Liquidia vs. United Therapeutics, IPR2021-00406

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Page 142
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             UNITED STATES PATENT AND TRADEMARK OFFICE
                                                                   APPEARANCES OF COUNSEL:
             BEFORE THE PATENT TRIAL AND APPEAL BOARD
                                                                   For Petitioner:
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     LIQUIDIA TECHNOLOGIES,
                                                                               COOLEY LLP
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                             )
                                                                               BY: JONATHAN DAVIES, ESQ.
                             ) IPR 2021-00406
                                                                                    DOUGLAS CHEEK, ESQ.
                Petitioner, ) U.S. Patent No. 10,716,793
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                             ) VOLUME II
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     UNITED THERAPEUTICS
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     CORPORATION,
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                                                               8
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                                                                   For Patent Owner:
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                Patent Owner.)
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                      REMOTE DEPOSITION OF
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                        IGOR GONDA, Ph.D.
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                         MARCH 14, 2022
                                                                   Also Present: Gianni Ortiz, Exhibit Tech
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     Reported by:
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24
     Susan Myong
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     CSR 13365
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25
     Job No. 10097372
                                                              25
                                                     Page 141
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             BEFORE THE PATENT TRIAL AND APPEAL BOARD
                                                                   WITNESS: IGOR GONDA, Ph.D.
                                                                   EXAMINATION BY:
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    LIOUIDIA TECHNOLOGIES. )
                                                                   MR. DYKHUIS
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                Petitioner, ) U.S. Patent No. 10,716,793
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     UNITED THERAPEUTICS
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                Patent Owner.)
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14
              REMOTE DEPOSITION OF IGOR GONDA, Ph.D., a
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              witness herein, taken on behalf of Patent
16
             Owner, at 1:09 p.m., on Monday, March 14,
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                                                                  EXHIBIT 2102
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17
              2022, before Susan Myong, CSR 13365.
                                                                  EXHIBIT 2103
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1	Monday, March 14, 2022	1 A I think that they're all still asleep.
2	1:09 p.m.	2 Q Do you have any communication devices open or
3		3 chat windows or anything of the like for communication
4	THE REPORTER: Pursuant to the Federal Rules of	4 during the deposition?
5	Civil Procedure, I am required to state the following:	5 A No. All that I have at present is the Zoom
6	My name is Susan Myong. My business address is 21143	6 screen.
7	Hawthorne Boulevard, Number 323, Torrance, California	7 Q Do you have any documents with you, Dr. Gonda?
8	90503. This is the deposition of Igor Gonda, Ph.D., in	8 A I got my reply declaration for this case, for
9	the matter of Liquidia Technologies v. United	9 IPR.
10	Therapeutics Corp, beginning at 1:09 Pacific Standard,	10 Q And is that just to confirm, you're talking
11	on Monday, March 14, 2022. This deposition is being	11 about Exhibit 1107?
12	taken remotely with the witness located in Melbourne,	12 A Yes, that's correct.
13	Australia.	13 Q Does that copy have any notes or annotations or
14	Do all counsel agree that I may swear in the	14 markings on it?
15	witness remotely?	15 A No, it does not.
16	MR. DYKHUIS: Yes.	16 Q Other than the reply declaration, do you have
17	MR. DAVIES: Yes.	17 any other documents with you?
18	THE REPORTER: Please state your appearances	18 A No, I don't.
19	and anyone with you, starting with the taking attorney,	19 Q As a reminder, Dr. Gonda, you understand that
