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Transcript of Robert Noecker, M.D.

Date: November 13, 2022

Case: Slayback Pharma LLC -v- Eye Therapies LLC (PTAB)

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WORLDWIDE COURT REPORTING & LITIGATION TECHNOLOGY

Transcript of Robert Noecker, M.D.
November 13, 2022

1 (1 to 4)

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22
UNITED STATES PATENT AND TRADEMARK OFFICE ----- BEFORE THE PATENT TRIAL AND APPEAL BOARD -----X SLAYBACK PHARMA LLC, : Petitioner, : Case No.: v. : IPR2022-00142 EYE THERAPIES LLC : U.S. Patent No. Patent Owner : 8,293,742 -----X Deposition of Dr. Robert Noecker Norwalk, Connecticut Sunday, November 13, 2022 9:25 a.m. Job No.: 468951 Pages 1-122 Reported by: Angela (Angie) Shaw-Crockett, CRR, RMR	APPEARANCES ON BEHALF OF THE PETITIONER, SLAYBACK PHARMA LLC: LINNEA P. CIPRIANO, ESQUIRE Goodwin Procter LLP 620 Eighth Avenue New York, New York 10018 212-813-8800 lcipriano@goodwinlaw.com ON BEHALF OF THE PATENT OWNER, EYE THERAPIES LLC: CHRISTINA YANG, ESQUIRE BRYAN DINER, ESQUIRE JASON ZHANG, ESQUIRE Finnegan, Henderson, Farabow, Garrett & Dunner LLP 901 New York Avenue NW Washington, District of Columbia 20001-4413 202-408-4004 ALSO PRESENT: Rocco Mercurio, The Videographer	Deposition of Dr. Robert Noecker, held at: Residence Inn Norwalk 45 South Main Street Norwalk, Connecticut 06845 Pursuant to Notice, before Angela (Angie) Shaw-Crockett, CRR, RMR, Notary Public in and for the states of New York, New Jersey and Connecticut.	INDEX Examination of: Page Dr. Robert Noecker CONTENTS MS. CIPRIANO 6 MR. DINER 118 EXHIBITS (Retained by the court reporter) DEPOSITION EXHIBIT PAGE Exhibit 1046 Figure 2 of '742 patent 80

November 13, 2022

5 1 THE VIDEOGRAPHER: We are now going on the 2 record. Today is November 13, 2022, and the time is 3 approximately 9:25. 4 This is media 1 of the video deposition of 5 Dr. Robert Noecker in the matter of Slayback Pharma 6 LLC v. Eye Therapies LLC, filed in the U.S. Patent and 7 Trademark Office, case number IPR2022-00142. 8 My name is Rocco Mercurio, and the court 9 reporter is Angie Shaw-Crockett, and we're with Planet 10 Depos. 11 Would counsel please introduce yourselves 12 and who you represent for the record. 13 MS. CIPRIANO: My name is Linnea Cipriano 14 of Goodwin, representing Petitioner. 15 MR. DINER: My name is Bryan Diner of the 16 Finnegan firm, representing the patent owner, with my 17 colleagues Christina Yang and Jason Zhang. 18 THE VIDEOGRAPHER: The court reporter will 19 now swear in the witness, and we can now proceed. 20 Dr. Robert Noecker, having been duly sworn, testified 21 as follows: 22 EXAMINATION	7 1 A It was for Combigan. 2 Q And was this the only time you served as an 3 expert witness in a patent case? 4 A No. 5 Q How many other times? 6 A About six. 7 Q Have you always represented the patent 8 owner in those proceedings? 9 A I've -- you know, these things come to 10 different levels. So it's -- sometimes it's -- 11 it's -- I've had all-different-level discussions with 12 defendants, plaintiffs, two branded product against 13 each other. 14 Q So this will probably proceed as your other 15 depositions, but I'd like to go over some ground rules 16 to make sure we're on the same page. 17 I'll be asking you questions, and you'll be 18 answering them today. Your answers will be -- you've 19 just been put under oath. You understand that your 20 answers are as if you were testifying in court. 21 Do you understand that? 22 A Yes.
6 1 BY MS. CIPRIANO: 2 Q Good morning. 3 A Good morning. 4 Q Would you please state your name for the 5 record? 6 A Robert Noecker. 7 Q Have you been deposed before? 8 A Yes. 9 Q How many times? 10 A Eight, ten. 11 Q Okay. And what was the most recent time? 12 A The most recent time was in conjunction 13 with a medicolegal thing. 14 Q Okay. How long ago was that? 15 A A year ago. During COVID. 16 Q Okay. Have you ever served as an expert 17 witness in a patent case before? 18 A Yes. 19 Q And when was that? 20 A The last one was two years ago. 21 Q And what product -- at a high level, what 22 product was that involved with?	8 1 Q During the course of the deposition, your 2 counsel may make objections, but unless you've been 3 instructed by your counsel not to answer, I will 4 expect you to answer my questions. 5 Do you understand that? 6 A Yes. 7 Q As you know, we have a court reporter here, 8 taking down everything we say. That means that you 9 and I both must make an effort to speak slowly and 10 clearly. And I'll try not to speak over you if you 11 try not to speak over me. 12 Do you understand? 13 A Yes. 14 Q We'll be taking breaks from time to time, 15 and if you can please let me know if you need a break 16 at any point. I'll just ask that we finish a question 17 and answer before we take a break. 18 Does that make sense? 19 A Yes. 20 Q Can you -- I will ask you today to listen 21 carefully to my questions, and if there's something 22 that you don't understand, please let me know. I'm

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November 13, 2022

9 1 sure that I will not be as clear as I intend to be at 2 times during the day. But if you do answer my 3 question, I'll assume that you understood the 4 question. 5 Does that make sense? 6 A Yes. 7 Q And you understand that while I'm asking 8 you questions today, you're not to permitted to 9 discuss the substance of your testimony with your 10 counsel. 11 Do you understand that? 12 A Yes. 13 Q Is there any reason that you will not be 14 able to answer my questions fully and truthfully 15 today? 16 A No. 17 Q Did you prepare for today's deposition? 18 A Yes. 19 Q So without revealing any privileged 20 communications with your counsel, at a high level, 21 what did you do to prepare for today's deposition? 22 A I read my expert report multiple times, and	11 1 looked at in preparation for the deposition? 2 A None specifically. Most that are related 3 to the expert report. 4 Q I'm going to hand you a copy of your 5 declaration, which is marked Exhibit 2020 in the IPR. 6 Do you recognize this as being the 7 declaration that you submitted in IPR2022-00142. 8 A Yes, it appears to be. 9 Q And at a high level, how did you prepare 10 your declaration? 11 A Basically, read the issues at hand in the 12 case, reviewed the literature, started composing the 13 document, met, at times, with the attorneys to fill in 14 the blanks, edited extensively. 15 Q Did you review any of the declarations from 16 the other experts in this case? 17 A Yes. 18 Q At what point did you review those in your 19 preparation? 20 A At some point in the last year. 21 Q Before you signed your declaration? 22 A I believe so. The time is a little vague
10 1 related materials, and met with the attorneys. 2 Q With whom did you speak concerning this 3 deposition? 4 MR. DINER: Vague. 5 A What do you mean by that? 6 BY MS. CIPRIANO: 7 Q Who did you talk to in preparation for the 8 deposition? 9 A So in preparation, I met with the three 10 attorneys here. 11 Q Anyone else? 12 A No. 13 Q Have you had conversations with any of the 14 other people who submitted declarations in this IPR? 15 A No. 16 Q Did you review any documents other than 17 your expert declaration to prepare for this 18 deposition? 19 A Well, as I always do, I review my own 20 personal experiences as well as the relevant 21 literature. 22 Q Do you recall any specific documents you	12 1 at this point. 2 Q Are there any corrections or changes you'd 3 like to make to this declaration at this point? 4 A No. 5 Q You're currently employed, correct? 6 A That's correct. 7 Q What is to your current title? 8 A I'm an ophthalmologist with Ophthalmic 9 Consultants of Connecticut. 10 Q And you understand you're being presented 11 as an expert in this proceeding, correct? 12 A That's correct. 13 Q What is your area of expertise? 14 A It's treatment of conditions of the -- 15 diagnosis and treatment of conditions of the eye. 16 Q And you're not a chemist, right? 17 A I'm not a chemist myself. 18 Q You're not an expert in the formulation of 19 eye drops? 20 A I'm familiar and I've done formulation 21 work, but I'm not an expert. 22 Q What do you mean by "done formulation

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November 13, 2022

13 1 work"? 2 A I've performed research in which we need to 3 formulate compounds. 4 Q Have you ever manufactured a formulation of 5 an eye drop? 6 A I have not. 7 Q Have you ever been involved in determining 8 which excipients will be used in the formulation of an 9 eye drop? 10 A For experimental purposes, not for 11 commercial purposes. 12 Q And when was that? 13 A Several years ago at the 14 University of Arizona. 15 Q And what product was that for? 16 A We were -- well, several glaucoma 17 medications. 18 Q What drugs? 19 A One called "latanoprost," another one 20 called "latanoprost 1," another one for some 21 antibiotics. 22 Q And what was your role in?	15 1 so just so we're on the same page. 2 You are not an expert in commercial 3 marketing, correct? 4 A That's correct. 5 Q So throughout your declaration, you make 6 statements that refer to what you understand other 7 experts or declarants in this proceeding will say. 8 Do you recall that? 9 A Yes. 10 Q And when you make those statements, you're 11 not offering independent opinions on what those other 12 experts said, correct? 13 A Correct. 14 Q So you're relying on the expertise of 15 others? 16 A That's correct. 17 Q I'd like to turn now to some vocabulary to 18 make sure that we're speaking the same language. 19 So let's turn to page 14 of your 20 declaration. 21 A (Witness complies.) 22 Q Are you there?
14 1 A We were doing experiments, so we were 2 basically developing these drugs to look at stability 3 and things like that. 4 Q And your input was on the clinical side? 5 A Well, some of these are rabbit studies, so 6 I was the guy who did stuff to the rabbits. 7 Depended -- yeah, I was basically the clinical 8 advisor, had to put things in clinical perspective. 9 Q You're not an economist, right? 10 A I am not. 11 Q And you're not an expert in commercial 12 marketing, correct? 13 THE VIDEOGRAPHER: Hold on. Your mic just 14 went out. 15 We're now going off the record. The time 16 is now 9:35. 17 (Recess.) 18 THE VIDEOGRAPHER: Now going back on the 19 record. The time is 9:44. 20 BY MS. CIPRIANO: 21 Q I might repeat some of the questions. I'm 22 not sure we got all of the answers to my last round,	16 1 A Yes. 2 Q Okay. And here you have a diagram of two 3 pictures of the eye, right? 4 A Yes. 5 Q And the bottom diagram, it's a 6 cross-section, and the front of the eye is facing 7 left, correct? 8 A Yes. 9 Q And that front section is called the 10 "anterior portion" of the eye, correct? 11 MR. DINER: Objection, vague. 12 A You have to be more specific. 13 BY MS. CIPRIANO: 14 Q Okay. Can you explain to me what's 15 referred to as the anterior portion of the eye? 16 A Well, it will depend on the context, but we 17 frequently refer to the "anterior chamber," so talking 18 about the inside of the eye, the anterior chamber is 19 divided from the post chamber -- in the side view, 20 we're speaking. 21 So everything kind of from the iris, the 22 colored part, forward, to the front -- toward the

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November 13, 2022

17 1 front of the eye is anterior chamber. Everything 2 behind the iris is the posterior chamber. 3 Q So the lens is in the posterior chamber; am 4 I understanding? 5 A That's correct. 6 Q Okay. You also have a diagram on page 16 7 of your declaration. And I'd like to take a look at 8 what's labeled "sclera" in this figure. 9 So the sclera label points to two different 10 things. 11 Do you see that? 12 A Yes. 13 Q One is pointing to the front picture of the 14 eye. And that's pointing to the white that surrounds 15 the iris, right? 16 A The sclera is dense connective tissue 17 that's kind of the back -- it's 80 percent of the eye. 18 The outside of the shell of the eye is the way to 19 think about it. 20 Q And what you can see of the sclera in the 21 picture of the front of a person's eye is the white 22 part, correct?	19 1 part. 2 Q Okay. So the sclera -- just so I 3 understand this correctly, the sclera is what's 4 pointed to in that -- in the blue triangle, if you 5 will, that includes the episclera, stroma, lamina 6 fusca, and endothelium? 7 A In that cross-section. 8 Q Okay. You agree that the blood vessels 9 that cause eye redness are the blood vessels that 10 reside in the sclera, correct? 11 MR. DINER: Objection, vague. 12 A No. I disagree with that. 13 BY MS. CIPRIANO: 14 Q Where are the blood vessels that cause eye 15 redness? 16 A If we're talking about eye redness as 17 relevant to this case, so we're talking about 18 hyperemia mostly, predominantly, those are 19 conjunctival blood vessels. 20 Q And they're not in the sclera? 21 MR. DINER: Objection. Mischaracterizes 22 testimony.
18 1 A The sclera is all white; it's collagen. 2 Q Maybe we're speaking past each other. 3 Where it points to -- where sclera points 4 to a section of the person's eye that you can see the 5 brown eye with the eyelashes and the eyebrow, there, 6 the arrow is pointing to the white space around the 7 iris, correct? 8 A Yeah. That -- that's part of it. 9 Q Okay. And the other line from the word 10 "sclera" goes to a box that's near the back of the eye 11 in the bottom diagram, correct? 12 A It's a cross-section, yes. 13 Q And that's because the sclera, as you said, 14 surrounds the entire part of the eye, not just the 15 part of the eye you can see, correct? 16 A It's the back. It's approximately 17 80 percent of the shell, the outside of the eye, 18 the -- it provides structural support to the eye. 19 Q So that square that the sclera line points 20 to is then magnified in a cross -- further 21 cross-section on the left of that diagram? 22 A It's a cross-section of the sclera in that	20 1 A They are not in the sclera. 2 BY MS. CIPRIANO: 3 Q In relation to the sclera, where is the -- 4 where are the conjunctival blood vessels? 5 A They're in the conjunctiva. 6 Q And where is that in relation to the 7 sclera? 8 A It's superficial, in part, to the eye. 9 It's superficial in the portion. 10 Q Okay. And superficial meaning it's on top 11 of the episclera? 12 A Correct. 13 Q Prior to Lumify, there were a number of 14 over-the-counter eye redness reducers on the 15 commercial market. 16 You agree with that, right? 17 A Yes. 18 Q So if we could turn to page 25 of your 19 declaration -- 20 A (Witness complies.) 21 Q -- just for reference. 22 You list a few in the chart that's at the

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November 13, 2022

21 1 bottom of that page. And some examples that you list 2 are Naphcon, Naphcon-A, All Clear, Ocu-Clear, Visine, 3 and Visine Advanced Redness Relief. 4 Do you see that? 5 A Yes. 6 Q And these were all FDA approved as 7 over-the-counter treatments, correct? 8 A Yes. 9 Q So you'd agree that all of these were 10 considered by the FDA to be particularly safe, 11 correct? 12 MR. DINER: Objection, vague. Lacks 13 foundation. 14 A I'd have to look at that closer -- what the 15 FDA said. 16 BY MS. CIPRIANO: 17 Q Well, let's look at what you said in 18 paragraph 61 of your declaration. 19 In -- starting four lines down, you say 20 "Because OTC products treat self-diagnoseable 21 conditions without a health care provider's 22 instructions, they are susceptible to misuse through	23 1 recognize these products are certainly not perfect. 2 And frequently, there's many patients sometimes we 3 recommend that they don't use these products. 4 So it depends on the context, depends on 5 the clinical scenario, what we say is particularly 6 safe or not. 7 BY MS. CIPRIANO: 8 Q When you say these products are not -- 9 certainly not perfect, you'd agree that all of these 10 products had side effects like hyperemia, 11 conjunctivitis, and medicamentosa? 12 A Those are possible. Don't happen every 13 time, but they're possible, yes. 14 Q You agree some people misused or overused 15 over-the-counter redness relievers, correct? 16 A I mean, generally, I think any therapy 17 people -- somebody, some person, has probably overused 18 or improperly used. We see that all the time. 19 Q And you agree that some people had to stop 20 using prior over-the-counter redness relievers because 21 either of the side effects or because they stopped 22 working, correct?
22 1 overuse. Therefore, they must not only be 2 efficacious, but they must also be particularly safe." 3 Do you see that? 4 A I do. 5 Q So you'd agree that if a product is 6 approved to be over-the-counter, it must be 7 particularly safe? 8 A Yeah. The context of that -- of that 9 phrase, or the sentence is -- is always -- in 10 medicine, we always take this risk-benefit position. 11 So the more bad your condition is or more serious, 12 say, in our field, glaucoma blinds you, so we'll 13 accept more risk. 14 Q Okay. But for redness reducers that are -- 15 were commercially available as over-the-counter 16 products, you'd agree that the products that are 17 listed in the charts on page 25 of your declaration -- 18 that those products were deemed to be particularly 19 safe, correct? 20 MR. DINER: Objection. Mischaracterizes 21 his testimony. Lack of foundation. 22 A No. I mean, these -- and we certainly	24 1 MR. DINER: Objection. Incomplete 2 hypothetical. Lacks foundation. 3 A For any specific, there's always a possible 4 scenario where that's true. And I think there's 5 certainly individual anecdotal cases where that's 6 happened with, once again, these products and every 7 other product that's ever been used to treat a human. 8 BY MS. CIPRIANO: 9 Q Let's talk a little bit about brimonidine. 10 You'd agree that brimonidine is known to 11 have ocular hypertensive effects, correct? 12 A We primarily use brimonidine to lower eye 13 pressure. 14 Q And when you say "lowering eye pressure," 15 that's lowering the intraocular pressure, correct? 16 A That's correct. 17 Q And when we say "intraocular pressure," 18 that's the fluid inside what -- I think what we 19 referred to as the posterior segment of the eye? 20 MR. DINER: Objection, vague. 21 A I don't exactly understand what you said 22 that last time.

