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Transcript of Daniel Stamer, Ph.D.

Date: February 13, 2025

Case: Dr. Reddy's Laboratories, S.A., et al. -v- Eye Therapies, LLC (PTAB)

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WORLDWIDE COURT REPORTING & LITIGATION TECHNOLOGY

Transcript of Daniel Stamer, Ph.D.
Conducted on February 13, 2025

1 (1 to 4)

1	2	3
1 UNITED STATES PATENT AND TRADEMARK OFFICE	1 A P P E A R A N C E S	
2 -----	2	
3 BEFORE THE PATENT TRIAL AND APPEAL BOARD	3 ON BEHALF OF PETITIONERS:	
4 -----	4 CHRISTOPHER J. CASSELLA, ESQUIRE	
5 DR. REDDY'S LABORATORIES S.A. and	5 GOODWIN PROCTER LLP	
6 DR. REDDY'S LABORATORIES, INC.,	6 1900 N Street NW	
7 Petitioners,	7 Washington, DC 20036	
8 v.	8 202.346.4000	
9 EYE THERAPIES, LLC,	9	
10 Patent Owner.	10 ON BEHALF OF PATENT OWNER:	
11 -----	11 CHRISTINA YANG, ESQUIRE	
12 Case No. IPR2024-00467; IPR2024-00563	12 BRYAN C. DINER, ESQUIRE	
13 U.S. Patent No. 11,596,600	13 FINNEGAN, HENDERSON, FARABOW, GARRETT &	
14	14 DUNNER, LLP	
15 DEPOSITION OF DANIEL STAMER, PH.D.	15 901 New York Avenue NW	
16 APPEARING REMOTELY FROM WASHINGTON, D.C.	16 Washington, DC 20001	
17 THURSDAY, FEBRUARY 13, 2025	17 202.408.4116	
18 9:00 A.M.	18	
19	19 ALSO PRESENT:	
20 Job No.: 569761	20 Jose Gonzalez - Videographer	
21 Pages 1 - 50	21 Miles Tag - Remote Technician	
22 Reported by: Adrienne M. Mignano, RPR	22	
2	4	
1 Deposition of DANIEL STAMER, PH.D., held via	1 C O N T E N T S	
2 Zoom videoconferencing, pursuant to Notice, before	2 EXAMINATION OF WILLIAM D. STAMER, PH.D. PAGE	
3 Adrienne M. Mignano, a Registered Professional	3 By Mr. Cassella 7	
4 Stenographic Reporter and Notary Public in and for the	4	
5 State of New York and Washington D.C.	5	
6	6 E X H I B I T S	
7	7 (Attached to the transcript)	
8	8 STAMER DEPOSITION EXHIBITS PAGE	
9	9 Exhibit 1 Declaration of Dr. W. Daniel 17	
10	10 Stamer, Ph.D. in Support of	
11	11 Plaintiffs' Motion for a	
12	12 Preliminary Injunction	
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16	16 a Preliminary Injunction	
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21	21	
22	22	

5 1 REMOTE TECH: Thank you to everyone 2 for attending this proceeding remotely, which we 3 anticipate will run smoothly. Please remember 4 to speak slowly and to do your best not to talk 5 over one another. 6 Please be aware that we are recording 7 this proceeding for backup purposes. Any 8 off-the-record discussions should be had away 9 from the computer. Please remember to mute your 10 microphones for those conversations. 11 Please have your video enabled to 12 help the reporter identify who is speaking. If 13 you are unable to connect with video and are 14 connecting via phone audio, please identify 15 yourself each time before speaking. 16 I apologize in advance for any 17 technical-related interruptions. Thank you very 18 much. 19 THE VIDEOGRAPHER: Please stand by 20 for video. 21 Here begins Media Number 1 in the 22 videotaped deposition of Dr. Daniel Stamer in	7 1 Whereupon, 2 W. DANIEL STAMER, Ph.D., 3 being first duly sworn or affirmed to testify to 4 the truth, the whole truth, and nothing but the 5 truth, was examined and testified as follows: 6 EXAMINATION BY COUNSEL FOR THE PETITIONERS 7 BY MR. CASSELLA: 8 Q Good morning, Dr. Stamer. 9 A Good morning. 10 Q How are you? 11 A I'm doing well. How about yourself? 12 Q I'm doing well, thanks. 13 Could you please state your full name 14 for the record. 15 A Sure. William Daniel Stamer. 16 Q And what is your home address? 17 A 3206 Horsebarn Drive, Durham, North 18 Carolina. 19 Q And where are you currently located? 20 A I'm in the Finnegan offices in 21 Washington, DC. 22 Q Is there anyone in the room with you?
6 1 the matter of Dr. Reddy's Laboratories S.A., 2 et al. versus Eye Therapies, LLC, et al. (PTAB) 3 in the United States Patent and Trademark Office 4 before the Patent Trial and Appeal Board, Case 5 Number IPR2024-00467, IPR2024-00563. 6 Today's date is February 13th, 2025. 7 The time on the video monitor is 9:01. The 8 remote videographer today is Jose Gonzalez, 9 representing Planet Depos. All parties of this 10 video deposition are attending remotely 11 Would counsel please voice identify 12 themselves and state whom they represent. 13 MR. CASSELLA: Good morning. This is 14 Chris Cassella, from the law firm Goodwin 15 Procter, on behalf of the petitioners. 16 MS. YANG: This is Christina Yang, 17 from Finnegan, on behalf of the patent owner and 18 the witness. Also with me is Bryan Diner, from 19 Finnegan as well. 20 THE VIDEOGRAPHER: The court reporter 21 today is Adrienne Mignano, representing Planet 22 Depos. The witness will now be sworn.	8 1 A Yes. There is Mrs. Yang and 2 Mr. Diner. 3 Q Anyone else? 4 A No. 5 Q Do you have any documents in front of 6 you? 7 A I do. I have two binders with 8 unmarked copies of my exhibits. 9 Q So those binders contain your 10 declarations that you submitted in connection 11 with the IPRs that were just -- the IPR numbers 12 that were just read aloud; is that right? 13 A That's right. 14 Q And you have clean copies, you said? 15 A That's correct. 16 Q So no markings, handwriting or 17 annotations on any of the declarations or 18 exhibits? 19 A That's correct. 20 Q Did you do anything to prepare for 21 your deposition today? 22 MS. YANG: Objection to the extent

