

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

MARINUS PHARMACEUTICALS, INC.,	) Case No.
	) PGR2023-00020
Petitioner,	)
	)
vs.	)
	)
OVID THERAPEUTICS, INC.,	)
	)
Patent Owner.	)
	)

DEPOSITION OF
DR. MICHAEL ROGAWSKI
Volume I
Thursday, March 28, 2024
--oOo--

Reported by: Michael C. Rowell, California CSR #13494
NCRA Registered Diplomate Reporter
NCRA Certified Realtime Captioner

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APPEARANCES:

For the Patent Owner OVID THERAPEUTICS:

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Also Present: Jennifer Chorazyczewski, videographer

--oOo--

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INDEX OF EXAMINATION

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WITNESS: DR. MICHAEL ROGAWSKI

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EXAMINATION BY

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Mr. McDonnell

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Mr. Kane

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EXHIBITS FOR REFERENCE

9

EXHIBIT NO.

DESCRIPTION

PAGE

10

EXHIBIT 2022

Web page - Ovid Therapeutics
OV320 and GABA-aminotransferase
inhibition

29

11

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EXHIBIT 2023

Email dated 3/26/24 10:06:12 a.m.
FW: EXTERNAL: Consulting
Agreement

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1 BE IT REMEMBERED, that set on Thursday, the
2 28th day of March, 2024, commencing at the hour of
3 1:12 p.m. (PDT) thereof, at the Hilton Sacramento Arden
4 West, 2200 Harvard Street, Sacramento, California,
5 before me, Michael C. Rowell, a Certified Shorthand
6 Reporter of the State of California, there personally
7 appeared

8 DR. MICHAEL ROGAWSKI,
9 having been called as a witness by the Patent
10 Owner, who, having been sworn by me to tell the truth,
11 the whole truth, and nothing but the truth, was
12 thereupon examined and testified as hereinafter set
13 forth:

14 --o0o--

15 THE VIDEOGRAPHER: Good afternoon. We're on	13:12:17
16 the record at -- sorry -- 1:12 p.m. I am Jennifer	13:12:19
17 Chorazyczewski from Henderson Legal Services in	13:12:25
18 Washington, DC. This is a matter pending in the United	13:12:27
19 States Patent and Trademark Office before the Patent	13:12:30
20 Trial and Appeal Board, in the case caption, Marinus	13:12:32
21 Pharmaceuticals, Inc. versus Ovid Therapeutics, Inc.,	13:12:37
22 Case Number PGR2023-00020. This is the beginning of	13:12:44
23 Media 1 of the deposition of Dr. Michael Rogawski on	13:12:49
24 March 28, 2024. This deposition is being held at 2200	13:12:59
25 Harvard Street in Sacramento, California.	13:13:02

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1 Counsel, would you please identify yourself 13:13:05

2 and state who you represent, starting with the 13:13:06

3 questioning attorney. 13:13:08

4 MR. MCDONNELL: Ryan McDonnell from Finnegan, 13:13:10

5 Henderson representing the patentor, Ovid Therapeutics. 13:13:13

6 MR. KANE: Michael Kane from Fish & 13:13:13

7 Richardson, and I'm representing Marinus and the 13:13:13

8 witness. 13:13:18

9 THE VIDEOGRAPHER: Thank you. The court 13:13:18

10 reporter today is Mike Rowell. 13:13:19

11 Mr. Court Reporter, will you please swear in 13:13:22

12 the witness. 13:13:24

13 THE REPORTER: Sure thing. 13:13:26

14 All right, sir. Do you swear or affirm, under 13:13:27

15 penalty of perjury, that the testimony you give in 13:13:27

16 today's proceedings will be the truth, the whole truth, 13:13:27

17 and nothing but the truth? 13:13:27

18 THE WITNESS: I do. 13:13:38

19 THE REPORTER: Thank you. 13:13:39

20 EXAMINATION 13:13:39

21 BY MR. MCDONNELL: 13:13:40

22 Q. Good afternoon, Dr. Rogawski. 13:13:41

23 A. Good afternoon. 13:13:43

24 Q. As a reminder, my name is Ryan McDonnell, and 13:13:44

25 I represent the patentor, Ovid, in this case. 13:13:48

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1	Would you please state your full name for the	13:13:53
2	record?	13:13:54

4 Q. And would you please also state the city and 13:13:57

5 state where you reside for the record? 13:13:59

7 Q. Do you remember that I took your deposition in 13:14:02
8 this matter in November of 2023? 13:14:05

10 Q. Have you been deposed since then? 13:14:08

12	Q. Well, I'll remind you of how this works. I	13:14:11
13	represent Ovid in this case. I'll ask questions, and	13:14:14
14	all that I ask is that you answer my questions	13:14:18
15	truthfully and accurately. If you need to take a break,	13:14:20
16	just let me know, but if we are in the middle of a	13:14:23
17	question, I would ask that you finish answering the	13:14:25
18	question, and then we can take a break.	13:14:27

19	For any reason, if you do not understand a	13:14:29
20	question I ask, please let me know, and I'll try to ask	13:14:32
21	it again. If you answer a question, I will assume that	13:14:35
22	you understood the question.	13:14:38

23 You also need to answer questions verbally, 13:14:40
24 because the court reporter cannot take head nods or head 13:14:43
25 shakes down. 13:14:46

1 Is that okay? 13:14:47

2 **A. I understand, yes.** 13:14:47

3 Q. Your attorney may object from time to time, 13:14:48

4 but it's still okay to answer my questions, unless 13:14:51

5 there's a question as to privilege. For the record, you 13:14:55

6 cannot consult your attorney regarding the substance of 13:14:57

7 your testimony unless it is regarding a question of 13:15:00

8 privilege. 13:15:02

9 Is there any reason why you cannot testify 13:15:03

10 truthfully and accurately today? 13:15:05

11 **A. No.** 13:15:07

12 Q. What did you do to prepare for your deposition 13:15:07

13 today? 13:15:11

14 **A. I re-read the deposition. I looked over some** 13:15:13

15 **of the exhibits, and I talked with my attorneys.** 13:15:17

16 Q. And who specifically did you meet with? 13:15:22

17 **A. I met with Deanna Reichel, with Katie Hyma,** 13:15:27

18 **and I met with the attorney that's with me today as** 13:15:32

19 **well.** 13:15:36

20 Q. And when did you meet with those attorneys to 13:15:37

21 prepare for your deposition? 13:15:39

22 **A. Over the last several -- several days, by** 13:15:41

23 **Zoom.** 13:15:44

24 Q. Do you know about how long you met to prepare? 13:15:45

25 **A. Somewhere in the range of about three hours, I** 13:16:00

8

1 think, three or four hours. 13:16:01

2 Q. Did you meet with anyone from Marinus to 13:16:03

3 prepare for your deposition today? 13:16:05

4 A. I did not, no.

13:16:06

5 Q. Did you review any documents to prepare for 13:16:07

6 your deposition? 13:16:10

[illegible]

8 Q. What documents were those? 13:16:10

9 A. I reviewed several of the exhibits that were 13:16:12

10 cited in the declaration. For example, I reviewed the 13:16:16

11 '817 patent. I reviewed some of the documents that are 13:16:22

12 considered prior art in the matter. 13:16:25

13 Q. And did you review any new documents that you 13:16:27

14 had not previously considered when preparing your 13:16:30

15 declarations in these cases? 13:16:33

16 A. I did look at Marinus' patents covering the 13:16:36

17 same subject matter. I downloaded those from the -- 13:16:44

18 from the patent office website and glanced at them. I 13:16:49

19 didn't study them in detail. 13:16:58

20 Q. Did you decide to review Marinus' patents 13:17:00

21 yourself? 13:17:04

22 A. Yes. I was just curious to know whether they 13:17:04

23 had issued or not. 13:17:08

24 Q. So, I'm going to hand you what has been 13:17:13

25 previously marked as Exhibit 1041. I think you might 13:17:16

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1 have a copy of it already. 13:17:19

2 And do you recognize this document? 13:17:25

3 **A. It appears to be my declaration, which is the** 13:17:28
4 **subject matter of this deposition.** 13:17:32

5 Q. And is this your supplemental declaration that 13:17:35
6 you submitted in this matter? 13:17:39

7 **A. It does say Supplemental Declaration of** 13:17:40
8 **Michael Rogawski on the front sheet.** 13:17:43

