

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

3

4 INSYS DEVELOPMENT

5 COMPANY, INC., Petition for Inter

6 Petitioner, Partes Review of

7 vs. U.S. Patent No.

8 GW PHARMA LIMITED, 9,066,920

9 Patent Owner.

10

11

12

DEPOSITION OF:

13

LESLIE BENET, PH.D.

14

October 5, 2017

15

9:03 a.m.

16

17

500 West Madison Street

18

Chicago, Illinois

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Reported By:

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Deanna Amore,

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CSR, RPR, 084-003999

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Job No. 2685666

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I N D E X

WITNESS	EXAMINATION
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EXHIBITS

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1 (Whereupon, the witness was
2 duly sworn.)

3 MS. HUFNAL: Good morning, Dr. Benet.

4 THE WITNESS: Good morning.

5 LESLIE BENET, PH.D.,
6 called as a witness herein, having been first duly
7 sworn, was examined and testified as follows:

8 CROSS-EXAMINATION

9 BY MS. HUFNAL:

10 Q. Have you been deposed before? 09:03:49

11 A. Yes.

12 Q. How many times?

13 A. Somewhere north of 50.

14 Q. Have any of those depositions been in the
15 context of a patent litigation?

16 A. Most of them.

17 Q. Have you been serving as an expert in
18 those depositions?

19 A. Yes.

20 Q. Have you ever testified before in an IPR 09:04:01
21 proceeding?

22 A. Not in the U.S. In Germany -- well,
23 different, yeah.

24 Q. Different type of proceeding?

25 A. Right. Yes.

1 Q. In those depositions where you're
2 testifying as an expert, can you give me a
3 high-level description of what you were testifying
4 as an expert in?

5 A. It's always validity of patents or
6 obviousness or...

7 Q. Have you been testifying as a
8 pharmacokinetics or --

9 A. Yeah. Drug development, pharmacokinetics,
10 pharmacodynamics, biopharmaceutics. 09:04:46

11 Q. Have any of those engagements been on
12 behalf of Inysis before this one?

13 A. No.

14 Q. I am going to go over a few ground rules.
15 You have been deposed before, but I'll do it for
16 the sake of procedure here. Okay?

17 A. Okay.

18 Q. I am going to be asking you questions
19 today, and you are going to be giving me answers.
20 You understand that? 09:05:14

21 A. I do.

22 Q. And since the court reporter is taking
23 everything down, we should try to speak
24 independently of each other. So let me finish my
25 question before you answer. Is that okay?

1 A. I will try.

2 Q. I will need verbal answers so the court
3 reporter can take it down. Do you understand that?

4 A. I recognize that.

5 Q. If I ask a question that you do not
6 understand at any point, will you please let me
7 know?

8 A. I will.

9 Q. And if you answer my question, I'm going
10 to assume that you have understood it. Is that 09:05:37
11 fair?

12 A. That's fair.

13 Q. You understand that you are under oath
14 today, correct?

15 A. I do.

16 Q. It's the same oath as if you were in a
17 courtroom in the United States; do you understand
18 that?

19 A. I do.

20 Q. Is there any reason, medical or otherwise, 09:05:51
21 why you are not able to give accurate and truthful
22 testimony today?

23 A. No reason.

24 Q. Dr. Benet, you have a Ph.D. in
25 pharmaceutical chemistry; is that right?

1 A. That's correct.

2 Q. You are also a professor at the School of
3 Pharmacy at UCSF?

4 A. That's correct.

5 Q. What do you teach at UCSF?

6 A. Pharmacokinetics, drug metabolism, drug
7 transporters, pharmacodynamics are my areas of
8 specialty.

9 Q. I'm going to give you the declaration that
10 you have submitted in this proceeding so you can 09:06:27
11 refer to it at any point. I'm handing you what's
12 been previously marked as Inysis Exhibit 1003.

13 Dr. Benet, does Inysis Exhibit 1003 appear
14 to be the expert declaration that you submitted in
15 this IPR proceeding? I think along with your CV?

16 A. Oh, wow. Got my more recent publications.

17 Yes.

18 Q. And so just so the record is clear
19 Exhibit 1003, up to page 11, is that the substance
20 of the declaration you have submitted in this 09:07:30
21 proceeding?

22 A. It is.

23 Q. And starting on page 12 of the exhibit
24 onward is the detailed curriculum vitae of you,
25 right?

1 A. It looks like it is, yes.

2 Q. If we could stick, actually, on page 12 of
3 Exhibit 1003, your CV, you have -- paragraph 4
4 states your areas of specialization; do you see
5 that?

6 A. Yes.

7 Q. And are those the areas in which you are
8 testifying as an expert here today and in this
9 proceeding?

10 A. Yes. Primarily pharmacodynamics in this 09:08:08
11 proceeding.

12 Q. Pharmacodynamics?

13 A. Uh-huh.

14 Q. Can you explain to me what
15 pharmacodynamics is?

16 A. Pharmacodynamics is what a drug does to a
17 patient. Pharmacokinetics is what a patient does
18 to a drug.

19 Q. Starting with pharmacodynamics, is that a
20 study of the impact -- the physiologic impact of a 09:08:49
21 drug on a patient?

22 A. Well, outcome -- giving a drug to a
23 patient and understanding the outcomes of efficacy,
24 toxicity and the model that you use to evaluate it.
25 But it's not just patients. It's models and

1 animals you could use also in predicting what's
2 going to happen.

3 Q. And pharmacokinetics, you say what a
4 patient does to the drug. Is that then, in other
5 words, how the drug is broken down in the body or
6 what happens to the drug in the body?