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9 1 that it calls for privileged information. I 2 caution the witness not to reveal any substance 3 of communications with the attorneys. 4 A Yes, I met with my attorneys prior to 5 this deposition. 6 Q Who did you meet with? 7 A With Ms. Yang and Mr. Diner. 8 Q And when did you meet with them? 9 A Yesterday. 10 Q For about how long did you meet with 11 them yesterday? 12 A It was about six hours, I guess. 13 Q Did you review any documents with 14 your attorneys yesterday? 15 MS. YANG: Same caution. 16 A Went through the -- what's in the 17 binders, essentially, the declaration and 18 exhibits. 19 Q Do you recall which exhibits you 20 reviewed specifically? 21 MS. YANG: Same caution. 22 A We reviewed a bunch of different	11 1 need to. 2 A Sounds good. 3 REMOTE TECH: Sir, this is the tech. 4 I just wanted to ask, the documents already have 5 the EX-2225. Did you want them marked as new 6 exhibits, 1 and 2? 7 MR. CASSELLA: No, these are already 8 exhibits in the IPRs. Thanks. 9 REMOTE TECH: All right. One moment. 10 '245 should be on screen. And if you 11 need me to go to the '600, just let me know. 12 It's right over here. 13 MR. CASSELLA: Okay. 14 Q Dr. Stamer, do you see the cover page 15 of the document titled "Declaration of 16 Dr. W. Daniel Stamer, Ph.D." with the -- in the 17 bottom right corner of this page, the IPR 18 caption "IPR2024-00467"? 19 A Yes. 20 Q And does this appear to be a true and 21 correct copy of the declaration that you 22 submitted in connection with the IPR on the '245
10 1 ones. 2 Q I believe you testified that you 3 submitted declarations in connection with these 4 IPRs, correct? 5 A Yes. 6 MR. CASSELLA: If we could have the 7 tech pull up the '245 declaration. There's two 8 declarations. They are titled -- they both have 9 "EX-2225 - Stamer Declaration," but the one is 10 annotated "'245 Patent" and the other is 11 annotated "'600 Patent." We can go ahead and 12 pull both of those up. We can look at one at a 13 time. 14 Q And Dr. Stamer, if you have hard 15 copies of these documents in front of you, feel 16 free to refer to those if that's easier. I'm 17 still going to ask the technician to display the 18 documents that I'm referring to on the screen 19 just for the benefit of the court reporter and 20 just so that everyone is sort of looking at the 21 same page to the extent possible. But please 22 feel free to refer to your hard copies if you	12 1 patent? 2 A It does. 3 Q If we could go to page 54 of the 4 document itself. And Dr. Stamer, do you see on 5 page 54 of this '245 declaration your signature 6 and date? 7 A Yes, I do. 8 Q And is that, in fact, your signature 9 on page 54 of this declaration? 10 A It is. 11 Q And did you sign this document on 12 November 19th, 2024? 13 A Yes. 14 Q Sitting here today, do you have any 15 corrections to make to your '245 declaration? 16 A No. I stand by what's in there. 17 Q Okay. 18 MR. CASSELLA: If I could have the 19 technician pull up the '600 declaration, please. 20 REMOTE TECH: On screen. 21 Q And Dr. Stamer, do you see displayed 22 on the screen the cover page of a document