9 Q. Okay. And if you turn to page 34, which 13:17:46
10 should be the page number on the bottom of the document, 13:17:52
11 not the -- there's two, but the lowest one. 13:17:55

12 **A. Okay.** 13:17:57

13 Q. Is that your signature on page 34? 13:17:57

14 **A. It is.** 13:18:00

15 Q. Okay. And then I see that you have a document 13:18:00
16 with you. Is that also your supplemental declaration? 13:18:03

17 **A. It is.** 13:18:06

18 Q. Okay. And you're welcome to use either 13:18:07
19 version today. I assume they're the same. 13:18:10

20 **A. I would imagine they are.** 13:18:13

21 Q. And then just to confirm, the version that you 13:18:15
22 brought with you doesn't have any markings or notes 13:18:18
23 taken on it? 13:18:20

24 **A. No. It was handed to me by my attorney just a** 13:18:21
25 **few moments before I entered the room here.** 13:18:24

10

1 Q. Okay. And if I refer to your supplemental 13:18:26
2 declaration, or Exhibit 1041, will you understand that 13:18:30
3 I'm referring to this document? 13:18:32

4 A. Yes, I will. 13:18:36

5 Q. Okay. Sitting here today, are there any 13:18:37
6 changes that you would like to make to your supplemental 13:18:43
7 declaration? 13:18:46

8 A. No. 13:18:46

9 Q. Okay. Are you aware of any errors in your 13:18:47
10 supplemental declaration? 13:18:52

11 A. Not any substantive errors. When I was 13:18:54
12 reviewing it, I saw maybe one or two slight 13:18:57
13 typographical errors. 13:19:05

14 Q. Okay. And how did you prepare your 13:19:07
15 supplemental declaration? 13:19:10

16 A. I -- I reviewed the declaration of Dr. Sankar. 13:19:11
17 I made a series of notes for my attorneys as to my 13:19:17
18 interpretation of and my -- my opinion of statements 13:19:24
19 that were made in that declaration. And I gave that to 13:19:31
20 the attorneys. They helped write a draft of this 13:19:37
21 document, and I extensively edited it. And that -- that 13:19:41
22 was a process that occurred over a period of several 13:19:48
23 days. 13:19:52

24 Q. And did you work with anyone besides the 13:19:54
25 attorneys in preparing your supplemental declaration? 13:19:57

1	A. I did not, no.	13:19:59
2	Q. Okay. Did you speak with Dr. Sharon Baughman	13:20:01
3	in connection with preparing your opinions in your	13:20:12
4	supplemental declaration?	13:20:16
5	A. I did not, no.	13:20:17
6	(Reporter requested clarification.)	13:20:21
7	BY MR. MCDONNELL:	13:20:21
8	Q. Did you read Dr. Baughman's declaration in	13:20:22
9	this proceeding in connection with forming your opinions	13:20:27
10	in your supplemental declaration?	13:20:30
11	A. No, I did not.	13:20:31
12	Q. And about how much time did you spend in the	13:20:35
13	hours preparing your supplemental declaration?	13:20:39
14	A. It was quite a number of hours. It could have	13:20:46
15	been more than eight or even ten hours.	13:20:49
16	Q. And do you plan to supplement your	13:20:55
17	supplemental declaration?	13:20:59
18	A. Not unless the attorneys ask me to.	13:21:00
19	Q. And what materials did you consider when	13:21:01
20	preparing your supplemental declaration?	13:21:04
21	A. As I mentioned, Dr. Sankar's declaration. I	13:21:07
22	read that. And I refreshed my memory about the patent	13:21:12
23	by re-reading the patent. And I also, again, looked at	13:21:19
24	some of the exhibits that are cited in my declaration --	13:21:26
25	or all of them. I have glanced at all of them to	13:21:31

12

1 refresh my memory in cases where I had already studied 13:21:34
2 them in the past. 13:21:36

3 Q. Are all of the materials you considered in 13:21:37
4 preparing your supplemental declaration cited within 13:21:41
5 that declaration? 13:21:44

6 A. I can't recall if I may have glanced at other 13:21:50
7 documents, but I think it's fair to say that the 13:21:57
8 documents that were most important in forming my opinion 13:22:04
9 about the matters that are commented on in the 13:22:08
10 declaration were based on -- on documents that are cited 13:22:11
11 in the declaration. 13:22:16

12 Q. Okay. So, it's fair to say that you aren't 13:22:17
13 aware, sitting here today, of any materials that you 13:22:24
14 considered in drafting your supplemental declaration 13:22:28
15 that aren't cited within your supplemental declaration? 13:22:30

16 MR. KANE: Objection, misstates the reference. 13:22:33

17 THE WITNESS: I believe that that's likely to 13:22:35
18 be the case, yes. 13:22:36

19 BY MR. MCDONNELL: 13:22:37

20 Q. Okay. Did you conduct an independent search 13:22:38
21 for any materials that are cited within your 13:22:44
22 supplemental declaration? 13:22:46

23 A. I did not, no. 13:22:47

24 Q. Okay. So, does that mean that all the 13:22:50
25 materials cited within your supplemental declaration 13:22:52

13

1 were provided to you by counsel? 13:22:54

2 **A. Many of the materials in the supplemental 13:22:57**
3 **declaration formed the basis of my original opinion 13:23:00**
4 **regarding the invalidity of the patent, and so they are 13:23:06**
5 **used here again. I didn't need to rely on any 13:23:12**
6 **additional documents to form my opinions because I felt 13:23:16**
7 **that the materials that we already had uncovered were 13:23:22**
8 **sufficient. 13:23:27**

9 Q. Okay. Since you were last deposed in this 13:23:29
10 matter on November 15th, 2023, have you treated any 13:23:39
11 humans for status epilepticus? 13:23:43

12 **A. I have not, no. 13:23:44**

13 Q. Okay. And if I refer to status epilepticus as 13:23:46
14 SE, is that okay with you? 13:23:49

15 **A. It is. 13:23:50**

16 Q. When was the last time that you treated a 13:23:51
17 human for status epilepticus? 13:23:53

18 **A. Most of the work that I do on status 13:23:59**
19 **epilepticus involves studies in animals, and in -- since 13:24:02**
20 **I had my last declaration, I have had many conversations 13:24:10**
21 **with laboratory personnel, including Dr. Dorota 13:24:14**
22 **Zolkowska, who works in my research lab under my 13:24:25**
23 **supervision about animal studies of status epilepticus. 13:24:29**

24 **But I don't routinely treat status epilepticus 13:24:34**
25 **as a physician, although I do practice medicine 13:24:36**

14

1 regularly. And I do treat patients, but I don't 13:24:42
2 encounter patients regularly who have status 13:24:46
3 epilepticus. 13:24:49

4 So, I can't really say when during my career I 13:24:50
5 might have encountered a patient. 13:24:53

6 Q. Would it be fair to say it was more than ten 13:24:56
7 years ago? 13:24:59

8 A. I think that would be fair to say, yes. 13:25:00

9 Q. More than 20 years ago? 13:25:02

10 A. It's -- it's likely. 13:25:05

11 Q. Do you recall any -- or do you recall how you 13:25:08
12 would have treated the last person that you treated for 13:25:19
13 status epilepticus? 13:25:22

14 A. Well, I should say that I'm regularly engaged 13:25:25
15 in research and teaching on status epilepticus, so I 13:25:33
16 mentioned that I'm regularly -- am engaged in laboratory 13:25:39
17 studies where animals have status epilepticus, and we 13:25:45
18 treat them in the laboratory. So, that's a regular 13:25:52
19 occurrence on a -- and also I teach medical students, 13:25:57
20 residents, other physicians how to -- how to think about 13:26:09
21 treating status epilepticus. 13:26:19

22 I'm scheduled to leave next week for an 13:26:20
23 international meeting on status epilepticus, where I'm 13:26:24
24 going to be lecturing on the treatment of status 13:26:26
25 epilepticus to an international audience. 13:26:30

15

1 Q. But do you recall how you treated the last 13:26:33
2 human that you treated with status epilepticus? 13:26:38

3 A. I do. 13:26:41

4 Q. And how did you treat that human? 13:26:42

5 A. I administered a benzodiazepine, and it very 13:26:45
6 likely would have been lorazepam intravenously. 13:26:51

7 Q. And was that the only drug product you 13:26:55
8 administered to that human? 13:26:57

9 A. I don't believe so. In that particular case 13:26:58
10 that I'm thinking of, I administered phenytoin as well 13:27:01
11 intravenously. The dose would have likely been about 13:27:09
12 one gram of phenytoin intravenously. 13:27:12