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November 13, 2022

25 1 BY MS. CIPRIANO: 2 Q Okay. So when we talk about lowering 3 intraocular pressure, the pressure that we're talking 4 about is the pressure of the fluid that's inside the 5 eye, correct? 6 MR. DINER: Objection, vague. 7 A Well, intraocular pressure is the pressure 8 inside the eye. 9 BY MS. CIPRIANO: 10 Q And what is causing that pressure? 11 Let me rephrase that. 12 What is exerting the pressure in the eye? 13 A Well, the eye always has a pressure. And 14 so there's this fluid aqueous which the eye makes and 15 drains it away. 16 Q And what I'm trying to get at is where that 17 fluid is held in the eye. 18 And is that in the -- if we need to go back 19 to the picture, maybe that would be helpful. 20 Is that in the section of the eye that's 21 behind the lens? 22 A Well, it circulates around the eye.	27 1 BY MS. CIPRIANO: 2 Q Yeah, let's step back. 3 What I'm trying to understand is, there 4 are -- "hypotensive" can have a couple of different 5 meanings in medicine. It's referred to a couple of 6 different ways. 7 There are agents that are characterized, at 8 least in my understanding of the literature, as 9 hypotensive agents that are administered to reduce a 10 patient's blood pressure. 11 You agree with that? 12 A Yes, there's some agents we use to reduce 13 blood pressure, yes. 14 Q Okay. But when you say that brimonidine is 15 known to have hypotensive effects, that's limited to 16 the fact that it's known to have ocular hypotensive 17 effects, correct? 18 MR. DINER: Objection. Mischaracterizes 19 the document. 20 A It depends on the root of administration. 21 BY MS. CIPRIANO: 22 Q And what do you mean by that?
26 1 Q It's everywhere in the eye? 2 A It's -- it's moving. 3 Q Okay. So intraocular pressure is not the 4 same as blood pressure, right? 5 A Correct. 6 Q So brimonidine hasn't ever been used to 7 reduce systemic blood pressure, right? 8 A I don't know if it's been attempted. 9 Q You're not aware? 10 A I'm not aware. 11 Q Okay. But you agree it's not known to be a 12 systemic hypotensive agent, right? 13 A On average -- once again, it depends how 14 you administer it. 15 Q I'm not sure I understand. 16 A How are -- the question is, how are you 17 administering it? 18 Q Systemically? 19 A Systemically. 20 MR. DINER: Objection, vague. 21 A So you're saying to give it to a person, 22 like, intravenously or --	28 1 A How are you giving it to the person? 2 Q Is it your opinion that a person of 3 ordinary skill in the art would understand that 4 brimonidine was known prior to 2008 to have systemic 5 hypotensive effects? 6 A Brimonidine? Depending how you administer, 7 it could. 8 Q Are you aware of any study published prior 9 to August of 2008 that showed brimonidine to be a 10 vasodilator in the anterior portion of the eye? 11 A I'm not sure exactly what -- those terms 12 aren't as specific as I'd like, but I think there's 13 certainly, from our clinical studies we've seen, blood 14 vessels on the surface of the eye get quite dilated 15 with the use of brimonidine, yes. 16 Q And in what -- strike that. 17 And what clinical studies are you referring 18 to? 19 A So Alphagan eye drop study used for 20 glaucoma, we saw significant red eyes or hyperemias 21 when used in eye-drop form at 0.2 percent. 22 Q Okay. So you're talking about the adverse

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November 13, 2022

29 1 event of hyperemia that is seen after administration 2 with brimonidine, correct? 3 MR. DINER: Objection to the extent it 4 mischaracterizes testimony. 5 A The -- well, it was 0.2 percent Alphagan 6 used. It was a glaucoma study, and that was one of 7 the endpoints that were measured. 8 BY MS. CIPRIANO: 9 Q What was an endpoint? 10 A Eye redness, hyperemia. 11 Q And what study is this? 12 A 1996. I'm trying to think of the first 13 author. 14 I can look it up. I can't remember off the 15 top of my head the author. But it was the 16 FDA-approval studies, the phase III trials submitted 17 for approval of Alphagan, that hyperemia was recorded 18 in that. 19 Q Do they measure redness? 20 A I'm sorry. What do you mean by "measure"? 21 Q Did -- was there a scale that was recorded 22 that measured redness in those studies?	31 1 hypothetical. 2 A I think what you're asking me is, can 3 these -- can drugs with alpha 1 properties cause 4 hyperemia, which is yes. 5 BY MS. CIPRIANO: 6 Q So hyperemia is not necessarily a -- strike 7 that. 8 So hyperemia is not necessarily a sign that 9 a drug is a vasodilator, correct? 10 A I don't understand the question. 11 Q Okay. Let's take it step by step. 12 You -- so I asked you whether you were 13 aware of any studies showing that brimonidine was a 14 vasodilator in the eye when applied topically -- let 15 me start over. 16 So it's your position that because 17 brimonidine causes hyperemia, that it can be a 18 vasodilator when applied topically to the eye; is that 19 correct? 20 A I think what we can say is that when we see 21 that the blood vessels on the surface of the eye are 22 engorged, they're vasodilators; the blood vessels are
30 1 A In that study, I'm not sure if there was a 2 scale, no. 3 Q So when you say recorded "redness," they 4 recorded whether hyperemia was observed, correct? 5 A I'd have to go back and look at the study 6 protocol, which we did. I'm not sure if there was a 7 grading scale. I can't remember. 8 Q To go back to my question about studies 9 showing brimonidine to be a vasodilator. 10 You agree that even -- well, strike that. 11 Let me back up a little bit. 12 You'd agree that alpha 1 agonist drugs are 13 accepted to be vasoconstrictors in the eye, correct? 14 A So I'll -- so to answer that, I'll assume 15 that you're -- that topically administrated [sic] in 16 the form of an eye drop that, applied to the eye, that 17 you can have -- you'll have a vasoconstrictive effect 18 on the surface blood vessels of the eye, yes. 19 Q And those same alpha 1 agonist drugs that 20 are applied topically in the form of an eye drop also 21 can cause hyperemia, correct? 22 MR. DINER: Objection. Incomplete	32 1 dilated. If they're red and engorged, hyperemia. 2 Q And that same type of hyperemia where when 3 the blood vessels of the eye are engorged occurs after 4 a topical administration of alpha 1 agonists, correct? 5 MR. DINER: Objection. Mischaracterizes 6 prior testimony. 7 A The answer is, it depends. 8 BY MS. CIPRIANO: 9 Q But it can? 10 A In a very specific scenario, based on the 11 timing when you're measuring these things. If you 12 give me a specific clinical scenario, we can address 13 whether or not it probably happens. 14 Q So when you say that brimonidine causes 15 hyperemia, what was the timing of measuring that 16 hyperemia? 17 A There are many time points. 18 Q Okay. Let's look at -- we'll look at some 19 specific studies a little bit later, maybe to get to 20 the bottom of that. 21 So we talked a little bit about the 22 Alphagan product. You mentioned that.

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November 13, 2022

33 1 A I did mention that, yes. 2 Q And Alphagan, I understand, was available 3 in concentrations of 0.5 percent brimonidine and 4 0.2 percent brimonidine; is that correct? 5 A What do you mean by "available"? 6 Q It was marketed in those strengths. 7 A It was never marketed in 0.5 percent. 8 Q Okay. So original Alphagan was marketed at 9 0.2 percent? 10 A That was the original Alphagan, yes. 11 Q And another product called "Alphagan P" was 12 also marketed in that family, correct? 13 A That's correct. 14 Q And that was available, commercially 15 available, at 0.15 percent and 0.1 percent? 16 A Yes. 17 Q And those Alphagan and Alphagan P were both 18 Alphagan products, correct? 19 A Yes. 20 Q And Alphagan concluded that all -- that the 21 Alphagan and Alphagan P products were safe and 22 comfortable for patients, correct?	35 1 clinical studies that were part of the NDA. 2 Do you see that? 3 A Yes. 4 Q Okay. And then on page 13, this is, if you 5 will, an expanded chart, providing a little more 6 information about the clinical studies that were 7 listed in on page 12; is that correct? 8 A Yes. 9 Q And the clinical studies listed on page 13 10 are categorized as "early dose tolerance studies." 11 Do you see that? 12 A Yes. 13 Q Okay. And then on the right-hand side, 14 there's a "study conclusions" column. 15 Do you see that? 16 A Yes. 17 Q And for all of these studies, Alphagan 18 represented to the FDA that brimonidine, at all the 19 concentrations tested, was safe and comfortable, 20 right? 21 MR. DINER: Objection, foundation. 22 Dr. Noecker, it is a large document. You
34 1 MR. DINER: Objection. No foundation. 2 A What's the context of that statement? 3 BY MS. CIPRIANO: 4 Q Do you disagree? 5 MR. DINER: Same objection. No foundation. 6 A I mean, they're approved by the FDA. 7 BY MS. CIPRIANO: 8 Q Let's take it a look at another exhibit. 9 I'm going to hand you what's been marked as 10 1031 in the IPR. 11 Do you recognize this as one of the 12 documents you relied on in your declaration? 13 A Yes. 14 Q And this is parts of the NDA that was 15 submitted for Alphagan at 0.2 percent, correct? 16 A Yes. 17 Q So if we could turn to page 12 of the 18 document. 19 A (Witness complies.) 20 Q So it's page 12 of 286, if you see that. 21 A I see it. 22 Q So here on page 12, this is a list of	36 1 should take the time to review the pages she pointed 2 to and any other information in this document you 3 think would be helpful to inform you in order to 4 answer her question. 5 A I have to look into -- it's been a long 6 time since I've looked at these. 7 BY MS. CIPRIANO: 8 Q You're welcome to look at whatever you need 9 to in this document. 10 But if you could just look at the "study 11 conclusions" column here and look at the first 12 sentence in every box here, Alphagan stated 13 "brimonidine concentrations of," and it lists the 14 concentrations that were studied "is safe and 15 comfortable," correct? 16 MR. DINER: Objection. Document speaks for 17 itself. 18 A Those words are there but, once again, it 19 all depends on the context of what we're talking 20 about. This is a glaucoma medication. 21 BY MS. CIPRIANO: 22 Q Were these studies administered to glaucoma

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November 13, 2022

37 1 patients? 2 MR. DINER: Again, Dr. Noecker, it's a 3 large document. The question is vague. If you need 4 to look at something, you should look at something. 5 And feel free to ask counsel any questions you may 6 have. 7 THE WITNESS: Sure. 8 BY MS. CIPRIANO: 9 Q To the extent it's helpful, the study -- a 10 narrative about the study design starts on page 20 of 11 the exhibit, if that's helpful. 12 A (Witness reviews document.) 13 Q Doctor, are you looking for something 14 specific in the document? 15 A Yes. I'm looking for the study reference 16 numbers A342-105-8042, 106-7831 119-7831, 120-8042. 17 So I don't see those in here. 18 Q I've reviewed the document as well, and I 19 can represent to you that they are not in -- the data 20 from that is not in this document. 21 A Okay. 22 Q Without looking at the study, do you have	39 1 BY MS. CIPRIANO: 2 Q For glaucoma patients? 3 A Yes. 4 Q And in what circumstances is that? 5 A Depending what you -- you have an 6 intervention, and then you have kind of a control arm. 7 Q So glaucoma can cause blindness, correct? 8 A That's correct. 9 Q As a treating physician, would you 10 recommend that a glaucoma patient refrain from 11 glaucoma medication for the purposes of a study? 12 MR. DINER: Objection, vague. 13 A Well, the answer is, it always depends. It 14 depends on the exact clinical scenario, but it is 15 not -- it is standard study protocol to do what we 16 call "washout." And it's actually clinical protocol, 17 as well, where we have periods of time we have 18 patients go without their medications. 19 BY MS. CIPRIANO: 20 Q Okay. Let's look at the dose column here. 21 And the dose column in each of these 22 studies, the four studies on page 13, lists that -- my
38 1 any information that would give you -- strike that. 2 Do you have any information that would tell 3 you whether or not these early dose tolerance studies 4 were performed on glaucoma patients? 5 A I'd like to look at the study protocol. 6 Q Okay. Can we look at the information 7 that's actually on this page, because I don't think we 8 have the study protocols in this proceeding. But -- 9 but let's look and see if we can come up with any kind 10 of conclusions based on the data that's here. 11 The treatment in these -- at least the four 12 studies that are listed on page 13 of Exhibit 1031 -- 13 the treatment is in that first row, 0.02 percent, 14 0.8 percent, and "vehicle." 15 Do you see that? 16 A Yes. 17 Q If these were glaucoma patients, would you 18 expect vehicle to be administered? 19 MR. DINER: Objection, vague. Incomplete 20 hypothetical. 21 A There are some -- there are some clinical 22 studies in which vehicle or placebo is administered.	40 1 understanding from what's noted here -- that the study 2 drug was administered to one eye; is that how you 3 interpret this? 4 A I think so. 5 Q As a practicing clinician, would you advise 6 your patient to administer a glaucoma medication to 7 only one eye? 8 MR. DINER: Objection. Incomplete 9 hypothetical. 10 A I typically don't, but especially back in 11 the '90s and even still today, it's called what's 12 called a "one-eye trial." So frequently, to 13 distinguish side effects, relative efficacy, it's 14 standard. It's still deemed standard clinical 15 protocol to do this at times in some patients, 16 depending on the circumstances. 17 BY MS. CIPRIANO: 18 Q So you're saying that it's standard 19 protocol to administer glaucoma medication to one eye 20 and vehicle to the other eye? 21 A It could be. 22 Q But without the study protocol, you can't

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November 13, 2022

41 1 be sure that these were administered to glaucoma 2 patients, correct? 3 A I'd need to look at the protocol. 4 Q Do you agree that -- we can put this 5 document away. I think I may have a couple more 6 questions about it to come later, but we can put it 7 away for now. 8 A (Witness complies.) 9 Q You would agree that brimonidine is known 10 to be an alpha-2 receptor agonist, right? 11 A Yes. 12 Q And when we refer to "alpha" here, we're 13 talking about alpha adrenergic receptor, correct? 14 A Yes. 15 Q In your declaration you talk about two 16 types: An alpha 1 adrenergic receptor and an alpha-2 17 adrenergic receptor, correct? 18 A Yes. 19 Q You agree that as of August 2008, a person 20 of ordinary skill in the art would have known that 21 there are several subtypes of each of these receptor 22 types, correct?	43 1 hypothetical. 2 A You'd have -- the answer, it would depend, 3 and it's unclear. So I'd have to know the specific 4 kind of scenario and what we were trying to 5 accomplish. 6 BY MS. CIPRIANO: 7 Q But you agree that in certain 8 circumstances, these receptor subtypes do different 9 things? 10 MR. DINER: Objection, vague. 11 A It's possible, but it would depend on the 12 scenario what question we're -- specific question 13 we're trying to ask. 14 BY MS. CIPRIANO: 15 Q You'd also agree that the different 16 receptor subtypes are known to be located -- let me 17 strike that and ask a better question. 18 Do you know if the different alpha-2 19 receptor subtypes are located in a homogenous manner 20 throughout the body? 21 MR. DINER: Objection, vague. 22 A It's a little bit difficult. What I can
42 1 MR. DINER: Objection, vague. 2 A It's possible. 3 BY MS. CIPRIANO: 4 Q You're aware there's an alpha-2A and 5 alpha-2B and an alpha-2C receptor subtype? 6 A Yes. 7 Q Scientists in 2008 would have understood 8 that the result of activating these receptors would 9 depend on the particular subtype that was present. 10 Do you agree with that? 11 MR. DINER: Objection, vague. Incomplete 12 hypothetical. 13 A I'm not sure what you mean by "subtype." 14 BY MS. CIPRIANO: 15 Q You just -- you're aware that there are 16 subtypes of alpha-2 receptors? 17 A There are, yes, and they have been 18 discovered. 19 Q And you agree that activating -- activating 20 alpha-2A versus alpha-2B versus alpha-2C receptors 21 could have different effects, correct? 22 MR. DINER: Objection. Incomplete	44 1 say as a general rule, all receptors are not 2 distributed homogeneously throughout the body. 3 BY MS. CIPRIANO: 4 Q So different tissues in the body have 5 different receptor subtypes of any type that are 6 present, correct? 7 MR. DINER: Objection, vague. 8 A It will depend on the organ and its 9 purpose, what receptors are there. 10 BY MS. CIPRIANO: 11 Q These alpha adrenergic receptors are found 12 in both the central nervous system and in the 13 periphery, correct? 14 A I'm sorry. Which receptors? 15 Q The alpha adrenergic receptors. 16 A Adrenergic receptors are found throughout 17 the body. 18 Q And that includes both on the central 19 nervous system and in the periphery? 20 A Yes. 21 Q Would you agree that the effect of 22 activating alpha adrenergic receptors in the central

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November 13, 2022

45 1 nervous system can exert a different effect than 2 activating these receptors in the periphery? 3 A It will depend on the specific scenario, 4 but it's possible, yes. 5 Q So in your declaration, you talk about 6 clonidine having a sedative effect, correct? 7 A Correct. 8 Q And clonidine is known to have alpha-2 9 adrenergic receptor activity, correct? 10 A Yes. 11 Q Would you agree that the sedative effect of 12 clonidine is a result of its effect on the central 13 nervous system? 14 A That's what's believed. 15 Q I'd like to take a look at an article. The 16 court reporter is going to hand you a document that's 17 been marked Exhibit 1019. 18 Do you recognize this as the document that 19 we referred to as "Lachkar" in your declaration? 20 A Yes. 21 Q So I'd like to take a look at page 3. And 22 in your declaration, you quote some language that's in	47 1 receptors may play a part and, thereby, have a role in 2 the autoregulation of capillary pressure and tissue 3 oxygen delivery." 4 A Yes, I see that sentence. 5 Q Okay. And I was just saying that you quote 6 the first phrase to the first comma, but you don't 7 quote the rest of that sentence in your declaration, 8 right? 9 MR. DINER: Objection. Mischaracterizes 10 the document. 11 A Well, I mean, this whole sentence, yeah, is 12 relevant. It's based on -- it's actually pulled from 13 this subarticle. It's cited from the Hoffmann article 14 Reference 30, which talks about adrenergic and 15 receptor antagonists. 16 BY MS. CIPRIANO: 17 Q So then you also in your declaration -- and 18 we can take a look. Feel free, if you need to refresh 19 your memory. 20 You also talk about that -- the next 21 sentence in that paragraph, "On the other hand, 22 brimonidine tartrate may also produce vasodilation via
46 1 kind of the middle of the right-hand column on page 3 2 of the exhibit. And you rely on the sentence that 3 starts "Vasoconstriction is mediated mainly via 4 alpha 1 adrenergic receptors." 5 Do you see that? 6 A I see the sentence. 7 Q And you cite that in your declaration? 8 A Yes. 9 Q In your declaration you don't quote the 10 rest of that sentence, but it continues "although 11 alpha-2 adrenergic receptors may play a part." 12 Do you see that? 13 MR. DINER: Objection. Mischaracterizes 14 the document. 15 A I'm sorry. Where are you referring to? 16 BY MS. CIPRIANO: 17 Q Sure. 18 Just the next couple of words after what I 19 just read. 20 So the whole sentence says 21 "Vasoconstriction is mediated mainly via alpha 1 22 adrenergic receptors, although alpha-2 adrenergic	48 1 the alpha-2 adrenergic receptors on endothelial cells 2 which release endothelial-derived relaxing factor." 3 Do you see that? 4 A Yes. 5 Q You see the article has two footnotes at 6 the end of that sentence? 7 A Yes, yes. 8 Q Did you review those articles to see what 9 the author was relying on for that statement? 10 A I believe so. It's been a while. 11 Q You did review them? 12 A I believe so, yes. 13 Q Can we take a look at your declaration, 14 Appendix B? 15 A (Witness complies.) 16 Yes. 17 Q And you'd agree that the articles by Angus 18 and the article by Bockman are not on your list of 19 materials considered? I don't see them. 20 A I don't see them. 21 Q So does that mean you did not review them 22 in preparation for this declaration?