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13 1 titled "Declaration of Dr. W. Daniel Stamer, 2 Ph.D.," this one with the caption in the bottom 3 right-hand side "IPR2024-00563"? 4 A Yes. 5 Q And does this document appear to be a 6 true and correct copy of the declaration you 7 submitted in connection with the IPR concerning 8 the '600 patent? 9 A It does. 10 Q And if we could go to page 53 of this 11 document, please, and on page 53 of this 12 declaration, is that your signature dated 13 December 2nd, 2024, Dr. Stamer? 14 A Just a second. 15 Yes, it is. 16 Q And sitting here today, do you have 17 any corrections to make to your declaration 18 concerning the '600 patent? 19 A I don't. 20 Q Did you draft these declarations? 21 A I drafted them in association with my 22 attorneys, yes.	15 1 with the attorneys. 2 A I worked with my attorneys to draft 3 these documents, just my attorneys. 4 Q So no, you did not speak with anyone 5 else in preparing these declarations, correct? 6 A No, just my attorneys. 7 Q Okay. So you didn't speak to, for 8 example, any patent owners, other experts in 9 these IPRs, correct? 10 A No. 11 Q Now, you also submitted a couple of 12 declarations in connection with preliminary 13 injunction proceedings in the District of New 14 Jersey concerning the '245 patent, correct? 15 A I'm sorry, say that again? I missed 16 that. 17 Q So if you recall, there were 18 preliminary injunction proceedings in connection 19 with a district court litigation in the District 20 of New Jersey that concerned the '245 patent, 21 which is the subject of one of your 22 declarations, correct?
14 1 Q Would you agree with me that the 2 substance of these two declarations is quite 3 similar? 4 A Yes. 5 Q Okay. So throughout the day I think 6 I will refer only to the '245 declaration, just 7 to save some time and be a little more 8 efficient, if that's all right with you. 9 A I like that idea. 10 Q Feel free to refer back to your '600 11 declaration if you need to at any time. 12 A Okay. 13 Q Now, I believe you testified that you 14 worked with counsel in drafting these 15 declarations, correct? 16 A Correct. 17 Q Did you speak to anyone other than 18 counsel in preparing these declarations? 19 MS. YANG: Objection to the extent 20 the question calls for a legal con- -- 21 privileged information, I caution the witness 22 not to reveal any substance of communications	16 1 A Yes. So this is referring to about a 2 year ago? 3 Q Yes, the hearing was just over a year 4 ago, I believe. 5 A Yeah. Yeah, I was involved with 6 that. 7 Q And you submitted a couple of 8 declarations in connection with those 9 preliminary injunction proceedings, correct? 10 A Correct. 11 MR. CASSELLA: Okay. If the tech 12 could please pull up -- the file name is "PI - 13 Stamer First Declaration," and the other file 14 name is "PI - Stamer Second Declaration." And 15 we can just look at the first one first. 16 REMOTE TECH: Yes, sir. Did you need 17 this marked? 18 MR. CASSELLA: Yeah, this is not a 19 previous exhibit, to my knowledge, so you can 20 just mark it Stamer 1. 21 REMOTE TECH: All right. One moment. 22

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17	19
1 (Stamer Exhibit 1 marked for	1 (Stamer Exhibit 2 marked for
2 identification and attached to the transcript.)	2 identification and attached to the transcript.)
3 REMOTE TECH: Should be on screen.	3 REMOTE TECH: Should be on screen.
4 Q Dr. Stamer, do you see displayed on	4 Doctor, you should just be able to
5 your screen here a copy of a document titled	5 click to regain control again.
6 "Declaration of Dr. W. Daniel Stamer, Ph.D. in	6 Q Dr. Stamer, do you see displayed on
7 Support of Plaintiffs' Motion for a Preliminary	7 the screen the document titled "Second
8 Injunction"?	8 Declaration of Dr. W. Daniel Stamer, Ph.D. in
9 A Yes.	9 Support of Plaintiffs' Motion for a Preliminary
10 MR. CASSELLA: And if we could just	10 Injunction"? And if you would like to go to
11 scroll to page 20 of this declaration, please.	11 page 16 of this declaration, I believe we'll see
12 Q And is that your signature appearing	12 your signature.
13 on page 20 of this declaration?	13 And do you see your signature on
14 A It is mine.	14 page -- it looks like page 17 maybe --
15 Q And please take a moment to scroll	15 A I do.
16 through the document if you need to, but does	16 Q -- of this declaration?
17 this document appear to be a true and correct	17 A I do. That's mine.
18 copy of the first declaration that you submitted	18 Q And does this appear to be a true and
19 in connection with the preliminary injunction	19 correct copy of the second declaration that you
20 proceedings?	20 submitted in connection with the preliminary
21 A Is that part of this binder? So I	21 injunction proceedings?
22 can't scroll through it because I don't have it	22 A Yeah, it does.
18	20
1 in front of me, sorry.	1 MR. CASSELLA: If we could go back to
2 Q You can get control on the --	2 the '245 declaration, which would have been the
3 A Oh, I see.	3 first one, yes.
4 REMOTE TECH: I'll just assign the	4 Q Okay, let's go to paragraph 38 of
5 witness remote control. One moment.	5 your '245 declaration, please.
6 THE WITNESS: Okay. And is it	6 REMOTE TECH: One moment, please.
7 possible to get full screen. It's like -- I can	7 You said 38?
8 hardly read it.	8 MR. CASSELLA: 38, yes, 3-8.
9 REMOTE TECH: Doctor, you should just	9 REMOTE TECH: It should be there.
10 be able to click on it now to be able to gain	10 Q Okay. So paragraph 38 is displayed
11 control of the document.	11 on the screen. Feel free to refer to your hard
12 (Witness reviewing document.)	12 copy if that is easier, Dr. Stamer. In
13 A Yeah, it appears to be the document	13 paragraph 38 you state that the therapeutic
14 that I submitted last year.	14 window "is a fundamental principle applied in
15 Q Okay.	15 drug development," correct?
16 MR. CASSELLA: If the tech could	16 A Yes.
17 display the file -- the "PI - Stamer Second	17 Q And on the next page, still in
18 Declaration," please.	18 paragraph 38, but on the next page, you provided
19 REMOTE TECH: One moment. And we	19 a figure or a graph demonstrating a hypothetical
20 want this marked as Exhibit 2?	20 therapeutic window for a drug, correct?
21 MR. CASSELLA: Yes, you can just mark	21 A I did.
22 it Stamer 2.	22 Q Now, in this figure, you have labeled

