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UNITED STATES PATENT AND TRADEMARK OFFICE

X

BEFORE THE PATENT TRIAL AND APPEAL BOARD

X

MARINUS PHARMACEUTICALS, INC.

Petitioner

vs.

OVID THERAPEUTICS, INC.,

Patent Owner.

X

PGR2023-00020

United States Patent No. 11,395,817 B2

Reported remotely by:

Gail L. Inghram Verbano,

Registered Diplomate Reporter,

Certified Realtime Reporter,

Certified Shorthand Reporter-CA (No. 8635)

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Videotaped deposition of
DR. MICHAEL A. ROGAWSKI, held at the Hilton
Sacramento Arden West, 2000 Harvard Street,
Sacramento, California, on Wednesday,
November 15, 2023, beginning at approximately
9:37 a.m., the proceedings being recorded
stenographically by Gail Verbano (present
remotely via Zoom), Registered Diplomate
Reporter, Certified Realtime Reporter, Certified
Shorthand Reporter-CA (No. 8635), and transcribed
under her direction.

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By Attorney McDonnell	8

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1 DEPOSITION SUPPORT INDEX

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3 QUESTIONS INSTRUCTED NOT TO ANSWER:

4 PAGE LINE

5 (None)

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8 REQUEST FOR PRODUCTION OF DOCUMENTS

9 PAGE LINE

10 (None)

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13 STIPULATIONS

14 PAGE LINE

15 (None)

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17 QUESTIONS MARKED

18 PAGE LINE

19 (None)

20

21 REPORTER'S NOTE:

22 ALL PARTIES WERE PRESENT IN THE DEPOSITION ROOM EXCEPT

23 THE COURT REPORTER, WHO WAS PRESENT VIA ZOOM

24 VIDEOCONFERENCING

25

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1 Sacramento, California,
2 Wednesday, November 15, 2023; 9:37 a.m.
3 - - -

4 THE VIDEOGRAPHER: Good morning.
5 We are on the video record at 9:37 a.m. I'm
6 Jennifer Chorzyczewski from Henderson Legal
7 Services. This is a matter pending before the
8 United States Patent and Trademark Office before
9 the Patent Trial and Appeal Board in the case
10 captioned Marinus Pharmaceuticals, Inc. verse
11 Ovid Therapeutics, Inc., Case Number
12 PGR2023-00020.

13 This is the beginning of Media 1
14 of the deposition of Dr. Michael Rogawski on
15 November 15th, 2023.

16 This deposition is being held at
17 2200 Harvard Street in Sacramento, California.

18 Counsel, would you please identify
19 yourself and state who you represent starting
20 with the questioning attorney.

21 ATTORNEY McDONNELL: Ryan McDonnell
22 from Finnegan, Henderson representing the patent
23 owner Ovid Therapeutics, Inc.

24 ATTORNEY KANE: Michael Kane for
25 Fish & Richardson representing Marinus and the

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1 witness Dr. Rogawski; and with me is my

2 colleague, Katie Hyma.

3 THE VIDEOGRAPHER: Thank you.

4 The court reporter today is Gail

5 Verbano. Madam Court Reporter, will you please

6 swear in the witness.

7 - - -

8 DR. MICHAEL A. ROGAWSKI,

9 after being duly sworn or affirmed to testify to
10 the truth, was examined and testified as follows:

11 - - -

12 EXAMINATION

13 BY ATTORNEY McDONNELL:

14 Q. Good morning, Dr. Rogawski. My
15 name is Ryan McDonnell, and I represent the
16 patent owner Ovid in this case. Could you please
17 state your name and address.

18 A. Michael Andrew Rogawski. My
19 address is 3308 White Oak Court, Sacramento,
20 California 95864.

21 Q. I'm going to tell you a little bit
22 how this process will work. So as I said, I
23 represent the --

24 THE REPORTER: I'm sorry. This is
25 the court reporter. Could we go off the record,

1 please.

2 THE VIDEOGRAPHER: This is the end
3 of Media Number 1. Off the record at 9:39 a.m.

4 (Discussion off the record.)

5 THE VIDEOGRAPHER: This marks the
6 beginning of Media Number 2. Back on the record
7 at 9:43 a.m.

8 BY ATTORNEY McDONNELL:

9 Q. So I'm going to tell you a little
10 bit about how this works. I represent Ovid in
11 this case, and I'm going to be asking you
12 questions; and all that I ask is that you answer
13 my questions truthfully and accurately.

14 If you need to take a break, just
15 let me know. But if we're in the middle of a
16 question, I'd ask that you please finish
17 answering the question, and then we can take the
18 break.

19 If for any reason you do not
20 understand a question I ask, please let me know,
21 and I'll try to ask it again. If you answer a
22 question, I will assume that you understood the
23 question I asked.

24 And you also need to answer
25 questions verbally because the court reporter

1 cannot take down head nods or head shakes. Is
2 that okay?

3 **A. Yes.**

4 **Q.** Your attorney may object from time
5 to time but it's still okay to answer my
6 questions unless there's a question as to
7 privilege. And for the record, you cannot
8 consult your attorney regarding the substance of
9 your testimony unless it is regarding a question
10 of privilege.

11 Is there any reason why you cannot
12 testify truthfully and accurately today?

13 **A. No.**

14 **Q.** Have you been deposed before?

15 **A. I have.**

16 **Q.** About how many times?

17 **A. Three times previously.**

18 **Q.** And what -- what kinds of matters
19 were those?

20 **A. One was in relation to an ANDA**
21 **litigation. The second one was in regard to a**
22 **medical insurance case in which I was the**
23 **treating physician. And in the third case, it**
24 **was a commercial litigation matter where I was a**
25 **fact witness but not a participant in the matter.**

1 Q. All right. And in the first ANDA
2 case, were you an expert witness?

3 A. I was an expert witness in that
4 case, yes.

5 Q. Have you ever been deposed in
6 connection with any post-grant review?

7 A. I have not.

8 Q. And in any of the cases that you
9 discussed you testified in, do those involve
10 status epilepticus?

11 A. No, I don't believe so.

12 Q. Okay. And did any of those cases
13 involve ganaxolone?

14 A. No, they did not.

15 Q. And do you understand that the
16 patent owner, Ovid, has noticed your deposition
17 related to a PGR in this matter?

18 A. Could you repeat that question.

19 Q. Yeah. Do you understand that the
20 patent owner, Ovid, in this case has noticed your
21 deposition in relation to a PGR?

22 A. I -- in -- in another deposition
23 are you asking?

24 Q. For this case, this deposition
25 noticed here?

1 **A. When you say "notice," what does**
2 **that mean?**

3 Q. Requested to take your deposition.

4 **A. Oh, well, we're here. I assume**
5 **that they must have.**

6 Q. Sure.

7 Could you tell me when you were
8 first contacted about this case.

9 **A. Could you clarify by whom you mean**
10 **I was contacted?**

11 Q. I guess just first, whoever first
12 contacted you about this case, regardless of
13 whether it was attorneys or someone else.

14 **A. Well, I assume you mean when I was**
15 **contacted by Marinus in regard to the matter.**
16 **And if that's what your question relates to, the**
17 **answer would be that I was contacted by Scott**
18 **Braunstein, the CEO of Marinus, and asked whether**
19 **I could help out with this matter.**

20 Q. Do you know roughly when that first
21 contact was about this matter?

22 **A. I don't recall exactly when that**
23 **was. It was a number of months ago.**

24 Q. What did you do to prepare for your
25 deposition today?

1 **A. I -- I had meetings with my**
2 **attorneys in preparation and reviewed some of the**
3 **documents related to the matter.**

4 Q. And about how long did you meet for
5 to prepare?

6 **A. Total of about eight hours, I would**
7 **imagine, with the attorneys.**

8 Q. Did you meet with anyone from
9 Marinus to prepare for the deposition today?

10 **A. I did not, no.**

11 Q. And earlier you mentioned that you
12 reviewed some documents. Generally what
13 documents did you review?

14 **A. Well, I prepared the declaration a**
15 **number of months ago; and so I glanced over the**
16 **declaration.**

17 **And some of the supporting**
18 **documents as well, I glanced at those.**

19 Q. Did you review any new documents
20 that you had previously not considered in forming
21 the opinions in your declaration?

22 **A. I did not, no.**

23 ATTORNEY KANE: I'm going to hand
24 you a document that's marked Exhibit 1003.

25

1 (Whereupon, previously marked Exhibit

2 Number 1003 was introduced.)

3 BY ATTORNEY KANE:

4 Q. Do you recognize this document?

5 A. **It looks to be my declaration.**

6 Q. Okay. And just, for the record,
7 this is your declaration without the Exhibit A,
8 your CV at the end. If you just confirm that.

9 A. **I'm ruffling through the document,**
10 **and I don't see the CV there.**

11 Q. Okay. If you turn to the last
12 page, is that your signature on page 54? And
13 I'm -- just for the reference, I'm going to use
14 the number at the bottom -- I think there's two
15 numbers -- when I reference a page number.

16 Is that your signature on page 54?

17 A. **It looks to be my signature, yes.**

18 Q. Okay. If I refer to this document
19 as your "declaration" or "Exhibit 1003," will you
20 understand that I'm referring to this document?

21 A. **I will.**

22 Q. And I see that you have another
23 document with you. Is that also your
24 declaration?

25 A. **Yes, this declaration was given to**

1 **me, before we walked into the room, by my**
2 **attorneys.**

3 Q. Okay. And is that -- that's the
4 same as the declaration that I just handed you
5 marked Exhibit 1003?

6 A. **It looks to be. Obviously, I can't**
7 **be sure that they're identical but it looks to be**
8 **about the same.**

9 Q. And are there any markings or
10 highlighting in the version that you have?

11 A. **There are not.**

12 Q. Okay. So sitting here today, are
13 there any changes that you'd like to make to your
14 declaration in connection with this case?

15 A. **No.**

16 Q. And sitting here today, are there
17 any corrections that you would like to make to
18 your declaration?

19 A. **No.**

20 Q. Are you aware of any errors in your
21 declaration?

22 A. **I'm not.**

23 Q. How did you prepare your
24 declaration?

25 A. **A very rudimentary rough draft was**

1 **provided by my attorneys. I extensively rewrote**
2 **the declaration, added substantial additional**
3 **materials, and finalized the document with my**
4 **signature.**

5 Q. All right. And did you work with
6 anyone besides your attorneys in preparing the
7 declaration?

8 A. **I did not.**

9 Q. And did you speak with anyone in
10 connection with forming the opinions in your
11 declaration?

12 A. **I did not.**

13 Q. And about how much time did you
14 spend preparing the declaration?

15 A. **I don't recall exactly how many**
16 **hours, but it was a considerable number of hours.**

17 Q. So, like, more than 20?

18 A. **Again, I can't recall precisely. I**
19 **did keep records of the hours that I spent but I**
20 **didn't -- I didn't review those prior to today's**
21 **meeting.**

22 Q. Okay. Do you have any plans to
23 supplement your declaration?

24 A. **If my attorneys requested**
25 **additional -- an additional declaration or**

1 **additional material, I'm happy to consider it.**

2 **Q. So what materials did you consider**
3 **when preparing your declaration?**

4 **A. I considered materials that were**
5 **provided by the attorneys as well as additional**
6 **material that I developed from the base of**
7 **information that I'm aware of and from research**
8 **using the internet and using standard databases**
9 **at some point.**

10 **Q. Are all of the materials that you**
11 **considered to prepare your declaration cited**
12 **within your declaration?**

13 **A. I'm sure I stumbled upon documents**
14 **that weren't relevant that were not included; so**
15 **I did quite an extensive literature search, and I**
16 **incorporated the ones that I felt were relevant**
17 **to the matter at hand.**

18 **Q. And how did you perform the**
19 **literature search that you mentioned?**

20 **A. Using standard searching tools that**
21 **I use in my everyday work, such as PubMed, Google**
22 **Search, that sort of thing.**

23 **(Whereupon, previously marked Exhibit**
24 **Number 1003A was introduced.)**

25

1 BY ATTORNEY KANE:

2 Q. I'm next going to hand you a
3 document marked what is Exhibit A to your
4 declaration.

5 Do you recognize this document?

6 A. **This looks to be my CV.**

7 Q. Is this your CV that was current as
8 of the date you submitted your declaration? I
9 believe it was March 10th, 2023.

10 A. **I believe it would have been close**
11 **to being current. I would have selected the most**
12 **recent version from my folder on my computer**
13 **where I keep my CV.**

14 Q. And it would have been accurate as
15 of that date as well?

16 A. **It would have been roughly**
17 **accurate, yes.**

18 Q. Are you aware of any additions or
19 corrections that need to be made to your CV from
20 around March 10th, 2023?

21 A. **Well, there are always new**
22 **activities that I'm involved in; so the CV is a**
23 **dynamic document but I add to it as -- as**
24 **activities and publications and so forth become**
25 **available. There may be some publications that**

1 have been published since this version of the CV
2 was submitted, and ordinarily I would update my
3 CV to include those.

4 But this was the version that I had
5 available at the time.

6 Q. Okay. Can you please briefly
7 describe your, like, education and training.

8 A. After graduating college, I
9 attended medical school. And I was in an
10 MD/Ph.D. program, where I conducted research in
11 neuropharmacology; and ultimately was granted
12 both the MD and Ph.D. degrees.

13 Following my education -- my
14 professional training I was -- I participated in
15 clinical training for internal medicine and then
16 neurology; and subsequent to that I was a
17 postdoctoral fellow at the National Institutes of
18 Health.

19 Q. So looking at page 1 of your CV,
20 are you still a professor in the department of
21 neurology at UC Davis?

22 A. I am.

23 Q. And what kind of courses do you
24 teach?

25 A. I -- I teach neurology to medical

1 students. I teach a course in drug discovery to
2 graduate students. I teach in various courses
3 different lectures related to antiseizure
4 medications for the medical student class in --
5 in neuroscience and neurology; and I lecture in
6 other courses in the school of medicine on topics
7 such as pharmacokinetics and pharmacology.

8 Q. What do you consider your area of
9 expertise?

10 A. I'm a neuropharmacologist with
11 special expertise in the evaluation of
12 antiseizure medications and the development of
13 antiseizure medicines both on the basis of animal
14 research in the laboratory as well as clinical
15 research.

16 Q. Have you done research involving
17 treating status epilepticus?

18 A. I have.

19 Q. And are you okay if I refer to
20 status epilepticus as "SE" today?

21 A. Yes, that would be okay.

22 Q. So what kind of research have you
23 done to treat status epilepticus?

24 A. I've conducted research using
25 animal models of status epilepticus; and I've

1 **evaluated the effects of antiseizure agents in**
2 **those models.**

3 Q. In what animal models are you
4 referring to?

5 A. **Typically, we use either rats or**
6 **mice in the laboratory.**

7 Q. Have you done any research on
8 treating SE in humans?

9 A. **I have.**

10 Q. And what was the general kind of
11 nature of that research?

12 A. **We have developed a treatment based**
13 **on animal research in the laboratory, and we had**
14 **an opportunity to collaborate with a group of**
15 **clinicians who were studying status**
16 **epilepticus -- or treating status epilepticus in**
17 **humans. And we provided our treatment to them,**
18 **and that resulted in jointly authored**
19 **publications. I believe there were three --**
20 **about three jointly authored publications that**
21 **resulted from that clinical research.**

22 Q. And what drug compound was that
23 research done with?

24 A. **That was with allopregnanolone.**
25 **(Interruption by the court reporter to**

1 **clarify the record.)**

2 **A. It's allopregnanolone,**
3 **A-L-L-O-P-R-E-G-N-A-N-O-L-O-N-E.**

4 Q. Are there any other compounds that
5 you've done human research related to SE for?

6 **A. Not that I've been involved in as a**
7 **collaborator and author on a publication.**

8 Q. Does that mean that you've done
9 research in humans for treating SE with other
10 compounds otherwise as in -- not related to a
11 collaboration or authoring a publication?

12 **A. Could you clarify what you mean by**
13 **I've "done research."**

14 Q. I mean, conducted research or
15 clinical trials in humans for treating SE that
16 wasn't related to a collaboration and was related
17 to a drug other than allopregnanolone?

18 **A. I think a fair answer to that would**
19 **be to say, no, I have not been an investigator in**
20 **a clinical trial of any other agent.**

21 Q. Was allopregnanolone granted orphan
22 drug status by the FDA for treating SE?

23 **A. I'd have to check the listing on**
24 **the FDA website.**

25 Q. So sitting here today, you're

1 not --

2 **A. I can't remember if the**
3 **allopregnanolone was given orphan drug status.**
4 **It's -- it's -- it's possible that it was. I'm**
5 **not 100 percent sure about that, though.**

6 Q. Did allopregnanolone advance to
7 clinical trials in humans for treating SE?

8 **A. It did.**

9 Q. Did it receive approval for
10 treating SE from the FDA?

11 **A. Not that I'm aware of, no.**

12 Q. Do you know why that was?

13 **A. There was a clinical trial in**
14 **super-refractory status epilepticus where**
15 **allopregnanolone was not found to meet the**
16 **predefined endpoints, and therefore the program**
17 **did not progress.**

18 Q. And were those predefined
19 endpoints, were they efficacy related?

20 **A. Yes. I believe there were efficacy**
21 **endpoints, and of course safety endpoints as**
22 **well.**

23 Q. And you said that allopregnanolone
24 did not meet those primary efficacy endpoints?

25 **A. Not in the -- the most recent**

1 **clinical trial.**

2 Q. And is allopregnanolone a
3 neuroactive steroid?

4 A. **It is.**

5 Q. Is it also an allosteric modulator
6 of the GABAA receptor?

7 A. **It is.**

8 Q. And ganaxolone is also a
9 neuroactive steroid; correct?

10 A. **It is.**

11 Q. And it's also an allosteric
12 modulator of the GABAA receptor?

13 A. **It is.**

14 Q. Have you done research in any other
15 neurosteroids besides ganaxolone and
16 allopregnanolone for treating SE?

17 A. **I have.**

18 Q. Which ones are those?

19 A. **There were a variety of neuroactive**
20 **steroids that we studied in the beginning of our**
21 **research effort in this area many years ago --**
22 **this would be in the 1980s. And I can't recall**
23 **precisely what compounds we studied. Those are**
24 **listed in our publication. But they all had some**
25 **degree of activity in -- in status epilepticus.**

1 Q. And when you say there's "some
2 degree of activity," was that in an animal model?

3 A. **That was in an animal model, yes --**
4 **or several animal models, I should say.**

5 Q. Okay. And did any of those other
6 compounds advance to clinical trials in humans?

7 A. **Not that I'm aware of, no.**

8 Q. So earlier you mentioned that you
9 completed your MD/Ph.D. around 1980 it looks like
10 from your CV.

11 Since you completed those degrees,
12 what experience do you have treating human
13 patients?

14 A. **I completed residency training in**
15 **neurology -- or I mentioned that I completed an**
16 **internal medicine internship, which involves**
17 **treating patients. Subsequent to that I have**
18 **experience -- had experience treating patients as**
19 **a resident.**

20 Following that I was a staff
21 researcher and staff clinician at the National
22 Institutes of Health. I treated some patients
23 with epilepsy there.