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November 13, 2022

49 1 MR. DINER: Objection, vague. 2 Mischaracterizes his prior testimony. 3 A Well, I mean, just -- did I do it 4 specifically in preparation for this? No, I don't 5 think so. But any time you read a scientific article, 6 it's good to know what the underlying sources are. 7 BY MS. CIPRIANO: 8 Q Do you remember what is discussed in the 9 Angus and Bockman articles cited in Lachkar? 10 A It discusses what's alluded to in this 11 sentence, that there's vasodilation effects. You can 12 see -- you can see from the titles of the articles in 13 the reference that there's responses in the 14 circulation. So they're evaluating vascular 15 structures and the effect of alpha-2 agonists. 16 Q But you agree that the Angus and Bockman 17 articles don't discuss anything about the eye, 18 correct? 19 A I can't say for sure. 20 Q Would it surprise you that they don't 21 mention anything about the eye? 22 A Would it surprise me? To the extent	51 1 of Alphagan. 2 Q But your position in this proceeding is 3 that a person of ordinary skill in the arts would have 4 understood from the Alphagan and Alphagan P labels 5 that this property of brimonidine was 6 concentration-dependent, correct? 7 A Conjunctival blanching happened with the 8 highest concentration that was available, the 9 0.2 percent. It was -- that happened with some 10 frequency at the highest concentration, the 11 0.2 percent. 12 Q We can look at paragraph 77 of your 13 declaration, but I'd like to look at the articles that 14 are cited in that paragraph. 15 So the first article that you cite in 16 paragraph 77 of your declaration is what's -- what you 17 referred to as "David, 1993." 18 Do you see that? 19 A Yes. 20 Q I'm going to hand you a document that's 21 been marked Exhibit 1029 in the IPR. 22 Do you recognize this as the article by
50 1 anything else surprises me, would I be surprised? No, 2 I would not be surprised. 3 Q We can put that away for now. 4 A (Witness complies.) 5 Q So it is your opinion that prior to 6 August 2008, a person of ordinary skill in the art 7 would have understood that brimonidine's ability to 8 reduce eye redness was concentration dependent; is 9 that accurate? 10 A Well, I think when we're talking about the 11 topical administration of brimonidine, our experience 12 is largely with the Alphagan formulation, so the 13 0.2 percent formulation, which is commercially 14 available, and then the 0.15 percent formulation and 15 the 0.1 percent formulation. So at those levels, 16 those concentrations we're finding, we see that -- I'm 17 sorry. What was the thing -- what was the property we 18 were talking about? 19 Q Ability to reduce eye redness. 20 A Yeah. So we could see some blanching, 21 short-term blanching, that was noted, especially at 22 the highest concentration, the 0.2 percent formulation	52 1 David that you cite in your declaration? 2 A Yes, it appears to be. 3 Q And this reports on a study that was done 4 with 0.5 percent brimonidine, correct? 5 A (Witness reviews document.) 6 Q Where I got the concentration was just in 7 the abstract at the beginning, where I list the 8 objective and the conclusion on the first page. 9 A I see that. I'd just like to confirm the 10 methods. I'm not seeing the methods, which is 11 interesting. I don't see the concentration listed in 12 the methods or the results. 13 Q If we look on the first page, in 14 "Objective," right under the list of authors, it says 15 "to evaluate the efficacy of 0.5 percent brimonidine 16 titrate." 17 Do you see that? 18 A I do. 19 Q So is it accurate to say that you agree 20 that this study was done with 0.5 percent brimonidine? 21 A I guess we have to assume that. It's a 22 little disturbing it's not in the methods or the

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November 13, 2022

53 1 results, but... 2 Q But you cite -- for the statement about -- 3 excuse me -- 0.5 percent brimonidine, this is the 4 article that you cite in your declaration? 5 A Yes. 6 MR. DINER: Objection. Mischaracterizes 7 his declaration. 8 BY MS. CIPRIANO: 9 Q So if we look at the conclusion in your 10 declaration, you point to page 3, correct? 11 A Yes. 12 Q In about the middle, a couple of lines up 13 from the comment section on page 3 in the left-hand 14 column, there's a statement about conjunctival 15 blanching. 16 Do you see that? 17 You can tell me when you're there. It's in 18 the paragraph starting "ocular side effects." 19 Do you see where it says "conjunctival 20 blanching"? 21 A I see the paragraph. 22 Q So I'm interested in the sentences that are	55 1 measured. I'm not sure how conjunctival blanching was 2 measured. So that's the first problem, who that 3 information came from. It's hard for me to comment 4 further. 5 Q So is there a standardized definition of 6 what "mild," "moderate," and "severe" blanching would 7 entail? 8 A It depends on -- it depends on the study. 9 This is a glaucoma study. So it could be like, "Hey, 10 person, did you have anything to report to us?" Or it 11 could be, "Hey, person, do you notice blanching?" Or 12 it could be, "Doctor, do you notice blanching?" Or, 13 "Doctor, here is this very vigorous graded scale to 14 blanching." It depends. 15 Q You don't have any information based on the 16 David article to understand how blanching was 17 monitored in the study; do you? 18 A I'm not -- like, that part of the 19 methodology -- it was basically to see if this drug 20 lowered eye pressure. 21 Q So the next reference that you talk about 22 or you cite in paragraph 77 of your declaration also
54 1 kind of in the middle of that paragraph. And just so 2 we're on the same page, they read: 3 "Conjunctival blanching was noted in 75 4 (40.9 percent) of 183 brimonidine-treated patients. 5 Again, the majority of these cases were reported as 6 mild. Blanching was rated as moderate in 16 patients 7 and severe in one patient in the B/B group (at the 8 first post ALT examination, one hour after the second 9 drop of brimonidine)." 10 Do you see that sentence -- those couple of 11 sentences? 12 A Yes. 13 Q In your understanding, what is the 14 difference between mild, moderate, and severe 15 blanching? 16 A Depends on the context. 17 Q Well, as you read it here, how do you 18 understand this? 19 A Well, I mean, this study was basically -- 20 used a very, very high concentration of brimonidine, 21 which never came to market. It was a primary study to 22 look at IOP lowering. So that's the endpoint that was	56 1 deals with 0.5 percent brimonidine in that -- in the 2 next sentence there in your paragraph 77, talking 3 about clinical trial with 0.5 percent brimonidine. 4 Do you see that? 5 A Yes. 6 Q And you cite to -- again, back to the 7 document that we looked at before, Exhibit 1031. 8 Do you see that? 9 A Yes. 10 Q Okay. If you could open that back up 11 again. 12 A (Witness complies.) 13 Q So you point to page 13 of Exhibit 1031. 14 A I'm sorry. What page was it? 15 Q Page 13, you reference study S342-108-8042, 16 which I believe is listed in the third row of the 17 table on page 13? 18 A Okay. 19 Q Do you see that? 20 A Yes. 21 Q Okay. Am I interpreting that correctly, 22 that that's the information that you were citing in

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November 13, 2022

57 1 your declaration? 2 MR. DINER: Objection to the extent it 3 mischaracterizes the definition. 4 A So it's that study. That statement comes 5 from that study, yes. 6 BY MS. CIPRIANO: 7 Q Okay. And it says -- in the study 8 conclusion section, it says "Significantly greater 9 incidences of conjunctival blanching and subjective 10 reports of dry eye were reported with use of 11 brimonidine 0.5 percent and vehicle," right? 12 A I need to look at this study. 13 Q As we said before, the data from these 14 early dose tolerance studies is not in Exhibit 1031 as 15 I have read them, but you're relying on this summary, 16 right, that's listed in this document? 17 That's what you're relying on in your 18 declaration? 19 MR. DINER: Objection. Mischaracterizes 20 his declaration. 21 A I relied on everything, not just the 22 summary. I mean, we need to look at the underlying	59 1 conjunctival blanching, that was also stated in the 2 next row of the chart on page 13, referring to 3 brimonidine 0.35 percent. 4 Do you see that? 5 A Yes, the high concentration of brimonidine 6 had more blanching than the vehicle. 7 Q Okay. And do you know if this blanching 8 was categorized as mild, moderate, or severe? 9 A No. I can't comment on that right now. 10 Q Okay. Do you know if redness was measured 11 in this -- in these studies with any scale? 12 A We need to look at the study protocol. I'm 13 sure it was listed. 14 Q The other thing you point to for this -- 15 for your information about 0.5 percent brimonidine is 16 the Alphagan label, the 2001 Alphagan label. 17 Do you see that in paragraph 77 of your 18 declaration? 19 A Yes. 20 Q So let's take a look at Exhibit 2012. 21 Do you recognize this as the Alphagan 22 0.5 percent product label?
58 1 principles behind these things. 2 BY MS. CIPRIANO: 3 Q Did you look at the data from study 4 S342-108-8042 in preparation for this declaration? 5 A I looked at the whole amount of data that 6 was available, so -- but to answer this question, I 7 want to make sure that we answer it in the proper 8 context. 9 Q So I'm trying to understand your opinions 10 in this matter, and you cite this page from -- you 11 cite two things for this sentence. And we'll look at 12 the Alphagan label in a second. 13 I just want to make sure I'm understanding 14 that your comment about 0.5 percent brimonidine 15 exhibiting significantly greater incidence of 16 conjunctival blanching -- in part, that's based on the 17 summary of this study listed on page 13 of 18 Exhibit 1031, correct? 19 A In part. 20 Q You'd agree that the same sentence, the 21 same statement that you quoted in paragraph 77 about 22 causing significantly greater incidence of	60 1 A Seems to be multiple product labels. 2 Q Apologies. 3 So the first several pages is -- refers to 4 a 0.5 percent, and then, starting at page 6 is 5 Alphagan 0.2 percent, and then, starting at page 11 is 6 .15 percent. 7 A Yes. 8 Q So you point to page 4 of this document. 9 And in the adverse reactions at the bottom 10 of the page, it says "The most common adverse events 11 reported in association with the use of Alphagan 12 0.5 percent in conjunction with ALT was transient 13 conjunctival blanching in 50 percent of patients." 14 Do you see that? 15 A Yes. 16 Q Do you know if this is reporting on the 17 same study as reported that we were just talking about 18 in Exhibit 1031? 19 MR. DINER: Objection, vague. 20 A I'm not positive. 21 BY MS. CIPRIANO: 22 Q And this document doesn't talk about the

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November 13, 2022

61 1 severity of the blanching, right? 2 A This package insert of 0.5 percent 3 Alphagan, no. 4 Q Do you know if redness was measured on a 5 scale in connection with the studies of 0.5 percent 6 Alphagan? 7 A This drug never came to market, and this 8 document is only a package insert. 9 Q But it's reporting on a clinical study, 10 right? 11 A It's reporting some clinical information. 12 All the information on a package insert does not come 13 from clinical studies. 14 MR. DINER: Is now a good time for a break? 15 MS. CIPRIANO: Yeah, we can take a break. 16 THE VIDEOGRAPHER: We're now going off the 17 record. The time is 11:05 a.m. 18 (Recess.) 19 THE VIDEOGRAPHER: We're now going back on. 20 The time is 11:15 a.m. 21 BY MS. CIPRIANO: 22 Q Welcome back.	63 1 Am I interpreting that correctly? 2 A I'm sorry. Where are you? 3 Q So I guess let's take a step back. 4 Page 52, of Exhibit 1031 lists adverse 5 events for this particular study -- 6 A Yes. 7 Q -- correct? 8 And this study administered 0.2 percent 9 brimonidine, correct? 10 A Yes. 11 Q So for the study group that was 12 administered 0.2 percent brimonidine, the adverse 13 event of conjunctival blanching was listed for 15 14 patients, which was 6.8 percent of that group. 15 Am I interpreting that correctly? 16 A Yeah, I'll have to look at the study 17 protocol, if that was every visit or once in a while. 18 But yes, that's the number. 19 Q Okay. Let's do that. 20 A Okay. 21 Q I don't have the study protocol, but I 22 have -- on page 21, these studies are described.
62 1 So I'd like to continue our march through 2 paragraph 77 of your declaration. And I'd like to 3 turn next to your discussion of data related to 4 0.2 percent brimonidine. 5 And the statement in your declaration is 6 that when the concentration was lowered to 0.2 percent 7 brimonidine, the rate of conjunctival blanching 8 sharply dropped to 6.8 percent. 9 Do you see that? 10 A Yes. 11 Q And then, so again you cite -- we cite back 12 to that Exhibit 1031 that we've looked at a couple of 13 times. So I'd like to turn to that. And this time 14 we'll look at page 52 that you cite. 15 A (Witness complies.) 16 Q Are you on page 52? 17 A Yes. 18 Q So near, I guess, in the bottom quarter of 19 the page or so, there's a line "conjunctival 20 blanching," and it says -- it lists 15 patients, which 21 was 16.8 percent [sic] of to 0.2 percent brimonidine 22 study group.	64 1 MR. DINER: That's page 21 of 286? 2 MS. CIPRIANO: Yeah. 3 MR. DINER: Yeah, he's got it. 4 BY MS. CIPRIANO: 5 Q So to be clear, in your declaration, you 6 talk about -- you refer to studies 103 and 104. And 7 that's shorthand for the two studies that are 8 discussed on page 21 of 286 of Exhibit 1031, correct? 9 A Those are the studies for the pooled data 10 for the approval study? 11 Q So let's go through a little bit of at 12 least the information that we have about the study 13 design here. 14 So about halfway down the page, there's a 15 section that says "Study Design." 16 Do you see that? 17 A Yes. 18 Q And my understanding -- and please correct 19 me if I'm wrong -- is this section at the bottom of 20 the page walks through what happens at each study 21 visit; is that correct? 22 A It's not everything happens.

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November 13, 2022

65 1 Q Okay. All right. Well, let's talk about 2 what it does say about the study visits. 3 So in the second line under "Study Design," 4 it says "At the pre-study visit (visit 1)." 5 And it talks about the different things 6 that were measured. "An ophthalmic evaluation 7 consisting of assessments of intraocular pressure, 8 IOP, visual acuity, biomicroscopy" -- I'm not going to 9 try to -- "ophthalmoscopy"? 10 A Uh-huh. 11 Q Okay. "Pupil size, Schirmer tear test, and 12 a visual field were performed to determine the 13 subject's eligibility." 14 So assessments of intraocular pressure, 15 that's a measurement done with a piece of equipment? 16 A It's a measurement of eye pressure. 17 Q Okay. Visual acuity, what is that 18 measurement? 19 A How well the patient can read the eye 20 chart. 21 Q Okay. Biomicroscopy, what is that? 22 A That's a detailed examination of the front	67 1 with one another, biomicroscopy and ophthalmoscopy? 2 A They're part of the eye exam. 3 Q And then an assessment of pupil size, what 4 does that entail? 5 A So it's a measurement of the diameter and, 6 under certain lighting situations, how the pupil is 7 responding. 8 Q And then a Schirmer tear test, what is 9 that? 10 A That's a measurement of tear production. 11 And there's various subtypes of the Schirmer tear 12 test, but it's a measurement of tear production. 13 Q And then a visual field, what is that? 14 A That's a measure of peripheral vision. 15 Q Okay. Now, from the information here, do 16 you know if redness was recorded in any of these 17 assessments during the pre-study visit? 18 A It doesn't say this explicitly, but I would 19 assume from my experience as a clinical investigator 20 it's one of the things you note, yes. 21 Q And how would it be noted? 22 A On the form.
66 1 part of the eye. 2 Q Is that the same thing as ultrasonic 3 biomicroscopy? 4 A No. 5 Q Is this biomicroscopy done with a 6 microscope? 7 A Yes. It's looking under the microscope at 8 a lot of different things. 9 Q What sort of things are analyzed in that 10 assessment? 11 A It's an assessment of the eyelids and 12 eyelashes, kind of the structures around the eye. And 13 then you look at the -- you assess the tear film and 14 all its various components, and you assess the cornea 15 and its different layers and status. And then the 16 conjunctival episclera/sclera. And then you look 17 deeper into the anterior chamber. And you look deeper 18 into the iris. You look at the angle of the eye, the 19 status of the lens, the anterior part of the vitreous. 20 Q Okay. And ophthalmoscopy, what is that? 21 A That's when you look deeper into the eye. 22 Q Okay. Those two are done in conjunction	68 1 Q Would redness always be recorded -- strike 2 that. 3 Would some information about redness always 4 be recorded in a patient's file? 5 A Once again, it always depends on what the 6 point of the clinical study is, but in a study such as 7 this, yes. 8 Q Was the point of this study to assess 9 redness? 10 A The primary endpoint was to measure eye 11 pressure, the effect of this drug -- this drug -- or, 12 these drugs, actually -- on eye pressure that was the 13 primary endpoints and secondary endpoints. And then 14 you have extra information. 15 Q Was an assessment of redness a secondary 16 endpoint in these studies? 17 A The study design was not to do -- not to 18 evaluate or do statistical analysis on redness, but 19 it's information that's collected. 20 Q Do you know if it was collected in a -- in 21 relation to a redness scale of any sort? 22 A I don't remember.

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November 13, 2022

69 1 Q Okay. So after -- those are the -- what we 2 just discussed are the assessments, if you will, that 3 occurred in visit 1 -- what they characterize as 4 visit 1, right? 5 Is that my understanding? 6 A Probably. We'd have to look. To be 7 100 percent sure, we'd have to look at the protocol. 8 Q Okay. Well, based on what information is 9 here, in the next paragraph, there's a description of 10 what happened at visit 2. 11 Do you see that? It's in the second line 12 of the next paragraph? Starts in second line of the 13 next paragraph. 14 A "Following washout"? 15 Q Uh-huh. 16 A Is that the sentence you're addressing? 17 Q Yes. "Following washout, all subjects 18 returned for a baseline examination (visit 2, day 19 zero)." 20 Do you see that? 21 A Do I see that? 22 Q And then in the next line, at the sentence	71 1 were done at the time -- at the measurements occurring 2 before administration or after administration? 3 A I don't, without looking at the protocol. 4 Q Okay. And the same is true for "subject 5 comfort" that was assessed? 6 A I'd have to look at the protocol. 7 Q Then in the next paragraph, the third 8 paragraph of the "study design" section, it says 9 "Subjects returned for follow-up examinations at weeks 10 1 and 2 and months 1, 2, 3, 6, 9, and 12." 11 Do you see that? 12 A Yes. 13 Q Again, it lists the assessments. 14 Says "Efficacy was assessed by evaluating 15 changes from baseline in IOP, visual fields, and 16 cup/disc ratio." 17 Do you see that? 18 A Yes. 19 Q And then it lists the ocular safety and a 20 Schirmer tear test and an ophthalmoscopic examination 21 at months 6 and 12. 22 Do you see that?
70 1 that begins at kinda the right-hand side of the page, 2 it again lists what happened at that visit. 3 Says "At this visit," presumably referring 4 to visit 2, "baseline measurements of IOP, visual 5 acuity, pupil size, heart rate, and blood pressure 6 were taken." 7 Do you see that? 8 A I do. 9 Q And then, so I want to make sure I 10 understand how this -- how this -- so the next couple 11 of sentences says "measurements of IOP were taken 12 between 7:30 and 9:30 a.m." 13 A Yes. 14 Q "And again between 9:30 and 11:30 a.m., 15 which was two hours after treatment." 16 So am I understanding that those -- IOP was 17 measured prior to administration and then again two 18 hours after administration of the drug? 19 A Yes. 20 Q And then it says "Biomicroscopy and a 21 Schirmer tear test were performed." 22 Do you know if that -- if those assessments	72 1 A Yes. 2 Q Do you know -- so the results from these 3 studies report on adverse events as a whole. 4 Am I understanding that correctly? 5 A Well, they're recorded in all of these 6 studies. 7 Q So in recording them, a patient could have 8 an adverse event at the visit 2 and not have any other 9 adverse events in -- you know, through month 12, 10 correct? 11 MR. DINER: Objection. Calls for 12 speculation. 13 A I'd have to look how they chose to record 14 it for that study. 15 BY MS. CIPRIANO: 16 Q Okay. 17 A It could be variable. 18 Q So you don't have any information to say 19 when conjunctival blanching occurred in this study, 20 correct? 21 A Well, the information is there. I just 22 don't have it in this sentence, in this paragraph. It