7 A. Yes. How it gets in, how it gets out, how
8 the body controls it or tries to control it.

9 Q. Dr. Benet, you are not a clinician, right?

10 A. I am not a -- well, what do you mean by 09:09:35
11 "clinician"?

12 Q. Have you ever treated patients?

13 A. What do you mean by "treated patients"?
14 Do I actually see patients and make drug dosing
15 decisions? No.

16 Q. Have you ever treated a patient with
17 seizures or epilepsy?

18 A. No.

19 Q. In your work have you worked on
20 antiseizure drugs? 09:10:00

21 A. Yes.

22 Q. How many?

23 A. How many drugs?

24 Q. Antiseizure drugs.

25 A. Well, my last paper last year, there were

1 probably 15 drugs in it.

2 Q. Have you, yourself, done research on those
3 antiseizure drugs?

4 A. Well, "do research."

5 I direct research on antiseizure drugs,
6 yes. Do I do research myself? No. I drink
7 coffee.

8 Q. Do you consider yourself an expert in
9 seizures or epilepsy?

10 A. No, I do not. 09:10:39

11 Q. We're going to be discussing the MES
12 model.

13 A. Correct.

14 Q. Have you ever run an MES study?

15 A. No.

16 Q. Have you ever used the MES model?

17 A. "Used" means physically used? What do you
18 mean by "used"?

19 Q. Yes, physically used.

20 A. No. 09:11:01

21 Q. Have you ever seen one run?

22 A. No -- yes, I have. I have seen one run.

23 Q. Have you published on the MES model?

24 A. No.

25 Q. Have you used other antiseizure models

1 other than the MES model in your research?

2 A. For efficacy or for what?

3 Q. For efficacy.

4 A. No.

5 Q. Have you published on any antiseizure
6 models other than the MES model?

7 A. Yes, but not efficacy model.

8 Q. Okay. What type of models?

9 A. Toxicity models.

10 Q. The MES model is an efficacy model, right? 09:12:01

11 A. Yes.

12 Q. Dr. Benet, have you ever worked on CBD?

13 A. Yes.

14 Q. Have you published on CBD?

15 A. Yes.

16 Q. How many publications?

17 A. Five.

18 Q. Can you give me rough years on when those
19 publications came out?

20 A. '80s and '90s. Probably -- yeah, more 09:12:34
21 likely '90s.

22 Q. What were you studying about CBD in those
23 publications?

24 A. How it's eliminated from the body and how
25 it can potentially interact with other drugs.

1 Q. Was any of that work related to the
2 efficacy of CBD on any particular disease or
3 ailment?

4 A. Well, it was related to what potential
5 user toxicity issues that could result from this
6 kind of interaction.

7 Q. Right.

8 So I just want to understand your work
9 with CBD. Other than looking at the potential
10 toxicity issues of CBD, were you studying whether 09:13:21
11 or not it was efficacious against any treatment?

12 A. No.

13 Q. Have you ever run any PK or PD studies on
14 CBD?

15 A. Yes.

16 Q. Have you published those studies?

17 A. Yes.

18 Q. Are you a named author on those papers?

19 A. Yes.

20 Q. You didn't rely on any of those papers for 09:13:57
21 purposes of this declaration, did you?

22 A. No.

23 Q. So let's look at your declaration,
24 Exhibit 1003.

25 This document contains all of the opinions

1 and the bases for those opinions that you provided
2 in this proceeding, fair?

3 A. Yes.

4 Q. Now, you also submitted a declaration in a
5 European proceeding between Inysis and Greenwich,
6 correct?

7 A. Yes.

8 Q. And that declaration is substantially
9 similar to the declaration you submitted here?

10 A. They are similar. 09:14:44

11 Q. How many hours would you say you spent
12 working on those two declarations?

13 MR. MONCO: Together?

14 MS. HUFNAL: Together.

15 THE WITNESS: 23.

16 BY MS. HUFNAL:

17 Q. I'm sorry. Does it say that in here?

18 A. No.

19 Q. Oh, okay. 23 hours?

20 A. Yes. 09:14:58

21 Q. You just pointed to your declaration, so
22 I thought I had missed it in here.

23 A. No. I was just answering your question.

24 Q. And I do believe in here you state that
25 your hourly rate in this matter is \$750 per hour;

1 is that right?

2 A. Yes. For the report, yes.

3 Q. Is it different for the deposition?

4 A. Yes.

5 Q. What is it for the deposition?

6 A. \$1,500 an hour.

7 Q. Did you prepare for the deposition today?

8 A. I did.

9 Q. What did you do to prepare?

10 A. I read my expert report and some of the 09:15:33
11 references, and yesterday I met with the attorneys
12 from Wood Phillips to prepare for today.

13 Q. How long would you say you spent preparing
14 for the deposition?

15 A. Independently, three hours, and with them
16 yesterday, seven hours.

17 Q. Is that preparation for the deposition at
18 the same rate, \$1,500 an hour?

19 A. It is.

20 Q. I'd like to look, if we could, at your 09:16:07
21 declaration, Exhibit 1003, on page 2. At the
22 bottom of page 2, there is a section called
23 "Materials Considered"; do you see that?

24 A. I do.

25 Q. And paragraph 8 states "The list of

1 materials I considered in setting forth the
2 declaration in this matter includes," colon, and it
3 has a list of papers; do you see that?

4 A. I do.

5 Q. Is that the entirety of the list of
6 documents that you considered in forming your
7 opinions in this case?

8 A. No. I read at least 30 or 40 other
9 papers.

10 Q. For -- why didn't you include them in this 09:16:53
11 list?

12 A. Well, because I didn't rely on them.

13 Q. These materials here listed under
14 paragraph 8 are the documents that you relied on in
15 setting forth your opinions in this case, right?

16 A. Right.

17 Q. Okay. And those include -- I am just
18 going to make sure I understand this list here --
19 the '920 patent? Is that one?

