAY: Jessica Tyrus Mackay from
Green Griffith & Borg-Breen, also on behalf of the
patent owners.
MR. FRESE: Bradford Frese from the firm
of Arent Fox on behalf petitioner and the witness.
MS. KIM: Yelee Kim from Arent Fox on
behalf of petitioner.
MR. HARRIS: Joshua Harris, Burford
Capital, for Nalox-1.
Whereupon,
MAUREEN DONOVAN, PH.D.,
being first duly sworn or affirmed to testify to
the truth, the whole truth, and nothing but the
truth, was examined and testified as follows:
EXAMINATION BY COUNSEL FOR THE PATENT OWNER
BY MS. REYES:
Q. Ma'am, you did not attend medical
school; correct?

1 M. DONOVAN, PH.D.

2 A. No, I didn't.

3 Q. You're not a medical doctor; correct?

4 A. No, I'm a registered pharmacist.

5 Q. You're not a clinician?

6 A. Could you define what you mean by
7 "clinician."

8 Q. You're not a medical doctor who treats
9 patients in clinics; correct?

10 A. That's correct.

11 Q. You never treated a patient for any
12 purpose; correct?

13 A. Not in a medical sense, no.

14 Q. You have never administered Naloxone to
15 a patient; correct?

16 A. No, I have not.

17 Q. You have never observed the withdrawal
18 effects of treating a patient with Naloxone;
19 correct?

20 A. Not directly, no.

21 Q. You have never had to treat a patient
22 suffering withdrawal effects from the
23 administration of Naloxone; correct?

24 A. Again, I'm not able to treat patients.

25 Q. So you have never treated a patient

1 M. DONOVAN, PH.D.

2 suffering withdrawal effects from the
3 administration of Naloxone; correct?

4 A. No, I have not.

5 Q. You're not a clinical pharmacologist;
6 correct?

7 A. Not by formal education, but I have
8 certainly education in areas related to clinical
9 pharmacology.

10 Q. Do you consider yourself an expert
11 clinical pharmacologist?

12 A. I have an awareness of the field, but I
13 would not say that I am an expert.

14 Q. Since 1991, you have never worked for
15 any pharmaceutical company; correct?

16 A. I'd have to look at my CV to look at
17 dates, but if I -- that's probably about right.

18 Q. Okay. Your work is not focused on
19 trying to develop FDA-approved products; correct?

20 A. I participate in early-phase development
21 in conjunction with other sponsors whose goals is
22 to develop an FDA-approved product, but most of
23 the time in my research, my goals are not to
24 develop products that would be moved forward for
25 FDA approval.

1 M. DONOVAN, PH.D.

2 Q. Your work is not focused on trying to
3 develop FDA-approved products; correct?

4 A. It's not focused on it, no.

5 Q. Before preparing your report, you did
6 not consult with a medical doctor concerning the
7 administration of Naloxone; correct?

8 A. That's correct.

9 Q. Before preparing your report, you did
10 not consult with a medical doctor concerning any
11 of the opinions in your report; correct?

12 A. That's correct.

13 Q. You have reviewed the expert report of
14 Güenther Hochhaus; correct?

15 A. I have.

16 Q. Güenther Hochhaus is not a medical
17 doctor; correct?

18 A. It's my understanding he's not.

19 Q. He's not a clinician; correct?

20 A. I expect he's not a clinician.

21 Q. He does not indicate anywhere in his
22 report that he consulted with a medical doctor in
23 preparing his report; correct?

24 A. I didn't see anything about that during
25 my review.

1 M. DONOVAN, PH.D.

2 Q. You're not an economist; correct?

3 A. I'm not an economist.

4 Q. You do not have any advanced training in
5 economist [sic]; correct?

6 A. No, I don't.

7 Q. Before preparing your report, you did
8 not consult with an economist concerning any of
9 the opinions in your report; correct?

10 A. I did not.

11 Q. You agree that each pharmaceutical
12 product is a formulation unique unto itself;
13 correct?

14 MR. FRESE: Objection; form.

15 THE WITNESS: Well, each pharmaceutical
16 product has -- may or may not have unique
17 materials compared to other products. They may
18 have unique properties, or they may have
19 measurable properties that are quite similar to
20 other products.