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November 13, 2022

73 1 exists somewhere. 2 Q Okay. But based on the document that 3 you've cited in your declaration, we don't have the 4 information to know when conjunctival blanching was 5 observed in these studies, correct? 6 MR. DINER: Objection, vague. Calls for 7 speculation. 8 A What do you mean by "when"? 9 BY MS. CIPRIANO: 10 Q At what point in the 12 months that were 11 involved in the study. 12 A I'd have to look at the study protocol. 13 Q But you don't cite the study protocol in 14 your declaration, right? 15 A I'm not sure what you're saying. 16 Q Did you -- is the study protocol part of 17 the information that you reviewed to prepare your 18 declaration? 19 A It's the underlying -- it's the basis of 20 where all of this information comes from. 21 Q Did you review it? 22 A Well, at some point I did, yes, because I	75 1 think it's 52 of 286, where -- that's the page that 2 you cite in paragraph 77 of your declaration with 3 respect to the 6.8 percent occurrence of conjunctival 4 blanching with 0.2 percent brimonidine. 5 So in these studies, the control group was 6 administered timolol. 7 Am I interpreting that correctly? 8 A Yes. That was the comparator. 9 Q And timolol is another glaucoma medication? 10 A That's correct. 11 Q And for conjunctival blanching, where it 12 lists 15 patients were 6.8 percent here in the 13 brimonidine column, in the timolol column, it lists 14 14, with a percentage of 6.3 percent. 15 Do you see that? 16 A Yes. 17 Q And then there's a "P" value. 18 Are you familiar with P values? 19 A Yes. 20 Q And this P value is 0.838. 21 And that P value essentially tells you that 22 there's not really a difference between the numbers,
74 1 helped the study. 2 Q Okay. I'm trying to get to bottom of your 3 reliance on these studies. And is the study protocol 4 something that you relied on for your opinions in this 5 matter? 6 A Well, to the extent that I performed these 7 studies in the past, I mean, as part of my fund of 8 knowledge. And it does contribute, knowing how these 9 studies work. 10 Q So based on your -- the information that 11 you're relying on, when was conjunctival blanch 12 observed in these studies? 13 A I'd have to go back and look at the 14 protocol. 15 Q Okay. So you're saying you're relying on 16 your memory because you didn't provide it as support 17 for your opinions here, but you don't remember when 18 the conjunctival blanching occurred? 19 A I'd have to look at the study protocol. 20 Q You don't remember right now? 21 A Off the top of my head, no. 22 Q Okay. I'd like to go back to page -- I	76 1 correct? 2 A That's not what a P value -- no. 3 Q Okay. What does a P value of .838 mean to 4 you? 5 A So what it means is that's the -- we'll 6 say, percentage of the difference that we're seeing 7 can be to chance. 8 Q So when -- you've published articles, 9 correct? 10 A Yes. 11 Q In order to say that the numbers are 12 different in your studies, what P value do you 13 normally aim for, for a conclusion that numbers are 14 different? 15 MR. DINER: Objection, vague. 16 A If the numbers are different, the numbers 17 are different. 18 BY MS. CIPRIANO: 19 Q So in order for numbers to be statistically 20 significantly different, does there have to be certain 21 P value associated with them? 22 A It depends on the study or what the

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November 13, 2022

77 1 question -- what we're trying to answer is. 2 Q In your view, is there any statistical 3 significance to the difference between 6.8 percent 4 conjunctival blanching in the brimonidine group versus 5 6.3 percent conjunctival blanching in the timolol 6 group? 7 A Well, there's a numerical difference. 8 Q That's not my question though. 9 A What was the question? 10 Q Is there any statistical significance to 11 the difference between those numbers in this study? 12 A There's always a difference. It depends 13 where you want to draw the line. 14 Q What do you mean by that? 15 A What difference you find acceptable to be 16 to chance. 17 Q Would you accept an 83 percent chance that 18 this is due to -- chance significant? 19 MR. DINER: Objection, vague. 20 A I don't understand your question. 21 BY MS. CIPRIANO: 22 Q Okay. Here there's an 83 percent chance	79 1 blanching is not mentioned at all in the label, right? 2 A Yes. 3 Q Do you know if eye redness was measured in 4 any of the clinical trials that are reported in this 5 label? 6 A I don't recall off the top of my head, but 7 I'm sure there's certainly some notation made, yes. 8 Q And by "some notation," you're talking 9 about the same sort of notation that you were talking 10 about in the Alphagan? 11 A On the form we have to fill out about the 12 patients' exams. 13 Q Okay. But you don't have any information 14 if a redness scale was used, right? 15 A I'd have to look at the protocol. 16 Q Okay. We can put that away. 17 A (Witness complies.) 18 Q Switching gears a little bit. 19 In your declaration, you talk a bit about 20 Figures 2 and 6 in the '74 [sic] patent. 21 Do you recall that? 22 A The '742 patent?
78 1 that the difference between 6.8 percent and 2 6.3 percent is due to chance, correct? 3 A Yes. 4 Q Okay. So you said you were involved with 5 the studies related to 0.2 percent brimonidine. 6 A Yes. 7 Q How were adverse events recorded in these 8 studies? 9 A There was a form you fill out. 10 Q Is it -- are the options laid out in the 11 study protocol and you check boxes, or is it an open 12 narrative? 13 A It depends on the study. 14 Q Okay. In this study, do you recall how it 15 was done? 16 A I don't recall exactly how it was, no. 17 Q I'd like to turn to the last part of 18 paragraph 77, when you talk about Alphagan P. 19 So if we look at -- look at Exhibit 2014. 20 I'm going to hand you a document that's been marked 21 Exhibit 2014 in the IPR. 22 You cite to Exhibit 2014 for the fact that	80 1 Q I think that's right. 2 Yes. Yes. 3 A Yes. 4 Q Okay. 5 MS. CIPRIANO: So for ease of reference, 6 I'm going to mark a document as Exhibit 1046. 7 (Exhibit 1046 was received and marked for 8 identification, as of this date.) 9 BY MS. CIPRIANO: 10 Q Just so we're on the same page, I thought 11 it would be easier to look at this side by side. And 12 if you could just take a moment to confirm that on the 13 left-hand side of this document, we've placed the 14 color figure -- or, the color version of Figure 2 of 15 the '742 patent. 16 And I can -- you can confirm that these 17 come from -- they come from the color version of the 18 '742 patent, which was produced as Exhibit 2161. 19 And I can give that to you if you want. 20 A Could I have a copy of that? 21 Q Yes, absolutely. 22 So just so we're on the same page, the

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81 1 document that I've marked as 1046, on the left-hand 2 page, has a copy of Figure 2 of the '742 patent as it 3 appears in Exhibits 2061. 4 Do you see that? 5 A Yes. 6 Q And then on the right-hand side of 7 Exhibit 1046, I've reproduced Figure 6 of the '742 8 patent as it appears in Exhibit 2161, correct? 9 A Yes. 10 Q So it doesn't matter to me which you refer 11 to, whether you want to look at them side by side or 12 look at them in the patent or look at them in your 13 declaration -- there's several copies here -- but I'd 14 like to talk a little bit about these Figures. 15 A Okay. 16 Q Let's start with Figure 2. 17 And to make sure that we're understanding 18 the figures -- we're on the same page as we understand 19 the figures, so on the X axis there are concentrations 20 of brimonidine, correct? 21 A Yes. 22 Q And there aren't any units on the Y axis,	83 1 what's labeled as "net vasoconstriction benefit," 2 correct? 3 A Yes. 4 Q So the net vasoconstriction benefit 5 represents the vasoconstriction effect in the black 6 line -- thick black line, minus the rebound hyperemia, 7 correct? 8 MR. DINER: Objection to the extent it 9 mischaracterizes the patent. 10 A I'm not sure it's minus. It's talking 11 about the desired endpoint, which is vasoconstriction 12 versus a bad thing. 13 BY MS. CIPRIANO: 14 Q Okay. So then when it says "net 15 vasoconstriction benefit," it takes into account the 16 bad thing that you're talking about, right? 17 A Yes. 18 Q And that bad thing, for the purposes of 19 this '742 patent, is rebound hyperemia, right? 20 A Yes. 21 Q So do you agree that this figure is not -- 22 the net vasoconstriction benefit is not actually
82 1 right? 2 MR. DINER: Objection. Mischaracterizes 3 the document. 4 A There's no units. There's a -- I mean, 5 it's understood that, as you go up, the magnitude 6 increases. 7 BY MS. CIPRIANO: 8 Q Okay. It goes from zero to four plusses on 9 effect? 10 A Correct. 11 Q And in this figure, the thick black line is 12 what is identified in the key of Figure 2 as 13 vasoconstriction, right? 14 A Yes. 15 Q And near the bottom of that -- of the 16 figure, there are a thinner black line, a dotted black 17 line, and a thin gray line that are labeled in the key 18 as "IOP reduction, endo cell pump inhibition," and 19 "rebound hyperemia," right? 20 A Yes. 21 Q And then the thicker gray line that goes up 22 into the yellow box and then comes back down -- that's	84 1 plotted as a direct comparison of two other of the 2 lines on the figure, right? 3 MR. DINER: Objection, vague. 4 A I don't understand the question. 5 BY MS. CIPRIANO: 6 Q So this could have been plotted as -- the 7 net vasoconstriction benefit could be plotted as the 8 vasoconstriction curve minus the values in the 9 rebound-hyperemia curve, right? 10 MR. DINER: Objection. No foundation. 11 Calls for speculation. 12 A I'm not sure you're talking about values. 13 BY MS. CIPRIANO: 14 Q Okay. Well, I mean, on a graph, we usually 15 are talking about values, right? 16 MR. DINER: Objection, vague. 17 A Depends what the graph is. 18 BY MS. CIPRIANO: 19 Q Okay. So this Figure 2 doesn't report 20 specific values, right? 21 A Specific numbers? 22 MR. DINER: Objection, vague.

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November 13, 2022

85 1 A It think it does report relative values. 2 BY MS. CIPRIANO: 3 Q Okay. But you'd agree that the net 4 vasoconstriction benefit is not directly a comparison 5 of the vasoconstriction value in relation to the 6 rebound-hyperemia value, right? 7 MR. DINER: Objection, vague to the extent 8 it mischaracterizes testimony. 9 A I don't understand exactly what you're 10 saying. 11 BY MS. CIPRIANO: 12 Q Okay. So the net vasoconstriction 13 benefit -- let me step back. 14 If there was zero hyperemia, the net 15 vasoconstriction benefit would mirror or mimic the 16 vasoconstriction curve, correct? 17 A So if rebound hyperemia never occurred, the 18 net would be the same. 19 Q But in this case, it doesn't, because this 20 is reporting on some rebound hyperemia. 21 Here, the net vasoconstriction benefit 22 decreases, so it -- let me step back.	87 1 A Yes. 2 Q And the change in the net vasoconstriction 3 benefit curve is more significant than the change in 4 the rebound-hyperemia curve, correct? 5 MR. DINER: Objection, vague. 6 A Ask me that question again. I'm sorry. 7 Didn't quite follow. 8 BY MS. CIPRIANO: 9 Q So the net -- let's step back. 10 The rebound-hyperemia curve here, right? 11 MR. DINER: Are we talking about Figure 2 12 or Figure 6? 13 MS. CIPRIANO: Figure 2. 14 BY MS. CIPRIANO: 15 Q The rebound-hyperemia curve that's the 16 thinner gray line gradually increases to about, I 17 guess, just higher than .05, and then has a steeper 18 slope after at concentrations above, we'll say, .05. 19 Do you see that? 20 A I'm sorry. Say it one more time. 21 Q Sure. I'm just trying to understand the 22 rebound-hyperemia line.
86 1 The net vasoconstriction benefit peaks at 2 around 0.3 percent brimonidine, correct? 3 A It's less than that, .02. 4 Q So if we could take a look at page 45 of 5 your declaration, paragraph 94. 6 A (Witness complies.) 7 Q You in the first -- second full sentence on 8 page 45, you said "Relatedly, Figure 2 teaches that 9 brimonidine's maximum vasoconstriction effect after 10 netting out its tendency to cause rebound hyperemia is 11 at 0.03 percent, as seen from the apex of the thick 12 gray arrow." 13 Do you see that? 14 A I see that. 15 Q So are you changing your mind that the apex 16 of the thick gray arrow is at .03 percent? 17 A I'll stand by what's in my report. 18 Q Okay. So going back to Figure 2, we see 19 that the net vasoconstriction benefit increases -- 20 comes to an apex at .03 percent and then drops off 21 after at higher concentrations above .3 percent, 22 correct?	88 1 So the rebound-hyperemia line, I see that 2 it gradually increases up to about a little above 3 .05 percent. There's one slope, if you will, of the 4 curve up until a little higher than .05 percent? 5 A Okay. 6 Q And then it changes in slope. It becomes 7 steeper, increases more quickly, higher than 8 .05 percent. 9 Do you see that? 10 A Okay. 11 Q Do you agree with that? 12 A Yes. 13 Q Okay. And what I'm trying to just confirm 14 is that the net vasoconstriction benefit curve starts 15 to decrease at .03, but the net -- but the rebound 16 hyperemia doesn't really start to increase in Figure 2 17 until after .05 percent, right? 18 MR. DINER: Objection to the extent it 19 mischaracterizes the graph. 20 A Well, it's increasing throughout. Starts 21 very low, and it just -- it's a positive slope 22 throughout the whole graph.

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89 1 BY MS. CIPRIANO: 2 Q Okay. Now, Figures 2 and Figure 6 don't 3 represent actual data from a clinical study, right? 4 MR. DINER: Objection, vague. 5 A They're not necessarily in association with 6 the clinical study. 7 BY MS. CIPRIANO: 8 Q Okay. These are more akin to illustrations 9 of what the data represents? 10 MR. DINER: Objection no foundation. Calls 11 for speculation. 12 A Yeah. These are from the patent. 13 BY MS. CIPRIANO: 14 Q Do you know where this data came from? 15 A I saw it in the patent. 16 Q Do you know where the patentee got this 17 information? 18 A I don't know. 19 Q And there's no -- there are no error bars 20 associated with Figure 2 and Figures 6, correct? 21 A There are no error bars. 22 Q Do you know if there are -- there's any	91 1 BY MS. CIPRIANO: 2 Q You agree that the rebound-hyperemia curve 3 in Figure 6 is different than the rebound-hyperemia 4 curve in Figure 2? 5 A No. I don't know to what -- I don't 6 understand what you're saying. 7 Q It has a different shape? 8 A They're fairly similar. 9 Q So in Figure 2, the rebound-hyperemia curve 10 is always lower than the endo-cell pump inhibition 11 curve, correct? 12 A In which graph? 13 Q Figure 2? 14 A Figure 2. I think the rebound is -- it 15 appears that the rebound-hyperemia curve is always 16 below the endothelial cell pump inhibition curve. 17 Q In Figure 2? 18 A Yes. 19 Q And in Figure 6, that's not the case, 20 correct? -- well, let's step back. Let me ask a 21 different question first. 22 You agree that -- or, your interpretation
90 1 information about a standard deviation or variable in 2 this data associated with Figures 2 and Figure 6? 3 A I haven't seen any of that. 4 Q And you agree that Figure 2 and Figure 6 5 represent -- let me start that again. 6 You agree that Figures 2 and Figure 6 are 7 different, correct? 8 MR. DINER: Objection to the extent it 9 mischaracterizes his testimony. 10 A I don't know what you mean by "different." 11 They're obviously similar. And I think I kind of go 12 back and forth when I interpret them together. 13 BY MS. CIPRIANO: 14 Q Okay. So in para 95, you said that "in, 15 effectively, an expanded version of Figure 2," and I'm 16 trying to understand that statement. 17 Figure 6 is not a reproduction of a section 18 of Figure 2, right? 19 MR. DINER: Objection to the extent it 20 mischaracterizes testimony. 21 A What do you mean by "reproduction"? 22	92 1 of Figure 6 is that the curves have the same, or 2 follow the same key as in the legend of Figure 2; is 3 that correct? 4 A Yeah. The way I interpret these is 5 together. I tend to use them as a package. 6 Q Okay. So the dotted line in Figure 6 is 7 also a line representing endothelial cell pump 8 inhibition? 9 A I believe so. 10 Q So in Figure 6, the rebound-hyperemia curve 11 is not always below the endo-cell pump inhibition 12 curve, right? 13 A In Figure 6? 14 Q In Figure 6. 15 A No. It's not always below there. 16 Q Okay. So then you'd agree that 17 rebound-hyperemia curve in Figures 2 and Figure 6 are 18 different? 19 MR. DINER: Objection. Mischaracterizes 20 prior testimony. And the document speaks for itself. 21 A I would use -- I mean, I use these 22 together. I kind of use them as a package.

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November 13, 2022

93 1 BY MS. CIPRIANO: 2 Q I understand how you use them. I'm just 3 trying to establish that you would agree that the data 4 represented in the figures is different? 5 MR. DINER: Objection, vague. Asked and 6 answered. To the extent it mischaracterizes 7 testimony, objection to form. 8 A I just used them interchangeably. I go 9 back and forth. 10 BY MS. CIPRIANO: 11 Q Okay. Have you seen any clinical data 12 comparing 0.025 percent and 0.03 percent brimonidine? 13 A What do you mean, "clinical data"? 14 Q Any clinical studies comparing those two 15 percentages of brimonidine. 16 A No. 17 Q Okay. We can put that away. 18 A (Witness complies.) 19 Q I'd like to turn now to what we referred to 20 in this case as the '553 patent. 21 I'm going to hand you a document that's 22 been marked Exhibit 1004.	95 1 Q In your -- have you ever performed radial 2 keratotomy? 3 A Yes. 4 Q Now, is the eye held still during the 5 procedure? 6 A What do you mean, "held still"? 7 Q Is there any device that's used to prevent 8 the patient from moving their eye? 9 A To prevent the patient from moving their 10 eye? 11 Q Yes. 12 A To prevent them from moving their eye, no. 13 Q So the patient can look around during the 14 procedure? 15 A Yes. 16 Q One of the things that's talked about in 17 the '553 patent is ocular inflammation. 18 Do you recall that? 19 A Can you point me specifically? 20 Q Sure. Let's look at example 1 in the third 21 paragraph. 22 A (Witness complies.)
94 1 Do you recognize this as the '553 patent 2 that's discussed in the papers in this proceeding? 3 A Yes. 4 Q And a focal point of this discussion, your 5 declaration and the other papers in this proceeding, 6 is example 1 of the '553 patent. 7 Do you recall that? 8 MR. DINER: Objection. Mischaracterizes 9 the declaration. 10 A It's one of the things talked about. 11 BY MS. CIPRIANO: 12 Q Example 1 discusses administration of 13 brimonidine following radial keratotomy surgery, 14 correct? 15 A Yes. 16 Q And radial keratotomy surgery is a 17 procedure where the surgeon uses a blade and makes 18 incisions in the cornea, correct? 19 A Yes. 20 Q And is it performed while the patient is 21 awake? 22 A Typically.	96 1 Q The second sentence in that third paragraph 2 under example 1 is "Symptoms of ocular inflammation 3 (burning/stinging, tearing, et cetera) are also 4 recorded." 5 Do you see that? 6 A So I see those words here. 7 Q Okay. You agree that redness could be one 8 sign of ocular inflammation, correct? 9 MR. DINER: Objection, vague. 10 A What kind of redness? 11 BY MS. CIPRIANO: 12 Q Redness in the eye. 13 MR. DINER: Objection, vague. 14 A You have to give me more information on the 15 clinical scenario. 16 BY MS. CIPRIANO: 17 Q So you don't agree that redness is a sign 18 of inflammation generally? 19 A It would have to be -- it depends on the 20 clinical scenario. 21 Q So in paragraph 146 of your declaration, 22 you state: "It has long been known that inflammation,

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1 including ocular inflammation, produces five cardinal 2 symptoms, including swelling, pain, redness, heat, and 3 loss of function." 4 Do you see that? 5 A Yes. 6 Q Do you agree with that statement? 7 A That's a general statement for medicine. 8 Q Okay. So in paragraph 49 of your 9 declaration, you refer to a clinical study near the 10 bottom of the page. 11 Do you see that? 12 A I'm sorry. Where are you? 13 MR. DINER: Paragraph 49? 14 MS. CIPRIANO: Paragraph 149. 15 THE WITNESS: 149? 16 MS. CIPRIANO: I'm sorry if I misspoke. 17 BY MS. CIPRIANO: 18 Q Are you there? 19 A I'm there. 149, yes. 20 Q So you talk about a redness scale, 21 including a redness scale from this clinical study, 22 including a zero, related to no eye redness, right?	1 study were ever recorded as having a zero on the 2 conjunctival redness descriptor scale? 3 A I need to look. 4 (Witness reviews document.) 5 I'm sorry. What was the question? 6 Q So my question was if you knew if any of 7 the patients in this study were ever recorded as 8 having a zero on the redness scale that's reported on 9 page 16 of the document. 10 A Well, I think at entry they had to probably 11 be zero. 12 Q That's your assumption? 13 A Yeah, for inclusion criteria. 14 Q And what about the inclusion criteria makes 15 you think -- 16 A Well, the exclusion criteria says that if 17 they have -- where does it say -- "of clinically 18 active conjunctivitis with greater than one redness in 19 any vessel bed." 20 So some of them must have. 21 Q Do you -- do you know what the average eye 22 redness score would be for healthy eyes, based on this
1 A Yes. 2 Q Do you know if anyone in that study 3 actually was rated a zero on the redness scale? 4 A Which study are you talking about? 5 Q The study that's reported in -- that you're 6 referring to in paragraph 149. 7 Do you want to take a look at it? 8 A (Witness reviews document.) 9 Yes. 10 Q We'll look at Exhibit 2166. 11 Do you recognize this as the clinical study 12 report that you cite in paragraph 149 of your 13 declaration? 14 A It appears to be. 15 Q Okay. And you cite to page 16 that sets 16 forth the redness scale -- 16 of the document which is 17 marked as page 30 of the study report. 18 Do you see the scale that's in the middle 19 of the page? 20 A Table 5? 21 Q Yeah. 22 Do you know if any of the patients in this	1 scale? 2 MR. DINER: Objection, vague. Incomplete 3 hypothetical. 4 A It would depend on the population. 5 BY MS. CIPRIANO: 6 Q This study report does not report on a 7 baseline eye redness score in this study population, 8 right? 9 MR. DINER: Objection, vague. Asked and 10 answered. 11 A I'm not sure what you're saying. I'm sure 12 it was recorded somewhere. 13 BY MS. CIPRIANO: 14 Q Is it reported in this clinical study 15 report? 16 A No, but you can also see on table 13 that 17 the mean is 0.48 or 0.61. So these are means, 18 less-than. So sometimes people have zeros. 19 Q In table 4 -- I'm sorry, what? 20 A Table 13, when the mean is less than 1, 21 that implies that somebody had to be a zero to make it 22 less than 1.