13 Q. And were there any other drugs that you 13:27:19
14 administered? 13:27:23

15 A. At the time I treated humans with status 13:27:23
16 epilepticus, phenytoin was the major second line agent. 13:27:28
17 Nowadays, valproic acid are also frequently used. 13:27:35
18 Levetiracetam is, l-e-v-e-t-i-r-a-c-e-t-a-m, I believe. 13:27:54

19 Q. So, you said you administered the 13:28:06
20 benzodiazepine lorazepam, is that correct, as a first 13:28:13
21 line? 13:28:18

22 A. Lorazepam, yes. 13:28:18

23 Q. Lorazepam. When you administer lorazepam 13:28:19
24 intravenously, do you use a bolus dose? 13:28:26

25 A. Typically, yes. 13:28:29

16

1 Q. When you administer phenytoin intravenously, 13:28:31
2 do you typically use a bolus dose? 13:28:39

3 A. Well, it really depends on -- on the 13:28:41
4 situation. You can use both a bolus in some cases and 13:28:43
5 sometimes a continuous infusion. I think probably in 13:28:45
6 the case that we are referring to that -- where I would 13:28:50
7 have treated the patient, it would have been a bolus 13:28:52
8 injection, but it's routine in an intensive care setting 13:28:55
9 to use continuous infusion. 13:28:58

10 Q. And would you use continuous infusion 13:29:02
11 separately from the bolus, or would you use them in 13:29:05
12 conjunction with each other? 13:29:10

13 A. You could use them in conjunction, or there's 13:29:10
14 separate medicines. There's different ways that could 13:29:14
15 be applied to treat status epilepticus. 13:29:18

16 Q. And I believe you said you also had 13:29:20
17 administered valproic acid; is that correct? 13:29:22

18 A. Valproic acid is nowadays frequently used. 13:29:26

19 Q. And do you typically administer valproic acid 13:29:33
20 as a bolus dose? 13:29:38

21 A. It can be administered rapidly as a bolus 13:29:40
22 dose. That's one way to administer it, even though that 13:29:43
23 is not the way that it is specified in the FDA-approved 13:29:47
24 labeling. Approved labeling requires a continuous 13:29:50
25 infusion. 13:29:54

17

1 But there is -- there are studies in the 13:29:56
2 literature demonstrating that a bolus of valproic acid 13:30:00
3 is safe to be administered up to a certain rate, ten 13:30:07
4 milligrams per kilogram or something of that nature. 13:30:13

5 Q. In the FDA-approved labeling for valproic 13:30:18
6 acid, is one of the indications for valproic acid status 13:30:24
7 epilepticus? 13:30:28

8 A. I don't recall if status epilepticus is in the 13:30:29
9 FDA-approved labeling. 13:30:35

10 Q. And I believe the last drug you had mentioned 13:30:37
11 that is commonly used as a second line medicine is 13:30:40
12 levetiracetam; is that correct? 13:30:44

13 A. Yes. 13:30:46

14 Q. And is that also -- levetiracetam, is that a 13:30:46
15 drug that's administered as a bolus dose for treating 13:30:50
16 status epilepticus? 13:30:55

17 A. It can be, yes. I should also add that there 13:30:56
18 are other medicines that are used in the treatment of 13:30:59
19 status epilepticus quite routinely. One would be 13:31:01
20 propofol. Another one would be pentobarbital. Both of 13:31:05
21 those are used, both as a bolus, in bolus dosing, and as 13:31:11
22 a continuous infusion. 13:31:15

23 Q. And you would agree that status epilepticus is 13:31:23
24 an emergency condition, correct? 13:31:25

25 A. It is. 13:31:26

18

1 Q. When you were treating patients for SE, was 13:31:29
2 there a general treatment protocol that you followed? 13:31:32

3 A. There was. 13:31:35

4 Q. And was the general treatment protocol the one 13:31:37
5 that you described earlier? 13:31:39

6 A. It was, yes. 13:31:41

7 Q. And what are the clinical goals of treating 13:31:48
8 SE? 13:31:51

9 A. Well, it's believed that SE can cause 13:31:54
10 potentially serious and permanent brain damage, and 13:32:01
11 potentially death as well. So, the objective is to 13:32:07
12 obtain an improvement, and, of course, the ultimate 13:32:12
13 improvement would be complete cessation of status 13:32:18
14 epilepticus, so-called breaking the status. But other 13:32:23
15 improvements would be desirable as well and could 13:32:28
16 benefit the patient. 13:32:31

17 Q. Is the rapid control of seizures one goal of 13:32:34
18 treating SE? 13:32:37

19 A. It is. 13:32:38

20 Q. And how is the rapid control of seizures 13:32:39
21 achieved? 13:32:42

22 MR. KANE: Objection, vague, lack of 13:32:45
23 foundation. 13:32:46

24 THE WITNESS: Generally, by rapidly 13:32:47
25 administering medications. 13:32:49

19

1 BY MR. MCDONNELL: 13:32:49

2 Q. And is it common to use a bolus dose to 13:32:55

3 rapidly administer a medication? 13:32:58

4 A. It really depends on the -- on the kind of 13:32:59

5 medication and its pharmacokinetic properties. 13:33:01

6 Q. But is it common to use a bolus dose to 13:33:04

7 achieve rapid -- 13:33:07

8 A. It is common, yes. 13:33:08

9 Q. I'm going to hand you what has been previously 13:33:11

10 marked as Exhibit 1053. 13:33:27

11 Have you seen this document before, 13:33:46

12 Dr. Rogawski? 13:33:48

13 A. I believe it's a document that we looked at. 13:33:48

14 It's not a document that I reviewed prior to the 13:33:54

15 deposition today. 13:33:59

16 Q. When you said that you -- it's a document that 13:34:01

17 you looked at, what are you referring to? 13:34:04

18 A. Well, I -- I have -- I have looked at this 13:34:06

19 document in the -- in the past, but as I say, you asked 13:34:09

20 me earlier which documents I used to prepare for the 13:34:12

21 deposition. I did not review this document. 13:34:16

22 Q. Did you review this document in preparing your 13:34:18

23 supplemental declaration? 13:34:21

24 A. I glanced at it, yes. 13:34:23

25 Q. And Exhibit 1053 is titled "The Treatment of 13:34:30

1 Super-Refractory Status Epilepticus: A Critical Review 13:34:35
2 of Available Therapies and Clinical Treatment Protocol." 13:34:38

3 Is that right? 13:34:41

4 **A. Yes.** 13:34:42

5 Q. And Exhibit 1053 was published in 2011; is 13:34:42
6 that right? 13:34:46

7 **A. It does state that it was published in the** 13:34:46
8 **journal Brain in 2011.** 13:34:50

9 Q. If we go to page 2804, the section titled "The 13:34:52
10 Evidence Base of Treatment" in the bottom right column. 13:35:06

11 Do you see that? 13:35:10

12 **A. Uh-huh.** 13:35:12

13 Q. Here, it says: "Super-refractory status 13:35:12
14 epilepticus is uncommon but not rare and yet is 13:35:17
15 ill-studied. We carried out a literature search of all 13:35:21
16 papers reporting therapy in refractory status 13:35:24
17 epilepticus, and we also searched the reference lists of 13:35:27
18 relevant review articles and book chapters and 13:35:30
19 identified 159 papers that formed the evidence base for 13:35:32
20 therapy (some papers describing several therapies)." 13:35:37

21 Do you see that? 13:35:41

22 **A. Uh-huh.** 13:35:41

23 Q. Okay. And then if we go to the first full 13:35:41
24 paragraph on page 2805, which is the same -- it should 13:35:45
25 just be the next paragraph, the second to last sentence 13:35:49

