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Transcript of Daniel W. Gil, Ph.D.

Date: February 12, 2025

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

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WORLDWIDE COURT REPORTING & LITIGATION TECHNOLOGY

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Eye Therapies Exhibit 2280, 2 of 34
Dr. Reddy's v. Eye Therapies - IPR2024-00563

Transcript of Daniel W. Gil, Ph.D.
Conducted on February 12, 2025

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5 1 EXAMINATIONS 2 WITNESS PAGE 3 DANIEL W. GIL, PH.D. 4 By Mr. Frederickson..... 7 5 By Mr. Luneack..... 55 6 7 8 EXHIBITS 9 EXHIBITS REFERENCED (NOT ATTACHED) PAGE 10 No. 1030 Alphagan NDA..... 55 11 No. 1067 Alphagan Label Excerpts..... 29 12 No. 2025 Declaration of Dr. Daniel W. 13 Gil, Ph.D. in Support of 14 Plaintiffs' Motion for a 15 Preliminary Injunction..... 13 16 No. 2108 Alphagan 0.2% Monograph..... 40 17 No. 2119 Alphagan P Monograph..... 46 18 19 20 21 22	7 1 Eye Therapies. I'm also joined by Kathryn Judson, 2 also of Finnegan Henderson on behalf of the Patent 3 Owner. 4 THE VIDEOGRAPHER: The court reporter 5 today is Michelle Yohler representing Planet Depos 6 as well. 7 The witness will now be sworn. 8 (WHEREUPON, the witness was duly sworn.) 9 DANIEL W. GIL, Ph.D., 10 called as a witness herein, having been first duly 11 sworn, was examined and testified as follows: 12 EXAMINATION 13 BY MR. FREDERICKSON: 14 Q Good afternoon, Dr. Gil. It's nice to see 15 you again. My name is Robert Frederickson. We 16 met about this time last year in connection with 17 some similar subject matter in a co-pending 18 district court case. 19 You may remember that? 20 A I do. 21 Q You understand that you're testifying 22 under oath today?
6 1 PROCEEDINGS 2 (Technician read-on.) 3 THE VIDEOGRAPHER: Here begins Media 4 Number 1 in the videotaped deposition of 5 Dr. Daniel Gil in the matter of Dr. Reddy's 6 Laboratories S.A., et al., versus Eye 7 Therapies, LLC, in the United States Patent and 8 Trademark Office before the Patent Trial and 9 Appeal Board, Case Numbers IPR2024-00467 and 10 IPR2024-00563. 11 Today's date is February 12th, 2025. The 12 time on the video monitor is 1:58 p.m. 13 The remote videographer today is William 14 Pantoja representing Planet Depos. 15 All parties of this video deposition are 16 attending remotely. 17 Would counsel please voice-identify 18 themselves and state whom they represent. 19 MR. FREDERICKSON: Robert Frederickson for 20 the petitioners, Dr. Reddy's Laboratories. 21 MR. LUNEACK: Matthew Luneack from 22 Finnegan Henderson on behalf of the Patent Owner,	8 1 A I do. Yes. 2 Q Have you testified either in a court 3 hearing or by deposition since I saw you last? 4 A No. 5 Q We're taking this deposition remotely. I 6 understand that you have some papers that you 7 brought with you. Can you tell me what you have 8 in front of you? 9 A Yeah, what I have in front of me is just a 10 binder that has my declarations from the '245 and 11 the '600, along with the documents that are cited 12 in the -- in those declarations. 13 Q Any marking or notations on any of those 14 documents? 15 A There are no markings, no notations, no. 16 Q Other than the Zoom application that 17 you're using to interact with me, do you have any 18 other computer programs on your computer? 19 A There are -- I think Microsoft Word might 20 be opened, but everything is minimized on the 21 computer. 22 Actually, I'll minimize my Chrome as well.

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9 1 Q If you could close out of those so there's 2 no notes or anything or no internet research 3 you're doing while we're -- while I'm asking you 4 questions. 5 A Yeah, I minimized that. And I remember 6 last time we talked about text messaging. I 7 closed the messaging app so it should not pop up 8 on the computer, but if it does, I will let you 9 know. 10 Q All right. Great. Thank you. 11 And then I understand that there's two 12 attorneys in the same room, but both from Finnegan 13 Henderson; is that correct? 14 A There's one attorney in the room. 15 Q And one on Zoom. I got you. 16 A Yeah, and one's on Zoom. 17 Q Anyone else other than Mr. Luneack in the 18 room with you? 19 A No. 20 Q Okay. So you understand you're testifying 21 today as part of two proceedings that are pending 22 in front of the patent trial and appeal board?	11 1 at your declaration in the -- for the '245 patent, 2 the 467 IPR. 3 A Yep. 4 Q There's also a reference in Paragraph 16 5 to United States Patent No. 11,833,254. 6 Do you see that? 7 A Yes. Yes. 8 Q And is that the same, that that 9 information about the '245 patent was provided to 10 you by counsel? 11 A Yes. And in that one, I was more explicit 12 about that in the footnote; whereas, in the 601, I 13 was -- I didn't provide as much information about 14 that on the footnote. 15 In the '245, it says: "I have been 16 informed and understand it is Patent Owner's 17 position..." and then it speaks to claim 1. And I 18 didn't -- I did not -- I neglected to indicate the 19 same in the '600. 20 Q Understood. 21 So in December of 2023, you prepared and 22 signed a declaration concerning subject matter
10 1 A Yes, I do. And I did want to make one 2 clarification. I don't know if this is the right 3 time to do it on -- 4 Q Sure. 5 A -- on my declaration, the information in 6 the declaration that relate to the substance of 7 the two patents that are at issue are not -- those 8 are based on information that was provided to me 9 by the Finnegan counsel, and haven't independently 10 reviewed those to form any opinions. 11 Q Can you just clarify specifically what 12 you're referring to? 13 A So there's a -- I think in both of my -- 14 here, let me -- sorry. Let me find the page -- 15 Q Sure. 16 A -- make sure I'm exactly... 17 So in the '600 declaration on -- in 18 Paragraph 16, I just briefly note what the subject 19 matter of the '600 patent is about, and I just 20 wanted to make clear that was based on information 21 provided by counsel. 22 Q Okay. And then why don't we take a look	12 1 that relates to the declaration that you've 2 submitted in these two IPR proceedings; is that 3 correct? 4 A Yes. 5 MR. LUNEACK: Form. 6 Could you just slow down and -- 7 THE WITNESS: Sorry. 8 MR. LUNEACK: -- object to the form. 9 BY MR. FREDERICKSON: 10 Q Do you have a copy of the declaration that 11 you submitted and signed in December of 2023 in 12 front of you? It's Exhibit 2025. 13 A I'm sure I have that -- wait a minute. 14 20... 15 Q 25. 16 MR. FREDERICKSON: And, Doru, would we be 17 able to drop that in the chat to the extent 18 Dr. Gil doesn't have a paper copy in front of him? 19 MR. LUNEACK: I don't believe there's a 20 paper copy of it -- 21 THE WITNESS: Yeah -- 22 MR. LUNEACK: -- if you find.