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November 13, 2022

101 1 Q I'm not seeing where you -- table 13? 2 A Yeah. So when you see these scores, so it 3 says "mean." 4 Q Understood. 5 A You know, if the mean is less than 1, that 6 means somebody is zero -- or, some people's. 7 Q And what does "ciliary redness" mean? 8 A It's redness around the limbus, which is 9 where the white part meets the colored part. 10 Q And is that different than hyperemia? 11 MR. DINER: Objection, vague. 12 A Depends on the clinical scenario. 13 BY MS. CIPRIANO: 14 Q Could it be? 15 A It depends how you define it. 16 Q So tables 9 through 12 report on 17 conjunctival redness. 18 Do you see that? 19 A Yes, yes. 20 Q And then, separately, it studies -- it 21 reports on ciliary redness. 22 A Yes.	103 1 testimony. 2 A They're anatomically -- they're just -- 3 they're surface blood vessels in different locations. 4 BY MS. CIPRIANO: 5 Q Okay. Is ciliary redness considered 6 hyperemia? 7 A Depends on the context. 8 Q In the context of this study. 9 A Ciliary redness is typically the ciliary 10 blood vessels engorging. 11 Q And is it considered the hyperemia that was 12 studied in this clinical study report? 13 A Well, it's something that they recorded in 14 this study. 15 Q Did they only record ciliary redness at 16 visit 6? 17 Well, let me ask a more direct question. 18 So if you look at page 26 of the exhibit, 19 there's a section titled "Ciliary Redness." 20 A Yes. 21 Q So ciliary redness was measured at more 22 than just visit 6, right?
102 1 Q So which of -- let me strike that. 2 Would you interpret conjunctival redness to 3 equate to hyperemia? 4 A It could be. 5 Q What else could it be? 6 A It could be a lot of different things. It 7 could be blood. 8 Q What do you mean "could be blood"? 9 A It depends. You're just talking about the 10 term "conjunctival redness" in a vacuum? 11 Q No. Conjunctival redness as it's reported 12 in tables 9 through 12 of this clinical study. 13 A So this is a study looking at hyperemia. 14 So that's what they're measuring. 15 Q Okay. So the study report makes -- calls 16 out the difference between conjunctival redness and 17 ciliary redness. 18 Do you agree? 19 A They're -- they're blood vessels on that 20 surface. 21 Q But they're measured differently here? 22 MR. DINER: Objection. Mischaracterizes	104 1 A I need to look at the protocol. 2 Q I mean, it says there were no statistically 3 significant differences in ciliary redness scores 4 among the treatment groups at visits 3B, 4B, or 5B. 5 Do you see that? 6 A Yes. 7 Q So at least they were measured at visits 8 3B, 4B, 5B, and visit 6. 9 A Okay. 10 Q Is that logical? 11 A That's logical. 12 Q Could someone be considered to have 13 hyperemia and have no ciliary redness? 14 MR. DINER: Objection, vague. Incomplete 15 hypothetical. 16 A I don't understand that question. 17 BY MS. CIPRIANO: 18 Q Okay. 19 So we've been talking about adverse events 20 related to various products today, and we've been 21 referring to it as -- generally as "hyperemia." 22 And I -- is that hyperemia limited to

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105 1 what's classified as "conjunctival redness" in this 2 study report? 3 MR. DINER: Objection, vague. 4 A So you're specifically talking about just 5 this study. Is that what this question is about? 6 MS. CIPRIANO: Let me ask a better question 7 then. 8 BY MS. CIPRIANO: 9 Q Hyperemia, in general, when we're talking 10 about hyperemia of the eye -- it can occur -- strike 11 that. Let me start over. 12 So what I'm trying to understand is, there 13 are -- if someone only had ciliary redness, would that 14 still classify as hyperemia? 15 MR. DINER: Objection, vague. 16 A Depends on the clinical criteria, what 17 you're defining it as. 18 BY MS. CIPRIANO: 19 Q So in the Alphagan clinical studies when it 20 talks about adverse event of hyperemia, what does that 21 mean to you? 22 A It depends -- it depends on the specific	107 1 BY MS. CIPRIANO: 2 Q I'm not sure I understand your answer. Let 3 me ask another question. 4 We can move on. 5 So the Norden paper states in the -- I 6 guess, in the second paragraph, if you want to take a 7 look in the right-hand column. 8 It states that the study was designed to 9 "objectively assess the effect of brimonidine 10 administration before LASIK on subconjunctival 11 hemorrhage, hyperemia, and micropannus bleeding." 12 Do you see that? 13 MR. DINER: I don't. 14 MS. CIPRIANO: The last paragraph before 15 "Patients and Methods." 16 THE WITNESS: Okay. 17 BY MS. CIPRIANO: 18 Q "This prospective, double-masked trial." 19 Do you see that? 20 A Yes. 21 Q I just want to make sure I understand your 22 declaration a bit.
106 1 clinical studies, how, number 1, the data was 2 solicited, and in the context that you're using it in. 3 Q I'd like to look at a different study. 4 I'm going to hand you what's been marked as 5 Exhibit 1006. 6 Do you recognize this as the document 7 that's referred to in the papers as "Norden"? 8 A Yes. 9 Q In your declaration, you talk a little bit 10 about the construction of ocular condition as it's 11 used in the claims of the '742 patent; is that 12 correct? 13 A Yes. 14 Q You do not dispute that LASIK would 15 constitute -- a patient that had LASIK would 16 constitute as a patient having an ocular condition 17 within the scope of the claims of the '742 patent, 18 correct? 19 MR. DINER: Objection to the extent it 20 calls for a legal conclusion. 21 A LASIK is a procedure. 22	108 1 So in paragraph 169, this is in the section 2 you're talking about Norden 2002, you state a 3 conclusion that -- end of the sentence, it states "a 4 conclusion that, in fact, was contemporaneously 5 questioned by ophthalmologists." 6 A Where are you reading from? 7 Q The last section of paragraph 169. 8 A Okay. 9 Q You don't cite anything in this paragraph, 10 but you're referring to the Euretman and Munos 11 articles that you cite later; is that correct? 12 A Yes. But also in the community, that's one 13 place, but also, just, I questioned it. 14 Q Okay. But the only -- so I guess if you 15 look at paragraph 175, it's where the two articles are 16 there, the only documents you point to as the 17 contemporaneous reports of other surgeons are 18 Exhibit 2175 by Munos and Exhibit 2186, by Euretman? 19 A Yes. 20 Q Looking at the Norden article a bit, you 21 discuss this in section of your declaration starting 22 at paragraph 166, if you want to take a look.

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109 1 But I understand that you essentially make 2 three criticism of the Norden data. 3 Does that sound familiar? 4 MR. DINER: Objection, vague. 5 A Could you elaborate? 6 BY MS. CIPRIANO: 7 Q Sure. Let's -- we can walk through them. 8 A Okay. 9 Q So you have paragraph 170. 10 You state "First, Norden 2002 measured 11 redness only once, five minutes after the LASIK 12 surgery." 13 Do you see that? 14 A Yes. 15 Q So in your view -- and this is -- I'm just 16 trying to understand this critique. 17 In your view, in order to inform a person 18 of ordinary skill about the ability of brimonidine to 19 reduce redness, redness needs to be measured at least 20 twice, correct? 21 MR. DINER: Objection to the extent it 22 mischaracterizes the document.	111 1 MR. DINER: Objection. Mischaracterizes 2 the testimony. 3 A What I'm -- what I'm saying is that, 4 because everyone had hyperemia, maybe everybody got 5 worse. Maybe nobody had hyperemia at the beginning of 6 the study. He didn't -- he didn't measure it. This 7 is a bad study. 8 BY MS. CIPRIANO: 9 Q Okay. But it's a bad study because -- one 10 of the reasons it's a bad study is that he didn't 11 measure twice? 12 MR. DINER: Mischaracterizes his testimony. 13 A He didn't establish a baseline. 14 BY MS. CIPRIANO: 15 Q Okay. And then -- so turning to the second 16 point in paragraph 172, you say "Second, Norden 2002 17 failed to establish proper exclusion criteria." 18 Do you see that? 19 A Yes. 20 Q And so, in your view, in order to provide 21 information about the ability of brimonidine to reduce 22 redness the study has to exclude patients taking other
110 1 A The biggest problem with that is there's no 2 baseline. 3 BY MS. CIPRIANO: 4 Q Okay. 5 A So how do you know -- how do you measure 6 where you're going if you don't know where you came 7 from? 8 Q Without a baseline measurement, you're 9 unable to understand the impact on redness? 10 MR. DINER: Objection, vague. 11 A The problem with the study is everybody had 12 hyperemia, almost. 95 percent of people had 13 hyperemia. So everybody has hyperemia. So how do you 14 measure anything? 15 BY MS. CIPRIANO: 16 Q I think that falls into your second -- your 17 second critique, but I'd like to focus on your first 18 critique, talking about the measurements. 19 And I just want to confirm that your 20 position is that in order to understand the impact on 21 redness, you need to have a baseline measurement and 22 then some test measurement at the minimum, right?	112 1 medication that could impact eye redness, right? 2 MR. DINER: Objection, vague. 3 A The biggest problem with this study is the 4 sloppiness of it. He didn't account for it. You can 5 do a study on anything if you account for it. The 6 problem is, we don't know. It's just he was winging 7 it. And there's all these other confounding factors 8 that could really skew the results. He didn't take -- 9 he didn't take into account other variables. 10 BY MS. CIPRIANO: 11 Q So in order to draw a conclusion about eye 12 redness, the study has to be limited to looking at eye 13 redness? 14 MR. DINER: Objection, vague. Incomplete 15 hypothetical. 16 A It always depends what you're trying to 17 measure. And this is -- this study didn't -- it 18 didn't set up success for accurate measurement. It 19 didn't get a baseline; it didn't define what the 20 patients could look like coming in. Maybe they all 21 had horrible red eyes to start with. Who knows? -- 22 those that treated and the untreated people. Who

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113 1 knows? He didn't randomize for individuals. We don't 2 like to make comparisons inside an individual because 3 eyes are different from one person to another. It's 4 flawed at every single level. 5 BY MS. CIPRIANO: 6 Q The third critique, starting on 7 paragraph 174 of your declaration, you state "Third, 8 the study protocol Norden 2002 had too many variables 9 to make any meaningful assessment." 10 And then you go on and you talk about the 11 hyperemia scale that Norden used, correct? 12 A Yes. 13 Q So in your view, in order to draw 14 conclusions about whether brimonidine could reduce 15 redness, you'd need more information about the scale 16 that was being used in the study correct? 17 MR. DINER: Objection. Mischaracterizes 18 the document. 19 A No. I'm saying it was a crummy study, and 20 we can't draw any conclusions from how he reported the 21 data. 22	115 1 that's the least of our problems. But yes, that would 2 be nice. 3 BY MS. CIPRIANO: 4 Q We can put Norden away. 5 If we could turn to paragraph 138 of your 6 declaration, and that's on page 65. 7 A Yes. 8 Q Now, this paragraph is talking a little bit 9 about the pH of an ocular formulation, right? 10 A Yes. 11 Q And you're not providing an opinion on the 12 motivation of a person of ordinary skill to target a 13 specific pH, correct? 14 MR. DINER: Objection. Mischaracterizes 15 the paragraph. 16 A Well, the eye is very sensitive to pH, and 17 we'd like to work at a physiologic pH if we can. 18 BY MS. CIPRIANO: 19 Q Again, you're not providing -- there's a 20 bunch of statements in this paragraph that refer to 21 what Dr. Williams will explain? 22 A Yes. And I will defer to him, yes.
114 1 BY MS. CIPRIANO: 2 Q Right. 3 I'm just trying to understand what makes a 4 crummy study. 5 A So when he's looking at the scale, he's 6 saying some eyes had blood; some had hyperemia. I 7 mean, how do you tell the difference? If a big blob 8 of blood is overwhelming the blood vessels, how do you 9 make any assessment of hyperemia? If there's a blob 10 of blood over it, how can you say anything? 11 Q So you'd want more information about the 12 scale that he used and how he assessed redness? 13 MR. DINER: Objection. Mischaracterizes. 14 A I'd like the study to be designed 15 appropriately. 16 BY MS. CIPRIANO: 17 Q Which would include some more information 18 about a subjective scale that was used to assess the 19 redness? 20 MR. DINER: Objection, vague. 21 Mischaracterizes testimony. 22 A Sure, that -- but that's -- honestly,	116 1 Q Near the bottom of the page in 2 paragraph 138, you state "In my experience, 3 administration of a topical eye drop with an acidic pH 4 leads to burning and stinging, tear production, or 5 redness." 6 Do you see that? 7 A Yes. 8 Q What was the pH of the eye drops where you 9 observed burning, stinging, tearing, and redness? 10 A Probably the lowest pH, like, 4.6. But I 11 mean, I personally put many of these medications in my 12 eye, and when it's -- the pH is less than 7, they tend 13 to sting more. 14 Q So less than 7. 15 Would -- in your experience, would an 16 eye drop at pH 6.9 cause burning and stinging? 17 MR. DINER: Objection, vague. Incomplete 18 hypothetical. 19 A It would depend on the eye drop. 20 BY MS. CIPRIANO: 21 Q And what would it depend on? 22 A Active ingredients, the other incipients,

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117 1 the other things in the formulation. PH is one 2 factor. 3 Q So in your experience, would an eye drop at 4 pH, for example, 6.9 cause burning and stinging due to 5 the pH? 6 MR. DINER: Objection. Incomplete 7 hypothetical. Asked and answered. 8 A It could. It would depend on the exact 9 clinical scenario. 10 BY MS. CIPRIANO: 11 Q Are you aware of any study comparing the 12 effects of 0.025 percent brimonidine with 0.2 percent 13 brimonidine? 14 MR. DINER: Objection, vague. 15 A For treatment of? 16 BY MS. CIPRIANO: 17 Q Anything. 18 A Not off the top of my head. 19 Q So are you aware of any clinical study 20 comparing the effects of 0.025 percent brimonidine 21 with 0.3 percent brimonidine? 22 A For treatment for?	119 1 having blood vessels that were dilated can make the 2 eye appear red? 3 A Yes. 4 Q Does the episclera -- strike that. 5 Do you have an opinion of whether the 6 episclera has blood vessels that, when dilated, can 7 make the eye appear red? 8 A Yes. They have some blood vessels that can 9 dilate and make the eye look red. 10 Q I'd like you to -- can you take a look at 11 paragraph 38? 12 A Yes. 13 Q Can you read that paragraph into the 14 record, please? 15 MS. CIPRIANO: Objection to form. 16 BY MR. DINER: 17 Q Can you read paragraph 38 into the record, 18 please? 19 A "Each of the conjunctiva, episclera, and 20 sclera have blood vessels. The conjunctiva and 21 episclera have blood vessels known as 'superficial and 22 deep conjunctival capillary and episcleral plexuses.'
118 1 Q Anything. 2 A Not off the top of my head. 3 MS. CIPRIANO: Let's take a quick break. 4 THE VIDEOGRAPHER: We're now going off the 5 record. The time is 12:43. 6 (Recess.) 7 THE VIDEOGRAPHER: We're now back on the 8 time is 12:52. 9 MS. CIPRIANO: Doctor, I really appreciate 10 your time. I don't have any further questions at this 11 time. 12 EXAMINATION 13 BY MR. DINER: 14 Q Dr. Noecker, I'd like to refer you to 15 paragraph 38 of your declaration. 16 A (Witness complies.) 17 Q Do you recall this morning that counsel was 18 asking you questions with regard to paragraph 38 and 19 the figures of the eye, asking you questions about the 20 sclera? 21 A Yes. 22 Q Do you recall talking about the conjunctiva	120 1 Dilation of these blood vessels make them more 2 visible, triggering eye redness. The surface of the 3 sclera, deep into the episclera, also contains blood 4 vessels. When dilated, these blood vessels at the 5 sclera interface with the episclera, which can make 6 the eye appear red." 7 Q And as you sit here today, do you maintain 8 the same opinion as you just read from paragraph 38 of 9 your declaration? 10 A Yes. 11 MR. DINER: No further questions. 12 MS. CIPRIANO: I have no further questions. 13 THE VIDEOGRAPHER: This concludes today's 14 deposition. The time is 12:54. We're now off the 15 record. 16 MS. CIPRIANO: Five business days. 17 MR. DINER: Five business days. 18 MS. CIPRIANO: Rough draft. 19 MR. DINER: Rough draft. 20 21 (Time noted: 12:54 p.m.) 22

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121

1 CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC

2 I, Angela (Angie) Shaw-Crockett, Certified
3 Reporter and Notary Public within and for the States
4 of New York, New Jersey and Connecticut, do hereby
5 certify: That Dr. Robert Noecker, the witness whose
6 deposition is hereinbefore set forth, was duly sworn
7 by me before the commencement of such deposition and
8 that such deposition was taken before me and is a true
9 record of the testimony given by such witness.

10 I further certify that the adverse party,
11 Eye Therapies, was represented by counsel at the
12 deposition.

13 I further certify that the deposition of,
14 Dr. Robert Noecker, occurred at the offices of
15 Residence Inn Norwalk, 45 South Main Street, Norwalk,
16 Connecticut 06845, on Sunday, November 13, 2022,
17 commencing at 9:25 a.m. to 12:54 p.m.