21

1 starts with "none of the widely recommended drugs." 13:35:54

2 Do you see that? 13:35:56

3 **A. Yes.** 13:35:57

4 Q. Okay. And it says: "None of the widely 13:35:57

5 recommended drugs or treatment approaches has been 13:36:01

6 subjected to any sort of systematic review," and then it 13:36:03

7 cites to Table 1. 13:36:09

8 Do you see that? 13:36:11

9 **A. Yes.** 13:36:11

10 Q. And then if we go down to Table 1, which is on 13:36:11

11 the same page, would you consider the list of therapies 13:36:15

12 in the far left column of Table 1 to have been widely 13:36:20

13 recommended drugs or treatment approaches for refractory 13:36:25

14 status epilepticus at the time this article was 13:36:29

15 published? 13:36:31

16 **A. Well, this article is referring to 13:36:31**

17 **super-refractory status epilepticus, so this table 13:36:34**

18 **doesn't relate to refractory status epilepticus. 13:36:38**

19 Q. Would you consider these to be widely 13:36:40

20 recommended drugs or treatment options for 13:36:44

21 super-refractory status epilepticus? 13:36:48

22 **A. Well, according to this paper and the table, 13:36:51**

23 **it appears that the authors considered them as -- in 13:36:57**

24 **their research to determine whether there were any 13:37:10**

25 **published cases in controlled or randomized studies or 13:37:15**

22

1 **in open series.** 13:37:19

2 Q. Do you have any reason sitting here today to 13:37:22
3 disagree with the authors as characterizing the 13:37:26
4 therapies listed in Table 1 as widely recommended drugs 13:37:29
5 or treatment approaches for super-refractory status 13:37:34
6 epilepticus? 13:37:37

7 A. Well, I don't believe there are any accepted 13:37:37
8 treatments for super-refractory status epilepticus. 13:37:43
9 There are treatments that are perhaps tried, but there 13:37:46
10 haven't been any successful clinical trials that would 13:37:56
11 meet, I think, the standard that most of us in the field 13:38:02
12 would accept regarding super-refractory status 13:38:11
13 epilepticus. 13:38:16

14 I should make it clear that super-refractory 13:38:19
15 status epilepticus is a special condition, has a special 13:38:22
16 definition and is not the same thing as refractory 13:38:26
17 status epilepticus. 13:38:29

18 Q. Is super-refractory status epilepticus the 13:38:32
19 same thing as status epilepticus? 13:38:35

20 A. Well, status epilepticus is a broad term, and 13:38:38
21 there are different types of status epilepticus. 13:38:42
22 Super-refractory is a subtype of status epilepticus. As 13:38:45
23 Dr. Shorvon and Ferlisi pointed out, it's a rare form. 13:38:56

24 (Reporter requested clarification.) 13:39:08

25 THE WITNESS: Ferlisi, F-e-r-l-i-s-i. 13:39:04

23

1 BY MR. MCDONNELL: 13:39:11

2 Q. Is pentobarbital considered an anesthetic 13:39:16

3 treatment of status epilepticus? 13:39:22

4 A. It is, yes. 13:39:23

5 Q. And is midazolam also an anesthetic treatment 13:39:24

6 for status epilepticus? 13:39:31

7 A. It's sometimes considered an anesthetic. It's 13:39:32

8 not really an anesthetic agent. It can't be used for 13:39:35

9 surgical anesthesia, and it's not -- it doesn't cause as 13:39:39

10 deep of anesthesia as pentobarbital does. 13:39:44

11 Q. Is propofol considered an anesthetic treatment 13:39:56

12 of status epilepticus? 13:40:00

13 A. And my answer was "yes." 13:40:06

14 Q. Is ketamine an anesthetic treatment for status 13:40:06

15 epilepticus? 13:40:11

16 A. It may be considered by some practitioners to 13:40:15

17 be such. Ketamine is an anesthetic. It's what's 13:40:19

18 referred to as a dissociative anesthetic, so it's 13:40:24

19 different from pentobarbital and propofol. In some 13:40:29

20 centers it may be used, but it's been inadequately 13:40:33

21 studied, however, so there's little information about 13:40:39

22 it. 13:40:41

23 Q. Are you aware what inhalational anaesthetics 13:40:42

24 refers to in Table 1? 13:40:47

25 A. Yes. It refers to anaesthetics that are given 13:40:51

24

1 through a facemask and inhaled by the patient or 13:40:54
2 administered through an endotracheal tube. 13:40:58

3 Q. And then would you classify any of the 13:41:01
4 remaining therapy options in Table 1 as an anesthetic 13:41:04
5 treatment for status epilepticus? 13:41:08

6 A. Well, if I go down the list, I think you've 13:41:14
7 covered the drugs that we would put into the category of 13:41:19
8 anesthetics, and the other treatments, if I'm glancing 13:41:23
9 down the list there, would not generally be considered 13:41:27
10 anesthetics, that's right. 13:41:32

11 Q. Okay. If we could go to page 2810. If we 13:41:33
12 could go to the section entitled "Conclusion" in the 13:41:59
13 right column, and there, it says: "Super-refractory 13:42:02
14 status epilepticus is a serious condition. The 13:42:08
15 mortality rate is substantial, reported in various 13:42:11
16 series between 30 and 50 percent. Yet, despite the fact 13:42:14
17 that it remains an important clinical problem in all 13:42:18
18 neurology centers worldwide, for many therapies and 13:42:22
19 treatment approaches, there's a remarkable lack of 13:42:25
20 published data concerning effectiveness, safety, or 13:42:27
21 outcome. Treatment protocols, therefore, are needed, 13:42:30
22 and in Figure 2, a general approach to treatment is 13:42:33
23 proposed based on the clinical experience in the 13:42:36
24 published literature. Doses and parameters of treatment 13:42:38
25 are shown in Tables 2 and 3." 13:42:41

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25

1 Did I read that correctly? 13:42:46

2 A. Yes. 13:42:47

3 Q. If we could go to page 2812 and look at 13:42:47

4 Table 2, and Table 2 has a list of four anesthetic 13:42:53

5 therapy options for super-refractory status epilepticus; 13:43:06

6 is that correct? 13:43:10

7 A. Yes. 13:43:11

8 Q. And for each of these anesthetic therapy 13:43:11

9 treatment options, they're each administered or 13:43:17

10 recommended to be administered as a bolus and an 13:43:20

11 infusion; is that correct? 13:43:23

12 MR. KANE: Objection, vague. 13:43:25

13 THE WITNESS: Well, if I look through the 13:43:28

14 table, I do see that the table indicates bolus and 13:43:34

15 infusion in many of the -- in many of the entries. 13:43:38

16 There's also NK in some of the entries, which says -- 13:43:44

17 indicates "not known," according to the legend. 13:43:50

18 BY MR. MCDONNELL: 13:43:59

19 Q. When you're referring to it saying "not 13:43:59

20 known," are you referring to the dose recommended for 13:44:02

21 children with ketamine? 13:44:04

22 A. Well, there are two entries for not known, one 13:44:05

23 under the dose recommended for children with ketamine 13:44:08

24 and also the dose -- the range of doses used from the 13:44:10

25 literature review indicates not known. 13:44:13

1 Q. And other than those two instances of the use 13:44:16
2 of not known, all of the other anesthetic therapy 13:44:19
3 treatment options use a bolus and an infusion; is that 13:44:23
4 correct? 13:44:27

5 MR. KANE: Objection, misstates the document. 13:44:27

6 THE WITNESS: Well, in the table, yes. I see 13:44:33
7 in other entries in the table where they're referring to 13:44:37
8 dose. I do see that the authors have indicated bolus 13:44:40
9 and infusion. 13:44:44

10 BY MR. MCDONNELL: 13:44:52

11 Q. Okay. You can set this document aside. 13:44:53

12 You do not hold a doctor of veterinary 13:44:59
13 medicine degree, correct? 13:45:03

14 A. I do not, no. 13:45:04

15 Q. You do not hold any degrees in veterinary 13:45:07
16 science; is that correct? 13:45:09

17 A. I do not, no. 13:45:10

18 Q. You do not hold any veterinary board 13:45:12
19 certifications, correct? 13:45:16

20 A. No. 13:45:17

21 Q. Other than work on animals in a laboratory 13:45:17
22 setting, you do not treat animals, correct? 13:45:20

23 A. I treat animals very frequently in the 13:45:22
24 laboratory setting. Much of my work involves studies on 13:45:25
25 status epilepticus in animals. 13:45:31

1 **Also, I have collaborators with veterinarians,** 13:45:33
2 **particularly at the University of Minnesota, who treat** 13:45:41
3 **animals routinely with status epilepticus, and I confer** 13:45:43
4 **with them on a regular basis.** 13:45:46