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21 1 the "Therapeutic Window," you have labeled a 2 curve in blue, "Therapeutic effect" and a curve 3 in red, "Off-target effect"; is that right? 4 A I did. 5 Q And the therapeutic effect is the 6 intended or desired effect of the drug; is that 7 correct? 8 A That's correct. 9 Q And the off-target effect, then, 10 would be the unintended or undesirable effect of 11 the drug; is that correct? 12 A Typically. 13 Q And the gray box on this figure 14 represents the therapeutic window, correct? 15 A Yes. 16 Q And is this what a layperson might 17 call the sweet spot for the drug? Does -- 18 MS. YANG: Objection. I'm sorry. Go 19 ahead. 20 Objection. Vague. 21 A I'm not sure what a layperson -- I 22 call it a therapeutic window. But, yeah, I	23 1 it is hard to answer that question because it is 2 such a -- you know, it encompasses a lot that 3 goes into it. 4 Q But the goal of -- sorry, let me 5 rephrase that. 6 So in drug development the one goal 7 of the drug development team would be to 8 determine or elucidate the therapeutic window of 9 a drug, correct? 10 MS. YANG: Objection. Incomplete 11 hypothetical. Calls for speculation. 12 A As part of the development of any 13 drug, that is an outcome of a bunch of different 14 clinical trials, pre-clinical experiments and so 15 on to determine what that therapeutic window is 16 and whether that particular drug has a wide 17 enough therapeutic window to move forward. I 18 guess -- your question sounds really -- well, it 19 is very general. It wasn't -- I'm having a hard 20 time answering it. 21 Q That's okay. It's meant to be a 22 general question. The question is, in general,
22 1 guess you can call it that. 2 Q So this -- what I mean by the sweet 3 spot is this is the concentration where you 4 achieve the intended therapeutic effect with 5 minimal off-target effect; is that right? 6 A That's what you -- the goal of drug 7 development is, yes. 8 Q Okay. Now, you testified that this 9 therapeutic window is a "fundamental principle 10 in drug development," correct? 11 A Yes. 12 Q So let's say you are part of a drug 13 development team. The determination of that 14 drug's therapeutic window would be a routine 15 part of developing that drug, correct? 16 MS. YANG: Objection. Incomplete 17 hypothetical. Calls for speculation. 18 A There's -- your question 19 oversimplifies what goes into it. There's a lot 20 of steps along the way to try to bring a drug 21 forward so that you have a compound that has a 22 pretty generous therapeutic window. That's --	24 1 the drug development team is motivated to figure 2 out what their drug's therapeutic window looks 3 like, correct? 4 MS. YANG: Objection. Incomplete 5 hypothetical. Calls for speculation. Asked and 6 answered. 7 A Yeah, I think I did answer that, that 8 there are multiple steps that go into 9 determining what is the therapeutic effect 10 versus the off-target effects of that particular 11 drug and whether it is in an acceptable range so 12 that you can move forward. 13 Q Would the determination of a drug's 14 therapeutic window be accomplished by 15 administering different concentrations of the 16 drug and then measuring the size of the 17 therapeutic effect and the size of the 18 off-target effect of those different 19 concentrations? 20 MS. YANG: Objection. Incomplete 21 hypothetical. Calls for speculation. 22 A Maybe I can be a little more