18 I further certify the inspection, reading
19 and signing of said deposition was not discussed on
20 the record. I further certify that I am not related
21 to any of the parties to this action by blood or
22 marriage, I am not employed by or an attorney to any

122

1 of the parties to this action, and that I am in no way
2 interested, financially or otherwise, in the outcome
3 of this matter.

4 IN WITNESS WHEREOF, I have hereunto set my
5 Hand this 18th day of November, 2022.

6
7 

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A			
a- 37:16 ability 50:7, 50:19, 109:18, 111:21 able 9:14 about 7:6, 16:18, 17:19, 19:16, 19:17, 24:9, 25:2, 25:4, 28:22, 30:8, 32:21, 35:6, 36:20, 37:10, 41:6, 41:13, 41:15, 45:5, 47:14, 47:20, 49:17, 49:21, 50:10, 50:18, 53:2, 53:12, 53:14, 55:21, 56:3, 58:14, 58:21, 59:15, 60:17, 60:22, 64:6, 64:12, 64:14, 65:1, 65:2, 65:5, 68:3, 78:18, 79:9, 79:10, 79:11, 79:19, 81:14, 83:11, 83:16, 84:12, 84:15, 87:11, 87:16, 88:2, 90:1, 94:10, 95:16, 97:20, 98:4, 99:14, 102:9, 104:19, 105:4, 105:5, 105:10, 105:20, 106:10, 108:2, 109:18, 110:18, 111:21, 112:11, 113:10, 113:14, 113:15, 114:11,	114:18, 115:9, 118:19, 118:22 above 86:21, 87:18, 88:2 absolutely 80:21 abstract 52:7 accept 22:13, 77:17 acceptable 77:15 accepted 30:13 accomplish 43:5 account 83:15, 112:4, 112:5, 112:9 accurate 50:9, 52:19, 112:18 acidic 116:3 action 121:21, 122:1 activating 42:8, 42:19, 44:22, 45:2 active 99:18, 116:22 activity 45:9 actual 89:3 actually 38:7, 39:16, 47:12, 68:12, 83:22, 98:3 acuity 65:8, 65:17, 70:5 address 32:12 addressing 69:16 administer 26:14, 28:6,	40:6, 40:19 administered 27:9, 36:22, 38:18, 38:22, 40:2, 41:1, 63:8, 63:12, 75:6 administering 26:17 administrated 30:15 administration 27:20, 29:1, 32:4, 50:11, 70:17, 70:18, 71:2, 94:12, 107:10, 116:3 adrenergic 41:13, 41:16, 41:17, 44:11, 44:15, 44:16, 44:22, 45:9, 46:4, 46:11, 46:22, 47:14, 48:1 advanced 21:3 adverse 28:22, 60:9, 60:10, 63:4, 63:12, 72:3, 72:8, 72:9, 78:7, 104:19, 105:20, 121:10 advise 40:5 advisor 14:8 after 29:1, 32:3, 46:18, 54:8, 69:1, 70:15, 70:18, 71:2, 86:9, 86:21, 87:18, 88:17, 109:11 again 24:6, 26:13,	36:18, 37:2, 54:5, 56:6, 56:11, 62:11, 68:5, 70:2, 70:14, 70:17, 71:13, 87:6, 90:5, 115:19 against 7:12 agent 26:12 agents 27:7, 27:9, 27:12 ago 6:14, 6:15, 6:20, 13:13 agonist 30:12, 30:19, 41:10 agonists 32:4, 49:15 agree 19:8, 20:16, 21:9, 22:5, 22:16, 23:9, 23:14, 23:19, 24:10, 26:11, 27:11, 30:10, 30:12, 41:4, 41:9, 41:19, 42:10, 42:19, 43:7, 43:15, 44:21, 45:11, 48:17, 49:16, 52:19, 58:20, 83:21, 85:3, 88:11, 90:4, 90:6, 91:2, 91:22, 92:16, 93:3, 96:7, 96:17, 97:6, 102:18 aim 76:13 akin 89:8 all 14:22, 18:1,

21:2, 21:6, 21:9, 23:9, 23:18, 33:20, 35:17, 35:18, 36:19, 44:1, 61:12, 65:1, 66:14, 69:17, 72:5, 73:20, 79:1, 112:7, 112:20 all-different-level 7:11 alluded 49:10 almost 110:12 alpha 30:12, 30:19, 31:3, 32:4, 41:12, 41:13, 41:16, 44:11, 44:15, 44:22, 46:4, 46:21 alpha-2 41:10, 41:16, 42:16, 43:18, 45:8, 46:11, 46:22, 48:1, 49:15 alpha-2a 42:4, 42:20 alpha-2b 42:5, 42:20 alpha-2c 42:5, 42:20 alphagan 28:19, 29:5, 29:17, 32:22, 33:2, 33:8, 33:10, 33:11, 33:17, 33:18, 33:20, 33:21, 34:15, 35:17, 36:12, 50:12, 51:1, 51:4, 58:12, 59:16, 59:21, 60:5,	60:11, 61:3, 61:6, 78:18, 79:10, 105:19 also 3:21, 17:6, 22:2, 30:20, 33:12, 43:15, 47:17, 47:20, 47:22, 55:22, 59:1, 92:7, 96:3, 100:16, 108:12, 108:13, 120:3 alt 54:8, 60:12 although 46:10, 46:22 always 7:7, 10:19, 22:9, 22:10, 24:3, 25:13, 39:13, 68:1, 68:3, 68:5, 77:12, 91:10, 91:15, 92:11, 92:15, 112:16 among 104:4 amount 58:5 analysis 68:18 analyzed 66:9 anatomically 103:2 anecdotal 24:5 angela 1:26, 2:12, 121:2 angie 1:26, 2:12, 5:9, 121:2 angle 66:18 angus 48:17, 49:9,	49:16 another 13:19, 13:20, 33:11, 34:8, 67:1, 75:9, 107:3, 113:3 answer 8:3, 8:4, 8:17, 9:2, 9:14, 30:14, 32:7, 36:4, 39:13, 43:2, 58:6, 58:7, 77:1, 107:2 answered 93:6, 100:10, 117:7 answering 7:18 answers 7:18, 7:20, 14:22 antagonists 47:15 anterior 16:10, 16:15, 16:17, 16:18, 17:1, 28:10, 66:17, 66:19 antibiotics 13:21 any 8:16, 9:13, 9:19, 10:13, 10:16, 10:22, 11:15, 12:2, 23:16, 24:3, 28:8, 31:13, 36:2, 37:5, 38:1, 38:2, 38:9, 44:5, 49:5, 55:15, 59:11, 67:16, 68:21, 72:8, 72:18, 77:2, 77:10, 79:4, 79:13, 81:22, 89:22, 90:3,	93:11, 93:14, 95:7, 98:22, 99:6, 99:19, 113:9, 113:20, 114:9, 117:11, 117:19, 118:10, 121:21, 121:22 anyone 10:11, 98:2 anything 49:17, 49:21, 50:1, 55:10, 108:9, 110:14, 112:5, 114:10, 117:17, 118:1 apex 86:11, 86:15, 86:20 apologies 60:2 appeal 1:3 appear 119:2, 119:7, 120:6 appears 11:8, 52:2, 81:3, 81:8, 91:15, 98:14 appendix 48:14 applied 30:16, 30:20, 31:14, 31:18 appreciate 118:9 appropriately 114:15 approval 29:17, 64:10 approved 21:6, 22:6, 34:6 approximately 5:3, 18:16 aqueous 25:14 area 12:13
--	--	---	--

aren't 28:12, 81:22 arizona 13:14 arm 39:6 around 18:6, 25:22, 66:12, 86:2, 95:13, 101:8 arrow 18:6, 86:12, 86:16 art 28:3, 41:20, 50:6 article 45:15, 47:13, 48:5, 48:18, 49:5, 51:15, 51:22, 53:4, 55:16, 108:20 articles 48:8, 48:17, 49:9, 49:12, 49:17, 51:13, 76:8, 108:11, 108:15 arts 51:3 asked 31:12, 93:5, 100:9, 117:7 asking 7:17, 9:7, 31:2, 118:18, 118:19 assess 66:13, 66:14, 68:8, 107:9, 114:18 assessed 71:5, 71:14, 114:12 assessment 66:10, 66:11, 67:3, 68:15, 113:9, 114:9	assessments 65:7, 65:14, 67:17, 69:2, 70:22, 71:13 associated 76:21, 89:20, 90:2 association 60:11, 89:5 assume 9:3, 30:14, 52:21, 67:19 assumption 99:12 attempted 26:8 attorney 121:22 attorneys 10:1, 10:10, 11:13 august 28:9, 41:19, 50:6 author 29:13, 29:15, 48:9 authors 52:14 autoregulation 47:2 available 22:15, 33:2, 33:5, 33:14, 33:15, 50:14, 51:8, 58:6 avenue 3:6, 3:18 average 26:13, 99:21 awake 94:21 aware 26:9, 26:10, 28:8, 31:13, 42:4, 42:15, 117:11, 117:19 away 25:15, 41:5,	41:7, 50:3, 79:16, 93:17, 115:4 axis 81:19, 81:22 B back 14:18, 17:17, 18:10, 18:16, 25:18, 27:2, 30:5, 30:8, 30:11, 40:10, 56:6, 56:10, 61:19, 61:22, 62:11, 63:3, 74:13, 74:22, 82:22, 85:13, 85:22, 86:18, 87:9, 90:12, 91:20, 93:9, 118:7 bad 22:11, 83:12, 83:16, 83:18, 111:7, 111:9, 111:10 bars 89:19, 89:21 based 32:10, 38:10, 47:12, 55:15, 58:16, 69:8, 73:2, 74:10, 99:22 baseline 69:18, 70:4, 71:15, 100:7, 110:2, 110:8, 110:21, 111:13, 112:19 basically 11:11, 14:2, 14:7, 54:19, 55:19 basis 73:19 because 18:13, 21:20,	23:20, 23:21, 31:16, 38:7, 73:22, 74:16, 85:19, 111:4, 111:9, 113:2 becomes 88:6 bed 99:19 been 5:20, 6:7, 7:19, 8:2, 13:7, 24:7, 26:6, 26:8, 34:9, 36:5, 42:17, 45:17, 48:10, 51:21, 78:20, 84:6, 93:22, 96:22, 104:19, 104:20, 106:4 before 1:3, 2:12, 6:7, 6:17, 8:17, 11:21, 56:7, 57:13, 71:2, 107:10, 107:14, 121:7, 121:8 beginning 52:7, 111:5 begins 70:1 behalf 3:2, 3:11 behind 17:2, 25:21, 58:1 being 11:6, 12:10, 113:16 believe 11:22, 48:10, 48:12, 56:16, 92:9 believed 45:14 below 91:16, 92:11, 92:15
---	---	--	---

benefit 83:1, 83:4, 83:15, 83:22, 84:7, 85:4, 85:13, 85:15, 85:21, 86:1, 86:19, 87:3, 88:14 better 43:17, 105:6 between 54:14, 70:12, 70:14, 75:22, 77:3, 77:11, 78:1, 102:16 big 114:7 biggest 110:1, 112:3 biomicroscopy 65:8, 65:21, 66:3, 66:5, 67:1, 70:20 bit 24:9, 30:11, 32:19, 32:21, 43:22, 64:11, 79:18, 79:19, 81:14, 106:9, 107:22, 108:20, 115:8 black 82:11, 82:16, 83:5, 83:6 blade 94:17 blanch 74:11 blanching 50:20, 50:21, 51:7, 53:15, 53:20, 54:3, 54:6, 54:15, 55:1, 55:6, 55:11, 55:12, 55:14, 55:16, 57:9, 58:16, 59:1, 59:6,	59:7, 60:13, 61:1, 62:7, 62:20, 63:13, 72:19, 73:4, 74:18, 75:4, 75:11, 77:4, 77:5, 79:1 blanks 11:14 bleeding 107:11 blindness 39:7 blinds 22:12 blob 114:7, 114:9 blood 19:8, 19:9, 19:14, 19:19, 20:4, 26:4, 26:7, 27:10, 27:13, 28:13, 30:18, 31:21, 31:22, 32:3, 70:5, 102:7, 102:8, 102:19, 103:3, 103:10, 114:6, 114:8, 114:10, 119:1, 119:6, 119:8, 119:20, 119:21, 120:1, 120:3, 120:4, 121:21 blue 19:4 board 1:3 bockman 48:18, 49:9, 49:16 body 43:20, 44:2, 44:4, 44:17 both 8:9, 33:17, 44:12, 44:18 bottom 16:5, 18:11,	21:1, 32:20, 60:9, 62:18, 64:19, 74:2, 82:15, 97:10, 116:1 box 18:10, 36:12, 82:22 boxes 78:11 branded 7:12 break 8:15, 8:17, 61:14, 61:15, 118:3 breaks 8:14 brimonidine 24:9, 24:10, 24:12, 26:6, 27:14, 28:4, 28:6, 28:9, 28:15, 29:2, 30:9, 31:13, 31:17, 32:14, 33:3, 33:4, 35:18, 36:13, 41:9, 47:22, 50:11, 51:5, 52:4, 52:15, 52:20, 53:3, 54:9, 54:20, 56:1, 56:3, 57:11, 58:14, 59:3, 59:5, 59:15, 62:4, 62:7, 62:21, 63:9, 63:12, 75:4, 75:13, 77:4, 78:5, 81:20, 86:2, 93:12, 93:15, 94:13, 107:9, 109:18, 111:21, 113:14, 117:12, 117:13, 117:20, 117:21	brimonidine's 50:7, 86:9 brimonidine-trea- ted 54:4 brown 18:5 bryan 3:14, 5:15 bunch 115:20 burning 96:3, 116:4, 116:9, 116:16, 117:4 business 120:16, 120:17 C call 39:16 called 13:19, 13:20, 16:9, 33:11, 40:11, 40:12 calls 72:11, 73:6, 84:11, 89:10, 102:15, 106:20 came 54:21, 55:3, 61:7, 89:14, 110:6 can't 29:14, 30:7, 40:22, 49:19, 59:9, 113:20 capillary 47:2, 119:22 cardinal 97:1 care 21:21 carefully 8:21 case 1:7, 5:7, 6:17, 7:3, 11:12,
--	--	--	--

11:16, 19:17, 85:19, 91:19, 93:20 cases 24:5, 54:5 categorized 35:10, 59:8 cause 19:9, 19:14, 30:21, 31:3, 39:7, 86:10, 116:16, 117:4 causes 31:17, 32:14 causing 25:10, 58:22 cell 82:18, 91:16, 92:7 cells 48:1 central 44:12, 44:18, 44:22, 45:12 certain 43:7, 67:6, 76:20 certainly 22:22, 23:1, 23:9, 24:5, 28:13, 79:7 certificate 121:1 certified 121:2 certify 121:5, 121:10, 121:13, 121:18, 121:20 cetera 96:3 chamber 16:17, 16:18, 16:19, 17:1, 17:2, 17:3, 66:17 chance 76:7, 77:16,	77:17, 77:18, 77:22, 78:2 change 87:2, 87:3 changes 12:2, 71:15, 88:6 changing 86:15 characterize 69:3 characterized 27:7 chart 20:22, 35:5, 59:2, 65:20 charts 22:17 check 78:11 chemist 12:16, 12:17 chose 72:13 christina 3:13, 5:17 ciliary 101:7, 101:21, 102:17, 103:5, 103:9, 103:15, 103:19, 103:21, 104:3, 104:13, 105:13 circulates 25:22 circulation 49:14 circumstances 39:4, 40:16, 43:8 cite 46:7, 51:15, 52:1, 53:2, 53:4, 55:22, 56:6, 58:10, 58:11, 62:11, 62:14, 73:13, 75:2, 78:22,	98:12, 98:15, 108:9, 108:11 cited 47:13, 49:9, 51:14, 73:3 citing 56:22 claims 106:11, 106:17 classified 105:1 classify 105:14 clear 9:1, 21:2, 64:5 clearly 8:10 clinical 14:4, 14:7, 14:8, 23:5, 28:13, 28:17, 32:12, 35:1, 35:6, 35:9, 38:21, 39:14, 39:16, 40:14, 56:3, 61:9, 61:11, 61:13, 67:19, 68:6, 79:4, 89:3, 89:6, 93:11, 93:13, 93:14, 96:15, 96:20, 97:9, 97:21, 98:11, 100:14, 101:12, 102:12, 103:12, 105:16, 105:19, 106:1, 117:9, 117:19 clinically 99:17 clinician 40:5 clonidine 45:6, 45:8, 45:12 closer 21:14 collagen 18:1	colleagues 5:17 collected 68:19, 68:20 color 80:14, 80:17 colored 16:22, 101:9 columbia 3:19 column 35:14, 36:11, 39:20, 39:21, 46:1, 53:14, 75:13, 107:7 com 3:9 combigan 7:1 come 7:9, 38:9, 41:6, 61:12, 80:17 comes 57:4, 73:20, 82:22, 86:20 comfort 71:5 comfortable 33:22, 35:19, 36:15 coming 112:20 comma 47:6 commencement 121:7 commencing 121:17 comment 53:13, 55:3, 58:14, 59:9 commercial 13:11, 14:11, 15:2, 20:15 commercially 22:15, 33:14, 50:13
---	---	--	---

common 60:10	conclusion 52:8, 53:9, 57:8, 76:13, 106:20, 108:3, 108:4, 112:11	2:14, 12:9, 121:4, 121:16, 122:10	correct 12:5, 12:6, 12:11, 12:12, 14:12, 15:3, 15:4, 15:12, 15:13, 15:16, 16:7, 16:10, 17:5, 17:22, 18:7, 18:11, 18:15, 19:10, 20:12, 21:7, 21:11, 22:19, 23:15, 23:22, 24:11, 24:15, 24:16, 25:5, 26:5, 27:17, 29:2, 30:4, 30:13, 30:21, 31:9, 31:19, 32:4, 33:4, 33:12, 33:13, 33:18, 33:22, 34:15, 35:7, 36:15, 39:7, 39:8, 41:2, 41:13, 41:17, 41:22, 42:21, 44:6, 44:13, 45:6, 45:7, 45:9, 49:18, 51:6, 52:4, 53:10, 58:18, 63:7, 63:9, 64:8, 64:18, 64:21, 72:10, 72:20, 73:5, 75:10, 76:1, 76:9, 78:2, 81:8, 81:20, 82:10, 83:2, 83:7, 85:16, 86:2, 86:22, 87:4, 89:20, 90:7, 91:11, 91:20, 92:3, 94:14, 94:18, 96:8, 106:12, 106:18, 108:11,
communications 9:20	conclusions 35:14, 36:11, 38:10, 113:14, 113:20	connection 61:5	
community 108:12	condition 22:11, 106:10, 106:16	connective 17:16	
comparator 75:8	conditions 12:14, 12:15, 21:21	considered 21:10, 48:19, 103:5, 103:11, 104:12	
comparing 93:12, 93:14, 117:11, 117:20	confirm 52:9, 80:12, 80:16, 88:13, 110:19	consisting 65:7	
comparison 84:1, 85:4	confounding 112:7	constitute 106:15, 106:16	
comparisons 113:2	conjuncture 6:12, 60:12, 66:22	construction 106:10	
complies 15:21, 20:20, 34:19, 41:8, 48:15, 50:4, 56:12, 62:15, 79:17, 86:6, 93:18, 95:22, 118:16	conjunctiva 20:5, 118:22, 119:19, 119:20	consultants 12:9	
components 66:14	conjunctival 19:19, 20:4, 51:7, 53:14, 53:19, 54:3, 55:1, 57:9, 58:16, 59:1, 60:13, 62:7, 62:19, 63:13, 66:16, 72:19, 73:4, 74:11, 74:18, 75:3, 75:11, 77:4, 77:5, 99:2, 101:17, 102:2, 102:10, 102:11, 102:16, 105:1, 119:22	contains 120:3	
composing 11:12		contemporaneous 108:17	
compounds 13:3		contemporaneously 108:4	
concentration 50:8, 50:22, 51:8, 51:10, 52:6, 52:11, 54:20, 59:5, 62:6		context 16:16, 22:8, 23:4, 34:2, 36:19, 54:16, 58:8, 103:7, 103:8, 106:2	
concentration-de- pendent 51:6		continue 62:1	
concentrations 33:3, 35:19, 36:13, 36:14, 50:16, 81:19, 86:21, 87:18		continues 46:10	
concerning 10:2		contribute 74:8	
concluded 33:20	conjunctivitis 23:11, 99:18	control 39:6, 75:5	
concludes 120:13	connecticut 1:17, 2:6,	conversations 10:13	
		copies 81:13	
		copy 11:4, 80:20, 81:2	
		cornea 66:14, 94:18	