5 Q. But other than the work you do on animals in a 13:45:47
6 laboratory setting, you do not treat animals, correct? 13:45:50

7 MR. KANE: Objection, vague. 13:45:52

8 THE WITNESS: I personally don't treat the 13:45:54
9 animals; but as I say, I confer frequently with 13:45:56
10 colleagues. For example, at the School of Veterinary 13:45:58
11 Medicine at the University of Minnesota, we do treat 13:46:01
12 animals with status epilepticus, and they routinely 13:46:03
13 describe their experiences. 13:46:07

14 BY MR. MCDONNELL: 13:46:07

15 Q. You do not consider yourself an expert in 13:46:10
16 veterinary science, correct? 13:46:12

17 A. I am not, no. 13:46:14

18 Q. So, if we could turn back to your supplemental 13:46:15
19 declaration and go to paragraphs 16 and 17. 13:46:19

20 And in paragraphs 16 and 17, you have a number 13:46:35
21 of statements about Ovid; is that correct? 13:46:38

22 A. Yes. 13:46:42

23 Q. And are these your own opinions about Ovid? 13:46:42

24 A. They're my own opinions based upon my general 13:46:47
25 knowledge, and some of the sources that I used to form 13:46:52

28

1 my opinion are indicated in my declaration. I examined 13:46:58
2 Ovid's official website. I reviewed ClinicalTrials.gov, 13:47:05
3 and I reviewed Ovid's financial filings. And based upon 13:47:10
4 my review of all of these various publicly available 13:47:16
5 documents, I formed my opinion. 13:47:23

6 Q. And the opinion you formed was that it is 13:47:25
7 unlikely that Ovid is engaged in the clinical 13:47:29
8 development of a treatment for status epilepticus; is 13:47:32
9 that right? 13:47:34

10 A. Yes. And in addition to this, being involved 13:47:34
11 in the field of epilepsy broadly and status epilepticus 13:47:39
12 treatment research, I talk to many people involved in 13:47:45
13 status epilepticus research and treatment, both from the 13:47:51
14 perspective of animal studies as well as clinical 13:47:58
15 trials. I've never encountered anybody who has been 13:48:01
16 involved in a clinical trial of an Ovid product for 13:48:04
17 status epilepticus. I think it's highly unlikely that 13:48:09
18 they would have been conducting research in status 13:48:12
19 epilepticus. 13:48:12

20 And, for me, being a -- being a member of the 13:48:16
21 community of researchers and clinicians that treats 13:48:23
22 status epilepticus, for me not to be aware of that would 13:48:26
23 have been very, very surprising to me. 13:48:29

24 Q. With respect to the statement in paragraph 16 13:48:31
25 about going on Ovid's official website, is this 13:48:35

29

1 statement based on your own personal experience going to 13:48:39
2 Ovid's website? 13:48:42

3 **A. Yes.** 13:48:43

4 Q. Okay. And when was the last time that you 13:48:44
5 went to Ovid's website to check whether Ovid disclosed 13:48:47
6 any program of research to develop a product for the 13:48:52
7 treatment of status epilepticus? 13:48:54

8 **A. It was certainly as I was drafting the** 13:48:56
9 **declaration. I do believe I checked Ovid's website in** 13:49:00
10 **the last few days as well.** 13:49:06

11 Q. I'll hand you a document that will be Patent 13:49:18
12 Owner's Exhibit 2022. 13:49:23

13 (Whereupon, Exhibit 2022 was marked for 13:49:23
14 identification.) 13:49:23

15 THE WITNESS: If I could maybe revise my last 13:49:31
16 statement, all of my comments related to Ovid's research 13:49:34
17 on ganaxolone, I want to make that very clear, that 13:49:42
18 every one of the statements that I just made about Ovid 13:49:46
19 being involved in research is with respect to ganaxolone 13:49:50
20 for the treatment of status epilepticus. I want to make 13:49:53
21 that very clear. 13:49:56

22 BY MR. MCDONNELL: 13:49:59

23 Q. So, in paragraph 16, where you say, "I am not 13:49:59
24 aware of Ovid having done any of its own clinical study 13:50:03
25 work on ganaxolone or that Ovid is engaged in the 13:50:06

30

1 clinical development of a treatment for status 13:50:10

2 epilepticus," you're saying that's only referring to 13:50:13

3 ganaxolone? 13:50:15

4 A. I'm not sure what I had in my mind at that 13:50:21

5 time, but I can say now that I -- my view is that Ovid 13:50:23

6 is not engaged in research on ganaxolone for the 13:50:32

7 treatment of status epilepticus and never has been. 13:50:35

8 Q. So, I guess why are you making this 13:50:40

9 distinction now, that Ovid is not engaged in any work 13:50:42

10 with respect to ganaxolone? 13:50:49

11 A. Well, firstly, the matter at hand relates to 13:50:50

12 ganaxolone and not other -- other treatments for status 13:50:56

13 epilepticus that Ovid might embark upon. And -- and 13:51:01

14 secondly, I do -- I am aware that Ovid has been 13:51:08

15 considering various clinical indications for one of the 13:51:14

16 products that they have in-licensed. They may have 13:51:19

17 considered status epilepticus as one of the clinical 13:51:24

18 indications for their in-licensed product, but not 13:51:29

19 ganaxolone. As far as I am aware, they have not engaged 13:51:32

20 in research on ganaxolone ever. 13:51:35

21 Q. And how did you become aware of Ovid's 13:51:36

22 development of a drug that they in-licensed for clinical 13:51:40

23 indications related to status epilepticus? 13:51:45

24 A. I believe personnel from the company have 13:51:47

25 mentioned it to me. 13:51:52

31

1 Q. Have you done any consulting work for Ovid? 13:51:53

2 A. Not any paid consulting, no. 13:51:57

3 Q. Have you been on any advisory boards for Ovid? 13:52:00

4 A. I -- oh, yes, yes. I -- I was on an advisory 13:52:04
5 board for Ovid. 13:52:07

6 Q. And what did that advisory board relate to? 13:52:09

7 A. That did relate to -- yes, that did relate to 13:52:13
8 status epilepticus, but not with ganaxolone. 13:52:16

9 Q. And you don't mention this work that you did 13:52:18
10 with Ovid related to status epilepticus in your 13:52:20
11 supplemental declaration; is that correct? 13:52:23

12 A. I don't, no. 13:52:25

13 Q. And you don't mention this consulting work you 13:52:26
14 did with Ovid related to status epilepticus in your CV; 13:52:29
15 is that correct? 13:52:32

16 MR. KANE: Objection, misstates the testimony. 13:52:33

17 THE WITNESS: I don't mention any consulting 13:52:35
18 work in my CV, which is my -- my academic CV, not a 13:52:37
19 reflection of my outside activities that I do outside my 13:52:44
20 academic work. 13:52:50

21 BY MR. MCDONNELL: 13:53:04

22 Q. In the course of your consulting relationship 13:53:05
23 with Ovid, did you receive any confidential information 13:53:07
24 from Ovid? 13:53:12

25 A. I don't think so. But I am not aware -- I 13:53:13

32

1 don't know if I did or not.

2 Q. Did you sign a confidentiality disclosure 13:53:19

3 agreement with Ovid for your consulting work? 13:53:21

4 A. That's generally part of the boilerplate in 13:53:24

5 Ovid's -- in a standard consulting agreement that I 13:53:29

6 would have with any -- any client. 13:53:32

7 Q. And for this particular consulting work you 13:53:35

8 did with Ovid, did you sign a confidentiality disclosure 13:53:37

9 agreement? 13:53:40

A. I can't recall. 13:53:42

11 Q. But you don't have any reason to believe that 13:53:44

```
12      you did not?                                     13:53:47
```