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13 1 THE WITNESS: -- I don't have it. 2 (WHEREUPON, Exhibit No. 2025 was first 3 referenced.) 4 MR. FREDERICKSON: So we'll go ahead and 5 introduce into this deposition as Exhibit 2025 the 6 declaration of Dr. Daniel W. Gil, Ph.D., in 7 support of plaintiff's motion for a preliminary 8 injunction. 9 BY MR. FREDERICKSON: 10 Q And you should see that in the chat, 11 Dr. Gil. 12 A Yes. You want me to open it up from here 13 or download it? What's the best -- 14 Q Yeah, please go ahead and open it up. 15 A Okay. 16 Okay. I have it open. 17 Q Okay. Do you recognize Exhibit 2025 to be 18 a declaration that you submitted in the district 19 court case pending in New Jersey on or around 20 December 12th of 2023? 21 A Yes. 22 Q And I understand from the last time that	15 1 A Yes. 2 Q Okay. Can you tell me the process by 3 which you prepared the IPR declaration that was 4 signed and dated on November 18th, 2024? 5 MR. LUNEACK: Dr. Gil, you may answer 6 generally, but I would caution you not to reveal 7 the substance of any communications you had with 8 counsel. 9 BY THE WITNESS: 10 A As you surmised, the starting point was 11 from the prior declaration that I -- that was 12 prepared, and I reviewed it, reviewed it, 13 identified some areas where I felt like maybe 14 there was some further clarification needed. 15 Counsel also -- because the subject 16 matter, I guess, was somewhat different between 17 the two cases, counsel suggested some additional 18 verbiage to clarify the differences between the 19 two cases -- 20 BY MR. FREDERICKSON: 21 Q And -- go ahead. Please finish. 22 A Yeah, and then the actual --
14 1 we spoke that you were first retained by Bausch 2 sometime in the fall of 2023; is that right? 3 A That's my -- yeah, that's my recollection, 4 yes. 5 Q And from the fall of 2023 through 6 December 12th of 2023, you worked with the Bausch 7 attorneys to prepare the declaration that's been 8 marked as Exhibit 2025, right? 9 A Yes. 10 Q More recently you've submitted two 11 declarations in the two IPR proceedings pending 12 before the Patent Trial and Appeal Board; is that 13 right? 14 A Yes. 15 Q And those declarations are designated in 16 each of the proceedings with the exhibit 17 number 2227; is that right? 18 A Yes. 19 Q Can you -- the declaration that was 20 submitted in connection with the IPR relating to 21 the '245 patent was signed and dated by you on 22 November 18th, 2024; is that right?	16 1 MR. LUNEACK: I'm just going to -- 2 THE WITNESS: Yeah -- 3 MR. LUNEACK: -- not to reveal -- 4 THE WITNESS: -- probably leave it at 5 that, yeah. 6 BY MR. FREDERICKSON: 7 Q Besides some minor clarification and 8 wordsmithing edits that were made from the 9 declaration you submitted in the district court 10 case to the '245 IPR proceeding, is the substance 11 of those declarations generally the same, Dr. Gil? 12 A Yes. 13 Q And then what about the preparation of the 14 declaration that you submitted in connection with 15 the '600 patent; are there any substantive 16 differences between that declaration and your 17 previous declarations? 18 MR. LUNEACK: Object to the form. 19 BY THE WITNESS: 20 A I would say that the -- they are 21 substantially -- substantially similar. 22

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17 1 BY MR. FREDERICKSON: 2 Q Let's take a look at the declaration that 3 you submitted in the '245 IPR proceeding and go to 4 Paragraph 1. 5 A I'm there. 6 Q And in Paragraph 1, towards the end you 7 acknowledge and state that you understand that 8 this declaration is being submitted in support of 9 Patent Owner's response in connection with 10 IPR2024-00467. 11 Do you see that? 12 A Yes. 13 Q Okay. Have you reviewed the petition that 14 Dr. Reddy's Laboratories filed in connection with 15 that IPR? 16 A No. 17 Q Have you reviewed the petition that 18 Dr. Reddy's filed in connection with the IPR on 19 the '600 patent? 20 A No. 21 Q Have you reviewed any of the expert 22 declarations that Dr. Reddy's submitted that	19 1 number of these were the same from the previous 2 declaration. For a couple of the new -- the 3 clarifications, additional references were 4 identified to back up the points. 5 BY MR. FREDERICKSON: 6 Q Did you review, in connection with either 7 the declarations that you submitted in these IPRs, 8 any materials that were not listed in Appendix B? 9 A Nope, I did not. 10 Q You may remember from your last deposition 11 I asked you about a journal article that's been 12 referred to as the Norden reference in these 13 proceedings. 14 Do you recall that reference? 15 A I remember you -- I remember we talked 16 about it, yes. 17 Q Have you reviewed the Norden reference 18 since you last testified in this -- in the 19 district court proceeding? 20 A No. 21 Q I also asked you about a reference that is 22 referred to as the Dean reference.
18 1 accompanied its petition from Reza Dana, Paul 2 Laskar, or John Galanis? 3 A Nope. 4 Q And that's true in both the '245 IPR and 5 the '600 IPR, that you have not reviewed those 6 declarations? 7 A Yes, that is true. 8 Q In your IPR declarations towards the end 9 you include an Appendix B of the materials that 10 you considered in preparation of your 11 declarations; is that correct? 12 A Yes, that's correct. 13 Q And how was the list of materials 14 considered for those two declarations prepared? 15 A So I -- how were they prepared? This was, 16 again -- and I don't want to -- being a little 17 careful what I should say -- 18 MR. LUNEACK: You may answer the question 19 generally, but, again, I caution you not to reveal 20 any privileged communications with counsel. 21 BY THE WITNESS: 22 A Okay. I think -- so, first off, I think a	20 1 Do you remember that? 2 A I recall. 3 Q And have you reviewed the Dean reference 4 since you last testified in the district court 5 proceedings? 6 A No. 7 Q So in connection with the preparation of 8 the declarations that you submitted in the 9 district court and the two declarations that you 10 submitted in the IPRs, you have not reviewed the 11 Norden or Dean references; is that correct? 12 A Correct. 13 Q Can you turn to Paragraph 43 of your 14 declaration in the '245 IPR. 15 A Which paragraph again? Tell me that 16 again. 17 Q 43. 18 A Yes, I'm there. 19 Q Okay. Paragraph 43 appears in your 20 declaration in a Section F entitled, "The Gil 21 Reference." 22 Do you see that?