20 A. Yes. 09:17:20

21 Q. The Cunha reference?

22 A. Yes.

23 Q. An office action dated August 25, 2015?

24 A. Yes.

25 Q. The WO '109 patent application?

1 A. Yes.

2 Q. A Mechoulam paper?

3 A. Yes.

4 Q. Pertwee book chapter?

5 A. Yes.

6 Q. Malfait?

7 A. Yes.

8 Q. Lindamood paper?

9 A. Yes.

10 Q. Zuardi paper?

09:17:50

11 A. Yes.

12 Q. Consroe and Wolkin paper?

13 A. Yes.

14 Q. Wallace paper?

15 A. Yes.

16 Q. And a Castel-Branco paper?

17 A. Yes.

18 Q. I got the complete list there, right?

19 A. You do.

20 Q. You did not rely on, for purposes of your

09:18:05

21 declaration, a paper authored -- first author Ames,

22 did you?

23 A. Did I rely on it?

24 I didn't reference it, but I'm well aware

25 of it.

1 Q. You didn't rely on it for purposes of your
2 expert opinion in your declaration, correct?

3 A. I didn't reference it.

4 Q. Well, and you understand the purpose of
5 submitting an expert report like this is so that we
6 have fair notice of your opinions and the bases for
7 those opinions? Do you understand that?

8 A. Yes.

9 Q. Okay. So in your declaration you did not
10 cite to and, therefore, rely on the Ames paper, 09:18:40
11 correct?

12 A. I did not cite it.

13 Q. And the same is true for the Bhattacharyya
14 paper?

15 A. Bhattacharyya, right.

16 Q. You did not list that in the materials in
17 your declaration, right?

18 A. I believe I did not.

19 Q. And you did not include, in your list of
20 materials considered in forming your opinions, a 09:19:08
21 declaration of Dr. Marson, correct?

22 A. Correct.

23 Q. If we flip over to just the next page,
24 page 3 of Exhibit 1003, under the "Legal
25 Standards," paragraph 9, you set forth a definition

1 for a person having ordinary skill in the art; do
2 you see that?

3 A. I do.

4 Q. And you set forth your definition of a
5 person of ordinary skill in the art in that
6 paragraph; is that correct?

7 A. Yes.

8 Q. And you state "A person of ordinary skill
9 in the art would typically have an MD, Ph.D. or
10 equivalent in pharmacology, chemistry, 09:19:56
11 biochemistry, neurology or in a related field in
12 the biological or chemical sciences"; do you see
13 that?

14 A. Yes, I do.

15 Q. And you agree with that definition?

16 A. Yes.

17 Q. Now, the Greenwich patent that we're
18 talking about, the '920 patent, do you understand
19 that that is directed to the treatment of partial
20 seizures using CBD generally? 09:20:23

21 A. I mean, it says more than that, yes.

22 Q. Well, for purposes of your person of
23 ordinary skill in the art, your definition doesn't
24 require any knowledge or experience with seizures,
25 correct?

1 A. That's correct. My definition says you
2 are a scientist; you know how to do pharmacology.
3 You know how to read the literature; you know how
4 to make decisions whether studies are valid or
5 invalid.

6 Q. Okay. But your definition of a person of
7 ordinary skill in this art does not require any
8 knowledge of or experience with seizures, correct?

9 A. That's correct.

10 Q. Okay. And your definition of person of 09:20:56
11 ordinary skill in the art, of this art, also
12 doesn't require any knowledge or experience with
13 CBD, correct?

14 A. That's correct.

15 Q. Let's go to paragraph -- the next page,
16 page 4. Section D is titled "Prior Art Suggests
17 Daily Dose of at Least 400 milligrams CBD for
18 Treatment of Partial Seizures"; do you see that?

19 A. Yes.

20 Q. And the first subsection is titled "Higher 09:21:45
21 Doses of CBD were Suggested in the Prior Art,"
22 right?

23 A. Yes.

24 Q. Is this where, in your declaration, you
25 discuss the clinical data or publications involving

1 CBD for treating seizures?

2 MR. MONCO: Objection. Vague.

3 THE WITNESS: Well, I mean, no, because
4 I reference all of these papers that review all of
5 this data, Pertwee and Zuardi. So this doesn't
6 limit it.

7 BY MS. HUFNAL:

8 Q. Sure.

9 So under this section "Higher Doses of CBD
10 Were Successful in the Prior Art," you specifically 09:22:31
11 cite to two papers, Cunha and Zuardi, correct?

12 A. Correct.

13 Q. And both of those papers are reporting on
14 a clinical study, fair?

15 A. I'm not sure Zuardi was a clinical study.
16 I mean, this was a study in humans, but
17 I'm not sure. I don't know how you are using
18 "clinical."

19 Q. Great point.

20 So Zuardi related to safety, not efficacy, 09:23:07
21 correct?

22 A. Correct.

23 Q. So, of those two, the only paper that
24 reports on the clinical efficacy in humans for CBD
25 is Cunha, right?

1 A. Of these two, is that what you're saying?
2 Is that your question?

3 Of the two papers listed here, Cunha is
4 the one paper that talks about clinical study in
5 humans, yes.

6 Q. And you don't cite anywhere else in here a
7 paper that is studying a clinical efficacy study of
8 CBD, do you?

9 A. Well, I cite Pertwee, and he reviews all
10 of it. 09:23:48

11 Q. Okay. But Pertwee -- I certainly want to
12 talk about Pertwee.

13 In terms of papers that are publishing on
14 clinical -- a discrete clinical study of the
15 efficacy of CBD, Cunha is the one you have in your
16 declaration, correct?

17 A. That's correct.

18 Q. And just so I'm clear, Cunha, in the
19 efficacy portion of the Cunha study, the maximum
20 dose used to treat seizures of CBD was 09:24:17
21 300 milligrams, correct?

22 A. Correct.

23 Q. So let's look at Zuardi. I would like to
24 look at Zuardi with you. It's Exhibit 1025. I'll
25 hand you that document.