24 And currently, in my role as a
25 professor in the department of neurology at the

1 **University of California at Davis, I have**
2 **responsibility caring for patients as well.**

3 Q. Have you treated patients with SE?

4 A. **I treated very few patients with SE**
5 **during my career as a physician and neurologist.**

6 Q. Do you have an estimate about how
7 many patients you have treated with SE throughout
8 your career?

9 A. **I don't know exactly how many. It**
10 **would be a small number.**

11 Q. Less than ten patients?

12 A. **Likely.**

13 Q. Do you have an active practice
14 treating epilepsy patients?

15 A. **I treat some epilepsy patients.**
16 **The majority of my effort is spent in research**
17 **and teaching; but as part of the mix of**
18 **activities that I'm involved in, I do have some**
19 **patient care responsibilities as well.**

20 Q. And do you know about how many
21 years ago you treated -- what was the last time
22 you treated a patient with SE?

23 A. **Well, can you specifically define**
24 **what you mean by "treated"?**

25 Q. As, like, a physician or a

1 clinician.

2 A. Well, there are different ways a
3 physician can participate in the care of a
4 patient with SE.

5 As I mentioned, I was a
6 collaborator in the study of -- or in the use of
7 allopregnanolone in the treatment of a number of
8 adults and children with status epilepticus. I
9 was not the physician in charge of those
10 patients, but I was part of the team that
11 conducted the research on the use of
12 allopregnanolone in those patients; and in that
13 sense you could say I -- I was involved in -- in
14 treating those patients.

15 Q. And what was your role in
16 conducting the research on those patients that
17 were being administered allopregnanolone?

18 A. My role was to a large extent
19 related to working with the team to define the
20 dosing of allopregnanolone for the patients,
21 procuring the allopregnanolone, manufacturing the
22 allopregnanolone solution that was -- that was
23 used.

24 Consulting with the treating
25 physicians on how to administer the medication,

1 how to make changes in the dosing, how to deal
2 with clinical events as they occurred during the
3 treatment process, that sort of thing.

4 Q. Are there any special
5 considerations you take into account when
6 creating a dosing regimen for treating SE as
7 opposed to other epilepsy or seizure disorders?

8 A. Well, treating SE is different than
9 treating epilepsy. SE is not epilepsy; it's an
10 acute seizure state. It's an acute seizure
11 emergency. So the considerations would be
12 entirely different.

13 Q. So how would you go about designing
14 a dosing regimen for treating SE?

15 A. Well, it would really depend on the
16 circumstances, what you were trying to achieve,
17 the type of patients that were involved; many --
18 many factors would go in -- come into play in
19 determining a dosing regimen.

20 Q. Is the dosing regimen important to
21 patients for treating SE?

22 A. Yes.

23 Q. How so?

24 A. Well, you'd need to have an
25 adequate dose in order to provide an improvement

1 **for the patient. If the incorrect dosing regimen**
2 **is chosen, the patient may not obtain an**
3 **improvement.**

4 Q. What do you mean by "improvement"
5 in the patient?

6 A. **The status epilepticus is**
7 **considered a serious, potentially**
8 **life-threatening neurological emergency. The**
9 **objective is to reduce the likelihood that the**
10 **patient will suffer serious consequences, and**
11 **that can take many different forms.**

12 Q. How are SE treatments typically
13 conducted? The dosing -- how is it administered?

14 ATTORNEY KANE: Objection; vague,
15 lack of foundation.

16 THE WITNESS: Most -- in most
17 cases, status epilepticus is treated with
18 intravenous medication.

19 BY ATTORNEY McDONNELL:

20 Q. And why is that?

21 A. **As I mentioned, status epilepticus**
22 **is a serious, life-threatening neurological**
23 **emergency. The objective is to administer**
24 **medication as quickly as possible with the**
25 **objective of providing improvement for the**

1 **patient as quickly as possible.**

2 Q. And that's accomplished through an
3 intravenous administration?

4 A. **Not always, but most commonly.**

5 Q. Is an intravenous administration
6 the fastest way to get the right amount of the
7 drug -- I mean, to control the seizures the
8 quickest?

9 ATTORNEY KANE: Objection;
10 foundation, vague.

11 THE WITNESS: There are multiple
12 ways of administering medications to patients.
13 The speed of onset depends on the mode of
14 delivery of the medicine as well the medicine
15 itself, the properties of the medicine. In the
16 case of the treatment of status epilepticus,
17 intravenous is frequently used; but there are
18 other routes of administration that could be
19 equally effective and are also commonly used in
20 the treatment of status epilepticus.

21 BY ATTORNEY McDONNELL:

22 Q. And what are those other common
23 routes of administration?

24 A. **Probably the most common would be**
25 **intramuscular. It's also possible to give**

1 medications, for example, intrapulmonary; and
2 that also provides very, very rapid delivery of
3 the medication to the target organ; namely, the
4 brain.

5 Q. And when you administer a drug
6 intravenously, there's a rate at which you
7 administer the drug; is that right?

8 A. It really depends on the situation.
9 There are multiple ways of administering
10 medications intravenously.

11 Q. And what are those multiple ways?

12 A. There are bolus injection
13 approaches. There's continuous infusion
14 approaches. There could be a mixture of both --
15 both of those approaches.

16 There could be pulsatile delivery
17 that's frequently used, for example, in induction
18 of anesthesia. It also could be used in the
19 treatment of status epilepticus. So there's a
20 myriad of ways that a drug could be administered
21 by the intravenous route.

22 Q. What is a bolus dose?

23 A. Bolus means that the medication is
24 administered rapidly with a single push on the
25 syringe; rather than setting up an infusion pump

1 **that would administer the medicine over a period**
2 **of time in a constant rate.**

3 Q. In the -- setting up an infusion
4 pump, is that considered continuous intravenous
5 infusion?

6 A. **It might be. But, again, the**
7 **infusion pump could be programmed in various**
8 **different ways.**

9 Q. And when you administer an
10 intravenous infusion, you said that the rate is
11 constant? Is it always -- the rate always
12 constant?

13 A. **Not necessarily, no.**

14 Q. So it can fluctuate depending on
15 the circumstances?

16 A. **It -- it could be administered --**
17 **as I mentioned, again, an intravenous infusion**
18 **could be conducted in many different ways,**
19 **depending upon the objective, depending upon the**
20 **circumstances of the patient, depending on the**
21 **medication.**

22 Q. But is one of those ways the
23 intravenous infusion could be administered is
24 that you would vary the rate of the drug that's
25 being infused?

1 **A. Yes.**

2 Q. Apart from being retained by
3 Marinus for this matter, do you do any other work
4 for Marinus?

5 **A. I do.**

6 Q. And what is that other work?

7 **A. I'm currently a member of the**
8 **scientific advisory board for Marinus.**

9 Q. And how long have you been on
10 Marinus' scientific advisory board?

11 **A. I don't know exactly. It's been**
12 **several years.**

13 Q. And what are your duties as a
14 member of Marinus' scientific advisory board?

15 **A. I participate in occasional**
16 **meetings, these have generally been over Zoom**
17 **recently, where the company provides updates on**
18 **their research and the members of the advisory**
19 **board provide commentary.**

20 Q. And is that scientific substantive
21 commentary?

22 **A. Yes.**

23 Q. Have you done any work for Marinus
24 related to using ganaxolone for treating SE?

25 **A. Well, as a member of the scientific**

1 **advisory board, I participated in the discussions**
2 **where the company presented information about**
3 **their programs and solicited comments from**
4 **members of the scientific advisory board,**
5 **including myself.**

6 Q. Are you compensated at all for your
7 time working on the scientific advisory board at
8 Marinus?

9 A. **I am.**

10 Q. And what is that compensation?

11 A. **I don't know exactly what it is.**

12 **Since I consult for many, many different**
13 **companies, I -- I receive statements at the end**
14 **of the year for many -- many companies; and I**
15 **would have to go back over those and look.**

16 Q. Was it a consulting rate that you
17 set or that Marinus set?

18 A. **I don't recall how that occurred.**
19 **I believe I was sent a consulting arrangement**
20 **agreement.**

21 Q. And do you -- are you compensated
22 by the hour, or is it a salaried position?

23 A. **It's not a salary. It's a -- you**
24 **know, I'd have to check on that.**

25 **And when I -- I -- just to clarify**

1 that, I'm not an employee of Marinus. I'm not an
2 employee of any of the companies that I consult
3 for. I'm only an employee of the University of
4 California at Davis. That's my only employer.
5 But precisely how the agreement is written, I'd
6 have to check on it.

7 Q. And you said that you meet with
8 Marinus on the scientific advisory board through
9 Zoom meetings or other meetings. How often do
10 those occur?

11 A. I would think those would occur
12 maybe quarterly; but that's just a guess. I -- I
13 mean, it really -- it seems like sometimes the
14 meetings are scheduled and then they're canceled
15 for whatever reason; may or may not be
16 rescheduled. So I don't exactly know what the --
17 the schedule that they host them on; but they're
18 relatively infrequent.

19 Q. And do you have any other duties
20 besides attending those meetings as a member of
21 the scientific advisory board?

22 A. I -- I do meet on occasion with the
23 leadership at Marinus to -- they, again, present
24 in a similar fashion information that relates to
25 their programs and solicit my comments.

1 Q. And those meetings with the
2 leadership of Marinus, is that within your
3 capacity as a member of the scientific advisory
4 board?

5 A. Yes.

6 Q. And are there any other times that
7 you consult with Marinus in relation to being on
8 the scientific advisory board?

9 A. Well, not in a formal capacity. I
10 might encounter employees of Marinus at
11 scientific meetings and may have discussions at
12 the meeting.

13 ATTORNEY McDONNELL: I'm going to
14 give you another document. This is marked as
15 Exhibit 1001.

16 (Whereupon, previously marked Exhibit
17 Number 1001 was introduced.)

18 BY ATTORNEY McDONNELL:

19 Q. Do you recognize this document?

20 A. Yes, I do.

21 Q. Is this U.S. Patent
22 Number 11,395,817 that is at issue in this case?

23 A. That's what's indicated on the face
24 sheet of the document you've handed me.

25 Q. And you considered the '817 Patent

1 in drafting your declaration; is that right?

2 A. I did.

3 Q. If I refer to this as "the '817
4 Patent," do you understand that this is the
5 document I'm referring to?

6 A. I do.

7 Q. What is your understanding of the
8 subject matter of the '817 patent?

9 A. Well, it's a patent related to
10 methods and compositions for the treatment of
11 epileptic disorders, as indicated in the title.

12 Q. Does that include SE?

13 A. I believe SE is mentioned in the
14 specification of the patent in the claims.

15 (Interruption by the court reporter to
16 clarify the record.)

17 A. In the claims.

18 Q. Is it your understanding that in
19 your declaration you provide opinions as to the
20 patentability of Claims 1 through 31 of the '817
21 Patent?

22 A. Yes, I believe that's the case.

23 ATTORNEY McDONNELL: Document
24 marked Exhibit 2001.

25

1 (Whereupon, previously marked Exhibit

2 Number 2001 was introduced.)

3 BY ATTORNEY McDONNELL:

4 Q. Do you recognize this document at
5 all?

6 A. I do not.

7 Q. Do you have an understanding that
8 Claims 20 -- 1 through 21 and 23 through 24 of
9 the '817 Patent have been disclaimed?

10 A. My attorneys have informed me that
11 some of the claims have been disclaimed, yes.

12 Q. And what is your understanding of
13 what it means for claims to be disclaimed?

14 A. My understanding is that those
15 claims are no longer inventions that are
16 protected by the patent.

17 Q. And do you understand that the
18 disclaimed claims have no effect on the remaining
19 claims, so Claims 22 and 25 through 31?

20 A. If what you mean by that is that
21 the inventions that are claimed by the claims
22 that have not been disclaimed are -- are still
23 protected by the patent, that would be my
24 understanding.

25 (Interruption by the court reporter to

1 **clarify the record.)**

2 **A. Protected by the patent.**

3 Q. So is it your understanding then
4 that the only claims remaining in the '817 Patent
5 for you to provide an opinion on are Claims 22
6 and 25 through 31?

7 **A. I do.**

8 Q. Did you read the entirety of the
9 '817 Patent before forming your opinions in your
10 declaration?

11 **A. I can't say that I read every word**
12 **of the patent. I focused on what I thought were**
13 **the relevant parts of the patent and of course**
14 **the claims of the patent.**

15 Q. How did you determine what the
16 relevant parts of the patent were?

17 **A. By glancing through the patent and**
18 **attempting to find language that I thought was**
19 **relevant to the task that I was being asked to**
20 **participate in.**

21 Q. Did you read the prosecution
22 history of the '817 Patent in forming your
23 opinions?

24 **A. I don't recall doing that.**

25 Q. Do you have an understanding that

1 the examiner at the Patent Office during
2 prosecution of the '817 Patent ultimately allowed
3 the claims of the patent at issue here?

4 **A. That's my understanding, yes. The**
5 **patent did issue so it's a good assumption that**
6 **the examiner did.**

7 Q. So is it your understanding that
8 the claims of the '817 Patent and the art at the
9 time should be interpreted from the perspective
10 of a person of ordinary skill in the art as of
11 August 11th, 2016?

12 **A. I do.**

13 Q. Okay. So let's look at -- and --
14 I'm sorry. Do your opinions in your report
15 consider any art or references that were
16 published after August 11th, 2016?

17 **A. The relevant references that I**
18 **considered were cited in my declaration, those**
19 **would be the references that form the basis of my**
20 **opinion, the ones that were cited in the**
21 **declaration.**

22 Q. And sitting here today, are you
23 aware of whether any of those were published
24 after August 11th, 2016?

25 **A. Well, in the declaration, I believe**

1 it's clearly laid out what the priority dates for
2 the prior art that is being cited -- what
3 those -- what that -- those priority dates are
4 and their relationship to the priority date of
5 the '817 Patent.

6 Q. And that would be based on the
7 priority date of August 11th, 2016?

8 A. Well, I could check their face
9 sheet of the patent to determine. And on line
10 that's marked 60 here, it says, "Provisional
11 application filed on April 26th, 2017,
12 provisional application filed on August 11th,
13 2016."

14 So I believe that would be the
15 relevant priority date.

16 Q. Sorry. What would be the relevant
17 priority date?

18 A. You had mentioned August 11th,
19 2016, yes, and I see that same date on the face
20 sheet of the patent.

21 Q. So you'd agree that that's the
22 relevant -- August 11th, 2016 --

23 A. I believe so, yes.

24 Q. -- is the relevant priority date?

25 ATTORNEY KANE: So -- two things.

1 Don't talk over him, for the court reporter; and
2 then secondly, I'll intersperse an objection
3 there as it calls for a legal conclusion.

4 BY ATTORNEY McDONNELL:

5 Q. So let's go to the end of the
6 patent and look at Claims 22 and 25 through 31.

7 Would you agree that Claim 21
8 recites:

9 "A method of treating status
10 epilepticus comprising administering to
11 a patient in need thereof a
12 pharmaceutical composition comprising
13 ganaxolone or a pharmaceutically
14 acceptable salt thereof, wherein the
15 pharmaceutical composition is
16 administered intravenously"?

17 A. Could you repeat the claim number
18 that you were referring to.

19 Q. Yes.

20 Actually let me take a step back.
21 Would you agree that each of Claims 22 and 25
22 through 31 depend from Claim 21?

23 A. Yes.

24 Q. And then would you agree that
25 Claim 21 recites:

1 "A method of treating status
2 epilepticus comprising administering to
3 a patient in need thereof a
4 pharmaceutical composition comprising
5 ganaxolone or a pharmaceutically
6 acceptable salt thereof, wherein the
7 pharmaceutical composition is
8 administered intravenously?"

9 **A. That's what I read there as well.**

10 Q. Would you agree that in Claim 21,
11 the amount of the pharmaceutical composition that
12 you are administering is the total amount of the
13 pharmaceutical composition required to treat SE?

14 **A. I can't conclude anything other**
15 **than what the specific language there is.**

16 Q. And what language are you referring
17 to?

18 **A. What's written in the claims, I**
19 **can't go beyond what is indicated in the claims**
20 **specifically.**

21 Q. Would you agree that in Claim 21
22 some amount of ganaxolone is administered to a
23 patient?

24 **A. I think it's fair to say some**
25 **amount, yes.**

1 Q. And what is your understanding of
2 what that amount would be?

3 A. On the basis -- are you referring
4 to on the basis of Claim 21 specifically?

5 Q. Yes, referring to Claim 21
6 specifically, what is your understanding of what
7 the amount of ganaxolone administered to a
8 patient in need thereof would be?

9 A. Well, I don't see any specification
10 of an amount in the words there.

11 Q. Would it be an amount that would be
12 administered to treat SE in a patient in need
13 thereof?

14 ATTORNEY KANE: Objection; vague.

15 THE WITNESS: I can only comment on
16 what's written there. I can't really go beyond
17 the language of the claim.

18 BY ATTORNEY McDONNELL:

19 Q. So you have no opinion beyond the
20 language of the claim of what amount of SE
21 would -- what amount of ganaxolone would be
22 administered in Claim 21?

23 A. I can only comment on what's
24 written in the claim.

25 Q. I think -- sorry. My question is a

1 little bit different.

2 So do you not have an opinion then
3 on what amount of ganaxolone is administered in
4 Claim 21 to a patient in need thereof?

5 **A. I can only say that Claim 21**
6 **relates to a method of treating status**
7 **epilepticus comprising administering to a patient**
8 **in need thereof a pharmaceutical composition**
9 **comprising ganaxolone or a pharmaceutically**
10 **acceptable salt thereof, wherein the**
11 **pharmaceutical composition is administered**
12 **intravenously.**

13 Q. And what is your understanding of
14 the amount of ganaxolone that's administered to a
15 patient in need thereof in Claim 21?