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21 1 A I see that, yes. 2 Q Then in Paragraph 43, you write: "I 3 understand that my patent" -- which you then 4 identify by number and name -- "has been cited as 5 prior art to the invention of Lumify and that 6 statements in my patent are being, in my opinion, 7 interpreted contrary to what I, as an inventor, 8 discovered and intended to convey with the patent, 9 both at the time and today." 10 Do you see that? 11 A Yes. 12 Q Okay. What's the basis for your 13 understanding on how statements in your patents 14 are being interpreted in these proceedings? 15 MR. LUNEACK: Again, I caution you not to 16 reveal the substance of any communications you've 17 had with counsel. 18 BY THE WITNESS: 19 A I think this goes back to at the time I 20 was originally asked to come into the original 21 case back in 2023. 22 Q But you haven't reviewed the IPR petition	23 1 IPR declaration. 2 A Yes, I'm there. 3 Q And Paragraph 27 through approximately 4 Paragraph 39, you have a discussion of some 5 analysis that you conducted based on the Burke 6 1996 reference and the Acheampong 2002 reference; 7 is that right? 8 A That is right. 9 Q You included the same analysis and 10 discussion in the declaration that you signed and 11 submitted to the district court in December 12 of 2023, right? 13 A Yes. 14 Q And during -- I had the opportunity to 15 take your deposition on that declaration; you 16 remember that? 17 A Yes. 18 Q And we spent some time talking about the 19 Burke reference, the Acheampong reference, and 20 some of the analysis that you performed then. 21 Do you remember that? 22 A I do.
22 1 that Dr. Reddy's filed in connection with these 2 two IPRs, right? 3 MR. LUNEACK: Objection. Asked and 4 answered. 5 BY THE WITNESS: 6 A Yeah, that -- the answer's the same as 7 before; I have not reviewed that, no. 8 BY MR. FREDERICKSON: 9 Q You have not reviewed any of the expert 10 declarations that Dr. Reddy's submitted in 11 connection with these two IPRs, right? 12 MR. LUNEACK: Same objection. 13 BY THE WITNESS: 14 A Correct. 15 BY MR. FREDERICKSON: 16 Q So what's your basis for having an 17 understanding as to how that petition and those 18 experts are interpreting the Gil reference? 19 A That was -- I mean, that was -- as I said 20 back in 2023, that was conveyed to me by counsel, 21 by -- when they brought me into the case. 22 Q Can you turn to Paragraph 27 of your '245	24 1 Q You didn't change any of that analysis in 2 Paragraphs 27 through 39 in connection with these 3 IPR proceedings; is that correct? 4 A I believe that's correct. 5 Q You were in charge of the alpha adrenergic 6 team at Allergan from about 1995/1996 7 through 2008; is that right? 8 A Yes. 9 Q What was your position at Allergan before 10 you led the alpha adrenergic team? 11 A So I joined Allergan in 1988, and my 12 initial responsibility -- I was Allergan's first 13 molecular biologist, so my responsibility was to 14 use molecular biology techniques to -- as a 15 scientist to basically create cell-based assay 16 systems for assessing the activity of drugs on a 17 range of different receptors. 18 And we would look at both the target 19 receptor as well as looking at off -- what are 20 called off-target receptors, which are the 21 receptors that we don't want to activate or block. 22 And, you know, that was really typically