1 Do you recall reviewing the Zuardi paper,
2 Exhibit 1025?

3 A. I do.

4 Q. Is this one of the documents you reviewed
5 in preparation for your deposition yesterday or
6 leading up to this deposition?

7 A. I actually did not read this paper
8 yesterday.

9 Q. I want to give you the time that you need
10 to review and to answer my questions. That's why I 09:25:28
11 was asking if it happened to be fresh in your mind.

12 A. Okay.

13 Q. Let's turn to page 272 of Zuardi,
14 Exhibit 1025.

15 And do you see a section in the right-hand
16 column, "No. 1. Antiepileptic Action"?

17 A. Yes.

18 Q. And there is a paragraph here in Zuardi
19 that's discussing -- kind of summarizing the
20 antiepileptic action of CBD that was known; is that 09:26:14
21 fair?

22 A. Yes.

23 Q. And you should feel free to read it, if
24 you want. My question is there is a discussion
25 here about a double-blind study, and it summarizes

1 the results, and it's followed by Footnote 38.

2 And so my question is is that discussion
3 in Zuardi that is supported by Footnote 38 the same
4 Cunha study that you cite in your declaration?

5 A. Yes. But he also references Ames. So...

6 Q. That was going to be my next question.

7 So after the discussion of Cunha, the next
8 sentence "In a less successful study, no
9 significant improvement in seizure frequency was
10 observed among 12 epilepsy patients who received 09:27:09
11 200 or 300 milligrams of cannabidiol per day in
12 addition to standard epileptic drugs"; do you see
13 that?

14 A. I do.

15 Q. And the footnote there is to Reference 39,
16 and that's the Ames paper?

17 A. Yes.

18 Q. You did not rely on the Ames paper in your
19 declaration for your opinions, right?

20 A. I did not cite the Ames paper. I mean, 09:27:30
21 Ames said he should try higher doses, but he
22 couldn't.

23 Q. You did not cite the Ames paper in your
24 declaration, did you?

25 A. That's correct.

1 Q. The Zuardi paper that you did cite
2 concludes this section on antiepileptic action
3 stating "Therefore, the clinical efficacy of CBD on
4 epilepsy is still uncertain"; do you see that?

5 A. Yes.

6 Q. Now, you cite to page 274 of the Zuardi
7 paper; is that correct?

8 A. Well, I cite 1500 milligrams.

9 Q. I do not want to be misleading you. So in
10 paragraph 13 of your declaration it says "Zuardi at 09:28:21
11 page 274"?

12 A. Right.

13 Q. I just want to make sure that I understand
14 what you are relying on. Are you then citing to
15 the discussion in the first full paragraph on the
16 left-hand column of 274 in Zuardi?

17 A. Correct.

18 Q. And that is a study in schizophrenic
19 patients; is that right?

20 A. Right. 09:28:43

21 Q. Receiving oral doses of CBD?

22 A. Correct.

23 Q. The studies there that you are relying on
24 were evaluating the efficacy of CBD as an
25 antipsychotic; is that correct?

1 A. Correct.

2 Q. They were not studying the efficacy on
3 epilepsy, right?

4 A. They were not.

5 Q. And they weren't studies that were
6 performed in seizure patients, right?

7 A. They were just looking at safety.

8 Q. I just want to make sure we are on the
9 same page. The studies that you are relying on
10 here in Zuardi were not studies that were done on 09:29:15
11 seizure patients, correct?

12 A. It was a schizophrenic patient.

13 Q. And that's not a seizure patient, correct?

14 A. Right.

15 Q. Okay. So we can go back to your
16 declaration. Something I should have said at the
17 beginning, Dr. Benet, if you need a break at any
18 point, please just let me know.

19 A. Thank you.

20 Q. So let's go back to your declaration, 09:29:42
21 paragraphs 4 and 5.

22 The next section "Higher Doses of CBD
23 Would be Likely to Increase CBD Effects"; do you
24 see that?

25 A. I do.

1 Q. Your opinion in this section of your
2 declaration is based on the assumption that CBD for
3 seizures has a sigmoidal dose response curve; is
4 that fair?

5 A. It's based on that all of the data and the
6 literature says that it is.

7 Q. Right. I just want to understand the
8 underlying assumptions to your opinions in this
9 case.

10 And one of the assumptions that is the 09:30:29
11 basis for your opinions is that CBD has a sigmoidal
12 dose response curve, correct?

13 A. It's not an assumption. It's based on the
14 data and the literature that shows that there is no
15 data that shows that that's not true.

16 Q. So your opinions, though, in this -- and
17 I don't mean to characterize your analysis as an
18 assumption -- but your opinion in this case is
19 based on your understanding that the dose response
20 curve for CBD for seizures is sigmoidal in shape, 09:30:58
21 correct?

22 MR. MONCO: Objection. Asked and answered.

23 THE WITNESS: Correct.

24 BY MS. HUFNAL:

25 Q. As opposed to a bell-shaped curve, right?

1 A. That's correct.

2 Q. Now to reach the conclusion that CBD for
3 seizures has a sigmoidal dose response curve, you
4 rely on, I think, but correct me if I'm wrong, two
5 references, Lindamood and Wallace?

6 A. I cite two references, Lindamood and
7 Wallace.

8 Q. Okay. And that's all I have to go off of.
9 So you cite to two references, Lindamood and
10 Wallace, for your conclusion that CBD for seizures 09:31:41
11 has a sigmoidal dose response curve, correct?

12 A. No. Pertwee does 16 different studies
13 that show a sigmoidal dose response curve.

14 Q. So it's your understanding that there are
15 16 studies in Pertwee that show a sigmoidal dose
16 response curve?

17 A. Right.

18 Q. Did you include that analysis, showing the
19 sigmoidal dose response curve, in your declaration?

20 A. I was giving examples, Lindamood and 09:32:08
21 Wallace, one in mice and one in rats.

22 Q. And, actually, in this section here of
23 your declaration, subheading (b), "Higher Doses of
24 CBD would be Likely to Increase CBD Effects,"
25 paragraph 14 through 23, you don't cite to Pertwee

1 in any of those paragraphs, right?