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25 1 specific. Typically, a phase 1 trial is a 2 safety trial or a dose-escalation trial where 3 they do what you say. They take a drug and they 4 expose humans to different doses and look at 5 both the therapeutic effects and the off-target 6 effects. So that's pretty standard in drug 7 development. 8 Q Would this process also be known as a 9 dose-response study? 10 A It's -- typically, it is a safety 11 study, the phase 1 -- or a dose-escalation 12 study. Because at that -- usually, early on, 13 the response is -- encompasses both -- or can 14 encompass both the therapeutic and the 15 off-target. So it's called -- that's why I 16 think it is called a safety study. 17 Q What differences, if any, are there 18 between a dose-response study and a safety 19 study? 20 MS. YANG: Objection. Assumes facts 21 not in evidence. 22 A So I think I answered that. So the	27 1 hypothetical. Calls for speculation. 2 A Yes, so you're -- what I'm hearing is 3 a lot is being wrapped into a -- sort of a 4 straightforward hypothetical where you have 5 to -- initially, you do this phase 1 study to 6 just see if the drug is safe, but you're also 7 getting a read out on the therapeutic benefit of 8 the drug because that's the goal. 9 That -- if it turns out to be safe, 10 the next step is you've gotten some information 11 but only on a few number of patients. The 12 safety -- they don't want to put a bunch of 13 patients at risk in a safety study. So, 14 typically, these are young, healthy people, very 15 few, you know, a dozen, maybe. But then it 16 moves into the phase 2 studies, where more 17 people are exposed to the drug. 18 And so it is a process. There is not 19 just we're going to do this and see what the 20 window is. The window is determined over a 21 period of time or a number of studies, if that 22 makes sense.
26 1 safety is using increasing doses, a 2 dose-escalation study, to determine how safe 3 this drug is in humans, phase 1. 4 A dose-response, at least in my 5 field, that typically is a pre-clinical trial to 6 really understand the molecule itself. And 7 those are typically in -- not in humans, they 8 are in animal models, to look at the efficacy of 9 the drug, so over a range of doses. That would 10 be a dose-response study. 11 Q Okay. Back to my hypothetical for a 12 moment. Say you are part of a drug development 13 team, and let's just say this drug development 14 team is trying to determine the therapeutic 15 window for the drug that they are developing. 16 In order to get a full picture of the 17 drug's therapeutic window, you would test low 18 concentrations, high concentrations and 19 concentrations in between and measure the 20 resulting therapeutic effects and off-target 21 effects of those concentrations, correct? 22 MS. YANG: Objection. Incomplete	28 1 Q But in order to determine the window, 2 eventually you would have to test concentrations 3 on the low end of the spectrum, on the high end 4 of the spectrum and in between in order to 5 figure out where on these therapeutic effect 6 curves and off-target effect curves you are at, 7 correct? 8 MS. YANG: Objection. Incomplete 9 hypothetical. Calls for speculation. Asked and 10 answered. 11 A Often that is not done because the 12 trials are very expensive. And so they have -- 13 the companies have to make a decision pretty 14 early on, the concentration. That can change 15 with time, but that's -- at least, in my 16 opinion, that's what dictates the initial 17 concentration. That is determined from these -- 18 the phase 1 and the phase 2 studies. But it is 19 just too expensive to go and try a bunch of 20 different doses after the phase 1 study. You 21 might do two different doses but not as you 22 described.

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29 1 Q You provide the example of 2 bimatoprost at the end of this paragraph 38, 3 correct? 4 A Yes. 5 Q And that is a glaucoma drug, correct? 6 A It is. 7 Q And for that drug, the drug 8 developers did, in fact, test lower 9 concentrations in order to reduce side effects 10 but maintain therapeutic efficacy, correct? 11 MS. YANG: Objection. Calls for 12 speculation. Assumes facts not in evidence. 13 A So I brought up the bimatoprost 14 because – this is a perfect example of what I 15 just said in answering the previous question. 16 They went forward with the dose that went on the 17 market, but they realized that they had a – you 18 know, that they were having significant amount 19 of off-target effects, in this case hyperemia, 20 so the eyes got redder. 21 And often – this isn't done by the 22 company, but often the clinicians will try	31 1 of the drug matters, correct? 2 A The dose of a drug matters? Any 3 drug? Yeah, this relates to a therapeutic 4 window. Fentanyl has a very narrow therapeutic 5 window. 6 Q Was it true for drugs generally in 7 2008? 8 A It's – the therapeutic window is 9 drug dependent. Each drug has its own window, 10 and it turns out that, fentanyl it's very 11 narrow. It is very effective so it is used, but 12 it is used under caution, typically, under the 13 supervision of a physician, where a very metered 14 amount of drug can be delivered at a time. 15 Q I'm just asking about drugs 16 generally. Is it true in 2008 that the dose of 17 the drug matters? 18 MS. YANG: Objection. Asked and 19 answered. Vague. 20 A It has been known for a long time, 21 including before 2008, that the dose of the drug 22 determines the relative effectiveness versus the
30 1 different things. And I don't know the story 2 behind bimatoprost, but it was observed not in a 3 formal way, as far as I know, that the lower 4 doses gave you the same benefit. But it 5 wasn't – there wasn't this dose-response like 6 you described. This was an observation that you 7 can reduce the off-target effects by lowering 8 the dose, and that's why the bimatoprost was 9 then – the dosage was changed and – you know, 10 and brought to market. 11 Q Let's go to paragraph 95 of this 12 declaration, please. 13 REMOTE TECH: One moment, please. 14 Should be on screen. 15 Q And Dr. Stamer, do you see in 16 paragraph 95 of your '245 declaration you state 17 that "We know that fentanyl kills, but it also 18 treats pain -- this is an example of dose 19 mattering even when the route of administration 20 is the same"? Correct? 21 A Correct. 22 Q And it was true in 2008 that the dose	32 1 off-target effects. 2 Q And so persons of ordinary skill in 3 the art would have known in 2008 that the dose 4 of the drug matters, correct? 5 MS. YANG: Objection. Asked and 6 answered. 7 A Yes, the person of ordinary skill in 8 the art would know that a dose of a drug is 9 quite important in the relative effectiveness 10 versus off-target effects. 11 Q So the person of ordinary skill in 12 the art in 2008 would have been motivated to 13 optimize the dose of the drug, correct? 14 MS. YANG: Objection. Calls for a 15 legal conclusion. Vague. 16 A There is a lot wrapped in that. Can 17 you be more specific. An example or – it 18 really depends – 19 Q I'm just asking generally. 20 MS. YANG: Same objections. Asked 21 and answered. 22 A Yeah, I'm – that's a very –