25 1 the basis of much of the work I did is -- was 2 always -- the concept was around receptor 3 selectivity; that we were constantly looking for 4 drugs that preferentially acted on the right -- on 5 the target and didn't hit other targets because 6 that was typically what resulted in side effects. 7 Q The receptors that you were working on 8 when you first started at Allergan, were those 9 alpha adrenergic receptors or different receptors? 10 A That was one of the programs. I was -- I 11 was, in fact, sort of working more in a core -- as 12 a core lab, and so the alpha -- the alpha 13 adrenergic program was one of the programs that I 14 supported at the start. 15 Q At some point did your role change where 16 you became more involved in working with alpha 17 adrenergic receptors? 18 A Yes. Yes, so around the time of -- and I 19 think we -- it was either '95 or '96 I was asked 20 to become the leader -- what's called the team 21 leader of the alpha adrenergic discovery team. 22 And so, yeah, my responsibility then	27 1 different programs, not just the alpha adrenergic 2 program at that time; is that right? 3 A I'm trying to think through the -- I think 4 that would be -- that would be right, yes. 5 Although, we were becoming more and more -- 6 because the alpha adrenergic program was a very -- 7 turning out to be a successful program, we were 8 certainly spending a lot of effort on that 9 program. 10 Q Let's go to Paragraph 25 of your IPR 11 declaration in the '245-case. 12 A Paragraph 25 you said? 13 Q Yep. 14 A Yep. I'm there. 15 Q And Paragraph 25 begins with the sentence: 16 "As of 2008, brimonidine was known to be a highly 17 selective alpha 2 agonist that was 1,000-fold more 18 selective for the alpha 2 receptor than alpha 1 19 receptor." 20 Do you see that? 21 A Yes. 22 Q And then the paragraph spills over into
26 1 became to work with -- you know, the team 2 consisted of chemists and pharmacokinetics folks 3 and toxicologists and the biologists who were 4 conducting various studies as well as interfacing 5 with folks in the clinical development area 6 because some of the drugs we were working on 7 coming out of the laboratory were moving into 8 clinical trials. 9 And, in fact, I ended up having a role, as 10 some of the drugs moved from the laboratory into 11 clinical trials, I became -- was asked on a couple 12 of occasions to be the -- what was called the 13 global team leader for the clinical development as 14 well. 15 Q So prior to assuming the role as the alpha 16 adrenergic team leader in 1995 or 1996, were you 17 still working in that core lab that you described 18 earlier? 19 A Yeah, I was leading the lab, so I would 20 say that the -- I was less and less doing the work 21 and more and more directing the work. 22 Q That core lab was supporting multiple	28 1 the next page, and there's a sentence that begins: 2 "This was consistent with our own clinical 3 experience with Alphagan." 4 Do you see that? 5 A I'm not finding it. Where -- tell me 6 where to look again. 7 Q It's -- 8 A Here. I see it now on the other -- on 9 Page 13. Okay. 10 Yes. Yes. 11 Q And you write: "This was consistent with 12 our own clinical experience with Alphagan. To the 13 extent patients experienced a side effect of 14 blanching, it was only at high doses." 15 Do you see that? 16 A Let me just -- give me a second to read 17 the preceding sentences -- 18 Q Sure. 19 A -- so I understand how this -- the context 20 of where we are. 21 Yes, I'm there. Okay. 22 Q And in that -- after that sentence, you

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29 1 cite Exhibit 1067 that has a collection of the 2 label for three Alphagan products; is that right? 3 A Yes. 4 Q The Alphagan products are Alphagan 5 0.5 percent, 0.2 percent, and Alphagan P 0.15, 6 right? 7 A Yes. 8 Q Alphagan 0.5 percent, that was never 9 approved for the treatment of glaucoma; is that 10 right? 11 A That's correct. 12 Q Do you know what indication Alphagan 13 0.5 percent was approved for? 14 A I do not recall. I know it was in our 15 early clinical trials that we were -- when we were 16 doing dose-ranging studies, but I do not recall if 17 it ever was approved and what it -- if -- what it 18 would have been used for. 19 Q Why don't you take a look at Exhibit 1067. 20 Let me know if you have that in front of you. 21 (WHEREUPON, Exhibit No. 1067 was first 22 referenced.)	31 1 You may -- 2 BY THE WITNESS: 3 A Yeah, it's a type of -- it's a type of 4 laser surgery on the trabecular mesh work, which 5 is a part of the eye where the -- that controls 6 the outflow of the fluid in the front of the eye. 7 BY MR. FREDERICKSON: 8 Q So you cite Exhibit 1067 as -- and the 9 Alphagan 0.5 percent label as one data point 10 concerning observations of conjunctival blanching 11 seen in the eye, right? 12 A Yes. 13 Q And that's -- that reference comes from 14 Page 4 of Exhibit 1067; is that right? 15 A Yes. 16 Q And the -- as best as you understand it, 17 was it the doctor or surgeon who was performing 18 the ALT surgery the individual that identified the 19 conjunctival blanching in those clinical trials? 20 MR. LUNEACK: Object to form. 21 BY THE WITNESS: 22 A I can't speak specifically to the protocol
30 1 BY THE WITNESS: 2 A Yes. 3 BY MR. FREDERICKSON: 4 Q You recognize Exhibit 1067 to be the 5 collection of the three Alphagan labels? 6 A Yes. 7 Q The Exhibit 1067 starts with Alphagan 8 0.5 percent, right? 9 A Yes. 10 Q If you go on to the second page, you see a 11 section "Indications and Usage"? 12 A Yes, I see that. 13 Q And according to the label for Alphagan 14 0.5 percent, that particular drug was indicated 15 for the prevention of postoperative IOP elevations 16 in patients undergoing argon laser 17 trabeculoplasty; is that right? 18 A That's well pronounced. 19 Q And it's abbreviated ALT; is that right? 20 A Yes. 21 Q What is ALT? 22 MR. LUNEACK: Objection. Scope.	32 1 for this trial, but, in general, adverse events in 2 clinical trials are -- the attending physician or 3 the principal investigator is responsible for 4 reporting the -- you know, doing assessment and 5 reporting and rating the adverse event, whether 6 it -- due around severity, as well as around 7 whether it's drug-related. 8 BY MR. FREDERICKSON: 9 Q Did you -- have you seen the protocol or 10 remember the protocol for the Alphagan 0.5 percent 11 clinical trials? 12 A I have not seen it. I do not remember it. 13 Q Okay. Do you know if that protocol has 14 been published in terms of who, what, when, and 15 how conjunctival blanching was assessed in the 16 clinical trials of Alphagan 0.5 percent? 17 MR. LUNEACK: Object to the form. 18 BY THE WITNESS: 19 A I do not know. 20 BY MR. FREDERICKSON: 21 Q You also point to Exhibit 1067 to identify 22 a data point from the clinical trials of Alphagan