16 **A. I don't have an opinion on that**
17 **topic.**

18 Q. Would you agree that the amount of
19 ganaxolone administered in Claim 21 could be
20 administered as a single dose?

21 **A. Again, I don't have an opinion on**
22 **that.**

23 Q. Could it be administered as
24 multiple doses?

25 **A. Again, I don't have an opinion on**

1 **that.**

2 Q. So look at Claim 22, which we
3 established depends from Claim 21, would you
4 agree that it further requires that the
5 "pharmaceutical composition provides improvement
6 to the patient after administration for more than
7 eight hours"?

8 A. **Yes, I do.**

9 Q. Would you agree that Claim 22
10 requires improvement to the patient for more than
11 eight hours after the total amount required to
12 treat SE is administered?

13 A. **I do not have an opinion on that.**

14 Q. Then if we look at Claims 25
15 through 31, would you agree that these claims
16 provide various ranges of doses of ganaxolone per
17 day?

18 A. **I do.**

19 Q. So we've been going for about an
20 hour. Would you want to take a break, or we can
21 keep going?

22 A. **I'm fine.**

23 Q. Keep going?

24 So let's go back to your
25 declaration, Exhibit 1003. If we could go to

1 paragraph 22, let me know when you get there.

2 **A. Yes, I'm there now.**

3 Q. So in paragraph 22, the last
4 sentence, you state, "In addition SE has
5 electrophysiological correlates detectable on an
6 electroencephalogram, EEG recording."

7 Do you see that?

8 **A. Yes, I do.**

9 Q. So what is the purpose of an EEG
10 recording as it relates to SE?

11 **A. An S -- an EEG recording provides a**
12 **method of monitoring the electrophysiological**
13 **activity occurring in the brain; and it can be**
14 **used to monitor such electrophysiological**
15 **activity during the occurrence of a seizure or a**
16 **status epilepticus.**

17 Q. And is an EEG recording used during
18 treatment of SE at all?

19 **A. It may be, or it may not be.**

20 Q. When it is used, how is it -- is it
21 used during treatment?

22 **A. In some cases, not all cases, it**
23 **may be used to monitor the -- again,**
24 **electrophysiological activity of the brain to**
25 **indicate the occurrence of seizure activity and**

1 **the change in that seizure activity that occurs**
2 **during the course of treatment.**

3 Q. Would a physician use the output of
4 the EEG recording to adjust the dose -- the
5 dosing regimen during treatment of SE?

6 ATTORNEY KANE: Objection; lack of
7 foundation.

8 THE WITNESS: It really depends on
9 the situation that relates specifically to the
10 patient, whether it's a rat patient or a human
11 patient or any other kind of patient that would
12 be treated, the circumstance, the situation.

13 BY ATTORNEY McDONNELL:

14 Q. In a human patient could a
15 physician use the output of an EEG recording to
16 adjust the dosing regimen that was administered?

17 ATTORNEY KANE: Objection; lack of
18 foundation.

19 THE WITNESS: Again, the -- excuse
20 me.

21 The EEG could be used in many
22 different ways in -- in the treatment of status
23 epilepticus, or it may not be used at all.

24 BY ATTORNEY McDONNELL:

25 Q. Is adjusting the dosing regimen

1 administered one of those many ways it could be
2 used?

3 **A. I suppose it's possible.**

4 Q. So if you look next to paragraph,
5 it's 25, it's just on the next page. And in this
6 paragraph you discuss, "Researchers often use
7 animal models to identify treatments that may be
8 effective in terminating SE in humans."

9 Is that right?

10 **A. Yes, I see that there.**

11 Q. Do animals naturally develop SE?

12 **A. They may.**

13 Q. And does that include like a rat
14 could naturally develop SE?

15 **A. Yes.**

16 Q. But typically, when you use animal
17 model for SE treatment, do you always chemically
18 induce the animal with SE?

19 **A. No.**

20 Q. So then there's examples of animal
21 models where SE is not chemically induced?

22 **A. Yes.**

23 Q. And the SE animal models that
24 you're aware of, are they only able to predict
25 whether a particular compound may be effective in

1 treating SE in humans?

2 **A. Perhaps you could clarify that**
3 **question for me.**

4 Q. Sure.

5 So an animal model that evaluates
6 the effectiveness of a compound in treating SE,
7 can that only be used to predict whether that
8 particular compound will be effective in treating
9 SE in a human?

10 **A. When you say "only," what does --**
11 **do you mean by "only"?**

12 Q. It doesn't definitively tell you
13 whether that compound would be effective to treat
14 SE in humans.

15 **A. I'm understanding your question to**
16 **mean, is there always a one-to-one correspondence**
17 **between an effect in an animal model and a human;**
18 **is that the question?**

19 Q. Yeah.

20 **A. And the answer to that question is,**
21 **no, not always a one-to-one correspondence.**

22 Q. So considering the rat pilocarpine
23 model -- are you familiar with that animal model?

24 **A. I am.**

25 Q. Can you just kind of walk me

1 through how that model is conducted.

2 **A. The animal, could be a rat, perhaps**
3 **a mouse, is initially possibly treated with**
4 **lithium and then -- or not; and then subsequently**
5 **treated with pilocarpine at an appropriate dose**
6 **to induce the occurrence of the status**
7 **epilepticus. And then at an interval after the**
8 **onset of the status epilepticus, a test agent is**
9 **administered, and the animal is monitored for an**
10 **effect of the test agent.**

11 Q. In paragraph 28 of your report --
12 actually, let me ask a different question first.

13 You mentioned that lithium is
14 administered. What is the purpose of
15 administering lithium in this model?

16 **A. The lithium may produce a more**
17 **reproducible occurrence of status epilepticus in**
18 **the animal.**

19 Q. If we go to paragraph 28, in about
20 the middle of the paragraph, you state that,
21 "Rats may be pretreated with a peripherally
22 acting muscarinic cholinergic antagonist such as
23 scopolamine methylnitrate to limit any peripheral
24 effects of pilocarpine."

25 What peripheral effects of

1 pilocarpine are you referring to?

2 **A. Well, that may be salivation, the**
3 **production of secretions in the airway that might**
4 **compromise breathing, that's typically why it's**
5 **done. It's not necessarily always done.**

6 **Q. Okay. And does the study protocol**
7 **typically reference administering one of these**
8 **peripherally acting muscarinic cholinergic**
9 **antagonists if it's, in fact, administered during**
10 **the study?**

11 **A. It -- it may. I'd have to know**
12 **specifically where you were referring to to know**
13 **if it was mentioned or not and whether -- it's**
14 **always possible that an experiment may not choose**
15 **to include certain details that are not**
16 **considered to be relevant.**

17 **Q. So in testing a substance or a**
18 **compound in the rat pilocarpine model, you'd**
19 **agree that you'd give the rat a specific dose or**
20 **amount of that compound; is that right?**

21 **A. Of the test article?**

22 **Q. Yeah.**

23 **A. Yes, you would -- you would choose**
24 **a dose of the test article.**

25 **Q. How is that dose typically**

1 determined of the test article?

2 **A. There are many different ways to**
3 **determine that.**

4 Q. And what are those ways?

5 **A. It could be based on reference to**
6 **other information that's known about the activity**
7 **of the drug. It could be related to**
8 **pharmacokinetic information that was developed in**
9 **other experiments. It could be just a random**
10 **choice that the experimenter felt would be**
11 **potentially effective, or there might not be any**
12 **rationale at all. They might just select a dose**
13 **and hope for the best.**

14 Q. You mentioned reference info or
15 information about the test article. What types
16 of reference information could that include?

17 **A. There could be information in the**
18 **literature about the test article that an**
19 **experimentalist might refer to in choosing the**
20 **dose, such as activity in other animal models or**
21 **pharmacokinetic information; a wide variety of**
22 **data that could be available that might provide**
23 **some guidance.**

24 Q. Do you typically take into
25 consideration the toxicity of the compound that's

1 administered?

2 **A. Again, if information was known**
3 **about that, that could be taken into**
4 **consideration as well.**

5 **Q. Would you take into consideration**
6 **the amount of a lethal dose to the test -- the**
7 **rat in this case?**

8 **A. It's possible that that could be**
9 **relevant information. But, again, it really**
10 **depends on the specific circumstance. Some**
11 **substances may not have a lethal dose. It might**
12 **be very safe, and very -- very large doses could**
13 **be tolerated. In other cases a compound could be**
14 **very, very toxic. So it really depends on the**
15 **situation.**

16 **Q. For ganaxolone specifically, are**
17 **you aware of what the toxic dose to a rat would**
18 **be?**

19 **A. And could you define what you mean**
20 **by "toxic"?**

21 **Q. I guess toxic in this case would be**
22 **an amount that would provide an effect that's not**
23 **intended in the rat?**

24 **A. And what kind of non-intended**
25 **effect are you referring to?**

1 Q. I guess what is your understanding
2 of a toxic dose?

3 A. Well, toxic could mean so many
4 different things.

5 Q. Such as?

6 A. Could be kill the animal. It could
7 have -- cause neurological impairment, cause
8 brain damage, could cause neuromuscular damage,
9 could cause liver damage. There just is a myriad
10 of meanings of the word "toxic."

11 Q. Are you aware of what the lethal
12 dose of ganaxolone in a rat would be?

13 A. I'm not.

14 Q. Are you aware of what an amount --
15 a toxic dose that would cause neurologic
16 impairment to a rat is of ganaxolone?

17 A. I could probably guess at a dose
18 that might cause neurologic impairment.

19 Q. What would that guess be?

20 A. Probably something less than --
21 well, you'd have to really specify more precisely
22 what kind of neurological impairment you were
23 referring to before I'd want to opine on that and
24 speculate. I could look up in the literature
25 information about that, but it would have to

1 specifically relate to what kind of neurological
2 impairment you were referring to.

3 And the reason I think it's
4 important for you to do that is because
5 neurological impairment may not necessarily
6 impact the treatment of status epilepticus. It's
7 perfectly okay to have a little bit of
8 neurologic -- or even a lot of neurological
9 impairment in the treatment of status
10 epilepticus. It's a very serious, potentially
11 life-threatening problem, and having some degree
12 of neurological impairment is almost expected.

13 Q. What kinds of neurological
14 impairment would impact the treatment of SE?

15 A. Death would.

16 Q. Any others?

17 A. An irreversible neurological
18 impairment could potentially -- if there was
19 irreversible brain damage, for example, that was
20 produced by the treatment agent.

21 Q. How about like ataxia?

22 A. That probably wouldn't be an issue.

23 Q. Would or would not?

24 A. That would probably not be an
25 issue.

1 Q. So earlier you said that you could
2 probably guess what a toxic dose would be for
3 neurological impairment; then said it would
4 depend on the type of neurological impairment.

5 For what kinds of neurological
6 impairment could you provide the toxic dose or an
7 estimate of the toxic dose for ganaxolone in a
8 rat?

9 A. Well, again, I could look up in the
10 literature -- if you specifically defined what
11 you meant by "a toxic dose," I could probably
12 look that up in the -- in the literature and give
13 you an estimate based on what your definition is.
14 If you had a definition where those experiments
15 hadn't been done, then of course we couldn't give
16 you that information.

17 Q. So if you go to paragraph 32, in
18 this paragraph you're talking about the rat
19 pilocarpine model. And you mention that you
20 monitor the behavior of the animal and the EEG
21 power in various frequency bands. Do you see
22 that?

23 A. I do.

24 Q. Are these the only two outputs that
25 are measured when looking at the efficacy of a

1 particular drug in the rat pilocarpine model?

2 A. Not necessarily, no.

3 Q. What are other outputs that you
4 would consider that relate to the efficacy of the
5 compound in treating SE?

6 A. Well, there are many different ways
7 of monitoring seizure activity. And there are
8 many different ways of analyzing the EEG. These
9 are approaches that are used in some instances
10 but in other instances different ways to score
11 the behavior or ways of evaluating the EEG are
12 used.

13 Q. And what are those other ways?

14 A. Well, I can't elaborate all of them
15 because there are thousands of papers that have
16 studied the lithium pilocarpine model, and each
17 experimenter may use a different approach.

18 Q. And what are those different
19 approaches? Why would a researcher or
20 experimenter choose one approach over the other?

21 ATTORNEY KANE: Objection; lack of
22 foundation.

23 THE WITNESS: Yeah, it's hard for
24 me to answer that question other than to say that
25 different experimenters may believe that their

1 approach is -- is more useful for what they're
2 attempting to study. The model is used in so
3 many different -- in so many different contexts
4 for addressing a wide variety of scientific
5 questions and for testing a wide variety of
6 different agents. So different endpoints will be
7 defined by the experimenter to accomplish their
8 specific scientific objectives.

9 BY ATTORNEY McDONNELL:

10 Q. So towards the end of paragraph 32,
11 still on the page we were just on, you stated
12 that, "The rat pilocarpine model demonstrates
13 efficacy in treating the SE condition if there's
14 a statistically significant reduction of the EEG
15 power in the frequently bands in relation to the
16 vehicle, or alternatively the test substance
17 protects, prevents, halts, or blocks convulsive
18 behavioral seizures."

19 Is that right?

20 A. That's what's stated there, yes.

21 Q. Are there other results or effects
22 in the rat pilocarpine model that indicate that a
23 test substance is effective in treating the SE
24 condition?

25 A. There -- there could be, yes.

1 Q. And what would those include?

2 A. Well, again, there are so many
3 different endpoints that it's not really possible
4 to elaborate all of them. The endpoints that are
5 mentioned here are commonly used and generally
6 accepted as being translational and relevant.

7 Q. Are these the only endpoints that
8 are considered acceptable criteria or
9 translationally relevant?

10 ATTORNEY KANE: Objection; vague --

11 THE WITNESS: Again, I think it
12 would be helpful if you defined what endpoints
13 you had in mind; then perhaps I could give an
14 opinion about that.

15 BY ATTORNEY McDONNELL:

16 Q. So you said, "The endpoints that
17 are mentioned here are commonly used and
18 generally accepted as being translationally
19 relevant."

20 Which endpoints were you referring
21 to when you said that?

22 A. The ones that are specified here.

23 So:

24 "If the test substance causes
25 a statistically significant reduction in

1 EEG power in the frequency bands in
2 relation to vehicle, this indicates that
3 the test substance at the dose
4 administered is effective in treating
5 the status epilepticus condition. Or
6 alternatively, if the test substance
7 protects, prevents, halts, or blocks
8 convulsive behavioral seizures, it is
9 effective in treating the SE
10 conditions."

11 So those are generally accepted.

12 Q. And are there other generally
13 accepted endpoints with respect to the rat
14 pilocarpine model for treating SE?

15 A. Again, I think it would be helpful
16 if you gave me some specific examples, I can
17 provide some opinions about that.

18 As I indicated previously, there
19 are many endpoints that experimenters used in
20 conjunction with the lithium pilocarpine model,
21 too many to enumerate here.

22 Q. So in paragraph 33 you mention that
23 you've been involved in studies that have used
24 the rat pilocarpine model to evaluate potential
25 treatments for SE; is that right?

1 **A. Yes, that's what it states.**

2 **Q. And what potential treatments have**
3 **you been involved in that were evaluated using**
4 **the rat pilocarpine model?**

5 **A. I'd have to go back to my**
6 **publications and review that; and I'm happy to do**
7 **that, but I don't have that in front of me right**
8 **now.**

9 **Q. Okay. Were any of these potential**
10 **treatments unsuccessful in treating SE in the rat**
11 **pilocarpine model?**

12 **A. I can't recall specifically.**

13 **Q. You can't recall whether any of**
14 **them were unsuccessful?**

15 **A. I can't recall.**

16 **Q. What about, can you recall whether**
17 **there are potential treatments that were found to**
18 **demonstrate a success in the rat pilocarpine**
19 **model?**

20 **A. I think what I can say is that the**
21 **rat pilocarpine model is used for many purposes.**
22 **It's -- it's used for generating spontaneous**
23 **recurrent seizures for studies of epilepsy.**
24 **It's -- it's -- it's used to study the**
25 **neuropathology of epilepsy and the histological**

1 changes that occur.

2 And it's also used as a
3 translationally relevant model to study
4 medications that are used in the treatment of
5 status epilepticus. And during my very long
6 career as a researcher, we've used it in various
7 ways, and that's the reason why it's not really
8 possible for me to give you the specific answers
9 that you are looking for.

10 Q. What about with respect to SE in
11 particular, though? Can you recall if there were
12 potential treatments that were successful in the
13 rat pilocarpine model for treating SE?

14 A. I can't recall the specifics, no.

15 Q. And then in paragraph 33 you then
16 say that, "It is well-recognized in the art as
17 satisfying the accepted criteria for a model that
18 predicts if a therapy could be useful in the
19 treatment of SE in humans."

20 What are you referring to when you
21 say "accepted criteria" there?

22 A. Accepted criteria means that the
23 model is useful in predicting whether the
24 treatment could be useful in treating status
25 epilepticus in humans.

1 Q. Right. And my question is, what is
2 the accepted criteria? What is the criteria that
3 you're referring to?

4 A. Well, there are many criteria that
5 are considered to be used to define whether an
6 animal model is potentially useful for this
7 purpose.

8 For example, phase validity would
9 be one: Does the animal exhibit the behavioral
10 activity that occurs in the human with status
11 epilepticus?

12 Another criteria would be if the
13 histopathologic changes that occur in the brain
14 during the model are similar to those that occur
15 in a patient.

16 A third criteria might be that the
17 electrographic phenomena that occur in the model
18 are similar to those that occur in a patient.

19 And in the case of the lithium
20 pilocarpine model, all of those criteria are met.
21 The model has phase validity, it demonstrates
22 histopathologic changes that are similar to what
23 are seen in humans, their EEG correlates that are
24 similar.

25 Q. Are there any other accepted

1 criteria as you used the word in paragraph 33
2 that the rat lithium pilocarpine model satisfies?

3 **A. There -- there might be. Those are**
4 **ones that come to mind.**

5 Q. So sitting here today, you aren't
6 aware of any other accepted criteria that the rat
7 lithium pilocarpine model satisfies?