20	and then you may begin.	20 even though this is a deposition being conducted
21	MR. DYKHUIS: Yeah. Art Dykhuis with	21 remotely, you're under the same oath as you would be in
22	McDermott, Will & Emery on behalf of the patent owner,	22 court; correct?
23	United Therapeutics Corporation, and with me is	23 A Yes.
24	Josh Revilla also from McDermott.	24 Q And just a reminder to let's try to not
25	MR. DAVIES: Jonathan Davies from Cooley LLP	25 speak over each other and not too quickly for our court
1	Page 145	Page 147
1	for petitioner Liquidia Technologies. And with me	1 reporter. And if you don't understand a question,
2		 reporter. And if you don't understand a question, please let me know. If you do answer, I'll assume you
2 3	for petitioner Liquidia Technologies. And with me today, also from Cooley, is my colleague, Douglas Cheek.	1 reporter. And if you don't understand a question,
3 4	for petitioner Liquidia Technologies. And with me today, also from Cooley, is my colleague, Douglas Cheek. IGOR GONDA, Ph.D.,	 1 reporter. And if you don't understand a question, 2 please let me know. If you do answer, I'll assume you 3 understood the question; is that fair? 4 A Yes.
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2 3 4 5 6 7	for petitioner Liquidia Technologies. And with me today, also from Cooley, is my colleague, Douglas Cheek. IGOR GONDA, Ph.D., a witness herein, having been sworn remotely, testifies	 1 reporter. And if you don't understand a question, 2 please let me know. If you do answer, I'll assume you 3 understood the question; is that fair? 4 A Yes. 5 Q Thank you. 6 A Yes. 7 Q I know that you have a stop later this morning,
2 3 4 5 6	for petitioner Liquidia Technologies. And with me today, also from Cooley, is my colleague, Douglas Cheek. IGOR GONDA, Ph.D., a witness herein, having been sworn remotely, testifies as follows:	 reporter. And if you don't understand a question, please let me know. If you do answer, I'll assume you understood the question; is that fair? A Yes. Q Thank you. A Yes. Q I know that you have a stop later this morning,
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	for petitioner Liquidia Technologies. And with me today, also from Cooley, is my colleague, Douglas Cheek. IGOR GONDA, Ph.D., a witness herein, having been sworn remotely, testifies as follows: EXAMINATION BY MR. DYKHUIS: Q Well, good morning, Dr. Gonda. A Hello. Q Thank you for finding some time for us for this deposition today. Some of this will be sound similar because we've done this a couple times before, but can you just state your full name for the record, please. A Igor Gonda. Q What is your address, sir? A My address in the United States is 683 Main Street, Dennis, Massachusetts ZIP Code 02638. And unit number is B24. But currently I'm at Unit 2, 58-62 Marne Street, South Yarra, Victoria, 3141 Australia. Q And are you at home for the deposition?	 1 reporter. And if you don't understand a question, 2 please let me know. If you do answer, I'll assume you 3 understood the question; is that fair? 4 A Yes. 5 Q Thank you. 6 A Yes. 7 Q I know that you have a stop later this morning, 8 so I'll try to move quickly today. Usually I do take a 9 break every hour or so. If you need a break at some 10 point, we can do that as long as you answer any pending 11 questions; is that fair? 12 A Yes. 13 Q Is there any reason you cannot give full, true, 14 and accurate testimony today? 15 A I'm unaware of any reasons. 16 Q How did you prepare for today's deposition, 17 Dr. Gonda? 18 A I had a conversation with the counsel about the 19 deposition yesterday. 20 Q For how long was that conversation? 21 A About three hours. 22 Q Who participated in that conversation?



igo	igor Gorida, Fil.D. Officed Therapedities, IFK2021-00406				
1	Page 148 Q Who was the other lawyer?	1	Page 150 Q Right. Thank you.		
2	A Deepa, if I can pronounce it, Kannappan. Yeah.	2	MR. DYKHUIS: So, Mr. Ortiz, if you could share		
3	Q Okay. Did you speak with anyone else other	3	an electronic copy of that Exhibit 1107, please.		
4	than that conversation with three lawyers yesterday in	4	Q Dr. Gonda, just let me know when that comes		
5	preparation for today's deposition?	5	through and then I have a couple questions on that.		