33 1 0.2 percent; is that right? 2 A Direct me to where you're looking. 3 Q Sure. On Page 13 of your declaration, 4 Paragraph 25 you cite Page 9 of Exhibit 1067, 5 which reports 3 to 9 percent of the blanching with 6 Alphagan 0.2 percent; is that right? 7 A Yes. 8 Q Now, Alphagan 0.2 percent, that was tested 9 in the clinic for prevention and treatment of 10 intraocular pressure in glaucoma patients; is that 11 right? 12 A Lowering of intraocular pressure, yes -- 13 Q Okay. 14 A -- opening of glaucoma. 15 Q And there's a description of those 16 clinical trials on Page 7 of Exhibit 1067, right? 17 A Yes. 18 Q That description refers to comparative 19 clinical studies, plural. 20 Do you see that? 21 A Yeah. 22 Q How many comparative clinical studies of	35 1 that patient groups were dosed BID. That's twice 2 daily, right? 3 A Yes. 4 Q Do you know in the clinical trials of 5 Alphagan 0.2 percent who assessed the side effect 6 of blanching? 7 MR. LUNEACK: Object to the form. 8 BY THE WITNESS: 9 A I can just answer generally as I did 10 before, that in clinical trials, the clinical 11 investigator at each of the sites is responsible 12 for assessing adverse events. 13 BY MR. FREDERICKSON: 14 Q Do you know if the patients were required 15 to maintain diaries or instructed to look and 16 report side effects that they experienced? 17 MR. LUNEACK: Object to the form. 18 BY THE WITNESS: 19 A I don't know for -- for that study. 20 BY MR. FREDERICKSON: 21 Q For the treatment of glaucoma and the use 22 of Alphagan, there's an expectation that there's a
34 1 Alphagan 0.2 percent were there? 2 A In comparison with timolol, you're asking? 3 Q Yes. 4 A I would not know without looking it up, 5 but typically in a -- for an FDA approval, one 6 needs to run Phase 3 clinical trials, and I -- and 7 I believe in those days, timolol was -- we were 8 running studies where we were using an active 9 comparator, and timolol was the standard of care. 10 Q Those clinical comparative clinical 11 studies with timolol lasted up to one year; is 12 that right? 13 MR. LUNEACK: Objection. Lack of 14 foundation. 15 BY THE WITNESS: 16 A Yeah, I don't remember -- I don't know all 17 the details. Typically one year would be you 18 would be generating safety data over one year. 19 I'm not -- but I don't know the details of timing 20 of end points. 21 BY MR. FREDERICKSON: 22 Q And in these studies, the label describes	36 1 longer-term use of the drug, right? 2 A Yes. 3 Q And it would be impractical for the 4 physician administering the clinical trial to be 5 present during every single administration of 6 Alphagan 0.2 percent for the duration of those 7 clinical trials, right? 8 MR. LUNEACK: Object to the form. 9 BY THE WITNESS: 10 A That sounds reasonable, yes. That would 11 be unlikely that they would be coming and visiting 12 the patients at home. 13 BY MR. FREDERICKSON: 14 Q And so do you know one way or the other, 15 when the label reports that a percentage of 16 patients suffered or experienced the side effect 17 of blanching, whether those were side effects that 18 a patient observed and reported or that a treating 19 physician observed or reported? 20 MR. LUNEACK: Object to the form. 21 BY THE WITNESS: 22 A In general, again, the -- such a side

37 1 effect as blanching, which, first off, is very 2 acute, happens on -- you know, in every dose would 3 be -- you know, the way you would run the study 4 would be the first -- at the beginning of the 5 trial, the initial drop would be in the doctor's 6 office or in the clinic, and you would -- the 7 patient -- the physician would observe it at that 8 time. 9 And then at various times during the 10 trial, the patients come back to the clinic for 11 the physicians to do an assessment. 12 BY MR. FREDERICKSON: 13 Q And do you know, was that process actually 14 followed for the Alphagan 0.2 percent clinical 15 studies? 16 A Without looking at the protocol, I 17 couldn't tell you. 18 Q And did you look at the protocol in 19 preparing any of your declarations for the IPR 20 proceeding or the district court proceeding? 21 MR. LUNEACK: Objection. Vague. 22	39 1 pay particular attention to known side effects of 2 a drug. 3 Q And so how was blanching defined in the 4 clinical trials for Alphagan 0.5 percent, 5 0.2 percent, or 0.15 percent? 6 MR. LUNEACK: Object to the form. 7 BY THE WITNESS: 8 A So we know from the -- again, I don't 9 know -- I haven't looked at the protocols, but I 10 know from the NDA, from some of the documents 11 here, that -- you know, in general, the AEs are 12 classified as either trace, mild, moderate, or 13 severe. 14 BY MR. FREDERICKSON: 15 Q Okay. Now, you -- at the end of 16 Paragraph 25, which spills onto Page 14 of your 17 '245 declaration, you write in the same vein: 18 "However, all observed cases of blanching in the 19 Alphagan clinical studies were reported as, quote, 20 mild to moderate, and no subjects were 21 discontinued due to blanching, confirming that 22 blanching was not severe or worrisome."
38 1 BY THE WITNESS: 2 A I did not look at the protocol; I'm just 3 speaking with general knowledge of how clinical 4 trials are conducted. 5 BY MR. FREDERICKSON: 6 Q What about the clinical trial for 7 Alphagan P 0.15 percent; did you look at the 8 clinical trial protocol for that -- for those 9 clinical trials to determine how blanching was 10 assessed? 11 A I did not. I would point -- I would point 12 out, interesting that, you know, the Alphagan P 13 studies were run several years after the studies 14 on Alphagan 0.2 percent and 0.5 percent. 15 So, certainly, you know, as -- once 16 there's labeling that indicates that an active 17 ingredient may have -- may result in a certain 18 side effect, the -- you know, the investigators, 19 first off, are informed. It's in the 20 investigative brochure. And they're certainly 21 obligated, both the company as well as the 22 clinicians, the investigators, are obligated to	40 1 Do you see that? 2 A Yeah, you -- tell me which paragraph 3 you're on. Sorry. I'm -- 4 Q 25, on Page 14 of your '245 declaration. 5 A Right at the top. 6 Yes, I see that. 7 Q Okay. And you cite, in support of that, 8 Exhibit 2108; is that right? 9 A Yes. 10 Q The product monograph for Alphagan 11 0.2 percent, correct? 12 A Correct. 13 Q Can you take a look at that Exhibit 2108. 14 (WHEREUPON, Exhibit No. 2108 was first 15 referenced.) 16 BY THE WITNESS: 17 A Yep. I'm at the exhibit. 18 BY MR. FREDERICKSON: 19 Q Exhibit 2108 indicates that it's -- date 20 of revision of September 29th 2022; is that right? 21 A Yes. 22 Q And then on the bottom left of the front