109:20, 113:11, 113:16, 115:13 corrections 12:2 correctly 19:3, 56:21, 63:1, 63:15, 72:4, 75:7 could 20:18, 28:7, 34:17, 36:10, 40:21, 42:21, 50:20, 55:9, 55:11, 55:12, 56:10, 72:7, 72:17, 80:12, 80:20, 84:6, 84:7, 86:4, 96:7, 101:14, 102:4, 102:5, 102:6, 102:7, 102:8, 104:12, 109:5, 112:1, 112:8, 112:20, 113:14, 115:5, 117:8 counsel 5:11, 8:2, 8:3, 9:10, 9:20, 37:5, 118:17, 121:11 couple 27:4, 27:5, 41:5, 46:18, 53:12, 54:10, 62:12, 70:10 course 8:1 court 4:10, 5:8, 5:18, 7:20, 8:7, 45:16 covid 6:15 criteria 99:13, 99:14, 99:16, 105:16, 111:17	criticism 109:2 critique 109:16, 110:17, 110:18, 113:6 cross 18:20 cross-section 16:6, 18:12, 18:21, 18:22, 19:7 crr 1:26, 2:13 crummy 113:19, 114:4 cup 71:16 current 12:7 currently 12:5 curve 84:8, 84:9, 85:16, 87:3, 87:4, 87:10, 87:15, 88:4, 88:14, 91:2, 91:4, 91:9, 91:11, 91:15, 91:16, 92:10, 92:12, 92:17 curves 92:1 D data 37:19, 38:10, 57:13, 58:3, 58:5, 62:3, 64:9, 89:3, 89:9, 89:14, 90:2, 93:3, 93:11, 93:13, 106:1, 109:2, 113:21 date 80:8 david 51:17, 52:1,	55:16 day 9:2, 69:18, 122:5 days 120:16, 120:17 deals 56:1 declarants 15:7 declaration 10:17, 11:5, 11:7, 11:10, 11:21, 12:3, 15:5, 15:20, 17:7, 20:19, 21:18, 22:17, 34:12, 41:15, 45:5, 45:19, 45:22, 46:7, 46:9, 47:7, 47:17, 48:13, 48:22, 51:13, 51:16, 52:1, 53:4, 53:7, 53:10, 55:22, 57:1, 57:18, 57:20, 58:4, 59:18, 62:2, 62:5, 64:5, 73:3, 73:14, 73:18, 75:2, 79:19, 81:13, 86:5, 94:5, 94:9, 96:21, 97:9, 98:13, 106:9, 107:22, 108:21, 113:7, 115:6, 118:15, 120:9 declarations 10:14, 11:15 decrease 88:15 decreases 85:22 deemed 22:18, 40:14	deep 119:22, 120:3 deeper 66:17, 66:21 defendants 7:12 defer 115:22 define 101:15, 112:19 defining 105:17 definition 55:5, 57:3 delivery 47:3 dense 17:16 depend 16:16, 42:9, 43:2, 43:11, 44:8, 45:3, 100:4, 116:19, 116:21, 117:8 depended 14:7 dependent 50:8 depending 28:6, 39:5, 40:16 depends 23:4, 26:13, 27:20, 32:7, 36:19, 39:13, 39:14, 54:16, 55:8, 55:14, 68:5, 76:22, 77:12, 78:13, 84:17, 96:19, 101:12, 101:15, 102:9, 103:7, 105:16, 105:22, 112:16 depos 5:10 deposed 6:7
--	---	---	---

deposition 1:16, 2:1, 4:11, 5:4, 8:1, 9:17, 9:21, 10:3, 10:8, 10:18, 11:1, 120:14, 121:6, 121:7, 121:8, 121:12, 121:13, 121:19 depositions 7:15 described 63:22 description 69:9 descriptor 99:2 design 37:10, 64:13, 64:15, 65:3, 68:17, 71:8 designed 107:8, 114:14 desired 83:11 detailed 65:22 determine 65:12 determining 13:7 developing 14:2 deviation 90:1 device 95:7 diagnosis 12:15 diagram 16:2, 16:5, 17:6, 18:11, 18:21 diameter 67:5 difference 54:14, 75:22,	76:6, 77:3, 77:7, 77:11, 77:12, 77:15, 78:1, 102:16, 114:7 differences 104:3 different 7:10, 17:9, 27:4, 27:6, 42:21, 43:8, 43:15, 43:18, 44:4, 44:5, 45:1, 65:5, 66:8, 66:15, 76:12, 76:14, 76:16, 76:17, 76:20, 90:7, 90:10, 91:3, 91:7, 91:21, 92:18, 93:4, 101:10, 102:6, 103:3, 106:3, 113:3 differently 102:21 difficult 43:22 dilate 119:9 dilated 28:14, 32:1, 119:1, 119:6, 120:4 dilation 120:1 diner 3:14, 4:7, 5:15, 10:4, 16:11, 19:11, 19:21, 21:12, 22:20, 24:1, 24:20, 25:6, 26:20, 27:18, 29:3, 30:22, 32:5, 34:1, 34:5, 35:21, 36:16, 37:2,	38:19, 39:12, 40:8, 42:1, 42:11, 42:22, 43:10, 43:21, 44:7, 46:13, 47:9, 49:1, 53:6, 57:2, 57:19, 60:19, 61:14, 64:1, 64:3, 72:11, 73:6, 76:15, 77:19, 82:2, 83:8, 84:3, 84:10, 84:16, 84:22, 85:7, 87:5, 87:11, 88:18, 89:4, 89:10, 90:8, 90:19, 92:19, 93:5, 94:8, 96:9, 96:13, 97:13, 100:2, 100:9, 101:11, 102:22, 104:14, 105:3, 105:15, 106:19, 107:13, 109:4, 109:21, 110:10, 111:1, 111:12, 112:2, 112:14, 113:17, 114:13, 114:20, 115:14, 116:17, 117:6, 117:14, 118:13, 119:16, 120:11, 120:17, 120:19 direct 84:1, 103:17 directly 85:4 disagree 19:12, 34:4 disc 71:16 discovered 42:18 discuss 9:9, 49:17,	108:21 discussed 49:8, 64:8, 69:2, 94:2, 121:19 discusses 49:10, 94:12 discussion 62:3, 94:4 discussions 7:11 dispute 106:14 distinguish 40:13 distributed 44:2 district 3:19 disturbing 52:22 divided 16:19 doctor 37:13, 55:12, 55:13, 118:9 document 11:13, 27:19, 34:18, 35:22, 36:2, 36:9, 36:16, 37:3, 37:12, 37:14, 37:18, 37:20, 41:5, 45:16, 45:18, 46:14, 47:10, 51:20, 52:5, 56:7, 57:16, 60:8, 60:22, 61:8, 73:2, 78:20, 80:6, 80:13, 81:1, 82:3, 92:20, 93:21, 98:8, 98:16, 99:4, 99:9, 106:6, 109:22, 113:18 documents 10:16, 10:22,
---	--	--	---

34:12, 108:16 doing 14:1 done 12:20, 12:22, 52:3, 52:20, 65:15, 66:5, 66:22, 71:1, 78:15 dose 35:10, 38:3, 39:20, 39:21, 57:14 dotted 82:16, 92:6 double-masked 107:18 down 8:8, 21:19, 64:14, 82:22 dr 1:16, 2:1, 4:3, 5:5, 5:20, 35:22, 37:2, 115:21, 118:14, 121:5, 121:14 draft 120:18, 120:19 drains 25:15 draw 77:13, 112:11, 113:13, 113:20 drop 13:5, 13:9, 28:19, 30:16, 30:20, 54:9, 116:3, 116:16, 116:19, 117:3 dropped 62:8 drops 12:19, 86:20, 116:8 drug 31:9, 40:2, 55:19, 61:7, 68:11, 70:18	drugs 13:18, 14:2, 30:12, 30:19, 31:3, 68:12 dry 57:10 due 77:18, 78:2, 117:4 duly 5:20, 121:6 dunner 3:17 during 6:15, 8:1, 9:2, 67:17, 95:4, 95:13 E each 7:13, 18:2, 39:21, 41:21, 64:20, 119:19 early 35:10, 38:3, 57:14 ease 80:5 easier 80:11 economist 14:9 edited 11:14 effect 30:17, 44:21, 45:1, 45:6, 45:11, 45:12, 49:15, 68:11, 82:9, 83:5, 86:9, 107:9 effectively 90:15 effects 23:10, 23:21, 24:11, 27:15, 27:17, 28:5, 40:13, 42:21,	49:11, 53:18, 117:12, 117:20 efficacious 22:2 efficacy 40:13, 52:15, 71:14 effort 8:9 eight 6:10 eighth 3:6 either 23:21 elaborate 109:5 eligibility 65:13 else 10:11, 50:1, 102:5 employed 12:5, 121:22 end 48:6, 108:3 endo 82:18 endo-cell 91:10, 92:11 endothelial 48:1, 91:16, 92:7 endothelial-deri- ved 48:2 endothelium 19:6 endpoint 29:9, 54:22, 68:10, 68:16, 83:11 endpoints 29:7, 68:13 engorged 31:22, 32:1, 32:3 engorging 103:10	entail 55:7, 67:4 entire 18:14 entry 99:10 episclera 19:5, 20:11, 66:16, 119:4, 119:6, 119:19, 119:21, 120:3, 120:5 episcleral 119:22 equate 102:3 equipment 65:15 error 89:19, 89:21 especially 40:10, 50:21 esquire 3:4, 3:13, 3:14, 3:15 essentially 75:21, 109:1 establish 93:3, 111:13, 111:17 et 96:3 euretman 108:10, 108:18 evaluate 52:15, 68:18 evaluating 49:14, 71:14 evaluation 65:6 even 30:10, 40:11 event 29:1, 63:13, 72:8, 105:20 events 60:10, 63:5, 72:3, 72:9,
--	---	---	--

78:7, 104:19 ever 6:16, 13:4, 13:7, 24:7, 26:6, 95:1, 99:1, 99:7 every 23:12, 24:6, 36:12, 63:17, 113:4 everybody 110:11, 110:13, 111:4 everyone 111:4 everything 8:8, 16:21, 17:1, 57:21, 64:22 everywhere 26:1 exact 39:14, 117:8 exactly 24:21, 28:11, 78:16, 85:9 exam 67:2 examination 4:2, 5:22, 54:8, 65:22, 69:18, 71:20, 118:12 examinations 71:9 example 94:6, 94:12, 95:20, 96:2, 117:4 examples 21:1 exams 79:12 excipients 13:8 exclude 111:22 exclusion 99:16, 111:17	excuse 53:3 exert 45:1 exerting 25:12 exhibit 4:11, 4:12, 11:5, 34:8, 37:11, 38:12, 45:17, 46:2, 51:21, 56:7, 56:13, 57:14, 58:18, 59:20, 60:18, 62:12, 63:4, 64:8, 78:19, 78:21, 78:22, 80:6, 80:7, 80:18, 81:7, 81:8, 93:22, 98:10, 103:18, 106:5, 108:18 exhibiting 58:15 exhibits 81:3 exists 73:1 expanded 35:5, 90:15 expect 8:4, 38:18 experience 50:11, 67:19, 116:2, 116:15, 117:3 experiences 10:20 experimental 13:10 experiments 14:1 expert 6:16, 7:3, 9:22, 10:17, 11:3, 12:11, 12:18, 12:21,	14:11, 15:2 expertise 12:13, 15:14 experts 11:16, 15:7, 15:12 explain 16:14, 115:21 explicitly 67:18 extensively 11:14 extent 29:3, 37:9, 49:22, 57:2, 74:6, 83:8, 85:7, 88:18, 90:8, 90:19, 93:6, 106:19, 109:21 extra 68:14 eye 1:10, 3:11, 5:6, 12:15, 12:19, 13:5, 13:9, 16:3, 16:6, 16:10, 16:15, 16:18, 17:1, 17:14, 17:17, 17:18, 17:21, 18:4, 18:5, 18:10, 18:14, 18:15, 18:17, 18:18, 19:9, 19:14, 19:16, 20:8, 20:14, 24:12, 24:14, 24:19, 25:5, 25:8, 25:12, 25:13, 25:14, 25:17, 25:20, 25:22, 26:1, 28:10, 28:14, 28:19, 29:10, 30:13, 30:16, 30:18, 30:20, 31:14,	31:18, 31:21, 32:3, 40:2, 40:7, 40:19, 40:20, 49:17, 49:21, 50:8, 50:19, 55:20, 57:10, 65:16, 65:19, 66:1, 66:12, 66:18, 66:21, 67:2, 68:10, 68:12, 79:3, 95:4, 95:8, 95:10, 95:12, 96:12, 97:22, 99:21, 100:7, 105:10, 112:1, 112:11, 112:12, 115:16, 116:3, 116:8, 116:12, 116:16, 116:19, 117:3, 118:19, 119:2, 119:7, 119:9, 120:2, 120:6, 121:11 eye-drop 28:21 eyebrow 18:5 eyelashes 18:5, 66:12 eyelids 66:11 eyes 28:20, 99:22, 112:21, 113:3, 114:6 F facing 16:6 fact 27:16, 78:22, 108:4 factor 48:2, 117:2 factors 112:7
--	--	--	--

failed 111:17 fairly 91:8 falls 110:16 familiar 12:20, 75:18, 109:3 family 33:12 farabow 3:16 fda 21:6, 21:10, 21:15, 34:6, 35:18 fda-approval 29:16 feel 37:5, 47:18 few 20:22 field 22:12, 65:12, 67:13 fields 71:15 figure 4:12, 17:8, 80:14, 81:2, 81:7, 81:16, 82:11, 82:12, 82:16, 83:21, 84:2, 84:19, 86:8, 86:18, 87:11, 87:12, 87:13, 88:16, 89:2, 89:20, 90:2, 90:4, 90:6, 90:15, 90:17, 90:18, 91:3, 91:4, 91:9, 91:13, 91:14, 91:17, 91:19, 92:1, 92:2, 92:6, 92:10, 92:13,	92:14, 92:17 figures 79:20, 81:14, 81:18, 81:19, 89:2, 89:20, 90:2, 90:6, 92:17, 93:4, 118:19 file 68:4 filed 5:6 fill 11:13, 78:9, 79:11 film 66:13 financially 122:2 find 77:15 finding 50:16 finish 8:16 finnegan 3:16, 5:16 firm 5:16 first 29:12, 36:11, 38:13, 47:6, 51:15, 52:8, 52:13, 54:8, 55:2, 60:3, 86:7, 91:21, 109:10, 110:17 five 97:1, 109:11, 120:16, 120:17 flawed 113:4 fluid 24:18, 25:4, 25:14, 25:17 focal 94:4 focus 110:17	follow 87:7, 92:2 follow-up 71:9 following 69:14, 69:17, 94:13 follows 5:21 footnotes 48:5 form 28:21, 30:16, 30:20, 67:22, 78:9, 79:11, 93:7, 119:15 formulate 13:3 formulation 12:18, 12:20, 12:22, 13:4, 13:8, 50:12, 50:13, 50:14, 50:15, 50:22, 115:9, 117:1 forth 90:12, 93:9, 98:16, 121:6 forward 16:22 found 44:11, 44:16 foundation 21:13, 22:21, 24:2, 34:1, 34:5, 35:21, 84:10, 89:10 four 21:19, 38:11, 39:22, 82:8 free 37:5, 47:18 frequency 51:10 frequently 16:17, 23:2, 40:12 front 16:6, 16:9,	16:22, 17:1, 17:13, 17:21, 65:22 full 86:7 fully 9:14 function 97:3 fund 74:7 further 18:20, 55:4, 118:10, 120:11, 120:12, 121:10, 121:13, 121:18, 121:20 fusca 19:6 G garrett 3:16 gears 79:18 general 44:1, 97:7, 105:9 generally 23:16, 96:18, 104:21 give 26:21, 32:12, 38:1, 80:19, 96:14 given 121:9 giving 28:1 glaucoma 13:16, 22:12, 28:20, 29:6, 36:20, 36:22, 38:4, 38:17, 39:2, 39:7, 39:10, 39:11, 40:6, 40:19, 41:1, 55:9, 75:9
---	--	--	--

go 7:15, 25:18, 30:5, 30:8, 39:18, 64:11, 74:13, 74:22, 82:5, 90:11, 93:8, 113:10 goes 18:10, 82:8, 82:21 going 5:1, 11:4, 14:15, 14:18, 34:9, 45:16, 51:20, 61:16, 61:19, 65:8, 78:20, 80:6, 86:18, 93:21, 106:4, 110:6, 118:4 good 6:2, 6:3, 49:6, 61:14 goodwin 3:5, 5:14 graded 55:13 grading 30:7 gradually 87:16, 88:2 graph 84:14, 84:17, 88:19, 88:22, 91:12 gray 82:17, 82:21, 86:12, 86:16, 87:16 greater 57:8, 58:15, 58:22, 99:18 ground 7:15 group 54:7, 62:22, 63:11, 63:14, 75:5, 77:4, 77:6	groups 104:4 guess 52:21, 62:18, 63:3, 87:17, 107:6, 108:14 guy 14:6 H halfway 64:14 hand 11:4, 11:11, 34:9, 45:16, 47:21, 51:20, 78:20, 93:21, 106:4, 122:5 happen 23:12 happened 24:6, 51:7, 51:9, 69:10, 70:2 happens 32:13, 64:20, 64:22 hard 55:3 head 29:15, 74:21, 79:6, 117:18, 118:2 health 21:21 healthy 99:22 heart 70:5 heat 97:2 held 2:1, 25:17, 95:4, 95:6 helped 74:1 helpful 25:19, 36:3,	37:9, 37:11 hemorrhage 107:11 henderson 3:16 here 8:7, 10:10, 16:2, 34:22, 36:11, 36:12, 37:17, 38:10, 39:20, 40:1, 41:12, 54:17, 55:13, 64:13, 67:15, 69:9, 74:17, 75:12, 77:22, 81:13, 85:21, 87:10, 96:6, 102:21, 120:7 hereby 121:4 hereinbefore 121:6 hereunto 122:4 hey 55:9, 55:11 high 6:21, 9:20, 11:9, 54:20, 59:5 higher 86:21, 87:17, 88:4, 88:7 highest 50:22, 51:8, 51:10 hoffmann 47:13 hold 14:13 homogeneously 44:2 homogenous 43:19 honestly 114:22 horrible 112:21	hour 54:8 hours 70:15, 70:18 human 24:7 hyperemia 19:18, 23:10, 29:1, 29:10, 29:17, 30:4, 30:21, 31:4, 31:6, 31:8, 31:17, 32:1, 32:2, 32:15, 32:16, 82:19, 83:6, 83:19, 85:14, 85:17, 85:20, 86:10, 88:16, 101:10, 102:3, 102:13, 103:6, 103:11, 104:13, 104:21, 104:22, 105:9, 105:10, 105:14, 105:20, 107:11, 110:12, 110:13, 111:4, 111:5, 113:11, 114:6, 114:9 hyperemias 28:20 hypertensive 24:11 hypotensive 26:12, 27:4, 27:9, 27:15, 27:16, 28:5 hypothetical 24:2, 31:1, 38:20, 40:9, 42:12, 43:1, 100:3, 104:15, 112:15, 116:18, 117:7 I identification 80:8
---	--	---	--