8 **A. Well, as I said, there might be.**
9 **But those are the ones that come to mind at the**
10 **moment.**

11 Q. Right. But sitting here today, you
12 can't articulate what those other accepted
13 criteria might be?

14 **A. As I said, no, none come to mind.**
15 **But there might be others.**

16 ATTORNEY KANE: It's been about an
17 hour and a half. Can we take a break?

18 ATTORNEY McDONNELL: Yeah, it's a
19 good time to take a ten-minute break.

20 THE VIDEOGRAPHER: This is the end
21 of Media Number 3. Off the record at 11:03 a.m.

22 - - -

23 (Whereupon, a short recess was taken.)

24 - - -

25 THE VIDEOGRAPHER: This marks the

1 beginning of Media Number 3. Back on the record
2 at 11:22 a.m.

3 BY ATTORNEY McDONNELL:

4 Q. So in paragraph 37 of your
5 declaration, I'll let you get there -- you
6 mentioned that by 2016 Marinus had done
7 substantial research using the rat lithium
8 pilocarpine model to assess the efficacy of
9 IV-administered ganaxolone for SE in humans.

10 Do you see that?

11 A. I do.

12 Q. And you're not saying here that
13 Marinus had actually tested ganaxolone for
14 treating SE in humans; correct?

15 A. Well, as indicated, Marinus had
16 done substantial research using the rat lithium
17 pilocarpine model, yes.

18 Q. So, I'm sorry, so the answer to my
19 question is yes?

20 A. Yes, they have done research on
21 the -- using the rat lithium pilocarpine model.

22 Q. But Marinus had not actually tested
23 the use of ganaxolone in its efficacy for
24 treating SE in humans?

25 A. I -- I can't say. I didn't work at

1 the company at the time. I was not privy to
2 everything that they had done; so I can't really
3 say what they had done at that point.

4 Q. So what is this statement then
5 based on? Like the --

6 A. Well, this would be based on many
7 publicly available documents, including Zhang
8 Exhibit 1009, as cited.

9 Q. So then you're not aware that
10 Marinus had done research testing the efficacy of
11 ganaxolone to treat SE in humans?

12 A. I can't really comment on what
13 Marinus had done.

14 Q. Okay. Other than what was publicly
15 available?

16 A. Well, I can comment on what I had
17 available to me to review, yes.

18 Q. And none of the documents that you
19 had reviewed that were publicly available showed
20 that Marinus had done substantial research on the
21 efficacy of administering ganaxolone to treat SE
22 in humans?

23 A. There -- there were documents that
24 had indicated Marinus had done research with
25 ganaxolone in humans that I believe I cite in the

1 expert -- expert report elsewhere.

2 Q. Was that related to treating SE in
3 humans?

4 A. I don't recall that it was
5 specifically; but, again, I can't really comment
6 on what Marinus might or might not have been
7 doing.

8 Q. Right. I'm still just talking
9 about what was publicly available.

10 A. Publicly available, yeah. I -- I
11 don't recall a publicly available document that I
12 reviewed that -- where Marinus had stated that
13 they had administered ganaxolone to humans with
14 status epilepticus. I don't recall such a --
15 such a document.

16 Q. Right. So would it be fair to say
17 that based on the publicly available documents
18 you reviewed, that Marinus had used the rat
19 lithium pilocarpine model to identify the use of
20 ganaxolone as a potential treatment for SE in
21 humans?

22 ATTORNEY KANE: Objection; lack of
23 foundation.

24 THE WITNESS: Well, again, as
25 stated in my expert report, Marinus had done

1 substantial research using -- excuse me -- the
2 rat lithium pilocarpine model to assess the
3 efficacy of IV-administered ganaxolone for the
4 treatment of status epilepticus in humans.

5 BY ATTORNEY McDONNELL:

6 Q. And the rat lithium pilocarpine
7 model would identify ganaxolone as a potential
8 treatment?

9 A. The rat lithium pilocarpine model
10 was, in my opinion, well accepted in the field as
11 a model to predict efficacy of a test article in
12 the treatment of status epilepticus in humans.

13 Q. Okay. And I think earlier you
14 testified that it's not a one-to-one correlation
15 between whether it is efficacious in the rat
16 pilocarpine model versus in humans; is that
17 right?

18 A. That is correct, yes.

19 Q. And you mention in paragraph 37 a
20 published patent application of Marinus' that you
21 refer to as Zhang; is that right? Exhibit 1009.

22 A. Yes.

23 ATTORNEY KANE: I hand you this
24 document marked Exhibit 1009.

25

1 (Whereupon, previously marked Exhibit
2 Number 1009 was introduced.)

3 BY ATTORNEY KANE:

4 Q. This is a published patent
5 application number WO 2016/127170 A1, and it is
6 entitled "Intravenous Ganaxolone Formulations and
7 Their Use in Treating Status Epilepticus and
8 Other Seizure Disorders."

9 And then do you see there it says
10 the first listed inventor has the last name of
11 Zhang?

12 A. I do.

13 Q. And do you recognize this document?

14 A. This appears to be the Zhang
15 reference cited in my expert report.

16 Q. And did you review this document to
17 prepare for your deposition today?

18 A. I did.

19 Q. If you could turn to paragraph 74.
20 Let me know when you are there.

21 A. I'm there now.

22 Q. Do you agree that paragraph 74 of
23 Zhang describes various doses of a substitute
24 beta-cyclodextrin-ganaxolone injectable
25 formulation that can be administered?

1 **A. I do.**

2 **Q. And paragraph 74 doesn't mention**
3 **using these beta-cyclodextrin-ganaxolone**
4 **injectable formulations for treating SE**
5 **specifically, does it?**

6 **A. Well, if I read the words in**
7 **paragraph 74 -- I'm just scanning down -- I don't**
8 **see the words "status epilepticus" there.**

9 **Q. Does paragraph 74 mention anything**
10 **about the efficacy of these**
11 **beta-cyclodextrin-ganaxolone injectable**
12 **formulations for treating SE?**

13 **A. Well, it does mention a method of**
14 **treatment of a patient suffering from seizures;**
15 **and since status epilepticus is a type of**
16 **seizure, it would be encompassed by this**
17 **statement.**

18 **Q. How many different disorders could**
19 **be encompassed by the statement "seizures,**
20 **traumatic brain injury, or stroke" in this**
21 **paragraph?**

22 **A. Well, I count three; seizures,**
23 **traumatic brain injury, and stroke being three.**

24 **Q. And SE isn't listed among those**
25 **three?**

1 **A. Well, SE is a subtype of seizures.**

2 Q. And are you aware of how many
3 subtypes of seizures there are?

4 **A. There are various types of**
5 **seizures, yes.**

6 Q. Are you aware of, like, an estimate
7 of how many subtypes could fall within seizures?

8 **A. I don't have an estimate of the**
9 **number, no. But -- but I will say that status**
10 **epilepticus is most definitely a type of seizure.**

11 Q. But it's not -- status epilepticus
12 isn't specifically mentioned in this paragraph,
13 though?

14 **A. I don't think it would need to be,**
15 **no.**

16 Q. And this paragraph does not
17 specifically mention the efficacy of using the
18 substituted beta-cyclodextrin-ganaxolone
19 injectable formulation and its efficacy in
20 treating SE?

21 **A. Well, again, my reading is that**
22 **this is a method of treatment for a patient**
23 **suffering from seizures; so that, as I pointed**
24 **out, would include status epilepticus.**

25 Q. But, again, it doesn't specifically

1 mention any efficacy in treating SE specifically?

2 ATTORNEY KANE: Objection; vague,
3 lack of foundation.

4 THE WITNESS: Well, you are correct
5 that the words "status epilepticus" are not
6 contained within the paragraph.

7 BY ATTORNEY McDONNELL:

8 Q. Does paragraph 74 say anything
9 about how long after an injection is administered
10 that there's improvement in SE?

11 A. Well, there is information in this
12 paragraph that relates to the dosing schedule.

13 Q. Is there any information about for
14 how long after any one of these doses is
15 administered that there's improvement in SE?

16 A. Well, it's indicated that it could
17 be given at various intervals; 1, 2 hours,
18 4 hours, 6 hours, 8 hours, 12 hours, or 24 hours.
19 So the implication is that there could be
20 improvement for all of those time periods,
21 including multiples of those time periods, since
22 it indicates that it could be administered
23 multiple times; so you could -- you could use any
24 of those dosing intervals and then multiply them.

25 Q. But it doesn't say anything about

1 for how long after you actually do the dosing
2 that there's improvement in SE?

3 ATTORNEY KANE: Objection; vague.

4 THE WITNESS: Well, again, I would
5 stand by the testimony that I just made, that the
6 dosing could be at any of these intervals and
7 multiples thereof to provide treatment for a
8 range of durations.

9 BY ATTORNEY McDONNELL:

10 Q. Sorry, what do you mean by "a range
11 of durations"?

12 A. A range of durations specified by
13 the -- by the dosing interval plus use of the
14 injectable formulation multiple times at any of
15 those intervals.

16 Q. I still don't think I know what you
17 mean. Does it say anywhere, though, for how long
18 after you give a dose at any of these intervals
19 that the dose that you provided or administered
20 provides improvement in SE?

21 A. Well, it says, "Method of treatment
22 of a patient suffering from seizures," which as I
23 specified would include status epilepticus. And
24 the -- it specifies that the treatment may be
25 administered intravenously at various doses at

1 intervals that are specified; there are 1, 2, 4,
2 6, 8, 12, and 24 hours. So that indicates the
3 duration given the dosing interval.

4 Q. Indicates the duration of what?

5 A. Between doses.

6 Q. If we go to paragraph 85. Does
7 paragraph 85 refer to treating any disease or
8 disorder?

9 A. Well, if I scan down paragraph 85
10 specifically, I don't see any disorder mentioned.

11 Q. You would agree that there's no
12 method of treating mentioned in paragraph 85?

13 A. I would agree that the words
14 "method of treatment" are not contained within
15 that paragraph.

16 Q. If you go four lines up from the
17 bottom of paragraph 85, do you see where it says,
18 "In certain embodiment, each bolus dose is
19 comprised of about 1 milligram per kilogram to
20 about 20 milligrams per kilogram ganaxolone"?

21 A. I do.

22 Q. And this sentence doesn't mention
23 that the bolus dose is being used to treat any
24 disease; is that correct?

25 A. Well, you're correct. I don't see

1 **the words relating to a specific disease in that**
2 **sentence.**

3 Q. Okay. So let's turn to Example 8,
4 which is -- begins at paragraph 117, which is
5 page 21. Let me know when you're there.

6 A. **Yes, I'm there now.**

7 Q. You would agree that Example 8 of
8 Zhang considers the effect of ganaxolone on the
9 rat lithium pilocarpine model; is that right?

10 A. **Well, the title there above**
11 **paragraph 117 mentions that. And also it's part**
12 **of the paragraph as well. It says inhibit**
13 **pilocarpine-induced status epilepticus.**

14 Q. So you would agree that Example 8
15 relates to looking at the effect of ganaxolone on
16 pilocarpine-induced SE?

17 A. **Yes, based on the title and the**
18 **words in there, in the paragraph, yeah.**

19 Q. Yeah. So looking at paragraph 117,
20 would you agree that in this example ganaxolone
21 was intravenously administered in two doses, 12
22 and 15 milligrams per kilogram?

23 A. **It's pretty much what you quoted.**

24 Q. And then you would also agree that
25 allopregnanolone alone was intravenously

1 administered at 15 milligram per kilogram dose?

2 **A. It states pretty much as you**
3 **quoted.**

4 Q. And that these two compounds were
5 separately administered to their own groups,
6 either 15 or 60 minutes after the onset of SE;
7 would you agree with that?

8 **A. Again, that's pretty much what --**
9 **what is stated in the paragraph.**

10 Q. So if we look at paragraph 118, it
11 says that, "EEG activity was reported in the rats
12 for five hours after the onset of SE."

13 Do you agree with that?

14 **A. It does state that at the top of**
15 **page 22.**

16 Q. And during this period of
17 five hours, the anticonvulsant activity, it was
18 "assessed by determining changes in EEG power."

19 Do you agree with that as well?

20 **A. Again, I think you read that pretty**
21 **much verbatim.**

22 Q. Okay. And if we go to paragraph
23 127, it's on page 24, the last sentence tells us
24 that, "Each animal was recorded once and
25 euthanized five hours after treatment."

1 Do you see that?

2 A. Again, what you stated is pretty
3 much what's written there.

4 Q. So does that mean that Zhang
5 provides no data in the rat lithium pilocarpine
6 model beyond five hours after treatment?

7 A. I -- I don't think that's correct,
8 no.

9 Q. Can you show me where in Zhang that
10 there's data beyond five hours post-onset of SE?

11 A. Well, Zhang is talking about
12 multiple --

13 Q. I'm sorry. I'm talking about
14 Example 8 specifically.

15 A. Well, again, Zhang is talking about
16 the possibility of administering ganaxolone
17 multiple times. So as I indicated in my expert
18 report, if, for example, it was given at two-hour
19 intervals, you could easily get to periods of
20 time greater than five hours, for example,
21 eight hours.

22 Q. Where in Example 8 of Zhang does it
23 reference administering ganaxolone multiple
24 times?

25 A. Well, it's indicated elsewhere

1 **in -- in Zhang that the treatment could be**
2 **administered multiple times.**

3 **Q. But Example 8 does not mention**
4 **administering ganaxolone multiple times; is that**
5 **right?**

6 **A. I don't see that in -- well,**
7 **perhaps you could again indicate what you're**
8 **specifically referring to, and then I can comment**
9 **on that more precisely.**

10 **Q. Sure. I'm referring to Example 8**
11 **of Zhang.**

12 **A. So 8 of Zhang.**

13 **Q. It's pages 21 through 27.**

14 **Does Example 8 of Zhang refer to**
15 **administering ganaxolone multiple times?**

16 **A. 8 of Zhang is specified according**
17 **to the protocol that we discussed; so I stand by**
18 **the description in Zhang of how they conducted**
19 **those experiments.**

20 **Q. Does the protocol, for example, 8**
21 **of Zhang that we just discussed mention**
22 **administering ganaxolone multiple times to the**
23 **rats?**

24 **A. I'll simply rely on the words that**
25 **are written here about how they -- they**

1 **administered it.**

2 Q. So going back to my previous
3 question, paragraph 127 says that, "Each animal
4 was recorded once and euthanized five hours after
5 treatment."

6 Does that mean that Example 8 of
7 Zhang does not provide any data in the rat
8 lithium pilocarpine model beyond five hours after
9 treatment?

10 A. Well, it does specify here that,
11 **"Each animal was recorded once and euthanized**
12 **five hours after treatment."**

13 Q. Right. And my question is a little
14 bit different.

15 Does that mean then that Zhang --
16 Example 8 provides no data in the rat lithium
17 pilocarpine model beyond five hours after
18 treatment?

19 A. Well, not necessarily because,
20 **again, the patent specification talks about the**
21 **possibility of administering ganaxolone multiple**
22 **times at multiple intervals. So the information**
23 **that's contained within this example could be**
24 **applied in that way to give information that is**
25 **relevant to a longer period of time.**

1 Q. But I'm only talking about what's
2 stated in the Example 8 itself. Does it provide
3 any data in the rat lithium pilocarpine model
4 beyond five hours?

5 ATTORNEY KANE: Objection; vague.

6 THE WITNESS: Well, as -- as we've
7 agreed and discussed, it states that, "Each
8 animal was recorded once and euthanized
9 five hours after treatment." That's what's
10 stated. Whether that provides information for
11 longer periods of time, in my view, is a
12 different question.

13 BY ATTORNEY McDONNELL:

14 Q. Are you aware of any data in
15 Example 8 of Zhang that provides information
16 about the rat lithium pilocarpine model beyond
17 five hours after treatment?

18 A. Well, again, the patent
19 specification describes administering ganaxolone
20 at various intervals. The data that is presented
21 could be interpreted in that way to give
22 information about longer durations of treatment.

23 Q. Again, I'm not talking about the
24 rest of the specification. I'm just talking
25 about Example 8, and it's pages 21 through 27.

1 Are you aware of any data in Example 8 that
2 provides data beyond five hours after treatment?

3 A. Well, as I've stated, the words
4 indicate that, "Each animal was recorded once and
5 euthanized five hours after treatment."

6 Q. So sitting here today, do you not
7 know if Zhang provides any data beyond five hours
8 after treatment in the rat lithium pilocarpine
9 model?

10 A. Well, the specification of the
11 patent indicates that ganaxolone could be
12 administered in different dosing intervals.

13 Q. And that's not my question. I'm
14 not talking about the rest of the specification.
15 I'm still talking about just Example 8, and I've
16 been pretty clear about that in the question.

17 ATTORNEY KANE: Counsel, read your
18 question. You did not limit to Example 8.
19 Talked about Zhang.

20 ATTORNEY McDONNELL: But I did talk
21 about the rat lithium pilocarpine model, which is
22 only in Example 8. So I'll ask again.

23 BY ATTORNEY McDONNELL:

24 Q. Sitting here today, do you know if
25 Example 8 of Zhang provides any data beyond

1 five hours after treatment in the rat lithium
2 pilocarpine model?

3 A. As -- as I've indicated, the
4 description states, "Each animal was recorded
5 once and euthanized five hours after treatment."

6 Maybe another way to answer your
7 question would be to say that how that would be
8 interpreted is a different question; and one
9 could interpret those data in various different
10 ways, including providing information on multiple
11 dosing that would provide an indication of
12 treatment for longer periods of time, including
13 eight hours, for example.

14 Q. Looking at Table 6 of Example 8, is
15 there any data provided in Table 6 of Example 8
16 that goes beyond three to five hours after
17 administration?

18 A. Well, my answer to your question is
19 similar to the one that I just gave. The table
20 indicates various times at the top. That to me
21 indicates how the experiment was done; but that
22 doesn't relate to the interpretation of the
23 results, and the interpretation could be in
24 various different ways, as I've described as
25 examples that I've given.

1 Q. But sticking to just the results
2 and not any additional interpretation, is there
3 any data provided in Table 6 beyond five hours?

4 A. Well, I can read the time intervals
5 to you that are specified here.

6 Q. Do any of those time intervals go
7 beyond five hours after administration?

8 A. Well, the time intervals are the
9 time intervals specified. But how one might
10 interpret those is in a variety of different --
11 different ways --

12 (Simultaneous cross-talk.)

13 Q. And I'm not asking you to interpret
14 them.

15 Does the table itself provide any
16 data for more than five hours post
17 administration?

18 A. Well, again, the time intervals are
19 as specified in the table.

20 Q. Do any of those intervals go beyond
21 five hours after administration?

22 A. Well, we can -- we can look at the
23 time intervals as written. But how one might
24 interpret those is in a variety of different --
25 different ways, as -- as we've discussed.