6	A No, I did not.	6	A I don't see that. Would it be in the chat?		
7	Q So you mentioned you have a copy of your reply	7	Q I believe it will come through in the chat.		
8	declaration in front of you, Exhibit 1107, in this IPR.	8	There you go. You have the link right now.		
9	A Yes, I do.	9	A Okay.		
10	Q Did you work with counsel to prepare that	10	MR. DYKHUIS: Oh, so this is the wrong one.		
11	declaration?	11	This is 1007. Can we have 1107, please.		
12	MR. DAVIES: Objection. Form.	12	•		
13	THE WITNESS: Sorry. Could you please repeat	13	•		
14	the question.	14	,		
15	BY MR. DYKHUIS:	15	Q And then while we're waiting for that one to		
16	Q Did you work with counsel to prepare the	16			
17		17			
18	A Yes, I did.	18	•		
19	MR. DAVIES: Objection to form.	19	A No, I did not.		
20	You can answer.	20	Q So now you should have a copy of 1107.		
21	THE WITNESS: Yes, I did.	21	A Yes, I do.		
22	BY MR. DYKHUIS:	22	Q And is that 1107 the same document as what you		
23	Q Which counsel did you work with to prepare the	23	-		
24		24	A I believe it is.		
25	A You know, I don't recall who are the people,	25			
	Touristic, Fuent result will are the people,	-0	Q 00 1001 1100 to 1001k at officer officer 1 just		
1	Page 149 but I think that it was the same three people that I	1	Page 151 wanted to confirm that we're looking at the same thing.		
2		2	A Okay.		
3	Q Okay. Who did you work with the most of	3	Q On the last page of the declaration		
4	Mr. Davies, Mr. Cheek, and Ms. Kannappan?	4	A Yes.		
5	MR. DAVIES: Objection. Form.	5	Q is that your signature on page 50?		
6	THE WITNESS: Mr. Douglas Cheek.	6	A It is.		
7	BY MR. DYKHUIS:	7	Q Is everything in this reply declaration true as		
8	Q There's also a litigation between United		far as you know?		
9	Therapeutics and Liquidia; correct? Are you aware?	9	A As far as I know, it is.		
10	A You mean the district court litigation.	10	Q Could you turn to paragraph 34, please. Just		
11	Q Right.	11			
12	A Yes. I'm aware of that, yes.	12	A Yes, I'm working on it.		
13	Q Did you work with the same counsel to prepare	13	Q Again, feel free to use the electronic or paper		
14	expert reports in that litigation?	14			
15	MR. DAVIES: Objection. Scope. Form.	15	A I'm using the electronic copy. Thirty-four,		
16	THE WITNESS: Can I answer?	16			
17	MR. DAVIES: You can answer that, but you	17	Q On paragraph 34, on page so it starts on		
18	can go ahead and answer that. That's okay.	18	page 25 and continues on to page 26. On page 26, the		
19	THE WITNESS: Yeah. There was one other	19	third line, you make a reference to water as the "By		
20	counsel involved from Cooley.	20	far the most common and likely only solvent used in		
21	BY MR. DYKHUIS:	21	FDA-approved nebulizer solutions in May 2006."		
22	Q And who was that?	22	And then at the end of paragraph 35 [sic], you		
23		23	state, "A POSA reading Voswinckel, J-E-S-C, JESC, would		
24		24	have reasonably assumed that the inhaled solution of		
	,		treprostinil was aqueous."		