13 A. It would be usual in a consulting arrangement 13:53:47

14 to sign a confidentiality agreement, yes. 13:53:51

15 Q. And when was the consulting work you did for 13:53:54

16 Ovid related to status epilepticus? 13:54:01

17 A. I'd have to look back over my records, because 13:54:04

18 I can't recall. 13:54:06

19 Q. Would it have been in November of 2023? 13:54:07

20 A. It could have been, yeah. 13:54:10

21 Q. Was it in November of 2023? 13:54:11

22 A. I don't recall exactly. 13:54:14

23 Q. Was it within the last year? 13:54:15

24 A. It could have been, yes. 13:54:17

25 Q. But you don't recall if it was within the last 13:54:19

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33

1 year? 13:54:22

2 A. I don't recall precisely, no. 13:54:23

3 (Whereupon, Exhibit 2023 was marked for 13:54:23

4 identification.) 13:54:51

5 BY MR. MCDONNELL: 13:54:51

6 Q. So, I'm going to hand you a document I'm going 13:54:51

7 to mark as Exhibit 2023. 13:54:54

8 A. Okay. 13:54:55

9 Q. If we could go to the second page, do you see 13:54:57

10 an email sent on Monday, November 27th, 2023, at 13:55:04

11 3:58 p.m. on the second page? 13:55:12

12 A. Where are you looking at? 13:55:18

13 Q. There should be an email about a third of the 13:55:20

14 way down the page from Alexis Francomano? 13:55:25

15 A. Yes, okay, I see that, yes. 13:55:31

16 Q. And is your email address Rogawski@yahoo.com 13:55:32

17 that's mentioned in this email? 13:55:39

18 A. Yes. 13:55:40

19 Q. And are you the Dr. Rogawski in the line that 13:55:40

20 says, "Dear Dr. Rogawski"? 13:55:44

21 A. I honestly don't remember this email, but that 13:55:45

22 is my email address. 13:55:48

23 Q. Okay. In the email, it says: "On behalf of 13:55:49

24 Ovid Therapeutics, it is my pleasure to confirm your 13:55:55

25 participation in the upcoming, a next generation GABA 13:55:59

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1 aminotransferase inhibitor" -- 13:56:07

2 (Reporter requested clarification.) 13:56:07

3 BY MR. MCDONNELL: 13:56:10

4 Q. "GABA aminotransferase inhibitor, as a 13:56:11

5 potential treatment of status epilepticus advisory board 13:56:23

6 on November 30th, 2023." 13:56:26

7 Do you see that? 13:56:29

8 A. Yes. 13:56:29

9 Q. And did you participate in that advisory board 13:56:30

10 on November 30th, 2023? 13:56:33

11 A. Well, I should say that I consult for many, 13:56:36

12 many companies on the topic of epilepsy, seizure 13:56:39

13 medicines, and so forth, and I do recall participating 13:56:46

14 in this activity. It's just one of the many, many 13:56:52

15 activities that I participate in. So, they all kind of 13:56:55

16 run together. 13:56:59

17 Q. You can set that aside. 13:57:01

18 A. And if I might, I want to make it very clear 13:57:22

19 for the record that the next generation GABA 13:57:25

20 aminotransferase inhibitor that I believe was the result 13:57:29

21 of that consulting has nothing whatsoever to do with 13:57:34

22 ganaxolone. It's not ganaxolone, and it's not related 13:57:37

23 in any way to ganaxolone, so it's an entirely separate 13:57:39

24 situation. 13:57:43

25 Q. So, would you agree then -- 13:57:47

35

1 **A. And I would also say that -- that there was no** 13:57:49
2 **discussion of ganaxolone during this. I do remember** 13:57:51
3 **that.** 13:57:55

4 **Q. So, would you agree then that Ovid is engaged** 13:57:55
5 **in the clinical development of a treatment for status** 13:57:58
6 **epilepticus?** 13:58:01

7 **A. No.** 13:58:02

8 **Q. Are they involved in the development of a** 13:58:04
9 **treatment for status epilepticus?** 13:58:06

10 **A. I don't know if they are or not.** 13:58:08

11 **Q. Okay.** 13:58:11

12 **A. The evidence that I have is that perhaps** 13:58:17
13 **they've discussed it, and I -- I refreshed my memory** 13:58:21
14 **that I was part of that discussion, but I can't say that** 13:58:30
15 **they're involved in the development of a drug for** 13:58:32
16 **treatment of status epilepticus. And they're certainly,** 13:58:34
17 **as far as I know -- have not been involved in the** 13:58:40
18 **development of ganaxolone for the treatment of status** 13:58:42
19 **epilepticus.** 13:58:45

20 **Q. In paragraph 17, you reference Ovid's annual** 13:58:47
21 **report. This is in your supplemental declaration.** 13:59:18

22 **Do you see that?** 13:59:24

23 **A. Yes, I do.** 13:59:25

24 **Q. Did you read Ovid's entire 2022 annual report?** 13:59:26

25 **A. I did not, no.** 13:59:30

36

1 Q. Was this statement in Ovid's 2022 annual 13:59:31
2 report something that you found yourself? 13:59:36

3 A. I did not, no. 13:59:39

4 Q. Did your counsel direct you to that statement? 13:59:40

5 A. They did. 13:59:42

6 Q. Okay. In paragraph 17, you state that Ovid 13:59:42
7 has stated publicly that its business model is primarily 13:59:50
8 to not develop drugs itself. 13:59:54

9 Do you see that? 13:59:57

10 A. I do. 13:59:57

11 Q. And then later, you point to a statement from 13:59:58
12 Ovid's 2022 annual report that says that Ovid seeks to 14:00:01
13 identify compounds with what Ovid believes is untapped 14:00:05
14 value sitting in other organizations, pipelines, and 14:00:09
15 look to in-license or enter into collaborative 14:00:15
16 agreements to secure such assets and advance clinical 14:00:18
17 development. 14:00:22

18 Do you see that? 14:00:23

19 A. I do. 14:00:23

20 Q. Is it your opinion that advancing the clinical 14:00:23
21 development of a drug is not drug development? 14:00:25

22 MR. KANE: Objection, vague. 14:00:34

23 THE WITNESS: No. 14:00:36

24 BY MR. MCDONNELL: 14:00:41

25 Q. So, if Ovid advances the clinical development 14:00:42

37

1 of drugs, would you consider that to be drug 14:00:45

2 development? 14:00:48

3 **A. Generally, yes.** 14:00:48

4 Q. Okay. You would agree that Marinus did not 14:00:49

5 invent the compound ganaxolone, correct? 14:01:04

6 **A. I do, yes.** 14:01:06

7 Q. Okay. Okay. If we could go to page 17 of 14:01:08

8 your report -- 14:01:18

9 **A. But maybe I should -- should qualify my** 14:01:19

10 **comment by saying that Marinus in-licensed ganaxolone,** 14:01:23

11 **and I have no knowledge that Ovid has ever in-licensed** 14:01:31

12 **ganaxolone for development.** 14:01:35

13 Q. Are the statements in paragraph 17 of your 14:01:42

14 supplemental declaration limited to ganaxolone? 14:01:45

15 **A. Well, the statements are as they're written,** 14:01:51

16 **because it -- the bulk of that paragraph is a quotation** 14:01:55

17 **from the annual report. So, it stands as it is.** 14:02:00

18 Q. Is it your opinion that Ovid has stated 14:02:04

19 publicly that its business model is primarily to not 14:02:17

20 develop drugs itself? 14:02:19

21 **A. I think that the statement that -- that Ovid** 14:02:32

22 **makes is -- is -- is clear from the quote that is in the** 14:02:35

23 **declaration.** 14:02:40

24 Q. Okay. If we could go to page 17 of your 14:02:44

25 report, which is the lower number, and I believe this is 14:02:51

1	Section IV-2.	14:03:02
2	MR. KANE: 17.	14:03:20
3	MR. MCDONNELL: Yeah.	14:03:21
4	MR. KANE: There's two numbers on there.	14:03:22
5	BY MR. MCDONNELL:	14:03:28
6	Q. This should be the section on -- on -- right	14:03:29
7	above paragraph 32.	14:03:31
8	A. Oh, okay.	14:03:35
9	Q. Let me know when you're there.	14:03:43
10	A. Yes.	14:03:45
11	Q. Okay. In this section is your opinion of the	14:03:45
12	meaning of improvement to the patient after eight hours;	14:03:49
13	is that correct?	14:03:53
14	A. That is correct, yes.	14:03:54
15	Q. And if we go to the next page, there's a	14:03:55
16	Section A, called "After Eight Hours."	14:04:02
17	A. Yes.	14:04:04
18	Q. Is this your opinion on the meaning of the	14:04:05
19	phrase "after eight hours"?	14:04:08
20	A. Yes.	14:04:10
21	Q. Paragraph 33, you state that Ovid's	14:04:10
22	interpretation is inconsistent with the '817 patent	14:04:19
23	specification, which explains that an improvement in	14:04:24
24	symptoms refers to a relative change and explicitly	14:04:27
25	states that such a change may be measured in a subject	14:04:30