1 Q. Based on this one -- the single
2 administration of ganaxolone provided in
3 Example 8 to the rats, do we know, based on
4 Table 6, how the rats responded to the effect of
5 that single treatment of ganaxolone beyond
6 five hours?

7 A. **The results of an experiment of**
8 **this type could be interpreted in many different**
9 **ways, as we've discussed.**

10 Q. I don't think that answers my
11 question, though. I said based on the single
12 administration of ganaxolone provided in
13 Example 8 to the rats, do we know, based on
14 Table 6, how the rats responded to the effect of
15 that single treatment of ganaxolone beyond
16 five hours?

17 A. **I think the answer, again, was down**
18 **to what's written on the page there and what**
19 **you're asking me as an expert to discern from**
20 **what's written on the page.**

21 We can agree as to what's written
22 on the page there. But you've asked me a
23 specific question related to my expertise, and
24 I'm providing my expert opinion. I can't really
25 go beyond -- beyond that.

1 Q. So do you not have an opinion
2 whether -- based on the single administration of
3 ganaxolone provided in Example 8 to the rats,
4 whether we know, based on the data provided in
5 Table 6, how the rats responded to the effect of
6 the single administration of ganaxolone beyond
7 five hours?

8 A. We have what's specified in the
9 words written on the page.

10 Q. Do we know, based on Table 6,
11 whether after the five hours the rats relapsed
12 and seizures returned?

13 A. We only have the information that's
14 provided in the table. But we can interpret the
15 results in various different ways.

16 Q. Based on the data available in
17 Table 6, could the rats have relapsed and
18 seizures returned after five hours post
19 administration?

20 ATTORNEY KANE: Objection.

21 THE WITNESS: I can't really
22 speculate on what might or might not have
23 happened.

24 BY ATTORNEY McDONNELL:

25 Q. So would you agree that we don't

1 know what happened to the rats in terms of the
2 effect of ganaxolone five hours after
3 administration?

4 ATTORNEY KANE: Objection.

5 THE WITNESS: We can base an expert
6 opinion on the information that we have in the
7 table.

8 BY ATTORNEY McDONNELL:

9 Q. If we go to paragraph 135, you see
10 where the first sentence says, "When dosed 15
11 minutes after SE onset, GNX reduced EEG power
12 across all frequency ranges to levels at or below
13 baseline for up to five hours"?

14 A. Yes. That's pretty much what's
15 written there.

16 Q. And "GNX" there is referring to
17 ganaxolone?

18 A. I believe it is, yes.

19 Q. Do you know what paragraph 135
20 means when it says that EEG power was reduced to
21 levels at or below baseline?

22 A. I believe that means that, based on
23 a fast Fourier analysis of the EEG data, the
24 amplitude in various frequency ranges following
25 administration of ganaxolone was reduced compared

1 **to that of baseline.**

2 Q. And if EEG power is below baseline,
3 does that mean seizures are being stopped or
4 blocked?

5 A. **It means that the test subject is**
6 **experiencing an improvement.**

7 Q. And if EEG power is returning back
8 towards baseline, what does that mean?

9 A. **That means that numerically the**
10 **values may not be as depressed or are not as**
11 **depressed as at previous time points; but there**
12 **still might be improvement.**

13 Q. If the EEG power is returning back
14 towards the baseline, does that mean that the
15 effects of the compound in this case, ganaxolone,
16 is reducing or waning off?

17 ATTORNEY KANE: Objection; vague.

18 THE WITNESS: It -- it really is
19 what it states there. Because as I mentioned,
20 there are a variety of parameters that indicate
21 the action of ganaxolone.

22 We're talking only about one here,
23 which is the EEG power in these various frequency
24 bands. And as stated, numerically the values may
25 be reducing. That doesn't necessarily give you

1 information about any other parameter that might
2 be -- might be studied; and there still might be
3 improvement during that period.

4 BY ATTORNEY McDONNELL:

5 Q. If you only had information
6 relating to EEG power, you don't have any other
7 parameters available to you, how would you
8 interpret the data showing that the levels are
9 returning back towards baseline?

10 A. Again, that would indicate that
11 numerically -- excuse me -- the EEG power was
12 less depressed than it had been at a prior --
13 prior time point.

14 Q. How does that correlate to how the
15 rat is responding to the ganaxolone that was
16 administered, if at all?

17 ATTORNEY KANE: Objection; vague.

18 THE WITNESS: Well, if EEG power is
19 reduced, I would interpret that as an
20 improvement.

21 BY ATTORNEY McDONNELL:

22 Q. What about if EEG power is
23 returning back towards the baseline, how would
24 you interpret that?

25 A. I would interpret that as still an

1 **improvement.**

2 Q. Does it mean that there's less of
3 an improvement than the time point immediately
4 before?

5 A. Well, again, it's not possible to
6 define whether there's more or less improvement;
7 but it does indicate that there's improvement.
8 There's less EEG power reduction.

9 Q. How does EEG power reduction relate
10 to improvement?

11 A. It's generally considered to be an
12 indication of improvement. It's not a one-to-one
13 correlation between improvement, since
14 improvement, of course, has many different
15 meanings and can relate to a wide variety of
16 different effects of a medication. EEG power is
17 one parameter that is considered to be an
18 indicator of improvement.

19 Q. So then a reduction in EEG power
20 wouldn't necessarily mean that there's
21 improvement?

22 A. It's generally accepted as a
23 parameter indicating improvement.

24 Q. But there could be other parameters
25 at the same time that there's EEG reduction that

1 would mean that there's not an improvement; is
2 that right?

3 **A. Well, there are different ways,**
4 **again, to define improvement; many different ways**
5 **that improvement could occur.**

6 **Q. In the context of Example 8, you**
7 **had mentioned that EEG power being reduced**
8 **results in an improvement. What improvement are**
9 **you referring to there?**

10 **A. I'm referring to the reduction in**
11 **EEG power.**

12 **Q. That there's an improvement in EEG**
13 **power?**

14 **A. Well, again, EEG power is a**
15 **generally accepted parameter that relates to**
16 **improvement, that gives a marker of -- provides a**
17 **marker for improvement.**

18 **Q. Improvement of what?**

19 **A. There are many ways in which there**
20 **could be improvement in status epilepticus.**
21 **Reduction in EEG power is considered one widely**
22 **accepted criteria indicating improvement.**

23 **Q. What are other widely accepted**
24 **criteria indicating improvement?**

25 **A. I mentioned some of them**

1 **previously; for example, improvement in**
2 **behavioral seizure activity, histopathologic**
3 **effects, various other kinds of parameters have**
4 **been used by investigators to indicate**
5 **improvement.**

6 Q. Does a reduction in EEG power
7 indicate improvement in behavioral seizures?

8 A. An indication [sic] in EEG power
9 indicates improvement in the EEG.

10 Q. Does EEG power -- reduction in EEG
11 power indicate an improvement in behavioral
12 seizures, though?

13 A. It's generally accepted as a
14 parameter that provides an indication of
15 improvement in the treatment of status
16 epilepticus.

17 Q. That's not my question. You said
18 that improvement can result in many different
19 things. So does a reduction in EEG power
20 demonstrate that there is an improvement in
21 behavioral seizures?

22 A. Well, I think it's fair to say that
23 it's widely accepted that it's correlated very
24 closely with -- with behavioral seizures.

25 Q. Is there -- does a reduction in EEG

1 power demonstrate that there is an improvement in
2 histological effects?

3 A. Again, I think it's fair to say
4 that there is general agreement that there's a
5 very close correlation between a reduction in EEG
6 power and histological effects.

7 Q. And what is that correlation based
8 on?

9 A. It's based on a very large amount
10 of studies in the lithium pilocarpine -- or the
11 pilocarpine model of status epilepticus that are
12 in the literature.

13 Q. Do you cite to any of those studies
14 or literature in your declaration?

15 A. I do in the -- I believe in the
16 first part of the declaration talk about the fact
17 that some -- that those are the reasons why the
18 lithium pilocarpine model is generally accepted
19 as relevant or translational studies.

20 For example, on paragraph 31 of my
21 expert report it states, "It is recognized in the
22 field that the rat pilocarpine model and the
23 related rat lithium pilocarpine model are both
24 translationally relevant models for identifying
25 treatments for status epilepticus in part because

1 studies have found similar
2 electrophysiological" -- that would be EEG, like
3 the power analysis we're talking about -- "and
4 morphological abnormalities" -- that would be the
5 histological that I was describing.

6 So I do talk about it in this
7 report, and I gave a reference there.

8 Q. Does that correlate -- does this
9 paragraph, though, correlate a reduction in EEG
10 to histological or morphological abnormalities?

11 A. Well, it's generally accepted that
12 they are very closely correlated.

13 Q. That EEG reduction and improvement
14 in histological effects are closely correlated?

15 A. Yes.

16 Q. And it's the same for, there's a
17 close correlation between a reduction in EEG and
18 an improvement in behavioral effects?

19 A. It's not a one-to-one
20 correspondence; but it's generally accepted that
21 these various parameters are related and indicate
22 improvement.

23 Q. So where in paragraph 31 does it
24 say that these parameters are related?

25 A. Well, I'm offering you my expert

1 **opinion about that; and I believe that's what is**
2 **the gist of paragraph 31.**

3 Q. So let's go back to paragraph 135
4 of Zhang. And about -- towards the middle, it's
5 five lines up, it says, "However, between two to
6 five hours" -- I'm sorry, let me ask a new
7 question.

8 In paragraph 135 it talks about
9 different frequency ranges, so it talks about 0
10 to 5 hertz, 5 to 70 hertz, 70 to 96 hertz. What
11 do those frequency ranges represent?

12 A. **They represent frequency ranges**
13 **based on the fast Fourier transform analysis of**
14 **the raw EEG recording, the power in those**
15 **specific frequency ranges.**

16 Q. And how does the power of those
17 frequency ranges, I guess, translate into
18 demonstrating like efficacy in treating SE?

19 A. **It's generally accepted that**
20 **reductions in the power in these various ranges**
21 **indicate improvement.**

22 Q. And do you have to have a reduction
23 in all of the ranges for there to be improvement?
24 Only some of them?

25 A. **Well, it's generally accepted that**

1 **those ranges are relevant to demonstrating**
2 **improvement.**

3 Q. So sticking with paragraph 135,
4 when it says that, "Between two to five hours EEG
5 power above 30 hertz was not different from the
6 vehicle group, indicating it was also not
7 significantly different from the baseline power
8 level," does that mean that ganaxolone was
9 producing no effect between two to five hours in
10 terms of EEG power?

11 A. **I have to read this paragraph --**

12 Q. Sure.

13 A. **-- to see exactly what it refers**
14 **to.**

15 (Witness reviews document.)

16 A. **Okay. I think what this is saying**
17 **is that when dosed 15 minutes after SE onset,**
18 **ganaxolone reduced the EEG power across a wide**
19 **variety of frequency bands.**

20 But this particular band that
21 **they're referring to, above 30 hertz, is not**
22 **different from the vehicle group, indicating it**
23 **was not significantly different from the baseline**
24 **EEG power level.**

25 Q. Does that mean that ganaxolone was

1 not producing an effect between -- at that
2 frequency level and time?

3 A. Well, what I'm reading there is the
4 fact that in these other frequency ranges -- 5 to
5 70, 0 to 5, 70 to 96 -- the EEG power remained
6 below baseline for the entire five hours. But it
7 does state that in this one range of frequencies
8 it wasn't different from the control group
9 between two and five hours.

10 Q. And what -- what does it mean that
11 it was not different from the control group? How
12 is that -- how does that correlate to what effect
13 ganaxolone had on reducing or stopping seizures?

14 A. Well, ganaxolone clearly
15 demonstrated an effect on EEG power in multiple
16 bands, that would indicate improvement. In that
17 particular band, it states that it was not
18 different from that vehicle group. But if what
19 you're getting at is, does this indicate that
20 ganaxolone is not indicating improvement, I would
21 disagree with that.

22 Q. I'm talking about just -- is it
23 indicating improvement at the two to five hours
24 at EEG power above 30?

25 A. Well, I don't think you can

1 interpret that in relation to the issue of
2 improvement. You'd have to look at the other
3 frequency bands.

4 Q. So you're saying that you would
5 disregard that statement when considering whether
6 ganaxolone was effective?

7 A. Well, I'd have to look at all the
8 data in the totality. I couldn't look at it
9 in -- the individual data in isolation to come to
10 a conclusion.

11 Q. And what effect does that statement
12 have on your interpretation of the data in its
13 totality?

14 A. Well, again, ganaxolone reduced EEG
15 power for up to five hours in these various
16 frequency ranges that were specified here.

17 Q. How do you interpret that between
18 two to five hours at above 30 hertz that
19 ganaxolone was not different from the control
20 group?

21 A. I'd have to look at it in the
22 context of all of the information provided in
23 that paragraph.

24 Q. So you can't tell me, sitting here
25 today, how you interpret that it says between two

1 to five hours, EEG power above 30-hertz was not
2 different from the vehicle group?

3 A. Well, I would say that given the
4 effect of ganaxolone in all of the ranges that
5 are indicated here, that 5 to 70, the 0 to 5 --
6 the 70096-hertz range, that ganaxolone is being
7 described as having an effect on EEG power that
8 would be interpreted as improvement.

9 Q. What about between two to five
10 hours at 30 -- above 30 hertz? What does it tell
11 you about the effect of ganaxolone there?

12 A. It tells you that in that
13 particular time frame and that particular
14 frequency range that is above 30 hertz, that the
15 EEG power was not different from the vehicle
16 group.

17 Q. And what does it mean when it says
18 that the EEG power was not different from the
19 vehicle group?

20 A. I don't know exactly what they did
21 to come to that conclusion. But reading --
22 reading the words there on the page, it specifies
23 that it was not different; and I'm assuming what
24 they mean is in a statistical sense that they did
25 some kind of a statistical analysis and

1 **determined that the power above 30 hertz was not**
2 **different from the vehicle group.**

3 Q. What does that mean in terms of the
4 effect ganaxolone has on improving SE?

5 A. Well, ganaxolone improved SE in the
6 range -- EEG ranges of 5 to 70 hertz, 0 to 5
7 hertz, and 70 to 96 hertz for the entire
8 five hours.

9 Q. Well, what about from between two
10 to five hours at above 30 hertz?

11 A. Well, between two to five hours,
12 the EEG power above 30 hertz was not different
13 from the vehicle group, indicating that it was
14 not significantly different from the baseline EEG
15 power level.

16 Q. And what does that mean about the
17 effect of ganaxolone on improving SE between two
18 to five hours at above 30 hertz?

19 A. It means that between two to
20 five hours, EEG power above 30 hertz was not
21 different from the vehicle group.

22 Q. So it doesn't mean anything -- you
23 wouldn't interpret it to mean anything beyond
24 what the words say?

25 A. I wouldn't -- I would look at it in

1 the total context and see that there was effect
2 at 5 to 70 hertz, 0 to 5 hertz, 70 to 96 hertz
3 for the entire four hour -- five-hour period,
4 reduction in EEG power.

5 Q. Where does it say that there was an
6 effect from 5 to 70 hertz, 0 to 5 hertz, 70 to
7 96 hertz?

8 A. It says, "The EEG power was reduced
9 below the baseline level."

10 Q. So you have to interpret what
11 "reduced below the baseline level" means in terms
12 of improvement?

13 A. Well, it's generally accepted that
14 a reduction in EEG power relates to improvement.

15 Q. How about the next sentence where
16 it says, "Note also that at the higher frequency
17 ranges EEG power in the vehicle groups returned
18 towards baseline after two hours so that
19 differences between the GNX and vehicle groups
20 were not significant."

21 Does that statement indicate that
22 the effect of ganaxolone on treating SE was
23 diminishing?

24 A. It does not, in my opinion. It's a
25 statement about the vehicle groups, not about the

1 **ganaxolone groups.**

2 Q. What about when it says, "so that
3 differences between the GNX and vehicle groups
4 were not significant"?

5 A. **That I believe means that it wasn't**
6 **possible to conduct a statistical analysis there.**

7 Q. Okay. So we go to tables -- back
8 to Table 6 and 7. Would you agree that Table 6
9 shows that for the 12 milligram and 15 milligram
10 per kilogram administrations of ganaxolone
11 15 minutes post SE onset, that only the 0 to
12 5 hertz frequency range demonstrated a
13 statistically significant effect at three to
14 five hours as compared to the vehicle?

15 A. **I see that in Table 6, which gives**
16 **information on two doses of ganaxolone and one**
17 **dose of allopregnanolone, that there are various**
18 **stars provided for different time periods; and I**
19 **do see stars in all of the boxes for the two**
20 **doses of ganaxolone at 0 to 5 hertz.**

21 I see stars in many of the other
22 boxes. I don't see any stars for the two
23 ganaxolone doses other than in the 0 to 5 line at
24 three to five hours, if that's what you're
25 asking.

1 Q. And it says "NS" instead; is that
2 right?

3 A. **It does.**

4 Q. Does that mean that there's no
5 statistically significant difference between the
6 vehicle as compared to ganaxolone at the specific
7 dose amounts provided?

8 A. Well, if I look on page 27 at the
9 bottom of Table 7, there is a legend for what
10 "NS" indicates, and it says, "NS equals not
11 significant claims." I'm assuming that word
12 "claims" is out of place.

13 Q. I think so too. Claims are on the
14 next page.

15 So then does that mean -- in the
16 legend would you interpret that as meaning that
17 there's no statistically significant difference?

18 A. **It does -- the legend does suggest**
19 **that "NS" indicate -- means not significant, yes.**

20 Q. All right. And if we look at
21 Table 7, again looking at the three to five hours
22 column. Do you see that?

23 A. **Yes, I do.**

24 Q. The only frequency that has any
25 stars in it for Table 7, would you agree, is the

1 0 to 5 hertz for the 12 milligram ganaxolone
2 administration?

3 A. In Table 7 we're talking about now?

4 Q. Yeah.

5 A. Yes.

6 Q. And all the other frequencies
7 besides 0 to 5 hertz at 12 milligrams has "NS,"
8 which means not significant; is that right?

9 A. Yes.

10 Q. And for the 15 milligram per
11 kilogram administration in Table 7, which is on
12 page 26, none of the frequency ranges showed any
13 statistical significance as compared to the
14 vehicle; is that right?