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33 1 incredibly – I'm not sure what you're asking, 2 sorry. 3 Q You testified that the person of 4 skill in the art would know that a dose of a 5 drug is quite important, correct? 6 MS. YANG: Objection. 7 Mischaracterizes prior testimony. Vague. 8 A The dose matters. I mean, that's 9 what I stand by. But it really depends – each 10 drug is different, and so that's why I say that. 11 And if the dose – sorry. 12 Q No, go ahead. 13 A And it depends on the situation. So 14 that's why it is hard to answer that question 15 because it really is situation dependent. With 16 the dose of fentanyl, for example, it is – you 17 know, has that very narrow therapeutic window. 18 So it's – you know, you – a lot surrounds it, 19 making sure that you get a very metered amount 20 of fentanyl. 21 Q So if the dose matters and if the 22 dose is, as you testified, quite important, the	35 1 on that curve, whether you're in the sweet spot 2 or not. And, typically, a drug won't be 3 approved for sure if you're not – if you don't 4 have enough benefit for the risk that you're 5 putting the patients under. 6 Q So my question is, generally, the 7 person of ordinary skill in the art is trying to 8 find a concentration in that therapeutic window, 9 correct? 10 MS. YANG: Objection. Asked and 11 answered. Vague. Incomplete hypothetical. 12 A I'll try to restate. The therapeutic 13 window, the understanding of the therapeutic 14 window – that's probably a better way to say 15 it – evolves over time. You – through a 16 number of steps. And so it – in the case of 17 the bimatoprost, that, I mean, took decades to 18 find a better sweet spot for the bimatoprost. 19 But that was on the market for – through all 20 that time. 21 Q You considered Dr. Gil's patent in 22 forming your opinions in this declaration,
34 1 person of ordinary skill in the art would be 2 motivated to optimize the dose, correct? 3 MS. YANG: Objection. 4 Mischaracterizes prior testimony. Asked and 5 answered. Calls for a legal conclusion. 6 A Yes. So when you say "optimize the 7 dose," I'm not sure what you mean by that. 8 There is a lot that's wrapped in optimizing the 9 dose, and sometimes you – you know, it really 10 depends. There's a lot of context there that I 11 can't answer the question without the context. 12 Q Would the person of ordinary skill in 13 the art in 2008 have been motivated to determine 14 the dose of a drug that would fall within that 15 drug's therapeutic window? 16 MS. YANG: Objection. Asked and 17 answered. Vague. Incomplete hypothetical. 18 A Again, I'm sorry, I'm not catching 19 you. Typically, the – you know, like I started 20 with, there's a lot of things that sort of 21 culminate into determining what the therapeutic 22 window of a drug is and where you are on that –	36 1 correct? 2 A I did. 3 Q Did Dr. Gil know that dose matters? 4 MS. YANG: Objection. Calls for 5 speculation. 6 A Yeah, I can't say what Dr. Gil knew 7 or didn't know. As somebody that works for a 8 major pharmaceutical company, I would be 9 surprised if he didn't. 10 Q You considered the Dean patent in 11 forming your opinions in this declaration also, 12 correct? 13 A I did. 14 Q Would Dean have known that dose 15 matters? 16 MS. YANG: Objection. Calls for 17 speculation. 18 A Yeah, I can't say what Dean – I 19 don't know Mr. Dean, so I couldn't say. 20 Q You considered the Alphagan and 21 Alphagan P products in forming your opinions in 22 this declaration, correct?