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41 1 page, it says: "Level III submission: May 22nd, 2 2024." 3 Do you know what that refers to? 4 A I don't. 5 Q Can you turn to Page 12 of Exhibit 2108. 6 A I'm there. 7 Q And exhibit -- Page 12 of Exhibit 2108, 8 the section in the middle is "10.2 9 Pharmacodynamics," right? 10 A Yes. 11 Q And in the second paragraph in that 12 section, about halfway down, there is a sentence 13 that starts: "Conjunctival blanching was 14 observed." 15 Do you see that? 16 A Yes. 17 Q And the sentence reads: "Conjunctival 18 blanching was observed primarily at the 19 0.35 percent and 0.5 percent concentrations and 20 was generally mild or moderate in nature." 21 Do you see that? 22 A I do.	43 1 that's what you cite, Exhibit 2108 at Page 12, 2 that has that language "mild or moderate in 3 nature." 4 MR. LUNEACK: Objection to the extent that 5 mischaracterizes. 6 Also, I'm not sure if that's a question, 7 so object to form. 8 BY THE WITNESS: 9 A I've lost the page. What page were we on? 10 MR. LUNEACK: The top of Page 14 is -- 11 THE WITNESS: There we go. Okay. 12 BY THE WITNESS: 13 A Yeah, I'm trying to remember because I'm 14 pretty sure, we may not have -- I may not have 15 cited it there, but there certainly are other 16 documents here where we looked at some of the 17 other data. 18 And also there is no -- there are no 19 reports of discontinuations due to blanching which 20 you would expect, for instance, if you had severe 21 blanching. 22 But at the moment without doing a little
42 1 Q Okay. This particular paragraph that you 2 cite to is describing short-term studies of up to 3 four days in normal healthy volunteers, right? 4 MR. LUNEACK: Object to the form. And to 5 the extent it mischaracterizes. 6 BY THE WITNESS: 7 A That's what the sentence starts with, yes. 8 BY MR. FREDERICKSON: 9 Q Okay. And so in your declaration you say 10 that all observed cases of blanching in the 11 Alphagan clinical studies were reported as, quote, 12 mild to moderate, but you cite language from 13 Exhibit 2108. That's only discussing short-term 14 studies of up to four days in normal healthy 15 volunteers, right? 16 MR. LUNEACK: Objection to the extent that 17 mischaracterizes. 18 BY THE WITNESS: 19 A I believe there's other -- wait. Was that 20 the only citation we're using? 21 BY MR. FREDERICKSON: 22 Q Well, if you look at your declaration,	44 1 more searching, I do believe that, within these 2 documents, there are other examples from the 3 other -- summarizing some of the other clinical 4 trials to the point. 5 BY MR. FREDERICKSON: 6 Q Would you at least agree with me that 7 Page 12 of Exhibit 2108 does not support the 8 proposition that all observed cases of blanching 9 in the Alphagan clinical studies were reported as, 10 quote, mild to moderate? 11 MR. LUNEACK: Object to the form. 12 BY THE WITNESS: 13 A Yeah, the cited -- the cited paragraph 14 here specifically is referring to a four-day -- is 15 referring to four-day dosing. 16 BY MR. FREDERICKSON: 17 Q Four-day dosing in normal healthy 18 volunteers, right? 19 A I think that's what it said, right? 20 Yes, that's -- 21 Q Normal healthy volunteers are not people 22 suffering from glaucoma, right?

45 1 A That is -- that is right. 2 Q And so what's being described here is a 3 safety study of the drug in people without 4 glaucoma? 5 A Yes. Now, just to be clear, the action of 6 blanching is independent of whether somebody had 7 glaucoma or not; different part of the eye, as you 8 know. And so putting the drug on the eye, you 9 know, this is -- the effects you see here -- and, 10 again, blanching is a very acute effect, happens 11 right away. 12 And so this certainly could be viewed as 13 a -- certainly I think is viewed -- would be 14 viewed in certainly the way a company would carry 15 out a clinical trial is, this is an earlier study, 16 you're assessing the overall assessment of 17 potential for various findings, and so just 18 because it's done in normal healthy volunteers 19 with respect to a -- in a side effect like 20 blanching, you wouldn't expect the incidence of 21 that to necessarily be different in somebody who 22 has glaucoma.	47 1 BY THE WITNESS: 2 A Yes, I'm there. 3 BY MR. FREDERICKSON: 4 Q Exhibit 2119, the date of that revision is 5 August 25th, 2022; is that right? 6 A Yes. 7 Q You cite Pages 8 and 9 of Exhibit 2119, is 8 that right, in Paragraph 25 on Page 14? 9 A Which page did I cite? I'm sorry. I'll 10 take your word for it. 11 Q 8 and 9. Do you see that in your 12 declaration? 13 MR. LUNEACK: He's referring you to 14 Page 14 of your declaration. 15 THE WITNESS: Yeah. 16 BY THE WITNESS: 17 A Yes, I see. At 8 and 9, yes. 18 BY MR. FREDERICKSON: 19 Q And you see -- and the point that you cite 20 Exhibit 2119 for is that, in the section entitled 21 "Adverse Reaction," the phrase "blanching" does 22 not appear, right?
46 1 Q But one of the points you make in your 2 declaration is that the concept of blanching is 3 something that doctors would look for in glaucoma 4 patients, right? 5 MR. LUNEACK: Objection to the extent that 6 mischaracterizes. 7 BY THE WITNESS: 8 A I made the point that in a clinical trial 9 where -- once one knows there's blanching going 10 on, yes, that doctors would know in a study of 11 brimonidine to look for that effect, whether it be 12 in healthy volunteers or in glaucoma patients. 13 BY MR. FREDERICKSON: 14 Q The other document that you cite in 15 support of your statement that all observed cases 16 of blanching in the Alphagan clinical studies were 17 reported as mild to moderate and no subjects were 18 discontinued due to blanching is Exhibit 2119, the 19 Alphagan P product monograph; is that right? 20 (WHEREUPON, Exhibit No. 2119 was first 21 referenced.) 22	48 1 A That's correct. 2 Right. So that's suggested as we -- as 3 you -- you know, we talked a lot about dose 4 response curves last time we met, so that's 5 suggestive right in the clinical trials 6 using -- you know, that we've defined here a 7 no-effect dose with respect to blanching at 0.15 8 percent. 9 Q If you can go back to Exhibit 2108, that 10 is the product monograph for Alphagan 0.2 percent. 11 A Yes. 12 Q Well, I'll actually ask just the basic 13 question, though, is: Neither Exhibits 2108 nor 14 2119 support the proposition that all observed 15 cases of blanching in the Alphagan clinical 16 studies were reported as, quote, mild to moderate, 17 right? 18 MR. LUNEACK: Objection to the extent that 19 mischaracterizes. 20 BY THE WITNESS: 21 A Yeah, so the monograph that the -- the 22 Alphagan P, we don't see any reference to