2 A. Paragraph 23, 20, 22. I don't list
3 Pertwee, but it's fairly obvious. The literature
4 has clearly shown according a skilled person
5 familiar with the literature. The literature isn't
6 Lindamood and Wallace.

7 Q. Okay. So other than Pertwee, Lindamood
8 and Wallace, what other references, in your
9 opinion, even though not included in your
10 declaration, do you think support the conclusion 09:33:05
11 that CBD has a sigmoidal dose response curve for
12 seizures?

13 A. The 16 studies cited by Pertwee.

14 Q. So let me focus on the two that you
15 actually cite in your declaration, Lindamood and
16 Wallace. Those were both studies done in the MES
17 model, correct?

18 A. Correct.

19 Q. Now, you state in paragraph 16 that the
20 "MES model is currently the best available model 09:33:42
21 for identifying and testing anticonvulsant
22 compounds, i.e., drugs that treat seizures"; do you
23 see that?

24 A. Referring to Castel-Branco, quoting him --
25 him -- her.

1 Q. So your support for that conclusion is
2 Castel-Branco?

3 A. Correct.

4 Q. Let's look at Castel-Branco. It's a
5 document previously marked as Exhibit 1028.

6 Is this one of the documents you have
7 recently reviewed?

8 A. I have.

9 By the way, it's -- in my declaration, the
10 "L" in Castel is missing in paragraph 16. 09:34:44

11 Q. Okay. If you look at -- well, first,
12 Castel-Branco is not reporting on partial seizures
13 specifically, is it?

14 A. Well, the paragraph I quote, no.

15 Q. If you go to the first page of
16 Exhibit 1028 under the "MES Test" heading, do you
17 see that?

18 A. Yes.

19 Q. And here it says that "The MES test is
20 probably the best validated preclinical test that 09:36:15
21 predicts drugs effective against generalized
22 seizures"; do you see that?

23 A. I do.

24 Q. Do you agree with that?

25 A. Yes.

1 Q. Castel-Branco in -- well, let me just ask
2 you instead of pointing you directly to sentences.

3 Would you agree that Castel-Branco
4 describes the MES model as useful in early stages
5 of testing?

6 A. Correct.

7 Q. And the MES model is a screening tool for
8 antiseizure drugs?

9 A. Correct.

10 Q. And Castel-Branco does reference partial 09:36:53
11 seizures on page 5 of Exhibit 1028 and states that
12 "The MES model can actually fail to identify drugs
13 that are clinically effective against partial
14 seizures." Do you agree?

15 A. Do you want to give me the page?

16 Oh, 5, I see. 5 and 6.

17 Q. Absolutely.

18 A. I see it.

19 Q. Do you agree that the MES test can fail to
20 identify drugs effective in treating partial 09:37:35
21 seizures?

22 A. I agree with that statement, yes.

23 Q. Okay.

24 A. But there -- actually, you know,
25 pilocarpine doesn't do it either, and penicillin

1 doesn't do it either.

2 Q. Those are other models used to test drugs
3 for antiseizure activity?

4 A. Those are the models in the patent.

5 Q. The MES model -- Castel-Branco goes on to
6 say -- "It does not distinguish between efficacy in
7 the treatment of primarily and secondarily
8 generalized tonic-clonic seizures"; do you see
9 that?

10 A. Yes. 09:38:14

11 Q. Do you agree with that?

12 A. Well, most of the models do not
13 distinguish. In reviewing the literature it's hard
14 to see any model that does a really good job of
15 distinguishing.

16 Q. Distinguishing between partial and
17 generalized seizures?

18 A. Right.

19 Q. So I want to go back to the MES model and
20 your -- another statement you made in the 09:38:38
21 declaration about that, if we could.

22 So if you go back to Exhibit 1003, page 5,
23 specifically paragraph 17, you state in your
24 opinion "MES is the best model for evaluating drugs
25 for partial seizures"?

1 A. Right.

2 So if you had asked me in the beginning do
3 I want to change anything in my declaration,
4 I would have said I wanted to supplement that
5 paragraph for saying "evaluating drug dosage for
6 partial seizure."

7 Q. So is it now your opinion that the MES
8 model is not the best model for evaluating drugs
9 for partial seizures?

10 MR. MONCO: Objection. Mischaracterizes his 09:39:40
11 testimony.

12 BY MS. HUFNAL:

13 Q. I just want to understand the --

14 A. I should have said -- no, I don't say
15 that.

16 I just said what I should have said was
17 that it's the "best model for evaluating drug
18 dosage" because, as I just told you, I don't think
19 any of the models do a good job of separating out
20 the different -- the models do a good job of 09:39:57
21 separating out the different -- partial versus the
22 generalized.

23 Q. So it's your opinion that the MES model is
24 the best model for evaluating drug dosage for
25 partial seizures. Did I get that right?

1 A. Correct.

2 Q. What is your basis for that opinion?

3 A. That all of the studies that are there in
4 the animal models don't show any difference between
5 the various models for the drug doses from the MES
6 model. When a drug is positive in partial
7 seizures, you get the same dose response in the
8 other models that you get for the MES model for the
9 drug dosage.

10 Q. See if I can break that down. 09:40:57

11 You said when a drug is positive in the
12 MES model?

13 A. Yes.

14 Q. Then what?

15 A. The dose that you would get from the MES
16 model is the same as a dose, for example, in the
17 Kindler model, as you would -- potentially could do
18 a better job in getting the partial seizure drugs.