120	Yup.	_ <u>_</u>	נו בטו טטנוווו אמט מעעבטעט.		

Page 154 Page 152 1 Do you see that text? 1 you do? 2 BY MR. DYKHUIS: 2 Yes, I do. Q Is there -- in the context of a continuous 3 Q If you covered or plugged the mouthpiece on the 4 nebulizer -- let me back up actually. nebulizer and then you run the nebulizer in a continuous 5 You recall the Voswinckel JESC reference as mode -- are you with me so far? 6 describing a continuous nebulizer; correct? 6 A Yes. A Yes. 7 Q -- eventually the air inside the nebulizer will 7 8 Q In the context of a continuous nebulizer, such become saturated with the aerosol; correct? 9 as that in Voswinckel JESC and a solution prepared using 9 MR. DAVIES: Objection. Form. water as the solvent, is there a maximum of how much 10 THE WITNESS: Yes. It would be accumulating. 11 water the air can hold as an aerosol upon nebulization? I'm not sure that it's going to be saturated, but it 12 MR. DAVIES: Objection. Form. will be accumulating. Now, I think, what I said before, 13 THE WITNESS: Yes, there is a limit to how the balance between the amount evaporated and the amount much -- sorry. Can you please just explain the question in the water droplet might be changing, yes. 14 15 15 Yeah. I don't know what you're getting at, so 16 BY MR. DYKHUIS: can you just --16 17 Q So --17 BY MR. DYKHUIS: 18 18 Q Well, what I'm --A Can you just rephrase it. Yes. 19 Q Sure. 19 A -- just explain what is the context of this, 20 Is there a limit as to how much water or 20 please. 21 21 nebulized drug solution that the air can hold as an Q Sure. I'll get there. 22 aerosol after nebulization? 22 I'm thinking of the word "condensation." I 23 23 MR. DAVIES: Objection. Form. don't know if that's the right terminology. But in the 24 You can answer. question I posed to you, with an OptiNeb nebulizer and 25 THE WITNESS: I don't understand the question the mouthpiece is capped and it's running in a Page 153 Page 155 1 "hold." There is no limit, provided that you've got 1 continuous mode -enough air. And then, of course, it will depend on the 2 A Yes. I mean, it's a hypothetical question. 2 3 I don't know why anybody would be using a continuous 3 temperature and humidity of the air. How much of that 4 material is in the liquid phase and how much has nebulizer with the mouthpiece plugged. I mean, I just don't understand why we are discussing it. 5 evaporated. So it's a complicated question that you're 6 asking. But in principal, no, there is no limit. 6 Q Sure. Yeah, no. That's fine. We'll get 7 there. 7 BY MR. DYKHUIS: 8 Q So if you have a finite quantity of air, then So my question is: You have talked about the 8 you would have a limit as to how much aerosol could be rate for continuous nebulizers before and their rate of 10 held in the air, depending on temperature and humidity output. And my question for you is: If the mouthpiece 11 as well; correct? on a nebulizer was capped, wouldn't the rate of the 12 A Yes. 12 nebulization slow down as the air inside the nebulizer 13 MR. DAVIES: Objection. Form. 13 becomes saturated with aerosol? 14 BY MR. DYKHUIS: 14 MR. DAVIES: Objection. Form. Q If you -- the Voswinckel JESC article, or 15 THE WITNESS: There is -- it's not called 15 abstract, identifies an OptiNeb nebulizer. condensation. It's called sedimentation. So some of 16 17 Do you remember that? 17 the droplets would sediment, but that still would not 18 A Yes. 18 have a big impact on output. No. 19 BY MR. DYKHUIS: 19 Q If you took the OptiNeb or a different 20 ultrasonic nebulizer and you capped or plugged the 20 Q So you said -- so if a nebulizer was running in continuous mode and the mouthpiece is capped, it's your 21 mouthpiece -- are you with me so far? Just cover the 22 22 opinion that the output would maintain essentially the mouthpiece up. Does that make sense so far? 23 23 MR. DAVIES: Objection. Form. same, no matter how long the nebulizer continued 24 24 running? THE WITNESS: The only -- sorry. You would 25 stop -- can vou just repeat it. You would -- what would 25 MR. DAVIES: Objection. Form.