15 A. Are you referring to page 27 as you
16 explained --

17 Q. The bottom, yeah.

18 A. Yeah, that's 27, not 26 then.

19 Q. The -- page 27 at the bottom?

20 A. Yeah, you mentioned --

21 ATTORNEY KANE: Your question,
22 Counsel, is 26 --

23 ATTORNEY McDONNELL: Oh, I
24 apologize, the double number throws me off.

25

1 BY ATTORNEY McDONNELL:

2 Q. Yeah, so for page 27, the bottom
3 page, would you agree that none of the
4 frequencies at three to five hours demonstrated
5 any significance as compared to the vehicle?

6 A. Well, I do see NS in all of the --
7 all of the boxes under the heading of three to
8 five hours, yes.

9 Q. Which means that there was no
10 significance demonstrated as compared to the
11 vehicle; is that right?

12 A. Based on the legend, yes.

13 Q. Okay. Do you understand that
14 there's eight examples in Zhang? In the example
15 section there's Examples 1 through 8?

16 A. If you mean by "examples,"
17 eight figures or eight --

18 Q. So if you go to page 18 -- I'll
19 help you out.

20 A. Oh, 18 -- yeah.

21 Q. So you see the section towards the
22 bottom, it says, "Examples"? On page 18, the
23 bottom of page 18. It's like --

24 (Simultaneous cross-talk.)

25 A. Oh, yeah, yeah.

1 Q. So there's Example 1 right below
2 that. Do you see that?

3 A. **Yes -- oh, I see, okay, great.**

4 Q. And then there's Example 2 on the
5 next page and Example 3?

6 A. **Yes.**

7 Q. Would you agree that there's 8 of
8 these examples in Zhang?

9 A. **I do.**

10 Q. Did you -- did you review the other
11 examples, Examples 1 through 7, when preparing
12 your declaration?

13 A. **I did not, no.**

14 Q. Okay. Why did you not review those
15 examples?

16 A. **Well, in glancing at them they
17 didn't seem to be relevant.**

18 Q. And why is that?

19 A. **Because they were titled such
20 things as "Preparation of Injectable Formulation,
21 and "Preparation of the Solution," and so forth.
22 That didn't seem to be relevant to my
23 determination of the validity of the '817 Patent.**

24 Q. All right. Would it be fair to say
25 that Examples 1 through 7 don't discuss the

1 efficacy of ganaxolone in treating SE?

2 **A. I couldn't tell you because I**
3 **didn't study them in detail.**

4 Q. Okay. If we go back to your
5 report, paragraph 37, you mention that, "Marinus
6 had presented the results of its research at
7 various times, including at the 2016 American
8 Academy of Neurology annual meeting."

9 Do you see that?

10 **A. I do.**

11 Q. Are you a member of the American
12 Academy of Neurology?

13 **A. I am.**

14 Q. Did you attend this 2016 meeting?

15 **A. I did.**

16 Q. Are your statements in paragraph 37
17 about this meeting based on your personal
18 knowledge of attending the meeting?

19 **A. It was based on my personal**
20 **knowledge and also reviewing information about**
21 **the meeting during the time I was preparing the**
22 **report. I -- I -- I looked to verify my memory**
23 **about how many members were -- had attended the**
24 **meeting, and it was indicated on the website and**
25 **there were some other materials, I believe I**

1 **found an annual report from the society that**
2 **mentioned this.**

3 Q. In paragraph 37 you referred to the
4 Saporito posters?

5 A. **Yes.**

6 Q. Do you see that?

7 A. **I do.**

8 ATTORNEY KANE: Let me give you
9 what is marked as Exhibit 1013.

10 (Whereupon, previously marked Exhibit
11 Number 1013 was introduced.)

12 BY ATTORNEY McDONNELL:

13 Q. This is a document titled
14 "Ganaxolone Administered Intravenously Prevents
15 Behavioral Seizures and Promotes Survival in the
16 Rat Lithium Pilocarpine Model of Status
17 Epilepticus."

18 Do you recognize this document?

19 A. **I do.**

20 Q. Is this the document you referred
21 to in Exhibit 1013 or Saporito Poster 1 in your
22 declaration?

23 A. **I believe it is, yes.**

24 Q. And did you review this to prepare
25 for your deposition today?

1 **A. I glanced at it, yes.**

2 **(Whereupon, previously marked Exhibit**
3 **Number 1014 was introduced.)**

4 BY ATTORNEY KANE:

5 Q. Okay. I'm also going to give you
6 what's marked as Exhibit 1014. And this document
7 is entitled "Intravenous Administration of
8 Ganaxolone Attenuates in Electroencephalographic
9 Seizures in a Diazepam Resistant Model of Status
10 Epilepticus."

11 **A. Yes.**

12 Q. And do you recognize this document?

13 **A. I believe I do.**

14 Q. Is this the document you referred
15 to as Exhibit 1014 or Saporito Poster 2 in your
16 declaration?

17 **A. I believe it is. I could have the**
18 **numbering off, but I believe it's likely to be**
19 **the one.**

20 Q. Okay. So sticking with this
21 Exhibit 1014 -- you can set the other one down
22 for right now -- I think you state in your
23 declaration at paragraph 38 that, "This poster
24 looks at the EEG or electrical effects of
25 ganaxolone on SE in rats."

110

1 Is that right?

2 A. Yes.

3 Q. And the model used in the study
4 described in Exhibit 1014 is the rat pilocarpine
5 model; is that right?

6 A. I believe it is, yes.

7 Q. Okay. Do you see the conclusion
8 box on the bottom right corner?

9 A. Yeah. Let me just clarify. This
10 specifies lithium pilocarpine model, which as I
11 testified in my expert report is similar to the
12 pilocarpine model --

13 Q. Right.

14 A. -- with similar implications.

15 Q. Could you remind me what the
16 lithium does.

17 A. As I indicated previously in my
18 testimony today, the lithium is believed to
19 provide a more reproducible seizure activity,
20 more consistent prolonged seizure activity.

21 Q. Okay. So if we look at the
22 conclusion box, do you see where it says, "GNX
23 administration elicits a sustained (greater than
24 equal to five hours) block of SE independent
25 treatment time after SE onset"?

1 **A. I do see those words there, yes.**

2 Q. And based on this statement alone,
3 all that you know was that there was a sustained
4 block of SE -- independent treatment time after
5 SE onset of greater than or equal to five hours;
6 is that right?

7 **A. Well, it specifies greater than or**
8 **equal to five hours, yes.**

9 Q. And this statement doesn't say for
10 how long that sustained block occurred other than
11 that it was at least five hours?

12 **A. It does specify greater than or**
13 **equal to five hour, yes.**

14 Q. But it doesn't tell you for how
15 long exactly after?

16 **A. It specifies greater than or equal**
17 **to five hours.**

18 Q. But you don't know whether that's
19 six hours?

20 **A. I can only tell you what I see**
21 **there, greater than or equal to five hours in**
22 **that particular statement.**

23 Q. But it could be -- could be six
24 hours; is that right?

25 **A. Well, six hours is greater than**

1 **five.**

2 Q. Right.

3 A. **And the "greater than" sign**
4 **indicates greater than, so could be six.**

5 Q. So that means that the ganaxolone
6 administration could have stopped blocking SE at
7 six hours?

8 A. **I can't really speculate on that.**

9 Q. Would you agree that the data in
10 Exhibit 1014 that supports this statement is
11 found in Figures 3 and 4? And that's the --
12 Figure 3 is the one at the bottom of the middle
13 column -- I know it's very small -- and then
14 Figure 4 is the figure on the right, far right
15 column.

16 I think the next pages kind of
17 provide blown-up versions of those figures that
18 are maybe a little more helpful.

19 A. **Thank you, yeah.**

20 **So if you could rephrase your**
21 **question now that I can focus my attention**
22 **specifically on the figures that you're referring**
23 **to.**

24 Q. Would you agree that the data in
25 Saporito Poster 2 that supports the statement

1 that ganaxolone administration elicits sustained,
2 greater than or equal to five-hour, block of SE
3 independent of treatment time after SE onset,
4 that that supporting data is found on Figures 3
5 and 4?

6 **A. Well, I don't see Figure 3 blown**
7 **up. I do see Figure 4 blown up.**

8 Q. I think Figure 3 is --

9 **A. The 15-minute interval.**

10 Q. That's page 4 of the document.
11 It's the first half of it.

12 **A. Oh.**

13 Q. And then I think page 3 is the
14 second half. Or maybe it's page 5 is. Sorry.

15 **A. Okay. So 3 is this one --**

16 Q. Yeah, I think 3 is this and this --

17 **A. Okay. Gotcha.**

18 Q. -- put together.

19 **A. Gotcha.**

20 **Maybe you can now ask your**
21 **question.**

22 Q. Is the data in Figures 3 and
23 Figure 4 the data that supports the statement and
24 the conclusion that we had discussed earlier?

25 **A. Well, what I see in Figure 3 is**

1 that ganaxolone causes a reduction in EEG power
2 during a period that's indicated on the X axis of
3 the graphs from 0 to 7 hours; and I believe that
4 the 0 time is taken as time of treatment,
5 although it's a little bit off there.

6 Q. Because it was 15 minutes after the
7 time; is that right?

8 A. Well, 15 -- 15 -- so Time 0 is the
9 onset of status, and then 15 minutes was the --
10 okay. So that should indicate that the one-hour,
11 one --

12 Q. So would six hours, in Figure 3 on
13 the graph, that represents --

14 A. Yeah, Treatment 4, it's one hour,
15 yeah.

16 Q. So Figure 3, the six-hour mark,
17 represents 5 hours and 45 minutes after you
18 administered ganaxolone; is that right?

19 A. That is correct, yeah.

20 Q. And then in Figure 4, where the
21 ganaxolone was administered an hour after SE
22 onset, the six-hour mark on the graph would
23 represent five hours after treatment?

24 A. I believe that would be correct,
25 yes.

1 Q. Okay. And you would agree that the
2 last time point at which data was taken was, in
3 the case of Figure 3, 5 hours and 45 minutes
4 after administration of ganaxolone; right?

5 A. Well, I don't know that. I -- I
6 can say that it appears that the data presented
7 in the graph is the last time point where the
8 data provided in the graph is taken at, as you
9 say, 5 hours and 45 minutes.

10 Q. And then for Figure 4, the last
11 data point that's presented in the graph is --
12 would be five hours after administration on the
13 ganaxolone; is that right?

14 A. Yes, I would agree with that.

15 Q. And based on the data that's
16 presented in the graphs in Figures -- in
17 Figure 3, we don't know what effect ganaxolone
18 had after 5 hours and 45 minutes post
19 administration?

20 A. Well, I can only comment on what's
21 in the graph. As we said in the conclusions,
22 it's specified that ganaxolone elicits
23 sustained -- that is, greater than or equal to a
24 five-hour -- block of SE independent of treatment
25 time after SE onset.

1 **So this particular poster seems to**
2 **specify that.**

3 Q. If we could turn to Exhibit 1013,
4 which is the other -- I think it's Saporito
5 Poster 1, as you referred to it.

6 And in paragraph 39 of your
7 declaration you state that this document looks at
8 the behavioral effects of ganaxolone in rats with
9 SE; is that right?

10 A. Yes. And also I specify in
11 paragraph 39 that it relates to survival,
12 measured at 24 hours after CSE onset.

13 (Interruption by the court reporter to
14 clarify the record.)

15 Q. And "CSE" refers to convulsive SE?

16 A. It does.

17 Q. And that's -- for layman's terms,
18 that's like the same as SE or --

19 A. It's a type of SE.

20 Q. Type of SE.

21 And this Exhibit 1013 also uses the
22 rat pilocarpine model; is that right? With a
23 lithium pilocarpine model?

24 A. Yes, I believe it's stated here
25 that it does.

1 Q. So if you look at Figure 2 of
2 Exhibit 1013 -- I think it's the same thing where
3 Figure 2 is blown up. It's a little trickier
4 because it's on all the pages, but little
5 snippets of it are included on the other pages.

6 But Figure 2 looks at the number of
7 rats that were protected from seizures after
8 ganaxolone was administered at four time points
9 after the onset of convulsive SE; is that right?

10 A. I believe that is correct.

11 Yes, it states in the methods,
12 **"Compounds were administered via IV**
13 **administration, time of CSE onset, Time 0, and**
14 **15, 30 and 60 minutes after onset."**

15 So those would be the four display
16 **items that we see in Figure 2.**

17 Q. And if we go to the next bullet
18 point, in the methods it says:

19 "After compound
20 administration, animals were observed
21 for the presence or absence of
22 convulsive seizures (Stage 3 or greater)
23 for an additional two hours. Animals
24 that did not exhibit a convulsive
25 seizure during that time period were

1 considered protected." And then it says

2 "Figure 2" in parentheses.

3 So you would agree that this method
4 only -- the animals that were tested were
5 observed for only two additional hours after the
6 administration of ganaxolone; is that right?

7 ATTORNEY KANE: Objection; lack of
8 foundation.

9 THE WITNESS: Yeah, I don't know
10 exactly what they did. I can only confirm that
11 the words that are written and the methods that
12 you read, that they were observed for an
13 additional two hours. It doesn't specifically
14 explain what is being graphed there.

15 BY ATTORNEY McDONNELL:

16 Q. If it does not state -- if it says
17 that they weren't -- they were only observed for
18 an additional two hours, then we don't know what
19 effects ganaxolone was having beyond those two
20 hours on seizure protection; is that right?

21 A. **Well, again, I can't go beyond what**
22 **is stated there, what they were observed, for the**
23 **presence or absence of convulsive seizures**
24 **Stage 3 or greater for duration of two hours.**

25 Q. And why can't you go beyond what is

1 stated in the document?

2 **A. Well, I don't know exactly what**
3 **they did beyond that.**

4 Q. And Figure 3 of Exhibit 1013 looks
5 at the survival rate of rats 24 hours after CSE
6 onset; is that right?

7 **A. Yes, that's what it states.**

8 Q. And would the survival rate be the
9 percentage of rats that survived the treatment
10 paradigm in each group?

11 **A. Yes. I believe those graphs**
12 **indicate the percent of animals that survived**
13 **when they were treated with various doses of**
14 **ganaxolone and also one dose of allopregnanolone.**

15 Q. And Figure 3 itself doesn't show
16 anything about whether or not ganaxolone was
17 blocking seizures; is that right?

18 **A. Well, one thing that's very, very**
19 **clear here is that there was dramatic improvement**
20 **in the animals that were treated with ganaxolone**
21 **at all doses, at the 24-hour time point that was**
22 **assessed here. Because less of them were**
23 **damaged, it's clearly an improvement.**

24 Q. That didn't represent an
25 improvement in all the rats necessarily?

1 **A. Almost all of them survived when**
2 **they were given ganaxolone, so it does seem like**
3 **nearly all of them were improved at 24 hours.**

4 **Q. The only conclusion that's drawn in**
5 **the conclusion box about Figure 3, would you**
6 **agree that the only conclusion is GNX IV promoted**
7 **survival at rates similar to those observed with**
8 **administration of allopregnanolone as measured at**
9 **24 hours after CSE onset in CSE-induced rats?**

10 **A. Am I understanding your question to**
11 **say that this is the only conclusion that can be**
12 **derived from these data?**

13 **Q. Yes.**

14 **A. I would not agree with that.**

15 **Q. Is there another conclusion that's**
16 **presented on the poster that relates to Figure 3?**

17 **A. Well, there are many, many**
18 **interpretations that could be made of the data in**
19 **the poster. The conclusions that are listed are**
20 **just a brief summary of what the investigators**
21 **felt was something they wanted to highlight or**
22 **that they had space to highlight or that, just at**
23 **the time, they decided to highlight.**

24 **Q. Is that the only conclusion that**
25 **they did actually make, though?**

1 ATTORNEY KANE: Objection.

2 THE WITNESS: I have no idea what
3 was in their mind. All I know is what was
4 written on the poster.

5 BY ATTORNEY McDONNELL:

6 Q. Does the -- does Exhibit 1013 at
7 all correlate the 24-hour survival rate of rats
8 with continued seizure protection?

9 A. I think that would be a reasonable
10 interpretation, yes.

11 Q. And what are you basing that
12 interpretation on?

13 A. Well, if the rats had continued to
14 seize, they might very well have died; but most
15 of them did not die, in the animals that were
16 treated with ganaxolone.

17 Q. But Exhibit 1013 doesn't itself
18 explicitly say that, does it?

19 A. I think that would be a very
20 reasonable interpretation that any person who is
21 knowledgeable about this field would conclude.

22 Q. Do we know, based on Figure 3,
23 whether the rats were still exhibiting seizures?

24 A. I think it's fair to say that there
25 was a dramatic improvement at 24 hours, given

1 **that most of the animals survived when they were**
2 **treated with ganaxolone; whereas, the vehicle**
3 **animals in most cases, more often than not, they**
4 **died.**

5 Q. In most cases, more often than not,
6 the rats died in the vehicle group?

7 A. **It looks that way, based on what's**
8 **shown in Figure 3.**

9 ATTORNEY McDONNELL: Okay. You
10 want to break for lunch now?

11 ATTORNEY KANE: Sure.

12 THE VIDEOGRAPHER: This is the end
13 of Media Number 3. Off the record at 12:53 p.m.

14 - - -

15 (Luncheon recess taken from 12:53 p.m.
16 to 1:33 p.m.)

17 - - -

18 THE VIDEOGRAPHER: This marks the
19 beginning of Media Number 4. Back on the record
20 at 1:33 p.m.

21 BY ATTORNEY McDONNELL:

22 Q. So we can turn back to your
23 declaration, and look at paragraph 41. And here
24 you discuss some of Marinus' clinical work in
25 2016 that involved using ganaxolone to treat SE;

1 and, in particular, you mention Marinus receiving
2 orphan drug designation for ganaxolone for the SE
3 indication, and also Marinus dosing its first
4 patients in a Phase I clinical trial; is that
5 right?

6 **A. Yes.**

7 **(Whereupon, previously marked Exhibit**
8 **Number 1011 was introduced.)**

9 BY ATTORNEY McDONNELL:

10 Q. I'm going to hand you what's marked
11 as Exhibit 1011. This document is titled
12 "Marinus Pharmaceuticals Receives FDA Orphan Drug
13 Designation for Ganaxolone IV to Treat Status
14 Epilepticus." And then it's dated April 15th,
15 2016; is that right?