19 Q. So we haven't talked about the Kindler
20 model yet. 09:41:36

21 A. And I never mention it in my expert
22 report.

23 Q. You never mention the Kindler model in your
24 declaration, right?

25 A. Yes.

1 Q. Did you just say that could potentially
2 identify drugs for partial seizures better than the
3 MES model?

4 A. According to Loscher and Bialer, it does
5 because it -- for the Castel-Branco drugs that are
6 listed that MES doesn't say are effective, the
7 Kindle model appears to say they are.

8 Q. So why -- I'm not trying to be obtuse.
9 I want to understand why do you think that the MES
10 model is better -- well, is the best model for 09:42:27
11 evaluating drug dose as opposed to any other model?

12 A. Right. Because it's simple, easy to do,
13 and you can get the dose from it, and it doesn't
14 show any differences in dosage from the other
15 models.

16 Q. So when you say "it doesn't show any
17 difference in dosage from the other models," are
18 you referring to, like, the data in Pertwee, for
19 example?

20 A. The animal study. 09:43:07

21 Q. The animal study.

22 A. Right.

23 But there is not a lot in Pertwee about
24 the Kindle data.

25 Q. Okay. I don't want to get to the Kindle

1 yet. I want to understand the basis for the MES
2 model as best I can.

3 So you went and looked at the dosage
4 amounts reported for the MES models and then
5 compared them to the other dosage amounts in the
6 other studies to conclude that the MES model dosage
7 was consistent?

8 A. Yes.

9 Q. And the reason that you think the MES
10 model was the one to start with or the one to look 09:43:54
11 at is because it's simple and easy to do?

12 A. Yeah, and reproducible.

13 Q. Are there any other reasons other than
14 simple, easy to do and reproducible that you
15 started with the MES model to compare it to the
16 dosage in the other models?

17 A. Well, that's where most of the data in
18 animals is, is in the MES model.

19 Q. Are there any other reasons?

20 A. Those are the ones I can think of now. 09:44:30

21 Q. So let me ask you, you cite to, in
22 paragraph 21 of your report, a sentence in Wallace
23 that says "The MES model is a model of partial
24 seizures with secondary generalization"; do you see
25 that?

1 A. I do.

2 Q. Do you agree with that?

3 A. I'm citing that because a POSA would read
4 that and have no reason to think it was wrong, and
5 so I don't actually know that that's true.

6 Q. You don't know one way or the other if
7 that were true?

8 A. Well, as I said, all of these models show
9 contradictory results depending on what study you
10 look at.

09:45:36

11 Q. Let's go to a document that you have
12 referenced now a few times, the Pertwee paper.
13 It's Exhibit 1022.

14 A. Okay.

15 Q. I'll hand you that document. I think we
16 already established that there were models other
17 than the MES model to test the efficacy of drugs
18 against placebo in 2009, right?

19 A. Yes.

20 Q. And you mentioned that you didn't discuss
21 the Kindle model in your declaration. Other than
22 the MES model, you didn't discuss any other models
23 in your declaration for treating efficacy in
24 seizures, correct?

09:47:06

25 A. Right.

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1 And the reason being that I can't see any
2 differentiation between the pilocarpine and the
3 penicillin in the patent and the MES models.

4 Q. You mentioned those a few times.

5 Have you, yourself, used either of those
6 two models in the '920 patent?

7 A. I haven't used any of the models.

8 Q. By 2009 in the MES model there were
9 reports of CBD not showing any activity against
10 seizures, correct?

09:48:10

11 A. One paper.

12 Q. And that one paper is one of the papers
13 that's listed in Pertwee, correct?

14 A. Reference 125.

15 Q. And Reference 125 is one of the references
16 in Table 6 of Pertwee, correct?

17 A. Yes.

18 Q. In your declaration you didn't engage in
19 any discussion about Table 6 of the Pertwee
20 reference, correct?

09:48:38

21 A. I did not.

22 Q. On Table 6 there are three other
23 references cited under the seizures induced by
24 passing maximal electric shock currents through a
25 corneal electrode model?

1 A. That's correct. But they are also listed
2 as positive models in Table 4.

3 Q. So they are listed under both?

4 A. They are listed under both.

5 Q. So Pertwee is reporting on the same
6 studies as having both no activity --

7 A. No. Different hertz. 6 hertz is the
8 positive. 60 hertz is the negative. But it's the
9 same study.

10 Q. Fair enough. 09:49:43

11 So portions of the same study show no
12 activity and portions show some activity, correct?

13 A. Correct.

14 Q. And in Table 6 there are eight different
15 seizures or behavior models listed?

16 A. Yes.

17 Q. If we look at Table 4 of Pertwee, there
18 are also eight behavior models listed in Table 4,
19 correct?

20 A. Correct. 09:50:32

21 Q. Are they the same behavior models listed
22 on both?

23 A. Not exactly but there is a lot of overlap.

24 Q. So according to Pertwee, in several
25 behavior models there was reported activity of CBD

1 against seizures and reports of inactivity of CBD
2 against seizures?

3 A. Yeah, but the same paper. For example,
4 look at Kindle. Look at Reference 11. It is
5 listed as a positive in Table 4. It's listed as a
6 negative in Table 6. So it's the same study, same
7 paper, list, and this frequently -- if you go and
8 look at the individual references, most of them are
9 listed both places because it depends on what their
10 pharmacodynamic measure is and whether they want to
11 make a decision of whether yes or no. But the same
12 papers will show positive effects for the same
13 model as showing negative effects for the same
14 model depending on what they measure.

09:51:23

15 So, I mean, the reason I don't reference
16 any of these in my expert report is I haven't seen
17 Dr. Whalley's response or rebuttal to me where he
18 says I cherry-picked from these. Of course, I
19 didn't cherry pick. There is 16 positive
20 references for MES and 1 negative reference for
21 MES.

09:51:58

22 Q. I'm not trying to characterize your
23 opinion. I simply want to understand it here
24 today. Okay?

25 And I think we are in agreement that there

1 is both positive and negative results for CBD
2 against seizure as reported in the literature in
3 different models, correct?