21 Q. But each pharmaceutical product is a
22 formulation unique unto itself; correct?

23 MR. FRESE: Objection; cumulative.

24 THE WITNESS: It may or may not be. It
25 may actually be an identical formulation, and it

1 M. DONOVAN, PH.D.

2 may actually have an identical manufacturing
3 sequence to another pharmaceutical product.

4 BY MS. REYES:

5 Q. A pharmaceutical formulation can contain
6 therapeutic and nontherapeutic ingredients;
7 correct?

8 A. Yes.

9 Q. The formulation must be such that all
10 components are compatible?

11 MR. FRESE: Objection; form.

12 THE WITNESS: The formulation and the
13 product itself need to meet compendial quality
14 standards and standards specified by the
15 manufacturer and understood by the FDA.

16 Q. They have to be compatible with each
17 other?

18 MR. FRESE: Objection; form.

19 THE WITNESS: They have to meet
20 compendial requirements for pharmaceutical
21 quality.

22 Q. The active therapeutic agents, the
23 pharmaceutical ingredients and the packaging
24 containers must all be compatible; correct?

25 MR. FRESE: Objection to form.

1 M. DONOVAN, PH.D.

2 THE WITNESS: All of the things you've
3 listed, the pharmaceutical product, the
4 ingredients in that, the container, the packaging
5 system, again, they must meet quality
6 specifications as determined by the developer.
7 And they have been evaluated by the FDA and
8 approved for the characteristics of that
9 particular product and its packaging.

10 BY MS. REYES:

11 Q. And that would include that they would
12 have to be compatible with each other; correct?

13 A. Not in an infinite sense.

14 Q. What about in a finite sense?

15 A. The quality standards define the finite
16 sense --

17 Q. Okay. Ma'am --

18 A. -- by which materials are compatible or
19 interact with one another or don't interact with
20 one another.

21 Q. Ansel's Pharmaceutical Dosage Forms and
22 Drug Delivery is a textbook in your field?

23 A. I'm familiar with that, yes.

24 Q. It is a textbook in your field that you
25 and your students refer to; right?

1 M. DONOVAN, PH.D.

2 A. I've referred to it, certainly. I don't
3 know that my students have, but I don't recall all
4 of the references in all of their dissertations
5 and papers we've written.

6 Q. Have you looked at your website
7 recently?

8 A. To tell you the truth, not recently.

9 Q. It's a reference book listed on your
10 website. Would that surprise you?

11 A. On my personal website?

12 Q. On the Iowa website for your graduate
13 school, the one that you participate in.

14 A. I guess I'd like to see what you're
15 actually talking about.

16 Q. Sure. No problem.

17 (Deposition Exhibit 2040, University of
18 Iowa Printout, was marked for identification and
19 attached to the transcript.)

20 MR. FRESE: I object to this document.
21 It's outside the scope of the deposition.

22 MS. REYES: Okay. You do that.

23 I'm going to introduce Exhibit 1, which
24 is -- Exhibit 2040, which is a portion of the Iowa
25 graduate school website.

1 M. DONOVAN, PH.D.

2 BY MS. REYES:

3 Q. Here you go.

4 A. Actually, I don't think you correctly
5 characterized where this came from.

6 Q. Okay. You tell me where it comes from.

7 A. This appears to me to be a hard copy of
8 the web page -- of a web page that is curated by
9 our University of Iowa libraries. And it also
10 appears to be in the subsection that is likely the
11 guides or the subset of materials that our
12 university libraries have placed into sort of an
13 easy access site based on subject matter.

14 Q. If you turn to page 5 of this, ma'am, do
15 you see that it says, "Compounding reference
16 resources"?

17 A. Yes.

18 Q. And that one of the compounding
19 reference resources is Pharmaceutical Dosage Forms
20 and Drug Delivery, which is the Ansel's that I
21 just cited to you?