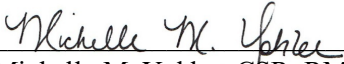
49 1 blanching, so obviously there's no differentiation 2 in terms of the gradation of blanching. 3 And, yes, in the other monograph, it did 4 not -- it's not capturing all the -- all the 5 studies; it's providing -- it's providing an 6 example from a study where, again, short-term 7 dosing showed there was clearly -- clearly 8 blanching effects, but they were mild to moderate. 9 BY MR. FREDERICKSON: 10 Q Since you last submitted the declaration 11 in the district court proceeding in December 2023, 12 did you do any research or anything to refresh 13 your memory further as to how the clinical trials 14 for Alphagan 0.5 percent, 0.2 percent, or 15 0.15 percent were conducted as it relates to this 16 issue of blanching? 17 MR. LUNEACK: Object to the form. 18 BY THE WITNESS: 19 A Only -- the only thing I refreshed my 20 memory on was the fact that there were gradations 21 as to how the -- as I said, how the ratings of 22 blanching were described.	51 1 Q And how much time did you spend 2 repurposing that declaration for resubmission in 3 the '600 IPR? 4 A When I say the three hours, that's 5 actually for both -- cumulative for both of them. 6 Q Okay. What about just the -- the IPR on 7 the '245 patent was filed first. I don't know, 8 did you know that? 9 A No. 10 Q Okay. And so by the time you got involved 11 in the need to submit another declaration for IPR 12 proceedings, you had understood or knew that there 13 was two IPRs that had been filed? 14 A Repeat that. Sorry. I didn't understand. 15 Q At some point you were made aware that 16 Bausch and Eye Therapies wanted to submit a 17 declaration from you in connection with IPR 18 proceedings; is that right? 19 A Yes, that's correct. 20 Q And that occurred sometime after December 21 of 2023 and your testimony in the district court 22 case, right?
50 1 BY MR. FREDERICKSON: 2 Q And how did you -- how exactly did you 3 refresh your memory on that? 4 A I was going back to these documents that 5 we have here. 6 Q Okay. So the reference to mild to 7 moderate in Exhibit 2108 refreshed your memory 8 that there was some gradation in how blanching was 9 assessed? 10 A Yes. 11 MR. LUNEACK: Objection. 12 Mischaracterizes. 13 BY THE WITNESS: 14 A Yes, I -- you -- the -- I can't remember 15 if it was that precise document, but, yes, I 16 was -- I refreshed my memory that those 17 descriptors were used in these clinical trials. 18 BY MR. FREDERICKSON: 19 Q How much time did you spend preparing your 20 declaration that you submitted in November of 2024 21 in the '245 IPR? 22 A Somewhere around three hours.	52 1 A Yes. 2 Q At the time you were made aware that 3 Patent Owner was looking to submit declarations 4 from you in IPR proceedings, was it your 5 understanding that there were two IPR proceedings 6 against the '245 and '600 patent? 7 A I became aware of it at that time, yeah. 8 Yes. 9 Q And I believe your declaration in the '600 10 proceeding is signed and dated on November 27, 11 2024; is that right? 12 A The '600 you're talking about now, right? 13 Q Yep. 14 A November 27, 2024. 15 Q Nine days after you signed and dated the 16 declaration in the '245 patent and IPR on 17 November 18th, 2024, right? 18 A Your math, but I'll take your word for it. 19 Q And so, just in terms of your process, 20 Dr. Gil, did you work first on the declaration for 21 the '245 IPR and then repurpose that for the '600 22 IPR, or were you working on both simultaneously?