39

1 prior to treatment and again one or more times after 14:04:33
2 treatment is initiated. 14:04:36

3 Do you see that? 14:04:39

4 A. Yes. 14:04:39

5 Q. And then you cite to the '817 patent at 14:04:40
6 Column 29, lines 57 through 60; Column 9, lines 43 14:04:45
7 through 46; and Column 13, lines 35 through 3; is that 14:04:47
8 right? 14:04:54

9 A. Yes. 14:04:54

10 Q. I'm going to hand you a copy of Exhibit 1001, 14:04:56
11 which is the '817 patent. 14:05:07

12 And let's go to Column 9, lines 43 through 46. 14:05:19

13 And Column 9, lines 43 through 46 of the 14:05:38
14 '817 patent says: "In embodiments, the symptom, 14:05:43
15 pharmacologic, and/or physiologic indicator is measured 14:05:47
16 in a subject prior to treatment, and again one or more 14:05:52
17 times after treatment is initiated." 14:05:54

18 Is that correct? 14:05:56

19 A. I think I'm looking at -- oh, oh, I see. 46, 14:05:57
20 yes, I do see that. 14:06:02

21 If you could re-read that just to make sure 14:06:04
22 we're looking at the same thing, I would appreciate it. 14:06:07

23 Q. Sure. It says: "In embodiments, the 14:06:08
24 symptom" -- 14:06:14

25 A. Hold on. That to me looks like 41, two, 14:06:15

40

1 **three, four -- 44, not 46.** 14:06:19

2 Q. Sorry. I'm reading Column 9, lines 43 through 14:06:21

3 46. 14:06:27

4 **A. Okay, yeah.** 14:06:27

5 Q. And it says: "In embodiments, the symptom, 14:06:28

6 pharmacologic" -- 14:06:34

7 (Reporter requested clarification.) 14:06:39

8 BY MR. MCDONNELL: 14:06:41

9 Q. -- "and/or physiologic indicator is measured 14:06:42

10 in a subject prior to treatment, and again one or more 14:06:45

11 times after treatment is initiated." 14:06:49

12 Is that right? 14:06:56

13 **A. Yes.** 14:06:56

14 Q. And part of that sentence is what you've 14:06:56

15 quoted in paragraph 33 of your supplemental declaration; 14:07:07

16 is that right? 14:07:11

17 **A. Yes.** 14:07:11

18 Q. Okay. The word "improvement" does not appear 14:07:12

19 in Column 9, lines 43 through 46; is that right? 14:07:16

20 **A. Well, it may be implied there, I think,** 14:07:26

21 **because they're talking about measuring.** 14:07:29

22 Q. But the word "improvement" is not explicitly 14:07:31

23 stated -- sorry, could you let me ask the question? 14:07:34

24 The word "improvement" is not stated in 14:07:39

25 Column 9, lines 43 through 46, correct? 14:07:42

41

1 A. That is correct. 14:07:45

2 Q. The phrase "after eight hours" does not appear 14:07:45
3 in Column 9, lines 43 through 46; is that correct? 14:07:48

4 A. I don't see the words "eight hours" there, no. 14:07:52

5 Q. And the word "improvement" does not appear in 14:07:56
6 the paragraph that lines 43 through 46 is in; is that 14:08:06
7 correct? 14:08:10

8 A. Well, I would have to scan down there, but 14:08:11

9 I'll take your word for it if you -- 14:08:13

10 Q. You're welcome to scan, if you would like. 14:08:15

11 A. I may have missed it, but I don't -- I'm 14:08:33

12 not -- on a quick read, I didn't see the word 14:08:38

13 "improvement," no. 14:08:40

14 Q. Okay. If we could next go to Column 13, lines 14:08:41
15 35 through 38, and let me know when you're there. 14:08:45

16 **A. Column 13, lines 35 through 38?** 14:09:05

17 Q. Yes. 14:09:09

18 **A.** Uh-huh. 14:09:10

19	Q. And there, the sentence says: "In	14:09:10
20	embodiments, the symptom, pharmacologic, and/or	14:09:14
21	physiologic indicator is measured in a subject prior to	14:09:19
22	treatment, and again one or more times after treatment	14:09:21
23	is initiated."	14:09:24

24 Is that right? 14:09:25

25 **A. Yes.** 14:09:25

42

1 Q. And is that the same sentence that appeared in 14:09:26
2 Column 9, lines 43 through 46? 14:09:28

3 A. It does appear to be similar. It might be 14:09:41
4 identical. 14:09:44

5 Q. Okay. And, again, the word "improvement" does 14:09:45
6 not appear in Column 13, lines 35 through 38; is that 14:09:47
7 correct? 14:09:52

8 A. Again, I don't see the word "improvement" 14:09:52
9 there, no. 14:09:55

10 Q. The phrase "after eight hours" does not appear 14:09:55
11 in Column 13, lines 35 through 38; is that right? 14:09:58

12 A. I don't see those words, no. 14:10:01

13 Q. And then if we could go to Column 29 and look 14:10:03
14 at lines 57 through 60. 14:10:21

15 A. Okay. 14:10:27

16 Q. And here, it says: "Improvement refers to the 14:10:27
17 treatment of symptoms or conditions associated with 14:10:34
18 epileptic disorders measured relative to at least one 14:10:37
19 symptom or condition of the metabolic disease." 14:10:41

20 Do you see that? 14:10:44

21 A. I do. 14:10:44

22 Q. And I believe in your report you said that you 14:10:45
23 think the reference to metabolic disease is a typo and 14:10:48
24 should instead be epileptic disorders; is that -- 14:10:52

25 A. Yes. 14:10:57

43

1 Q. -- right? 14:10:57

2 And this passage at Column 29, lines 57 14:10:58

3 through 60, does not use the word "initiated"; is that 14:11:07

4 correct? 14:11:11

5 A. In other words, you're asking me whether the 14:11:15

6 word "initiated" is in those lines? 14:11:18

7 Q. That's right. 14:11:21

8 A. I don't see the word "initiated" there, no. 14:11:21

9 Q. Okay. And it also does not say "after 14:11:23

10 treatment is initiated"; is that correct? 14:11:28

11 A. I don't see those words there, no. 14:11:31

12 Q. Okay. 14:11:33

13 THE REPORTER: Mr. McDonnell -- 14:11:33

14 MR. MCDONNELL: Yes? 14:11:33

15 THE REPORTER: -- sometime in the next ten, 14:11:33

16 20 minutes, could I get a break? 14:11:55

17 MR. MCDONNELL: Yeah, we can do one right now. 14:11:55

18 Let's take a quick break. Ten minutes good? 14:11:58

19 THE VIDEOGRAPHER: This is the end of Media 14:12:02

20 Number 1. Off the record at 2:11 p.m. 14:12:04

21 (Whereupon, a recess was taken.) 14:12:20

22 THE VIDEOGRAPHER: This marks the beginning of 14:27:34

23 Media Number 2. Back on the record at 2:27 p.m. 14:27:36

24 BY MR. MCDONNELL: 14:27:41

25 Q. Welcome back. 14:27:43

44

A. Thank you.

2 Q. So, if we go to Section 5 of your report, 14:27:44
3 supplemental declaration, which I think is on -- around 14:27:49
4 paragraph 42. 14:27:53

[illegible]

6 Q. Okay. And then within this section, if we 14:28:16
7 actually go to paragraph 50, you have a section that is 14:28:20
8 Roman numeral V-A3; is that right? It says "Claims 25 14:28:27
9 through 31." 14:28:37

10 **A. Yes.** 14:28:40

11 Q. I just want to make sure there is no section 14:28:40
12 V-A1 in your declaration; is that right? 14:28:46

13 A. That does look like a typographical error. 14:28:56

14	Q. Yeah. I just want to make sure. I wasn't	14:29:01
15	trying to trick you. I just wanted to make sure I	14:29:03
16	wasn't missing anything. And then the same thing for	14:29:07
17	V-A2. I don't think that was in there either; is that	14:29:15
18	right?	14:29:20

19 **A. Right, right, right.** 14:29:20

20	Q. So, if we go back to paragraph 42, then,	14:29:21
21	starting with the second sentence of that paragraph, you	14:29:24
22	state: "Furthermore, I understand, as explained to me	14:29:27
23	by Marinus's attorneys, that Zhang does not need to show	14:29:31
24	an experimental example where ganaxolone was	14:29:35
25	administered to an SE patient (human or otherwise) or	14:29:39