16 **A. Yes.**

17 Q. Do you recognize this document?

18 **A. I can't really remember looking at**
19 **it because it's in a printed form, and if I had**
20 **looked at it, it would have been on the web --**
21 **website. But it's possible that I looked at**
22 **that.**

23 Q. Does it appear to be the Exhibit 11
24 or the April 15th, 2016, press release that you
25 describe in your declaration?

1 A. It -- it very likely is. As I say,
2 I would have looked at it on the internet and not
3 had it in the printed form, so the formatting and
4 so forth would be different. But I don't have
5 any reason to believe it's not.

6 (Whereupon, previously marked Exhibit
7 Number 1022 was introduced.)

8 BY ATTORNEY KANE:

9 Q. Okay. I'm going to also hand you
10 what's marked as Exhibit 1022. This is a
11 document titled "Marinus Pharmaceuticals Doses
12 First Subject in Phase I Clinical Trial for
13 Ganaxolone IV," and, it's dated June 22nd,
14 2016.

15 Do you see that?

16 A. I do.

17 Q. Do you recognize this document?

18 A. Well, again, it's in a format that
19 would be different than how I would have looked
20 at it. I don't have any reason to believe it's
21 different from what I saw, but I would have
22 looked at it in the internet, not in a printed
23 form.

24 Q. Okay. And when you say they differ
25 from what you saw earlier, you're referring to

1 Exhibit 1022 -- or what you referred to as
2 Exhibit 1022, or the June 22nd, 2016, press
3 release in your declaration?

4 A. And it's marked Exhibit 1022?

5 Q. Yeah.

6 A. Yes.

7 Q. Okay. So let's stick with this
8 Exhibit 1022.

9 In the first paragraph it says
10 that:

11 "Marinus Pharmaceuticals,
12 Inc., a biopharmaceutical company
13 dedicated to the development of
14 innovative therapeutics to treat
15 epilepsy and neuropsychiatric disorders,
16 today announced that it has dosed the
17 first subject in its Phase I clinical
18 trial of ganaxolone IV, an intravenous
19 formulation of Marinus' CNS-selective
20 GABAA modulator, for the treatment of
21 SE."

22 Do you see that?

23 A. I do.

24 Q. Would you agree then that this
25 press release only announces that Marinus has

1 dosed the first subject in its Phase I clinical
2 trial?

3 A. Well, the words state that, but I
4 have no idea what was going on behind the scenes
5 or what Marinus had done apart from this.

6 But I do agree that that's what's
7 stated here in this document.

8 Q. And the press release does not
9 report any data from this Phase I clinical trial,
10 does it?

11 A. Well, just scanning it over and
12 refreshing my memory of the document, it does
13 appear that it's an announcement of the -- oh,
14 no, the title says "doses first subject." So the
15 title indicates that they had dosed, it's in the
16 past -- or it's in the affirmative. So it sounds
17 like they -- they dosed their first subject.

18 Q. Would you agree that it doesn't
19 present any data from that Phase I clinical
20 trial, though?

21 A. Again, scanning through, I don't
22 see any mention of data.

23 Q. So the last sentence of that first
24 paragraph says that:

25 "The study is designed to

1 evaluate the safety, pharmacokinetics
2 and pharmacodynamics of ganaxolone IV in
3 healthy volunteers which data
4 participated in the second half of
5 2016."

6 Do you see that, in the last
7 sentence of the first paragraph?

8 **A. Oh, okay. Yes, I do.**

9 Q. And you would agree that among the
10 kind of objectives listed, that evaluating the
11 efficacy of ganaxolone IV in treating SE was not
12 one of those objectives of the Phase I clinical
13 trial?

14 **A. Well, again, I don't know what they**
15 **had in mind, what they were planning, what they**
16 **had done. All I can say is that the document**
17 **itself states that it evaluates the safety,**
18 **pharmacokinetics and pharmacodynamics.**

19 Q. Does the document state that this
20 Phase I clinical trial evaluated the efficacy of
21 ganaxolone IV in treating SE?

22 **A. Well, I don't see any words to that**
23 **effect here.**

24 Q. And that's because ganaxolone was
25 only dosed in healthy volunteers; is that right?

1 **A. Well, again, I only know what's in**
2 **this document. I don't have -- I'm not privy to**
3 **any information about what Marinus might or might**
4 **not have done.**

5 Q. You would agree that the last
6 sentence of this first paragraph says that
7 ganaxolone IV was administered to healthy
8 volunteers in efforts Phase I clinical trials?

9 **A. Yes.**

10 Q. And here "healthy volunteers" means
11 that the subjects did not have SE?

12 **A. I think that's a fair assumption,**
13 **if they used the term healthy volunteers, yes.**

14 Q. And this press release also does
15 not disclose any dose amounts for -- that were
16 used in the Phase I clinical trial; is that
17 right?

18 THE COURT REPORTER: I'm sorry.
19 Could you please repeat your question. I missed
20 something in there.

21 (Interruption by the court reporter to
22 clarify the record.)

23 BY ATTORNEY McDONNELL:

24 Q. Sure. I said the press release
25 doesn't disclose any dose amounts that were

1 administered to the subjects in the Phase I
2 clinical trial; is that right?

3 **A. I don't see any indication of dose**
4 **amounts in the document that you showed me.**

5 Q. So if we look at the second
6 paragraph, there's a quote from Marinus' chief
7 medical officer.

8 Do you see that?

9 **A. I do, yeah.**

10 Q. And in the first sentence he says,
11 that, "Status epilepticus is a life-threatening
12 medical emergency associated with high mortality
13 and limited treatments."

14 Do you see that?

15 Do you agree with that statement,
16 at the time it was made?

17 **A. Yes, she is making a statement that**
18 **seems reasonable.**

19 Q. And then she says that:

20 "Typically, single or
21 combination IV antiepileptic drugs are
22 used in an attempt to break the
23 seizures, however there are
24 approximately 45,000 patients in the US
25 who do not respond to treatment and

1 progress to established SE."

2 Do you agree with that statement,
3 as of the time that it was made?

4 A. I haven't investigated the
5 epidemiology of status epilepticus at that time,
6 so I can't really confirm the -- excuse me --
7 confirm the veracity of the epidemiological
8 estimates that she's providing there.

9 But I would say that, in general,
10 the concepts are -- are in line with medical
11 thinking.

12 Q. Sitting here today, do you have any
13 reason to doubt the veracity of that statement?

14 A. I can't really comment on it
15 because I haven't investigated it. I haven't
16 investigated the epidemiology of status --
17 particularly in that time frame.

18 Q. And then about three lines up from
19 the bottom of that paragraph, she says:

20 "Our preclinical research
21 suggests ganaxolone IV could be a
22 promising therapeutic in this difficult
23 to treat seizure disorder, especially
24 after first-line benzodiazepine fails to
25 halt the seizures."

1 Do you see that?

2 A. I do.

3 Q. Do you agree with this statement,
4 as of the time it was made?

5 A. I do.

6 Q. If we go back to your declaration
7 at paragraph 126, you discuss Marinus' Phase I
8 press release in this paragraph; is that right?

9 A. I do.

10 Q. And is that the same press release
11 that's Exhibit 1022?

12 A. I think it is. Again, I hadn't
13 seen it in this format, so I can't be 100 percent
14 sure. But there's the -- it -- it seems
15 reasonable that it would be.

16 Q. And the last sentence on page 43,
17 you say -- sorry, that carries over. It says:

18 "Since this study was
19 conducted in the United States and
20 ganaxolone was not an approved drug, the
21 FDA permitted the study to be undertaken
22 under an IND."

23 "Then you state that:

24 "In order for the FDA to
25 permit a clinical study to be undertaken

1 under an IND, those of skill in the art
2 understand that the sponsor must provide
3 evidence that the 'compound exhibits
4 pharmacological activity that justifies
5 commercial development.' "

6 Do you see that?

7 **A. I do.**

8 **Q.** And then so are you saying here
9 then that the sponsor must provide evidence to
10 the FDA that the compound exhibits
11 pharmacological activity that justifies
12 commercial development in order to conduct the
13 study under an IND?

14 **A. It depends, of course, what the**
15 **purpose of the IND would be for.**

16 In this case, I mention here that
17 the purpose of the trial was to advance
18 commercial development of ganaxolone for the
19 treatment of SE. And in that situation, yes, the
20 FDA would require justification -- nonclinical
21 justification to support the product being
22 developed for that indication.

23 **Q.** So the sentence that begins at the
24 top of page 44, you quote from part of FDA.gov;
25 is that right?

1 **A. I do.**

2 **(Whereupon, previously marked Exhibit**
3 **Number 1021 was introduced.)**

4 BY ATTORNEY KANE:

5 Q. I'm going to hand you what's marked
6 as Exhibit 1021. This document is titled "Drug
7 Development and Review Definitions."

8 Do you recognize this document?

9 **A. I can't say that I do. If I'd seen**
10 **it on the internet, I -- would have been in a**
11 **different format, so it's hard for me to be sure.**

12 Q. If you compare the URL that you
13 cite on page 44 in paragraph 124 with the URL at
14 the bottom of Exhibit 1021, is that the same?

15 **A. It looks to be the same URL, yes.**

16 Q. So is this likely where you got the
17 quote in paragraph 124?

18 **A. Well, assuming that this URL is an**
19 **indication of where this document was obtained,**
20 **and assuming it hadn't been changed -- because**
21 **you'll note that my declaration doesn't give a**
22 **specific date, so I can't be -- be sure that the**
23 **document that you've downloaded is -- is the**
24 **same, given the fact that it could be changed on**
25 **the internet.**

1 Q. Okay. Remember that this was
2 submitted as an exhibit with -- that Marinus
3 submitted.

4 A. **Okay.**

5 Q. So -- but if we go to page 5 of
6 Exhibit 1021, you see the heading Investigational
7 New Drug Application?

8 A. **Yes.**

9 Q. And the second -- I'm sorry. If
10 you look at the second paragraph under that
11 heading, the first sentence says:

12 "During a new drug's early
13 preclinical development, the sponsor's
14 primary goal is to determine if the
15 product is reasonably safe for initial
16 use in humans, and if the compound
17 exhibits pharmacological activity that
18 justifies commercial development."

19 Do you see that?

20 A. **Uh-huh, yes.**

21 Q. Does that appear to be the sentence
22 where you got the quote that's in paragraph
23 124 -- or, sorry -- 126 of your expert
24 declaration?

25 A. **It looks to be the case, yes.**

1 Q. Does this first sentence in the
2 second paragraph of the Exhibit 1021 state that
3 evidence that the compound exhibits
4 pharmacological activity must be submitted to the
5 FDA for a sponsor to file an Investigational New
6 Drug Application?

7 A. **Having been involved in the filing
8 of many Investigational New Drug Applications
9 myself as part of my academic work, I was aware
10 that the FDA does generally require that.**

11 Q. When you say "does generally," are
12 there instances where the FDA does not require
13 that type of evidence?

14 ATTORNEY KANE: Objection; lack of
15 foundation.

16 THE WITNESS: In my experience, it
17 is required.

18 BY ATTORNEY McDONNELL:

19 Q. Does it say it anywhere in that
20 second paragraph or on -- under the heading
21 Investigational New Drug Application that the FDA
22 required the sponsor to submit evidence that the
23 compound exhibits pharmacological activity that
24 justifies commercial development?

25 A. **Well, again, in my experience it**

1 **does.**

2 Q. Does it say that anywhere in
3 Exhibit 1021, in that paragraph?

4 A. Well, it does state, as you quoted,
5 **"if the compound exhibits pharmacological**
6 **activity that justifies commercial development,"**
7 **any other hypothetical statement that you might**
8 **make, you can't expect that anything that you**
9 **come up with to be part of a document.**

10 Q. Does it say in this document that
11 in order for the FDA to permit a clinical study
12 to be undertaken under an IND, that the sponsor
13 must provide evidence that the compound exhibits
14 pharmacological activity that justifies
15 commercial development?

16 A. It says -- it says the sponsor's
17 **primary goal is to determine if the product is**
18 **reasonably safe and if the compound exhibits**
19 **pharmacological activity that just commercial**
20 **development.**

21 That's the sponsor goal, but then
22 **the sponsor has the responsibility to provide**
23 **that information in the IND document for the FDA**
24 **to review.**

25 Q. And you're relying on your own

1 personal knowledge for that requirement, nothing
2 from this Exhibit 1021; is that right?

3 **A. Well, I think the statement is**
4 **fairly clear there as written, that the sponsor's**
5 **goal is to conduct these investigations and then**
6 **present it in the IND document, because they're**
7 **talking about Investigational New Drug**
8 **Applications; and they're defining what is to be**
9 **included in the -- in the IND document.**

10 **Q. Where does it say that this**
11 **information has to be included in the IND?**

12 **A. Well, it says it on the next**
13 **paragraph: Generally this includes data**
14 **information in three broad areas: Animal**
15 **pharmacology and toxicology; manufacturing**
16 **information; and clinical protocols.**

17 **Q. I guess, where does it say that**
18 **animal pharmacology and toxicology studies,**
19 **manufacturing information, and clinical protocols**
20 **and investigator information are included in the**
21 **IND?**

22 **A. Well, I mean, it says, as you**
23 **stated:**

24 **"During a new drug's early**
25 **preclinical development, the sponsor's**

1 primary goal is to determine if the
2 product is reasonably safe for initial
3 human use -- for initial use in humans,
4 and if the compound exhibits
5 pharmacological activity that justifies
6 commercial development."

7 So that's part of the
8 responsibility of the sponsor at the time they're
9 making an IND filing.

10 Marinus announced publicly that
11 they were making an IND filing. You would just
12 need to go up to the FDA website to determine
13 what was their responsibility in the context of
14 making the IND filing. And it clearly
15 demonstrates here that it would be their
16 responsibility to demonstrate that the compound
17 exhibits pharmacological activity that justifies
18 commercial development.

19 Q. And this section doesn't talk about
20 the FDA making a determination as to the --
21 whether it's reasonably likely that a particular
22 compound would be successful in treating whatever
23 indication you're submitting an IND for?

24 A. Well, it -- the way I read that is
25 that the sponsor must have obtained

1 **pharmacological activity that justifies**
2 **commercial development for the indication that is**
3 **being sought in the development program.**

4 Q. You would agree that's the
5 sponsor's primary goal; right?

6 A. Well, the primary goal there --
7 there's two primary goals here. Let's see.

8 One is to determine whether the
9 product is safe; and secondly, if the compound
10 exhibits pharmacological active that justifies
11 commercial development.

12 Q. Would you agree that that's
13 something that the sponsor is determining?

14 A. It's the sponsor's goal to
15 determine.

16 Q. This doesn't state that the FDA is
17 determining if the product is reasonably safe for
18 initial use in humans or if the compound exhibits
19 pharmacological activity that justifies
20 commercial development?

21 A. Well, to me that's the clear
22 implication of this, based on what's written
23 here; and also my own experience, having
24 submitted INDs to the FDA.

25 Q. Do the descriptions of the three

1 broad areas of data and information in the next
2 paragraph of this section -- do any of these
3 discuss in the document evaluating the efficacy
4 of a test compound?

5 **A. Well, again, it's my experience**
6 **that this is routine to include in the IND**
7 **application and that the FDA does indeed review**
8 **them when determining whether an IND should be**
9 **permitted to be opened.**

10 Q. Does data assessing whether a
11 product is reasonably safe for initial testing in
12 humans, does that go towards whether a product is
13 effective for treating a condition in humans?

14 **A. This talks about three broad areas.**
15 **I don't believe it's inclusive. There's other**
16 **documentation that the FDA provides on how to**
17 **submit an IND application that would be more**
18 **complete. This is just simply a summary**
19 **overview.**

20 Q. But, again, these three categories
21 don't -- themselves, that are listed in this
22 document that you cited in your report, don't
23 talk the efficacy -- data involving the efficacy
24 of the compound, does it?

25 **A. Well, again, it states that, during**

1 a new drug's early preclinical development, a
2 sponsor's primary goal is to determine if the
3 product is reasonably safe for initial use in
4 humans, and if the compound exhibits
5 pharmacological activity that justifies
6 commercial development.

7 I think that's as plain as the nose
8 on our faces, that it does require a sponsor to
9 conduct those studies. They're included in the
10 IND document, and the FDA reviews the entire
11 document, is my understanding -- and my
12 experience, I should say.

13 Q. If we go back to Exhibit 1011,
14 which is the first press release I think I gave
15 you, do you agree that the press release in
16 Exhibit 211 [sic] was published on April 15th,
17 2016?

18 A. That's what it states on the first
19 page.

20 Q. And that's about two months earlier
21 than the Phase I press release we discussed on
22 Exhibit 1022, which was June 2016?

23 A. Yes, roughly about two -- two
24 months.

25 Q. That means that this press release

1 was published before Marinus had announced that
2 any healthy volunteers had been dosed with
3 ganaxolone IV for its Phase I clinical trial; is
4 that right?

5 **A. It's hard for me to know exactly**
6 **what Marinus announced, what it didn't announce.**

7 **I am aware of this June 22nd,**
8 **2016, disclosure, based upon the research I did**
9 **for my declaration and the review that we're**
10 **doing now. I don't know of what other**
11 **disclosures they may or may not have made.**

12 **Q. Scrolling to the last sentence of**
13 **the first paragraph in Exhibit 1011, it says:**

14 **"A Phase I clinical trial**
15 **evaluating the safety, tolerability and**
16 **pharmacokinetics of ganaxolone IV is**
17 **expected to initiate in the first half**
18 **of 2016.**

19 **Do you see that?**

20 **A. I do see those words, yes.**

21 **Q. Would that lead you to believe that**
22 **Marinus had not dosed its first subject with**
23 **ganaxolone for its Phase I clinical trial?**

24 **A. It's -- it's hard for me to know**
25 **what they did and did not do, other than to say**

1 **that the words there announce what you read.**

2 **Oftentimes, companies are engaged in activities**
3 **that are not publicly announced.**

4 Q. So this says that they are
5 expecting to initiate their Phase I clinical in
6 the first half of 2016. You don't know based on
7 that statement whether the Phase I clinical had
8 actually begun?

9 A. **I only --**

10 ATTORNEY KANE: Objection; lack of
11 foundation.

12 THE WITNESS: I only know what's
13 written in the document. I can't go beyond there
14 or really provide any additional information
15 beyond that.