4 A. That's correct.

5 Q. Including the MES model, correct?

6 A. Correct.

7 Q. And for purposes of your declaration here,
8 you looked at -- and here we have Lindamood is
9 Reference 63, and I think Wallace is Reference 113.
10 Do you understand that? 09:52:49

11 A. Right.

12 Q. Those are two of the references that are
13 listed under the Behavior Model 1 in Table 4,
14 correct?

15 A. That's correct.

16 Q. And there aren't any other behavior models
17 in Table 4 that you discussed or considered in your
18 declaration, fair?

19 A. No. No. Considered in my declaration.

20 I considered all of these. What I discussed were 09:53:10
21 Lindamood and Wallace. I reference Pertwee, and
22 I say "literature."

23 Q. Sure.

24 And in paragraph 8 of your expert report,
25 it's "The list of materials I considered in forming

1 the opinions set forth in this declaration."

2 A. Which is Pertwee.

3 Q. Correct. But I'm trying to talk about the
4 references -- the studies that are identified as
5 references in Pertwee.

6 A. Correct.

7 Q. So I think you also, to be fair to you --
8 because I'm not trying to trick you -- Consroe is
9 also one of the references in the Pertwee Table 4?

10 A. Correct.

09:53:52

11 Q. So other than Consroe, Lindamood and
12 Wallace, you did not list in your "Materials
13 Considered" any of the other references that are
14 identified in the Pertwee Table 4?

15 A. Correct. I said "literature."

16 Q. And you did not list in your "Materials
17 Considered" for this declaration -- I think it's
18 any of the references in Table 6 of Pertwee, right?

19 A. No. Because the only references are the
20 three that you mentioned that I particularly
21 discuss, yes.

09:54:31

22 Q. And none of those three -- I'm checking
23 myself right now -- but none of those three are
24 listed in Table 6 of Pertwee?

25 A. I'll look.

1 Can you help me with the reference number
2 to Consroe?

3 Q. I absolutely can. I just lost my page.

4 So I believe it's 98, 63 and --

5 A. So Consroe is 98 then?

6 Q. Yes.

7 Let's make this record clear so when we're
8 trying to go back and read it we will all know what
9 we're talking about.

10 In Table 4 of Pertwee, Reference 98 is the 09:55:18
11 Consroe reference that you discuss in your
12 declaration, correct?

13 A. Yes.

14 Q. And Reference 63 is the Lindamood
15 reference you talk about in your declaration?

16 A. Correct.

17 Q. And Reference 113 is the Wallace reference
18 that you talk about in your declaration, correct?

19 A. It is.

20 And I did not specifically mention any of 09:55:43
21 the Table 6 but -- okay. Yeah.

22 MS. HUFNAL: We are almost an hour. Let's take
23 a short ten-minute break.

24 (A short break was taken.)

25 MS. HUFNAL: We have no further questions.

1 MR. MONCO: Okay. We'll take a break.

2 (A short break was taken.)

3 DIRECT EXAMINATION

4 BY MR. MONCO:

5 Q. Dr. Benet, what qualifies you to be an
6 expert with regard to the subject matter of the
7 '920 patent?

8 A. So as it says in my background and
9 information, I'm chair of the pharmacology study
10 section at NIH. I served as editor of journals. 10:34:29
11 I review for journals. Basically, I'm an expert
12 scientist in the area of pharmacology, and
13 I review all kinds of data of which I have no
14 personal experience with.

15 I know how to look at data. I know how to
16 analyze experiments. I know how to test whether
17 something is valid or not valid and whether the
18 interpretation has been correct. And this is what
19 I do every day.

20 Q. As part of the duties that you just 10:34:57
21 identified, in your experience, have you done what
22 is called or referred to as peer review of
23 documents submitted for publication with regard to
24 various drugs?

25 A. Correct. I do that -- I probably review

1 25 papers a year in peer review in terms of papers
2 for the scientific literature.

3 Q. As part of your review, do you attempt to
4 reproduce the experiments that are disclosed in the
5 papers you review?

6 A. No.

7 Q. How do you conduct your review?

8 A. On the basis of good scientific
9 procedures, whether they've been followed; whether
10 there was a valid methodology; whether they've 10:35:41
11 analyzed the data correctly; how they have used the
12 prior literature; and whether they've been biased
13 in terms of their interpretation.

14 That's the kind of information that I use
15 to make my decision in terms of whether a paper is
16 valid and whether the conclusions are valid.

17 Q. Do you recall your testimony with, I think
18 you referenced, correct me if I'm wrong, I think
19 you referenced Examples 5 and 6 of the patent, the
20 '920 patent; do you recall that? 10:36:13

21 A. I do.

22 Q. I'd like to hand to you, Dr. Benet, what
23 has been previously marked as Inysis Exhibit 1001.

24 MS. HUFNAL: Object to testimony on this
25 document. Outside of the scope of the declaration.

1 BY MR. MONCO:

2 Q. Now, again, you reference the '920 patent
3 in your declaration, correct?

4 A. I did.

5 Q. And we saw counsel going through the list
6 of documents you had, and that included the
7 '920 patent, correct?

8 A. It did.

9 Q. Now, do you recall any questions -- do you
10 recall the questions that counsel asked you with 10:37:04
11 regard to bell-shaped curve and sigmoidal curve --
12 not sigmoidal curve but sigmoidal graph?

13 MS. HUFNAL: Objection to form.

14 THE WITNESS: I do.

15 BY MR. MONCO:

16 Q. To your knowledge, Dr. Benet, is there any
17 evidence in the '920 patent, Exhibit 1001, that
18 would support the conclusion that the data shows a
19 bell-shaped curve?