22 A. It doesn't indicate that it's the Ansel
23 text. It just --

24 Q. Was there a different text that's
25 Pharmaceutical Dosage Forms and Drug Delivery,

1 M. DONOVAN, PH.D.
 2 ma'am?
 3 A. There actually may be.
 4 Q. But do you know, sitting here today?
 5 A. I'm not aware of exact titles of all the
 6 reference texts in the area.
 7 Q. You just don't know? You've been doing
 8 this for how long? How many decades have you been
 9 teaching?
 10 MR. FRESE: Objection to form.
 11 Q. How many decades have you been teaching
 12 in this area, ma'am?
 13 A. I've been teaching about 30 years.
 14 Q. Okay. In the 30 years that you've been
 15 teaching, you know that there's an Ansel's
 16 Pharmaceutical Dosage Forms and Drug Delivery
 17 textbook; correct?
 18 A. I believe the name actually for the
 19 series of textbooks that Ansel has edited actually
 20 may have changed during the time period of those
 21 texts, but I will -- I will choose to believe that
 22 you've given me the correct title.
 23 Q. Thank you.
 24 And this Pharmaceutical Dosage Forms and
 25 Drug Delivery, if we could turn to that, that is

1 M. DONOVAN, PH.D.
 2 Q. And it's the ninth edition. And if you
 3 look at the -- if you look at this page right
 4 here, it's a 2011 date.
 5 A. Oh, so you've indicated the most recent
 6 copyright date as 2011.
 7 Q. And this would be prior art?
 8 A. It's my understanding it would be prior
 9 art.
 10 Q. Okay. And if we could --
 11 MS. REYES: Now it's back in the scope.
 12 Q. Now, if we could please turn to page 2.
 13 If you could go to the second column, third
 14 paragraph, it says, "Each particular
 15 pharmaceutical product."
 16 Do you see that?
 17 A. Yes.
 18 Q. So Ansel's, the prior art textbook
 19 referenced at the Iowa library, says, "Each
 20 particular pharmaceutical product is a formulation
 21 unique onto [sic] itself."
 22 Do you see that?
 23 A. I see that statement. However --
 24 Q. Okay. Ma'am, that's all I asked you.
 25 That's all I asked you, if you saw it.

1 M. DONOVAN, PH.D.
 2 what your library tells people is a reference
 3 book.
 4 MR. FRESE: Is this marked as an
 5 exhibit?
 6 MS. REYES: Yeah, 2041.
 7 (Deposition Exhibit 2041, Ansel's
 8 Pharmaceutical Dosage Forms and Drug Delivery
 9 Systems 9th Edition, was marked for identification
 10 and attached to the transcript.)
 11 MR. FRESE: Okay. I'm going to object
 12 to this as outside the scope of the deposition and
 13 an improper excerpt of a larger reference.
 14 MS. REYES: Okay.
 15 BY MS. REYES:
 16 Q. Ma'am, Exhibit 2041 is an excerpt from
 17 Ansel's Pharmaceutical Dosage Forms and Drug
 18 Delivery Systems, the ninth edition.
 19 Do you see that?
 20 A. Well, I see the cover page that looks
 21 like the cover page that I've seen.
 22 Q. Okay.
 23 A. And certainly this title page indicates
 24 what I would expect from the title page of that
 25 textbook series.

1 M. DONOVAN, PH.D.
 2 A. Okay.
 3 Q. And that is prior art that the POSA
 4 would be aware of; correct?
 5 A. I don't know. I haven't had a chance to
 6 review this. It's a single sentence that you've
 7 asked me about.
 8 Q. And I'm asking you --
 9 A. I see that sentence on the page.
 10 Q. Yes, the sentence is on the page.
 11 And the POSA would see that sentence on
 12 the page; correct?
 13 A. The POSA would see the sentence on the
 14 page --
 15 Q. Okay. Thank you.
 16 A. -- but the POSA would understand that
 17 they read single sentences in the context of the
 18 full document.
 19 Q. Sure. Fair enough.
 20 "In addition to the" -- and it goes on,
 21 "In addition to the active therapeutic
 22 ingredients, a pharmaceutical formulation contains
 23 a number of nontherapeutic or pharmaceutical
 24 ingredients."
 25 And I think you gave me that one.

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