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37 1 A I did. 2 Q Would the developers of Alphagan and 3 Alphagan P have known that dose matters? 4 MS. YANG: Objection. Calls for 5 speculation. 6 A These were -- there's a lot of people 7 that went into the development of Alphagan. And 8 each has their own expertise, medicinal 9 chemistry, how to formulate the drug, how to 10 look for adverse events, how to -- you know, so 11 there is a big team, and there's a lot of people 12 that go into that and have their different 13 expertise that are pulled together by the 14 company. So it is sort of hard to ask the 15 developers or -- embody a lot of people. 16 Q The developers of Alphagan applied 17 for and received FDA approval of formulations of 18 Alphagan with lower concentrations of 19 brimonidine several times, correct? 20 MS. YANG: Objection. Vague. 21 A The dose of brimonidine decreased as 22 well as the preservatives changed with time,	39 1 solution, and (2) the number of ocular drops 2 that are administered," correct? 3 A Yes. 4 Q So you would agree that a dose can be 5 more than a single drop, correct? 6 MS. YANG: Objection. Calls for a 7 legal conclusion. 8 A In my field, working with companies 9 to develop glaucoma drops, a dose is a single 10 drop. 11 Q And you state that the administered 12 dose is a product of the number of drops, 13 correct? 14 MS. YANG: Objection. Asked and 15 answered. 16 A If there is a situation where 17 multiple drops are given, the dose that the eye 18 sees is a product of the number of drops. But 19 when a drug is developed, it is developed so 20 that a single drop is a dose, that's -- at least 21 glaucoma meds is what I work with companies to 22 help them develop. That's the intent.
38 1 yes. 2 Q The therapeutic effects -- 3 MR. CASSELLA: Strike that. Let me 4 rephrase. 5 Q The intended therapeutic effect for 6 Alphagan and Alphagan P is lowering intraocular 7 pressure, correct? 8 A Correct. That's what it's used for. 9 Q If we could go back up to 10 paragraph 39 of the '245 declaration, please. 11 REMOTE TECH: One moment, please. 12 It should be on screen. 13 MR. CASSELLA: 39. 14 REMOTE TECH: My apologies. 15 MR. CASSELLA: No problem. 16 Q Do you see or do you have it in front 17 of you, Dr. Stamer, paragraph 39 of your '245 18 declaration? 19 A I do. 20 Q Now, in paragraph 39 you state that 21 "the administered dose of the drug is a product 22 of (1) the concentration of the drug in the	40 1 Q Would the size of the ocular drop 2 affect the amount of brimonidine that is 3 administered to the eye? 4 MS. YANG: Objection. Incomplete 5 hypothetical. Vague. 6 A So you're asking, if the drop is 7 bigger, will it contain more brimonidine, for 8 example? 9 Q Yes. Or if it is smaller, would it 10 contain less brimonidine. 11 MS. YANG: Same objections. 12 A The drop is a volume, and the dose of 13 the drug is a percentage of that volume. So 14 more drug would be in a bigger drop. 15 Q And less drug in a smaller drop? 16 A Correct. 17 Q Now, just a few paragraphs down, in 18 paragraph 41, that paragraph begins, "Assuming 19 the volume of ophthalmic solution that is 20 administered is held constant." 21 Do you see that? 22 A Uh-huh.

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41 1 Q To your knowledge, Dr. Stamer, do any 2 of the claims of the '245 or '600 patents 3 specify the volume of brimonidine to be 4 administered? 5 MS. YANG: Objection. Calls for a 6 legal conclusion. 7 A I'm not a claims person. I'm sorry, 8 I can't answer that. That's outside of my 9 expertise. 10 Q So, to your knowledge, there is no 11 limitation in the claims that indicates what 12 volume of brimonidine is administered in the 13 methods, correct? 14 MS. YANG: Objection. Asked and 15 answered. Calls for a legal conclusion. 16 A Yeah, I wouldn't -- I understand that 17 the terms have legal implications, but beyond 18 that, I don't understand the -- what those are, 19 so that's beyond my expertise to answer that, 20 sorry. 21 Q Fair enough. 22 You considered the Norden reference	43 1 intent of the patent, to locally treat ocular 2 pain with an eye drop. 3 Q I'm not sure what that has to do with 4 the question I asked. The question was, Gil did 5 not specify the volume of the drops that were 6 administered and the methods disclosed in his 7 patent, correct? 8 MS. YANG: Objection. Asked and 9 answered. To the extent that the question 10 mischaracterizes the document. 11 A As I remember the Gil patent, it 12 describes the use of brimonidine -- multiple 13 drops of brimonidine in some cases -- to treat 14 local ocular pain because of, let's say, like 15 our case, surgery at the time that would have -- 16 so something that would cause pain on the ocular 17 surface. 18 Q So, again, I'm asking whether Gil 19 disclosed the volume of those drops. 20 MS. YANG: Objection. Same 21 objections. Asked and answered. To the extent 22 the question mischaracterizes the document.
42 1 in forming your opinions in this declaration, 2 correct? 3 A I did. 4 Q Norden did not specify the volume of 5 the drops that were administered as part of the 6 method disclosed in that paper, correct? 7 A As I remember, it was a commercial 8 bottle of the Alphagan, which has a 9 predetermined drop size by the company. So 10 Norden didn't -- as far as I know, Norden didn't 11 alter that. 12 Q I believe you testified earlier you 13 reviewed the Gil patent, correct? 14 A I did. 15 Q Gil did not specify the volume of the 16 drops that were administered in the method 17 disclosed in his patent, correct? 18 MS. YANG: Objection to the extent 19 the question mischaracterizes the document. 20 A Again, for the Gil patent, as I 21 remember it, the -- they were -- Gil was using 22 brimonidine to treat ocular pain. That was the	44 1 A So, yeah, I guess -- 2 MR. CASSELLA: He hasn't answered the 3 question. 4 A I guess -- 5 MS. YANG: He has. 6 MR. CASSELLA: I'm asking about the 7 volume of the drops. 8 MS. YANG: Chris, he has. 9 And Dr. Stamer, feel free to take a 10 look at the document itself before you answer 11 the question. 12 THE WITNESS: Okay. 13 A What exhibit is the Gil patent? 14 Q It's Exhibit 1004. 15 (Witness reviewing document.) 16 A So the -- I just reread the patent. 17 It does talk about delivering drops to the eye, 18 and it talks about the amount of -- the range of 19 drug that's delivered to the eye. And the drop 20 size is, in our field -- in my field is 21 determined by the company, so the manufacturer 22 of the drop. And it is within quite a narrow