20 MS. HUFNAL: Objection to the form. Outside 10:37:33
21 the scope of the testimony and the declaration.

22 THE WITNESS: No, no data in the patent to
23 suggest that there is a bell-shaped curve for CBD
24 in these analyses.

25

1 BY MR. MONCO:

2 Q. During your review of the '920 patent,
3 what's the nature of the data that is shown in the
4 '920 patent?

5 MS. HUFNAL: Objection. Outside the scope of
6 the examination and the declaration.

7 THE WITNESS: The examination of animal data
8 using the -- well, using a bunch of examples but
9 relying on pilocarpine and penicillin seizure data
10 in Examples 5 and 6. 10:38:12

11 BY MR. MONCO:

12 Q. What type of animals were used in the '920
13 patent?

14 MS. HUFNAL: Same objections. Outside the
15 scope.

16 THE WITNESS: Rats.

17 BY MR. MONCO:

18 Q. And in your list of documents that you
19 identified in your declaration, counsel also
20 referenced the Cunha reference; do you recall that? 10:38:27

21 A. I do.

22 Q. What's the -- what type of data is used in
23 the Cunha reference?

24 A. Human data.

25 Q. Based on your expertise in determining the

1 significance or the importance of the data for
2 ultimate clinical use in humans, what reference
3 would you -- would you rely on references
4 pertaining to human data more than you would with
5 regard to animal data?

6 MS. HUFNAL: Objection to the form. Outside
7 the scope.

8 THE WITNESS: I would. I would.

9 BY MR. MONCO:

10 Q. You would what? 10:39:16

11 A. Give a preference to human data over
12 animal data.

13 Q. Referring to the '920 patent -- and
14 I believe you said you testified that they relied
15 on rat data -- was there anything in the
16 '920 patent that would -- or is there anything in
17 the '920 patent that shows how you would convert
18 the dosage for the rats to dosage for humans?

19 MS. HUFNAL: Objection to form. Outside the
20 scope of the declaration and the examination. 10:40:20

21 THE WITNESS: In lines -- in column 13 at
22 lines 36 through 39, the authors of the patent show
23 how they convert this CBD data in rats to humans
24 and come up with at least 600 milligrams and
25 optionally between 400 milligrams and

1 800 milligrams for CBD.

2 BY MR. MONCO:

3 Q. In your opinion is that a correct
4 calculation?

5 MS. HUFNAL: Object to the form. Outside the
6 scope.

7 THE WITNESS: No, it's not.

8 BY MR. MONCO:

9 Q. Why not?

10 MS. HUFNAL: Outside the scope of the 10:41:16
11 declaration and the examination.

12 THE WITNESS: Apparently, what the patent
13 writers have done is misinterpret the way that you
14 convert animal data to human data, rat data to
15 human data. What they've done is take the number
16 that is used to convert milligrams per kilograms to
17 milligrams per meters squared. That's the
18 number of six in rats.

19 But the appropriate way to calculate animal
20 data to human data, according to the FDA guidance, 10:41:51
21 is you take a rat number of 0.16. You multiply it
22 by the dose and multiply it by the weight.

23 If you take the data of 100 milligrams per
24 kilograms in rats, you would come out with over a
25 thousand as the data that you should have had

1 suggested the data in Examples 4 and 5 show
2 efficacy.

3 They showed -- they carried out studies with
4 1 milligram per kilogram, 10 milligrams per
5 kilogram and 100 milligram per kilogram.

6 They state that it's significant that
7 100 milligrams per kilogram and close to
8 significant or almost significant at 1 milligram
9 and 10 milligrams. 1 and 10 milligrams, with the
10 correct calculation, would come out to be a human 10:42:37
11 dose of 10 milligrams or 100 milligrams in a human,
12 which are doses less than Cunha used.

13 But the 100 milligram per kilogram dose in rats
14 comes out to a value of a thousand. And that's
15 using an average body weight of 65 kilograms, which
16 in the United States is hard to imagine that's an
17 average body weight. So at the low end the
18 calculation that they should have used would have
19 said that the data is a thousand, not 600.

20 BY MR. MONCO: 10:43:10

21 Q. Based on that analysis that you just
22 described, what is your opinion regarding the
23 foundation for the dosage in claim 1 of
24 400 milligrams?

25 MS. HUFNAL: Object to form. Outside the scope

1 of the declaration and the proceedings of the IPR.

2 THE WITNESS: No basis for the 400 milligrams.
3 There is no scientific basis for the 400 milligrams
4 or the statement of preferably between 400 and 800.

5 MR. MONCO: We have no further questions.

6 MS. HUFNAL: Five minutes, please.

7 (A short break was taken.)

8 MS. HUFNAL: Back on the record.

9 We have no questions.

10 (Whereupon the proceedings

11 concluded at 10:52 a.m.)

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DECLARATION UNDER PENALTY OF PERJURY

I declare under penalty of perjury that I have read the entire transcript of my deposition taken in the above-captioned matter or the same has been read to me and the same is true and accurate, save and except for changes and/or corrections, if any, as indicated by me on the DEPOSITION ERRATA SHEET hereof, with the understanding that I offer these changes as if still under oath.

Signed on the _____ day of _____, 20__.

LESLIE BENET, PH.D.

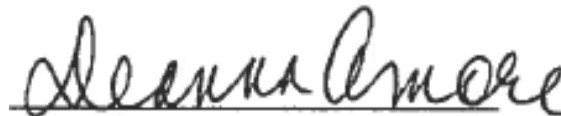
C E R T I F I C A T E

I, DEANNA AMORE, a Shorthand Reporter and notary public, within and for the State of Illinois, County of DuPage, do hereby certify:

That LESLIE BENET, PH.D., the witness whose examination is hereinbefore set forth, was first duly sworn by me and that this transcript of said testimony is a true record of the testimony given by said witness.

I further certify that I am not related to any of the parties to this action by blood or marriage, and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 12th day of October, 2017.



Deanna M. Amore, CSR, RPR

[& - anticonvulsant]

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