Page 158 Page 156 1 Do you see that? You can answer. 1 2 THE WITNESS: No. But I just said it's a 2 A Correct. 3 hypothetical question because in reality, the nebulizer 3 Q Do all ultrasonic nebulizers have an efficiency 4 would be -- the mouthpiece would be open because the 4 of 86 percent? 5 patient -- the subject is inhaling on it. So I just 5 A No. 6 don't understand why we are discussing it. I mean, if 6 Did all ultrasonic nebulizers in 2006, have an 7 it is in the -- yeah, if it is in continuous mode, then 7 efficiency of 86 percent? 8 8 the aerosol would be either going out into the patient Α No. 9 or it would be coming out of the mouthpiece when the 9 Q But some ultrasonic nebulizers in 2006, would patient is exhaling. So I just don't understand what is have an efficiency of lower than 86 percent; correct? 11 the situation in reality that this would represent. 11 MR. DAVIES: Objection. Form. 12 BY MR. DYKHUIS: 12 THE WITNESS: That is possible. 13 13 Q So when a patient breathes, they inspire, and But in the context of JESC, that group of 14 then they might either immediately breathe out or they 14 people, addition, were in a number of the publications 15 might hold their breath momentarily; is that correct? emphasizing that they are striving towards high A Yes. But with continuous nebulization there is efficiency, rapid nebulization to increase the 16 16 17 not -- usually it is not recommended that the patient 17 convenience for patients. So I would have expect that will hold their breath. They continuously -- they whatever that group was using in that abstract, which 19 breathe normal. was quite late in the process -- the product development 20 Q And when the patient breathes out, they keep for pulmonary artery hypertension treatment with 21 their mouth on the mouthpiece; correct? prostacyclin, that they would have used one of the 22 A There is usual -- yes. Yeah. They will keep higher efficiency nebulizers. 23 typically their mouths on the mouthpiece if it's usually BY MR. DYKHUIS: 24 an exhaust valve. 24 Q But as far as my question, some ultrasonic 25 Q Can the humidity -- excuse me. You mentioned nebulizers in 2006, would have had an efficiency of Page 157 Page 159 earlier temperature and humidity. lower than 86 percent; correct? 1 2 Both of those things affect how much aerosol 2 MR. DAVIES: Objection. Form. 3 THE WITNESS: Yes. 3 can be held in the air; correct? 4 A Yes. 4 MR. DAVIES: You can answer. 5 Q Could temperature and humidity have an effect 5 THE WITNESS: That -- yes. 6 on the rate of nebulization from a continuous ultrasonic 6 BY MR. DYKHUIS: 7 nebulizer? 7 Q Do you have an opinion on how many ultrasonic A They have relatively smaller effect than the nebulizers were available and known to the POSA in 2006? 8 jet nebulizers. There is some effect, but it's 9 A I really wouldn't know how many ultrasonic nebulizers were familiar to the POSA, no. relatively small. 10 10 11 Q Let's look at paragraph 22 in your reply 11 Q Do you think it would be ten or more? declaration, please. And just let me know when you're 12 A Yes. That would be a reasonable number, yeah. 13 Q Could it be 20? 13 there, Dr. Gonda. 14 A I don't think that a POSA would have considered 14 A Yes, I'm there. So on the first sentence, you reference as many as 20, no. 15 Q 15 16 Professor McConville and his position regarding 16 Q Let me make sure I understand. You said -- you nebulizer devices can have a wide variety of 17 used the word "considered." 17 18 efficiencies. 18 Do you think that there were publicly available 19 19 or in existence in 2006, at least 20 ultrasonic You see the first sentence in your -- in 20 nebulizers? 20 paragraph 22? 21 21 A Yes, I do. MR. DAVIES: Objection. Form. 22 22 Q And then about halfway down the page, still in THE WITNESS: I would say I probably would have paragraph 22, you say, "In fact, the only ultrasonic 23 been aware of 5 to 10 ultrasonic nebulizers, but not 20. nebulizer cited by Professor McConville had an 24 No.



25 efficiency of 86 percent."

25 ///

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