53 1 A I -- my recollection is I was working on 2 both simultaneously. 3 Q And your recollection is the total amount 4 of time you spent preparing the two, leveraging 5 the work you had done from the district court 6 proceedings, was about three hours? 7 A That's correct. 8 MR. FREDERICKSON: All right, Dr. Gil, 9 shorter than last time. I don't have any further 10 questions for you. Thank you for taking the time. 11 MR. LUNEACK: Let's take a break and come 12 back in maybe 15 minutes or so. 13 MR. FREDERICKSON: Okay. 14 THE VIDEOGRAPHER: We are now going off 15 record. The time on the video monitor is 16 2:57 p.m. 17 (WHEREUPON, discussion was had off the 18 record.) 19 THE VIDEOGRAPHER: We are now back on 20 record. The time on the video monitor is 21 2:58 p.m. 22 MR. LUNEACK: This is Matthew Luneack on	55 1 EXAMINATION 2 BY MR. LUNEACK: 3 Q Dr. Gil, on behalf of Patent Owner, I just 4 have a few questions for you. 5 Do you recall being asked certain 6 questions today about who was responsible for 7 reporting blanching in the Alphagan clinical 8 studies? 9 A Yes. 10 Q I'd like you to take a look at 11 Exhibit 1030. 12 (WHEREUPON, Exhibit No. 1030 was first 13 referenced.) 14 BY THE WITNESS: 15 A Yes. I'm there. 16 BY MR. LUNEACK: 17 Q Dr. Gil, do you recognize Exhibit 1030 as 18 a copy of the Alphagan NDA? 19 A I do. 20 Q If you could please turn to Page 119 of 21 Exhibit 1030. 22 A Yes, I'm there.
54 1 behalf of Patent Owner. I just wanted to make it 2 clear on the record that my application for 3 pro hoc vice admission as backup counsel for 4 Patent Owner, which the Petitioner has consented 5 to, remains pending. 6 The issue was discussed with Petitioner's 7 counsel before the deposition began. 8 Mr. Frederickson, can you confirm that 9 Petitioner consented to my defense of Dr. Gil's 10 deposition today? 11 MR. FREDERICKSON: Yes, Petitioner 12 consented. 13 MR. LUNEACK: We can go back off the 14 record. 15 THE VIDEOGRAPHER: We are now going off 16 record. The time on the video monitor is 17 2:58 p.m. 18 (WHEREUPON, a recess was had.) 19 THE VIDEOGRAPHER: We are now back on 20 record. The time on the video monitor is 21 3:14 p.m. 22	56 1 Q And the fourth paragraph on Page 119 2 states: "Throughout the study, subjects were 3 monitored for signs and symptoms of adverse 4 events, ocular and general discomforts. Any 5 adverse event occurring during the study was 6 recorded by the investigator, graded for severity 7 (trace, mild, moderate, or severe), and assessed 8 for relationship to the study treatment." 9 Do you see that? 10 A Yes. 11 Q And did I read that correctly? 12 A Yes. 13 Q Dr. Gil, how, if at all, does this 14 statement inform the person of ordinary 15 skill's under -- in the art's understanding as to 16 whether -- as -- strike that. 17 Dr. Gil, how, if at all, does this 18 statement inform the person of ordinary skill in 19 the art's understanding as to how blanching was 20 monitored and recorded during the Alphagan 21 clinical studies? 22 A It states clearly that the adverse events

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57 1 were recorded by the investigator. And on -- very 2 typically that could be either the investigator -- 3 it's definitely the investigator observing it and 4 then rating it to -- in terms of magnitude. 5 I think also the patient could presumably 6 have observed it on their own and reported it to 7 the investigator and then the investigator would 8 do their own assessment. 9 Q Dr. Gil, let's take a look at your 10 declaration for the '600 patent. 11 A Yes, I'm there. 12 Q And I'd like to refer you to Paragraph 25. 13 A Yes. 14 Q The last sentence in Paragraph 25 of your 15 '600 IPR declaration reads: "However, all 16 observed cases of blanching in the Alphagan 17 clinical studies were reported as mild to moderate 18 and no subjects were discontinued due to 19 blanching, confirming that the blanching was not 20 severe or worrisome." 21 Do you see that? 22 A I see that, yes.	59 1 BY MR. LUNEACK: 2 Q And, Dr. Gil... 3 A Yes, go ahead. 4 Q Why did you cite to Page 51 of the 5 declaration -- of this exhibit? 6 A So this is reporting on adverse events 7 that resulted in termination. And there's no 8 reports of blanching having contributed to 9 termination from the study, which would, again, 10 indicate that when there were reports of 11 blanching, it would not have been so severe to 12 cause the investigator to terminate the patient 13 from the study. 14 It would have probably been more in the 15 range of -- they would have been in the range of, 16 you know, mild to moderate, which is really -- you 17 know, that would be in the terms of, if you were 18 going after a hyperemia -- a reduction of a 19 hyperemia indication, that's what you would want 20 to be targeting. 21 MR. FREDERICKSON: Just note an objection. 22 Calls for speculation.
58 1 Q And you have citations to the product 2 monographs for Alphagan 0.2 percent and Alphagan P 3 0.15 percent that you were asked about earlier. 4 Do you see that? 5 A Yes, I do. 6 Q And there's a third citation at the end of 7 the paragraph to Exhibit 1030, the Alphagan NDA, 8 at 51. 9 Do you see that? 10 A Yes. 11 Q Let's take a look at that. So back to 12 Exhibit 1030 at Page 51. 13 A Yes. 14 Q And, Dr. Gil, can you describe what's 15 depicted on Page 51 of Exhibit 1030? 16 MR. FREDERICKSON: For the record, can we 17 confirm, Page 51 of 286, the IPR pagination? 18 MR. LUNEACK: That's correct, Page 51 of 19 286. 20 BY THE WITNESS: 21 A Yeah, I see that. 22	60 1 MR. LUNEACK: Thank you, Dr. Gil. No 2 further questions from Patent Owner. 3 MR. FREDERICKSON: I have no further 4 questions. 5 THE VIDEOGRAPHER: This marks the end of 6 the deposition of Dr. Daniel Gil. The time on the 7 video monitor is 3:21 p.m. 8 (WHEREUPON, the deposition was concluded 9 at 3:21 p.m. CST.) 10 11 12 13 14 15 16 17 18 19 20 21 22

61 1 CERTIFICATE OF SHORTHAND REPORTER 2 3 I, Michelle M. Yohler, Certified 4 Shorthand Reporter, Registered Professional 5 Reporter, Registered Merit Reporter, Certified 6 Realtime Reporter, within and for the State of 7 Illinois do hereby certify: 8 That DANIEL W. GIL, Ph.D., the witness 9 whose deposition is hereinbefore set forth, was 10 duly sworn by me before the commencement of such 11 deposition and that such deposition was taken 12 before me and is a true record of the testimony 13 given by such 14 witness. 15 I further certify that the adverse party, 16 EYE THERAPIES, was represented by counsel at the 17 deposition. 18 I further certify that the deposition of 19 DANIEL W. GIL, Ph.D., occurred on Wednesday, 20 February, 12, 2025, commencing at 1:58 p.m. CST to 21 3:21 p.m. CST. 22	
62 1 I further certify that I am not related to 2 any of the parties to this action by blood or 3 marriage, I am not employed by or an attorney to 4 any of the parties to this action, and that I am 5 in no way interested, financially or otherwise, in 6 the outcome of this matter. 7 8 IN WITNESS WHEREOF, I have hereunto set 9 my hand this 20th day of February, 2025. 10 11 12  13 Michelle M. Yohler, CSR, RMR, CRR 14 Certified Shorthand Reporter 15 CSR No.: 84-4531 16 17 18 19 20 21 22	

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