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45

1 data demonstrating clinical efficacy of the same in 14:29:41
2 order to anticipate claim 21. Rather, it need only 14:29:44
3 teach administering a composition comprising ganaxolone 14:29:48
4 or a pharmaceutically acceptable salt thereof 14:29:52
5 intravenously to a patient with status epilepticus 14:29:57
6 (human or otherwise)." 14:29:59

7 Do you see that? 14:30:00

8 **A. Yes, I do.** 14:30:01

9 Q. In that second sentence I read, what do you 14:30:01
10 mean by the word "teach"? 14:30:05

11 **A. That would mean explain in the specification 14:30:09**
12 **of the patent, the -- the performance of -- of that 14:30:17**
13 **activity in order to treat status epilepticus to 14:30:38**
14 **describe how -- how it's done.** 14:30:50

15 Q. So, if we could jump to paragraph 48. 14:30:57

16 **A. Yes.** 14:31:04

17 Q. And you state: "Even transient improvement, 14:31:05
18 for example, during the first five hours, as 14:31:09
19 demonstrated in Zhang's example 8, provides an 14:31:12
20 improvement in the overall risks of adverse consequences 14:31:17
21 of SE, such as brain damage, permanent disability, and 14:31:19
22 death at eight hours and beyond." 14:31:23

23 Do you see that? 14:31:24

24 **A. I do.** 14:31:25

25 Q. You don't cite to any paragraph in Zhang to 14:31:26

46

1 support this statement in paragraph 48 of your 14:31:30

2 supplemental report; is that correct? 14:31:34

3 **A. No, there's no citation for that.** 14:31:36

4 Q. And you don't cite to any data in Zhang to 14:31:38

5 support the statement in paragraph 48 of your 14:31:43

6 supplemental report; is that correct? 14:31:46

7 **A. Well, it's -- it's my expert opinion.** 14:31:51

8 Q. Okay. So, is it fair to say, then, that your 14:31:55

9 opinion in paragraph 48 is based on your expectation 14:32:00

10 that there would be an improvement in the overall risks 14:32:03

11 of adverse consequences of SE at eight hours and beyond? 14:32:06

12 **A. Yes, I think you could say that.** 14:32:15

13 Q. Okay. And then if we go to paragraph 49, you 14:32:18

14 discuss Saporito Poster 1 and Saporito Poster 2 as part 14:32:24

15 of the Anticipation section of your supplemental 14:32:31

16 declaration; is that right? 14:32:33

17 **A. I do.** 14:32:34

18 Q. Are you using Saporito Poster 1 and Saporito 14:32:34

19 Poster 2 as part of your anticipation analysis? 14:32:39

20 **A. In my opinion, Zhang is fully adequate at** 14:32:42

21 **providing anticipation. Saporito Poster 1 and Poster 2** 14:32:49

22 **provide additional evidence, but it's not necessary.** 14:32:56

23 Q. When we took the break earlier, did you 14:33:23

24 discuss the substance of your testimony at all with 14:33:25

25 counsel? 14:33:27

47

1 A. We did not. 14:33:28

2 Q. Okay. 14:33:30

3 MR. MCDONNELL: I do not think I have any 14:33:31

4 other questions. 14:33:33

5 (Discussion held off the record.) 14:33:48

6 MR. KANE: Can you give me five minutes to 14:33:48

7 look at something, and then I'll be back? 14:33:52

8 THE VIDEOGRAPHER: This is the end of Media 14:33:55

9 Number 2. Off the record at 2:33 p.m. 14:33:58

10 (Whereupon, a recess was taken.) 14:37:43

11 THE VIDEOGRAPHER: This marks the beginning of 14:38:03

12 Media number 3. Back on the record at 2:38 p.m. 14:38:05

13 EXAMINATION 14:38:09

14 BY MR. KANE: 14:38:10

15 Q. Dr. Rogawski, I wonder if you could look at 14:38:13

16 the '817 patent, which has been marked as Exhibit 0001? 14:38:15

A. I have it. 14:38:25

18 Q. And if you turn to Column 29, do you recall 14:38:26

19 being asked earlier about the section beginning at 14:38:29

```
20 line 57, that just says: "Improvement refers to the 14:38:35
```

21 treatment of symptoms or conditions associated with 14:38:39

22 epileptic disorders measured relative to the at least 14:38:44

23 one symptom or condition of the metabolic disease"? 14:38:48

[illegible]

25 Q. Okay. And other than the correction there at 14:38:51

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1 the end about metabolic disease, that's your 14:38:57
2 understanding of the use of the word "improvement" in 14:38:59
3 the '817 patent? 14:39:02

4 **A. That's a statement about improvement, yes.** 14:39:11

5 Q. Okay. And then if you turn to -- back to 14:39:14
6 Column 9 of the patent, please. If we look at -- 14:39:17
7 starting at para- -- line 34, beginning of the paragraph 14:39:27
8 states: "In embodiments, the methods described herein 14:39:32
9 are effective to reduce, delay, or prevent one or more 14:39:37
10 other clinical symptoms of an epileptic disorder, such 14:39:42
11 as acute repetitive seizures." 14:39:46

12 Do you see that? 14:39:48

13 **A. I do.** 14:39:49

14 Q. So, do you have an opinion as to whether the 14:39:49
15 reduction, delay, or prevention of clinical symptoms in 14:39:58
16 an -- of an epileptic disorder is an improvement for the 14:40:01
17 patient? 14:40:07

18 **A. Yes, it would be an improvement.** 14:40:08

19 MR. KANE: No further questions. 14:40:11

20 MR. MCDONNELL: I don't have any. 14:40:13

21 THE VIDEOGRAPHER: All right. This concludes 14:40:19
22 today's deposition of Dr. Michael Rogawski. We are off 14:40:21
23 the record at 2:40 p.m. Master media will be retained 14:40:27
24 by Henderson. 14:40:32

25 THE REPORTER: Just for the written record, 14:40:33

49

1 could I ask Mr. Kane, will you be ordering a copy of 14:40:33

2 today's transcripts? 14:40:33

3 MR. KANE: Yes. 14:40:37

4 THE REPORTER: Okay. 14:40:37

5 MR. KANE: Could I get a rough and whatever 14:40:41

6 the order is for the -- 14:40:45

7 MR. MCDONNELL: Same for me. 14:40:50

8 THE REPORTER: Okay. And I had a standing 14:41:00

9 order, a two-day expedite due on Monday for the final; 14:41:02

10 does that sound right? 14:41:03

11 Okay. Thanks. 14:41:04

12 MR. KANE: The witness will read and sign as 14:41:04

13 well. 14:41:08

14 THE REPORTER: Okay.

15 (Thereupon the deposition was concluded at

16 2:41 p.m. [PDT])

17

18 Signed under penalty of perjury:

19

20

DR. MICHAEL ROGAWSKI

21

22

23

Date

24

--oOo--

25

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1 I, MICHAEL C. ROWELL, a Certified Shorthand
2 Reporter of the State of California, duly authorized to
3 administer oaths, do hereby certify:

4 That the foregoing proceedings were taken
5 before me at the time and place herein set forth; that
6 any witnesses in the foregoing proceedings, prior to
7 testifying, were duly sworn; that a record of the
8 proceedings was made by me using machine shorthand which
9 was thereafter transcribed under my direction; that the
10 foregoing transcript is a true record of the testimony
11 given.

12 Further, that if the foregoing pertains to the
13 original transcript of a deposition in a Federal Case,
14 before completion of the proceedings, review of the
15 transcript was requested.

16 I further certify I am neither financially
17 interested in the action nor a relative or employee of
18 any attorney or party to this action.

19 WITNESS WHEREOF, I have this date subscribed
20 my name.

21 Dated: April 1, 2024
22
23

24 *Michael C. Rowell*
25 MICHAEL C. ROWELL, RDR, CRR, CSR NO. 13494

1

--oOo--

2

I, DR. MICHAEL ROGAWSKI, make the
following changes to my deposition taken in the matter
of, MARINUS PHARMACEUTICALS, INC., Petitioner, vs. OVID
THERAPEUTICS, INC., Patentor, Case No. PGR2023-00020

4

5

Date

DR. MICHAEL ROGAWSKI

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