16 BY ATTORNEY McDONNELL:

17 Q. Do you have any reason to believe
18 that that statement is incorrect?

19 A. **I'm not aware of any information**
20 **that I have that would -- that would indicate**
21 **that that was not correct, no.**

22 Q. Okay. So the first paragraph, the
23 first sentence states:

24 "Marinus Pharmaceuticals,
25 Inc., a biopharmaceutical company

1 dedicated to the development of
2 innovative therapeutics to treat
3 epilepsy and neuropsychiatric disorders,
4 today announced that the US Food and
5 Drug Administration has granted orphan
6 drug designation to the intravenous
7 formulation of its CNS-selective GABAA
8 modulator, ganaxolone, for the treatment
9 of status epilepticus."

10 Do you see that?

11 **A. I do.**

12 Q. This statement does not state that
13 ganaxolone is effective for treating SE in
14 humans, does it?

15 **A. It states that they were granted**
16 **orphan drug designation to the intravenous**
17 **formulation of ganaxolone for the treatment of**
18 **SE.**

19 Q. And it does not mention that
20 ganaxolone is effective for treating SE in
21 humans; is that right?

22 **A. Well, again, it indicates that they**
23 **were granted orphan drug designation for the**
24 **treatment of status epilepticus.**

25 Q. And it does not say that ganaxolone

1 is effective for treating SE in humans, does it?

2 **A. I don't see the word "effective" in**
3 **that statement that you read.**

4 Q. If you look back at your
5 declaration, at paragraph 125.

6 **A. Yes.**

7 Q. And you -- in this paragraph you
8 talk about a person of ordinary skill in the
9 art's understanding of what it takes to receive
10 orphan drug designation from the FDA; is that
11 right?

12 **A. I do.**

13 Q. And you quote from a regulation in
14 Title 21 of the Code of Federal Regulations that
15 states that the:

16 "FDA must refuse to grant
17 orphan drug designation if there's
18 insufficient information about the drug,
19 or the disease or condition for which it
20 is intended, to establish a medically
21 plausible basis for expecting the drug
22 to be effective in the prevention,
23 diagnosis or treatment of that disease
24 or condition."

25 Is that right?

1 **A. That's what it states here, yes.**

2 **Q. And then you go on to state that a:**

3 "Skilled artisan would have
4 recognized that at the time of
5 designation, sufficient information
6 about ganaxolone had been provided to
7 the FDA to establish a medically
8 plausible basis for ganaxolone to be
9 effective in the treatment of status
10 epilepticus."

11 Is that right?

12 **A. Yes, that's what I stated.**

13 **Q. What is your understanding of what**
14 "medically plausible basis" means in this
15 regulation that you cite?

16 **A. Well, it could be a wide variety of**
17 **types of information. However, there needs to be**
18 **some information; and my understanding is that it**
19 **could be of the sort that Marinus had developed**
20 **with the animal models of status epilepticus, for**
21 **example; but it might not necessarily be those.**

22 **I'm not privy to their orphan drug**
23 **filings, so they might have provided all manner**
24 **of evidence beyond what I'm familiar with. Could**
25 **be various different kinds of data.**

1 What's critical in my mind is that
2 they would not have been, under law, permitted by
3 the federal agency to be granted orphan drug
4 designation had they not provided that
5 information to the agency on a confidential
6 basis.

7 Q. When reading the regulation that
8 you cite, did you consider any regulatory or
9 statutory definitions in Title 21 for what
10 "medically plausible basis" means when you made
11 the statement in paragraph 125?

12 A. Again, I considered the fact that
13 it could be a wide range of types of evidence,
14 either the type of evidence that I was familiar
15 with that was available at that time and that was
16 publicly accessible; or it might have been other
17 types of information.

18 Not being privy to that document, I
19 can't speculate on what was in the document. But
20 what I do know is that they, under law, would
21 have been required to provide a medically
22 plausible basis.

23 Q. Does your interpretation of what
24 "medically plausible basis" means come from your
25 own personal experience then?

1 A. Well, I have been involved in
2 filing orphan drug applications and in preparing
3 material related to defining the medically
4 plausible basis. So I have -- I do have
5 experience personally in that regard.

6 And we were successful in obtaining
7 orphan drug designation, presumably because the
8 FDA accepted the information that was provided in
9 our filings.

10 Q. Does the applicant for organ drug
11 designation determine what -- whether there's a
12 medically plausible basis?

13 A. My understanding, that it's the
14 agency that makes that determination.

15 Q. Okay. Are you aware of any drugs
16 that have been granted FDA orphan drug status
17 that are ultimately found to not be effective in
18 treating the particular condition that orphan
19 drug status was designated for?

20 A. I don't know of any offhand. I'll
21 be surprised if there were many.

22 But, of course if there's medically
23 plausible basis, that does not mean that a
24 specific drug is going to be shown in a specific
25 set of clinical trials to necessarily be

1 **effective. It might be effective and not show**
2 **efficacy in the clinical trial. It might not be**
3 **effective and not show efficacy. All manner of**
4 **different possibilities could -- could occur.**

5 **The issue is whether, at the time**
6 **of filing of the orphan drug application, there's**
7 **a plausible basis for expecting that the drug**
8 **would be effective.**

9 Q. What is your understanding of the
10 purpose for why the FDA grants orphan drug
11 designation for certain drugs?

12 A. **The FDA is required by federal law**
13 **to offer that program.**

14 Q. Do you have any understanding of
15 what the purpose of conferring orphan drug status
16 on a particular compound is?

17 ATTORNEY KANE: Objection; lack of
18 foundation.

19 THE WITNESS: Well, there might be
20 many reasons why Congress decided to enact the
21 orphan drug program. I could perhaps speculate.
22 I don't know how useful my specification would
23 be. I wasn't present at the time the laws were
24 enacted, what was in the minds of the senators
25 and congressmen who created the laws.

1 I can provide some personal view
2 on it, but I don't know how useful that would be.
3 BY ATTORNEY McDONNELL:

4 Q. If you look at the third paragraph
5 of Exhibit 1011, the last sentence it says
6 that -- referring to orphan drug designation:

7 "The designation provides the
8 drug developer with a seven-year period
9 of US marketing exclusivity as well as
10 tax credits for clinical research costs,
11 the ability to apply for annual grant
12 funding, clinical research trial design
13 assistance and waiver of Prescription
14 Drug User Fee Act filing fees."

15 Do you see that?

16 A. Yes, I do.

17 Q. So you said the orphan drug
18 designation process provides certain incentives
19 to a drug developer to apply and receive orphan
20 drug designation status?

21 A. Yes. It looks like there's some
22 incentives there.

23 Q. If you go to -- if you go back to
24 the patent, the '817 Patent, take a look at the
25 claim.

1 So we already discussed that
2 Claim 22 depends from Claim 21 and further
3 requires wherein the pharmaceutical composition
4 provides improvement to the patient after
5 administration for more than eight hours; is that
6 right?

7 **A. Well, that's what the words state,**
8 **yes.**

9 Q. And if we look at paragraph 93 of
10 your declaration.

11 **A. I have it.**

12 Q. And you state that "Zhang does not
13 expressly state that the composition provides
14 improvement for more than eight hours after
15 administration."

16 Do you agree with that?

17 **A. That's what the words state, yes.**

18 Q. Does that mean that you were
19 relying on an inherent anticipation theory for
20 Claim 22, based on Zhang?

21 ATTORNEY KANE: Objection; calls
22 for a legal conclusion.

23 THE WITNESS: Perhaps you could
24 explain what your question means in lay
25 terminology.

1 BY ATTORNEY McDONNELL:

2 Q. So look at paragraph 49 of your
3 declaration. You state that:

4 "It is my understanding that
5 a prior art reference 'anticipates' a
6 claim, and thus renders the claim
7 unpatentable, if all elements of the
8 claim are disclosed in that single prior
9 art reference, either explicitly or
10 inherently (i.e. necessarily present or
11 implied)."

12 So when looking at your statement
13 on paragraph 93, you state that "Zhang does not
14 expressly state the composition provides
15 improvement for more than eight hours after
16 administration," are you relying on your
17 understanding of inherent anticipation?

18 A. Well, perhaps you can explain what
19 you mean by "inherent" in the context of this
20 question.

21 Q. Well, according to your
22 paragraph 49 "inherent" means necessarily present
23 or implied.

24 A. I'm relying on additional
25 information in Zhang than what you're focusing on

1 **here in order to come to the conclusion of**
2 **anticipation.**

3 Q. You continue in paragraph 93 and
4 state that:

5 "In Zhang's Example 8, the
6 rats experiencing SE were sacrificed
7 after five hours and, so, even though
8 some effects of ganaxolone were
9 sustained for the entire five hours,
10 because the experiment was stopped at
11 five hours, there's no data
12 demonstrating a response for more than
13 eight hours."

14 Do you see that?

15 A. **I do.**

16 Q. So you would agree that meant
17 Example 8 of Zhang provides no data beyond the
18 five-hour mark?

19 A. **Again, taking the Zhang disclosure**
20 **in its totality, where it describes multiple**
21 **administrations, multiple dosing schedules,**
22 **various ways of administering, I concluded that**
23 **the reference did anticipate.**

24 Q. I'm just asking, again, about
25 Example 8 of Zhang. You state "because the

1 experiment was stopped at five hours, there's no
2 data demonstrating a response for more than eight
3 hours."

4 Do you disagree with that
5 statement?

6 **A. I don't disagree with that**
7 **statement.**

8 Q. So you would agree then that
9 there's no data in Zhang Example 8 that
10 demonstrates a response for more than eight
11 hours?

12 **A. I don't agree with that, because as**
13 **I stated, taking all of the information within**
14 **Zhang together provides, in my mind, strong**
15 **evidence of anticipation.**

16 Q. So you disagree with the statement
17 that in Example 2 of Zhang, there's no data
18 demonstrating a response for more than eight
19 hours?

20 **A. I do not disagree with anything**
21 **that's written in the declaration, no.**

22 Q. Okay. The next sentence you say:
23 "To the extent that
24 improvement to the patient were to occur
25 after that time period, however, it

1 would be the natural result of
2 administering the ganaxolone
3 formulations in the manner taught in
4 Zhang."

5 (Interruption by the court reporter to
6 clarify the record.)

7 Q. When you say that to the extent
8 that improvement to the patient were to occur
9 after that time period, are you acknowledging
10 that it's possible that the improvement may not
11 be occurring after that time period?

12 A. **I think it's possible that there**
13 **could be improvement, there might not be**
14 **improvement. When one is treating a medical**
15 **condition, there's always a degree of variability**
16 **and one doesn't expect a certain outcome.**

17 Q. So basically, we don't know whether
18 there necessarily would be improvement to the
19 patient --

20 (Simultaneous cross-talk.)

21 A. **I don't think I would characterize**
22 **it as don't know. I would say we probably do**
23 **know that there's going to be variability, but**
24 **that there's a reasonable expectation of**
25 **improvement.**

1 Q. So we go to paragraph 103 of your
2 declaration, you mention that Zhang describes
3 weight-based dosing; and you state that "a person
4 of skill in the art would readily be able to
5 calculate the total daily dose in milligrams."

6 Do you see that?

7 A. **I do.**

8 Q. And then you use 70 kilograms for
9 the average human patient to calculate the total
10 daily dose in milligrams; is that right?

11 A. **Yes.**

12 Q. And you conclude that Zhang's bolus
13 doses of 1 milligram per kilogram to 20-milligram
14 per kilogram for a 70-kilogram patients
15 encompasses each of the amounts recited in
16 Claims 25 through 31; is that right?

17 A. **Yes.**

18 Q. How did you arrive at a 70-kilogram
19 weight for the average weight of the human
20 patient?

21 A. **When I was in medical school, we**
22 **were taught that 70 kilograms is a reasonable**
23 **weight to use for a human. May not relate --**
24 **obviously, every human is not 70 kilograms, but**
25 **it's a reasonable number. Could be more or less.**

1 Q. And why did you decide to use a
2 human patient as the patient that you calculated
3 the weight-based dose on?

4 Let me rephrase the question.

5 Why do you use a human patient to
6 calculate the total daily doses in milligrams
7 that you have in your chart?

8 A. As an example, to relate to a human
9 patient. But, of course, in the circumstances
10 we're discussing, the dosing of Zhang could
11 relate to other types of patients -- other
12 species, because, again, Zhang speaks about
13 different species that could be treated.

14 Q. Could you use a rat to calculate
15 the total daily doses in milligrams?

16 A. You could.

17 Q. So if you look at Example 8 of
18 Zhang again -- it's Exhibit 1009 -- if we go to
19 paragraph 120, which is on page 22, and you see
20 where it says the mean weight of the rats used in
21 Example 8 were 321 plus or minus 3 grams?

22 A. Uh-huh.

23 ATTORNEY KANE: You have to answer
24 yes or no.

25 THE WITNESS: Yes.

1 BY ATTORNEY McDONNELL:

2 Q. So if we used 321 grams as the
3 average weight of a rat and you applied that to
4 Zhang's bolus dose of 1 milligram per kilogram to
5 20 milligrams per kilogram, would you agree that
6 you would get a range of .321 milligrams per day
7 to 6.42 milligrams per day?

8 A. **I'd have to go back and calculate**
9 **that out.**

10 Q. Assuming that's correct, that it
11 equates to a range of .321 milligrams per day to
12 6.42 milligrams per day, you would agree that
13 that's below the lowest dose recited in Claims 25
14 through 31 of the '871 patent?

15 A. **Maybe you could show me where**
16 **you're referring to "per day" there.**

17 Q. I'm just taking this from the
18 claim. I'm using the similar -- sorry. Maybe I
19 meant milligram per kilogram.

20 A. **Okay. So maybe you can restate**
21 **your question.**

22 Q. Sure. So I'm basically making a
23 similar calculation to what you made in your
24 table in paragraph 103 of your declaration. But
25 instead of using the average weight of a human

1 patient that's 70 kilograms, I'm instead using
2 the average weight of a rat that was used in
3 Example 8 of Zhang.

4 ATTORNEY KANE: Object to form of
5 the question.

6 BY ATTORNEY McDONNELL:

7 Q. So you if you get --

8 A. Let me ask you: Why would you use
9 the average weight of a rat from page 22 of
10 Zhang?

11 Q. Is there an average weight of a rat
12 that you would use based on your experience in
13 medical school?

14 A. Rats have a very wide range of
15 weights, based on my experience. I won't
16 speculate on what that range might be but it's
17 very large. There can be very small rats, and
18 you could have very large, older rats.

19 Q. Would you agree that the range that
20 a human patient could weigh is also very large?

21 A. There is a range of weights, yes.

22 Q. Would you agree that it could also
23 be -- it would be very large?

24 A. I don't know how the range relates
25 to that of rats. I know that rats have very

1 **large range of weights. How that relates to**
2 **humans is not something I've thought about or**
3 **studied.**

4 Q. And what is the range of weight for
5 rats that you're aware of?

6 A. Again, I don't want to speculate on
7 what that range might be other than to say it's a
8 very wide range.

9 Q. So sitting here today, you don't
10 know what the average weight of a rat is? Is
11 that accurate?

12 A. Well, it's not even a question that
13 you can answer, because, of course, it's going to
14 depend on the species of the rat, the age of the
15 rat, the sex of the rat and many different
16 factors. So it's not a question I don't think I
17 can answer.

18 Q. Would the weight of a human -- the
19 average weight of a human vary based on the sex
20 of the human?

21 A. It would vary, yes.

22 Q. Would it vary based on the age of
23 the human?

24 A. It would, yes.

25 Q. Okay. So let's assume then that

161

1 the average weight of a rat, whether it's right
2 or not, is the average weight of a rat that's in
3 Example 8 of Zhang. Is that okay?

4 **A. Well, you can assume whatever you**
5 **want.**

6 **Q. Okay. So if we used 321 grams as**
7 **the average weight of a rat, and you applied**
8 **Zhang's bolus dose of 1 milligram per kilogram to**
9 **20 milligrams per kilogram, would you agree that**
10 **you would get a range of .321 milligrams to**
11 **6.42 milligrams?**

12 **A. I would agree that if you did the**
13 **calculation based on your assumption, that's what**
14 **you would get. I'm not endorsing that assumption**
15 **for any purpose.**

16 **Q. And you would agree that, based on**
17 **that assumption, the range that you get is below**
18 **the 500-milligram dose that's the lowest dose**
19 **recited in Claims 25 through 31 of the '817**
20 **Patent?**

21 **A. Again, based on your calculation,**
22 **your -- I can -- I can support your mathematical**
23 **calculations, but I can't support the endorsement**
24 **for any specific purpose.**

25 **Q. Are you aware of any publications**

1 in which 500 milligrams per day or more of
2 ganaxolone was administered to a rat to treat SE?

3 **A. Off the top of my head, I'm not,**
4 **no.**

5 ATTORNEY McDONNELL: Let's take a
6 quick five-minute break.

7 THE WITNESS: Sure.

8 ATTORNEY McDONNELL: Back at maybe
9 2:40?

10 THE VIDEOGRAPHER: This is the end
11 of Media Number 4. Off the record at 2:31 p.m.

12 - - -

13 (Whereupon, a short recess was taken.)

14 - - -

15 THE VIDEOGRAPHER: This marks the
16 beginning of Media Number 5. Back on the record
17 at 2:44 p.m.

18 BY ATTORNEY McDONNELL:

19 Q. During any of the breaks that we've
20 taken today, have you discussed the substance of
21 your testimony with counsel at all?

22 **A. No, I have not.**

23 ATTORNEY McDONNELL: So I don't
24 have any further questions.

25 ATTORNEY KANE: We do not have any

1 further questions at this time, and the witness
2 will read and sign.

3 THE COURT REPORTER: Do you want a
4 rough draft and 2-day turnaround?

5 ATTORNEY KANE: Yes, thank you.

6 ATTORNEY McDONNELL: Thank you.

7 THE VIDEOGRAPHER: This concludes
8 today's deposition of Dr. Michael Rogawski on
9 November 15th, 2023. We are off the record at
10 2:45 p.m.

11 (Whereupon, at 2:45 p.m. the
12 proceedings concluded.)
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I hereby certify that I have read
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changes, if any, are true and correct.

DR. MICHAEL A. ROGAWSKI

1 CERTIFICATE OF SHORTHAND REPORTER

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I, Gail Inghram Verbano, Registered

Diplomate Reporter, Certified Realtime Reporter,

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Public, the officer before whom the foregoing

proceedings were taken, do hereby certify that

the foregoing transcript is a true and correct

record of the proceedings; that said proceedings

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that I am neither counsel for, related to, nor

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CA-CSR No. 8635

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