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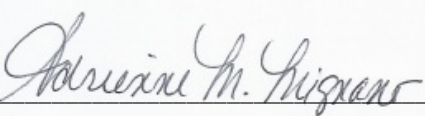
45 1 range so I guess I'm not understanding the 2 specif- -- what the patent specifies is the 3 amount of drug that would be in that drop. So 4 I'm not sure what you're asking about the drop 5 size. 6 Q I'm asking whether Gil specifies the 7 precise volume of the drop. 8 MS. YANG: Objection. Vague. Asked 9 and answered. Mischaracterizes the document. 10 A I would be surprised. It would be 11 highly unusual for -- in something like this to 12 specify a drop size. And, instead, as a 13 pharmacologist, I see that he is specifying the 14 amount of drug that's going to be delivered to 15 the eye, which is what I would care about and 16 what he cared about when he wrote the patent. 17 And the drop size is standard in the field. 18 Q Let's go to paragraph 82 of your 19 declaration, please. 20 REMOTE TECH: One moment, please. 21 Should be on screen. 22 Q Dr. Stamer, do you see in	47 1 ten-minute break, please. 2 MR. CASSELLA: Can we do like five? 3 MS. YANG: Five is fine. 4 Can we go off the record. 5 THE VIDEOGRAPHER: We are going off 6 the record. The time is 9:53. 7 (A recess was taken.) 8 THE VIDEOGRAPHER: We are going back 9 on the record. The time is 9:59. 10 MS. YANG: I have no further 11 questions. 12 MR. CASSELLA: Thanks, Dr. Stamer. 13 THE WITNESS: Thank you. 14 MS. YANG: Thank you, everyone. 15 THE VIDEOGRAPHER: This marks the end 16 of the deposition of Dr. Daniel Stamer. We are 17 going off the record at 9:59. 18 (Off the record at 9:59 a.m.) 19 20 21 22
46 1 paragraph 82 you state that the Jonescu paper 2 "clinically evaluated the effect of topically 3 applied 0.2 percent brimonidine on the blood 4 flow in retinal and retrobulbar vessels of the 5 eye"? Correct? 6 A Correct. 7 Q And retinal vessels would be at the 8 back of the eye, correct? 9 A That's correct. That's like the 10 ophthalmic artery, for example. 11 Q And retrobulbar vessels are also at 12 the back of the eye, correct? 13 A Well, they come forward. That 14 includes the ciliary arteries which branch, and 15 they come from the back, from the ophthalmic 16 artery towards the front of the eye to feed the 17 front of the eye. They are called ciliary 18 arteries because they feed the ciliary body, 19 which is in the front of the eye. 20 MR. CASSELLA: Thank you, Dr. Stamer. 21 I have no further questions. 22 MS. YANG: Can we take a quick	48 1 ACKNOWLEDGMENT OF DEPONENT 2 3 I, DANIEL STAMER, PH.D., do hereby 4 acknowledge that I have read and examined the 5 foregoing testimony, and the same is a true, 6 correct and complete transcription of the 7 testimony given by me and any corrections appear 8 on the attached Errata sheet signed by me. 9 10 _____ 11 (Date) (Signature) 12 13 14 15 16 17 18 19 20 21 22

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Transcript of Daniel Stamer, Ph.D.
Conducted on February 13, 2025

13 (49 to 52)

49 1 CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC 2 3 I, Adrienne Mignano, Certified Reporter and 4 Notary Public within and for the State of New York 5 and Washington D.C. do hereby certify: 6 7 That Daniel Stamer, Ph.D., the witness whose 8 deposition is hereinbefore set forth, was duly sworn 9 by me before the commencement of such deposition and 10 that such deposition was taken before me and is a 11 true record of the testimony given by such witness. 12 13 I further certify that the adverse party, 14 DR. REDDY'S LABORATORIES S.A. and DR. REDDY'S 15 LABORATORIES, INC., was represented by counsel at 16 the deposition. 17 18 I further certify that the deposition of 19 Daniel Stamer, Ph.D., occurred remotely on Thursday, 20 February 13, 2025 commencing at 9:01 a.m. to 21 9:59 a.m. 22	
50 1 I further certify the inspection, reading and 2 signing of said deposition was waived on the 3 record by agreement of all parties. I further 4 certify that I am not related to any of the parties 5 to this action by blood or marriage, I am not 6 employed by or an attorney to any of the parties to 7 this action, and that I am in no way interested, 8 financially or otherwise, in the outcome of this 9 matter. 10 11 IN WITNESS WHEREOF, I have hereunto set my hand 12 and affixed my notarial seal this 15th day of 13 February, 2025. 14 15 My Commission Expires: June 2026. 16 17  18 _____ 19 ADRIENNE M. MIGNANO, RPR 20 21 22	

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