identified 82:12 iii 29:16 illustrations 89:8 impact 110:9, 110:20, 112:1 implies 100:21 improperly 23:18 incidence 58:15, 58:22 incidences 57:9 incipients 116:22 incisions 94:18 include 114:17 includes 19:5, 44:18 including 97:1, 97:2, 97:21, 97:22 inclusion 99:13, 99:14 incomplete 24:1, 30:22, 38:19, 40:8, 42:11, 42:22, 100:2, 104:14, 112:14, 116:17, 117:6 increase 88:16 increases 82:6, 86:19, 87:16, 88:2, 88:7 increasing 88:20 independent 15:11 individual 24:5, 113:2	individuals 113:1 inflammation 95:17, 96:2, 96:8, 96:18, 96:22, 97:1 inform 36:3, 109:17 information 35:6, 36:2, 38:1, 38:2, 38:6, 55:3, 55:15, 56:22, 59:15, 61:11, 61:12, 64:12, 67:15, 68:3, 68:14, 68:19, 69:8, 72:18, 72:21, 73:4, 73:17, 73:20, 74:10, 79:13, 89:17, 90:1, 96:14, 111:21, 113:15, 114:11, 114:17 ingredients 116:22 inhibition 82:18, 91:10, 91:16, 92:8, 92:11 inn 2:4, 121:15 input 14:4 insert 61:2, 61:8, 61:12 inside 16:18, 24:18, 25:4, 25:8, 113:2 inspection 121:18 instructed 8:3 instructions 21:22	intend 9:1 interchangeably 93:8 interested 53:22, 122:2 interesting 52:11 interface 120:5 interpret 40:3, 90:12, 92:4, 102:2 interpretation 91:22 interpreting 56:21, 63:1, 63:15, 75:7 intervention 39:6 intraocular 24:15, 24:17, 25:3, 25:7, 26:3, 65:7, 65:14 intravenously 26:22 introduce 5:11 investigator 67:19 involved 6:22, 13:7, 73:11, 78:4 iop 54:22, 65:8, 70:4, 70:11, 70:16, 71:15, 82:18 ipr 1:9, 5:7, 10:14, 11:5, 11:7, 34:10, 51:21, 78:21 iris 16:21, 17:2, 17:15, 18:7, 66:18	issues 11:11 itself 36:17, 92:20 J jason 3:15, 5:17 jersey 2:14, 121:4 job 1:24 K keratotome 94:13 keratotomy 94:16, 95:2 key 82:12, 82:17, 92:2 kind 16:21, 17:17, 38:9, 39:6, 43:4, 46:1, 54:1, 66:12, 90:11, 92:22, 96:10 kinda 70:1 knew 99:6 know 7:9, 8:7, 8:15, 8:22, 26:8, 43:3, 43:18, 49:6, 59:7, 59:10, 60:16, 61:4, 67:16, 68:20, 70:22, 72:2, 72:9, 73:4, 79:3, 89:14, 89:16, 89:18, 89:22, 90:10, 91:5, 98:2, 98:22, 99:21, 101:5, 110:5, 110:6,
--	--	--	---

112:6 knowing 74:8 knowledge 74:8 known 24:10, 26:11, 27:15, 27:16, 28:4, 41:9, 41:20, 43:16, 45:8, 96:22, 119:21 knows 112:21, 113:1 L label 17:9, 58:12, 59:16, 59:22, 79:1, 79:5 labeled 17:8, 82:17, 83:1 labels 51:4, 60:1 lachkar 45:19, 49:9 lack 22:21 lacks 21:12, 24:2 laid 78:10 lamina 19:5 language 15:18, 45:22 large 35:22, 37:3 largely 50:12 lasik 106:14, 106:15, 106:21, 107:10, 109:11 last 6:20, 11:20, 14:22, 24:22,	78:17, 107:14, 108:7 latanoprost 13:19, 13:20 later 32:19, 41:6, 108:11 layers 66:15 lcipriano@goodwi- nlaw 3:9 leads 116:4 least 27:8, 38:11, 64:12, 104:7, 109:19, 115:1 left 16:7, 18:21 left-hand 53:13, 80:13, 81:1 legal 106:20 legend 92:2 lens 17:3, 25:21, 66:19 less 86:3, 100:20, 100:22, 101:5, 116:12, 116:14 less-than 100:18 let's 15:19, 21:17, 24:9, 27:2, 31:11, 32:18, 34:8, 38:9, 39:20, 59:20, 63:3, 63:19, 64:11, 65:1, 81:16, 87:9, 91:20, 95:20, 109:7, 118:3 level 6:21, 9:20,	11:9, 113:4 levels 7:10, 50:15 lighting 67:6 limbus 101:8 limited 27:15, 104:22, 112:12 line 18:9, 18:19, 62:19, 65:3, 69:11, 69:12, 69:22, 77:13, 82:11, 82:16, 82:17, 82:21, 83:6, 87:16, 87:22, 88:1, 92:6, 92:7 lines 21:19, 53:12, 84:2 linna 3:4, 5:13 list 20:22, 21:1, 34:22, 48:18, 52:7, 52:14 listed 22:17, 35:7, 35:9, 38:12, 52:11, 56:16, 57:16, 58:17, 59:13, 63:13 listen 8:20 lists 36:13, 39:22, 62:20, 63:4, 70:2, 71:13, 71:19, 75:12, 75:13 literature 10:21, 11:12, 27:8 little 11:22, 24:9,	30:11, 32:19, 32:21, 35:5, 43:22, 52:22, 64:11, 79:18, 81:14, 88:2, 88:4, 106:9, 115:8 llc 1:5, 1:10, 3:3, 3:12, 5:6 llp 3:5, 3:17 located 43:16, 43:19 locations 103:3 logical 104:10, 104:11 long 6:14, 36:5, 96:22 look 14:2, 17:7, 21:14, 21:17, 29:14, 30:5, 32:18, 34:8, 36:5, 36:8, 36:10, 36:11, 37:4, 38:5, 38:6, 38:9, 39:20, 41:3, 45:15, 45:21, 47:18, 48:13, 51:12, 51:13, 52:13, 53:9, 54:22, 57:12, 57:22, 58:3, 58:11, 59:12, 59:20, 62:14, 63:16, 66:13, 66:16, 66:17, 66:18, 66:21, 69:6, 69:7, 71:6, 72:13, 73:12, 74:13, 74:19, 78:19, 79:15, 80:11, 81:11, 81:12,
--	---	--	--

86:4, 95:13, 95:20, 98:7, 98:10, 99:3, 103:18, 104:1, 106:3, 107:7, 108:15, 108:22, 112:20, 119:9, 119:10 looked 11:1, 36:6, 56:7, 58:5, 62:12 looking 37:13, 37:15, 37:22, 66:7, 71:3, 102:13, 108:20, 112:12, 114:5 loss 97:3 lot 66:8, 102:6 low 88:21 lower 24:12, 91:10 lowered 55:20, 62:6 lowering 24:14, 24:15, 25:2, 54:22 lowest 116:10 lumify 20:13	majority 54:5 make 7:16, 8:2, 8:9, 8:18, 9:5, 12:3, 15:5, 15:10, 15:18, 58:7, 58:13, 70:9, 81:17, 100:21, 107:21, 109:1, 113:2, 113:9, 114:9, 119:1, 119:7, 119:9, 120:1, 120:5 makes 25:14, 94:17, 99:14, 102:15, 114:3 manner 43:19 manufactured 13:4 many 6:9, 7:5, 23:2, 32:17, 113:8, 116:11 march 62:1 mark 80:6 marked 11:5, 34:9, 45:17, 51:21, 78:20, 80:7, 81:1, 93:22, 98:17, 106:4 market 20:15, 54:21, 61:7 marketed 33:6, 33:7, 33:8, 33:12 marketing 14:12, 15:3 marriage 121:22 materials 10:1, 48:19	matter 5:5, 58:10, 74:5, 81:10, 122:3 maximum 86:9 maybe 18:2, 25:19, 32:19, 111:4, 111:5, 112:20 mean 10:5, 12:22, 22:22, 23:16, 27:22, 29:20, 33:5, 34:6, 42:13, 47:11, 48:21, 49:3, 54:19, 57:22, 73:8, 74:7, 76:3, 77:14, 82:4, 84:14, 90:10, 90:21, 92:21, 93:13, 95:6, 100:17, 100:20, 101:3, 101:5, 101:7, 102:8, 104:2, 105:21, 114:7, 116:11 meaning 20:10 meaningful 113:9 meanings 27:5 means 8:8, 76:5, 100:17, 101:6 measure 29:19, 29:20, 67:14, 68:10, 110:5, 110:14, 111:6, 111:11, 112:17 measured 29:7, 29:22, 55:1, 55:2, 59:10, 61:4,	65:6, 70:17, 79:3, 102:21, 103:21, 104:7, 109:10, 109:19 measurement 65:15, 65:16, 65:18, 67:5, 67:10, 67:12, 110:8, 110:21, 110:22, 112:18 measurements 70:4, 70:11, 71:1, 110:18 measuring 32:11, 32:15, 102:14 media 5:4 mediated 46:3, 46:21 medicamentosa 23:11 medication 36:20, 39:11, 40:6, 40:19, 75:9, 112:1 medications 13:17, 39:18, 116:11 medicine 22:10, 27:5, 97:7 medicolegal 6:13 meets 101:9 memory 47:19, 74:16 mention 33:1, 49:21 mentioned 32:22, 79:1 mercurio 3:22, 5:8 met 10:1, 10:9, 11:13 methodology 55:19
M			
made 79:7 magnified 18:20 magnitude 82:5 main 2:5, 121:15 mainly 46:3, 46:21 maintain 120:7			

methods	misused	N	
52:10, 52:12, 52:22, 107:15	23:14	name	3:18, 121:4
mic	moderate	5:8, 5:13, 5:15, 6:4	next
14:13	54:6, 54:14, 55:6, 59:8	naphcon	46:18, 47:20, 55:21, 56:2, 59:2, 62:3, 69:9, 69:12, 69:13, 69:22, 70:10, 71:7
micropannus	moment	21:2	nice
107:11	80:12	naphcon-a	115:2
microscope	monitored	21:2	nobody
66:6, 66:7	55:17	narrative	111:5
middle	month	37:10, 78:12	noecker
46:1, 53:12, 54:1, 98:18	72:9	nda	1:16, 2:1, 4:3, 5:5, 5:20, 6:6, 35:22, 37:2, 118:14, 121:5, 121:14
might	months	34:14, 35:1	none
14:21	71:10, 71:21, 73:10	near	11:2
mild	more	18:10, 62:18, 82:15, 97:9, 116:1	norden
54:6, 54:14, 55:6, 59:8	16:12, 22:11, 22:13, 35:5, 41:5, 59:6, 87:3, 87:20, 88:7, 89:8, 96:14, 103:17, 103:21, 113:15, 114:11, 114:17, 116:13, 120:1	necessarily	106:7, 107:5, 108:2, 108:20, 109:2, 109:10, 111:16, 113:8, 113:11, 115:4
mimic	morning	31:6, 31:8, 89:5	normally
85:15	6:2, 6:3, 118:17	need	76:13
mind	most	8:15, 13:2, 25:18, 36:8, 37:3, 41:3, 47:18, 57:12, 57:22, 59:12, 99:3, 104:1, 110:21, 113:15	norwalk
86:15	6:11, 6:12, 11:2, 60:10	needs	1:17, 2:4, 2:6, 121:15
minimum	mostly	109:19	notary
110:22	19:18	nervous	2:13, 121:1, 121:3, 122:9
minus	motivation	44:12, 44:19, 45:1, 45:13	notation
83:6, 83:10, 84:8	115:12	net	79:7, 79:8, 79:9
minutes	move	83:1, 83:4, 83:14, 83:22, 84:7, 85:3, 85:12, 85:14, 85:18, 85:21, 86:1, 86:19, 87:2, 87:9, 88:14, 88:15	note
109:11	107:4	netting	67:20
mirror	moving	86:10	noted
85:15	26:2, 95:8, 95:9, 95:12	never	40:1, 50:21, 54:3, 67:21, 120:21
mischaracterizes	multiple	33:7, 54:21, 61:7, 85:17	notice
19:21, 22:20, 27:18, 29:4, 32:5, 46:13, 47:9, 49:2, 53:6, 57:3, 57:19, 82:2, 83:9, 85:8, 88:19, 90:9, 90:20, 92:19, 93:6, 94:8, 102:22, 109:22, 111:1, 111:12, 113:17, 114:13, 114:21, 115:14	9:22, 60:1	new	2:12, 55:11, 55:12
misspoke	munos	2:14, 3:7,	november
97:16	108:10, 108:18		1:18, 5:2,
misuse	must		
21:22	8:9, 22:1, 22:2, 22:6, 99:20		
	myself		
	12:17		

121:16, 122:5 number 5:7, 20:13, 63:18, 106:1 numbers 37:16, 75:22, 76:11, 76:13, 76:16, 76:19, 77:11, 84:21 numerical 77:7 nw 3:18 o oath 7:19 objection 16:11, 19:11, 19:21, 21:12, 22:20, 24:1, 24:20, 25:6, 26:20, 27:18, 29:3, 30:22, 32:5, 34:1, 34:5, 35:21, 36:16, 38:19, 39:12, 40:8, 42:1, 42:11, 42:22, 43:10, 43:21, 44:7, 46:13, 47:9, 49:1, 53:6, 57:2, 57:19, 60:19, 72:11, 73:6, 76:15, 77:19, 82:2, 83:8, 84:3, 84:10, 84:16, 84:22, 85:7, 87:5, 88:18, 89:4, 89:10, 90:8, 90:19, 92:19, 93:5, 93:7, 94:8, 96:9, 96:13, 100:2, 100:9, 101:11, 102:22,	104:14, 105:3, 105:15, 106:19, 109:4, 109:21, 110:10, 111:1, 112:2, 112:14, 113:17, 114:13, 114:20, 115:14, 116:17, 117:6, 117:14, 119:15 objections 8:2 objective 52:8, 52:14 objectively 107:9 observed 30:4, 73:5, 74:12, 116:9 obviously 90:11 occur 105:10 occurred 69:3, 72:19, 74:18, 85:17, 121:14 occurrence 75:3 occurring 71:1 occurs 32:3 ocu-clear 21:2 ocular 24:11, 27:16, 53:18, 71:19, 95:17, 96:2, 96:8, 97:1, 106:10, 106:16, 115:9 offering 15:11 office 1:1, 5:7 offices 121:14 okay 6:11, 6:14,	6:16, 16:2, 16:14, 17:6, 18:9, 19:2, 19:8, 20:10, 22:14, 25:2, 26:3, 26:11, 27:14, 28:22, 31:11, 32:18, 33:8, 35:4, 35:13, 37:21, 38:6, 39:20, 47:5, 56:10, 56:18, 56:21, 57:7, 59:7, 59:10, 63:19, 63:20, 65:1, 65:11, 65:17, 65:21, 66:20, 66:22, 67:15, 69:1, 69:8, 71:4, 72:16, 73:2, 74:2, 74:15, 74:22, 76:3, 77:22, 78:4, 78:14, 79:13, 79:16, 80:4, 81:15, 82:8, 83:14, 84:14, 84:19, 85:3, 85:12, 86:18, 88:5, 88:10, 88:13, 89:2, 89:8, 90:14, 92:6, 92:16, 93:11, 93:17, 96:7, 97:8, 98:15, 102:15, 103:5, 104:9, 104:18, 107:16, 108:8, 108:14, 109:8, 110:4, 111:9, 111:15 once 24:6, 26:13, 36:18, 63:17, 68:5, 109:11 one 6:20, 13:19,	13:20, 17:13, 29:6, 34:11, 40:2, 40:7, 40:19, 54:7, 54:8, 67:1, 67:20, 87:20, 88:3, 94:10, 95:16, 96:7, 99:18, 108:12, 111:9, 113:3, 117:1 one-eye 40:12 only 7:2, 22:1, 40:7, 61:8, 103:15, 105:13, 108:14, 108:16, 109:11 open 56:10, 78:11 ophthalmic 12:8, 65:6 ophthalmologist 12:8 ophthalmologists 108:5 ophthalmoscopic 71:20 ophthalmoscopy 65:9, 66:20, 67:1 opinion 28:2, 50:5, 115:11, 119:5, 120:8 opinions 15:11, 58:9, 74:4, 74:17 options 78:10 order 36:3, 76:11, 76:19, 109:17, 110:20, 111:20, 112:11, 113:13 ordinary 28:3, 41:20,
---	---	---	--

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50:6, 51:3, 109:18, 115:12 organ 44:8 original 33:8, 33:10 otc 21:20 other 7:5, 7:13, 7:14, 10:14, 10:16, 11:16, 15:6, 15:11, 18:2, 18:9, 24:7, 36:2, 40:20, 47:21, 59:14, 72:8, 84:1, 94:5, 108:17, 111:22, 112:7, 112:9, 116:22, 117:1 others 15:15 otherwise 122:2 out 14:14, 78:9, 78:10, 79:11, 86:10, 102:16 outcome 122:2 outside 17:18, 18:17 over 7:15, 8:10, 8:11, 31:15, 105:11, 114:10 over-the-counter 20:14, 21:7, 22:6, 22:15, 23:15, 23:20 overuse 22:1 overused 23:14, 23:17 overwhelming 114:8 own 10:19	owner 1:12, 3:11, 5:16, 7:8 oxygen 47:3 P p 33:11, 75:17 package 61:2, 61:8, 61:12, 92:5, 92:22 page 4:2, 4:11, 7:16, 15:1, 15:19, 17:6, 20:18, 21:1, 22:17, 34:17, 34:20, 34:22, 35:4, 35:7, 35:9, 37:10, 38:7, 38:12, 39:22, 45:21, 46:1, 52:8, 52:13, 53:10, 53:13, 54:2, 56:13, 56:14, 56:15, 56:17, 58:10, 58:17, 59:2, 60:4, 60:5, 60:8, 60:10, 62:14, 62:16, 62:19, 63:4, 63:22, 64:1, 64:8, 64:14, 64:20, 70:1, 74:22, 75:1, 80:10, 80:22, 81:2, 81:18, 86:4, 86:8, 97:10, 98:15, 98:17, 98:19, 99:9, 103:18, 115:6, 116:1 pages 1:25, 36:1,	60:3 pain 97:2 paper 107:5 papers 94:2, 94:5, 106:7 para 90:14 paragraph 21:18, 47:21, 51:12, 51:14, 51:16, 53:18, 53:21, 54:1, 55:22, 56:2, 58:21, 59:17, 62:2, 69:9, 69:12, 69:13, 71:7, 71:8, 72:22, 75:2, 78:18, 86:5, 95:21, 96:1, 96:21, 97:8, 97:13, 97:14, 98:6, 98:12, 107:6, 107:14, 108:1, 108:7, 108:9, 108:15, 108:22, 109:9, 111:16, 113:7, 115:5, 115:8, 115:15, 115:20, 116:2, 118:15, 118:18, 119:11, 119:13, 119:17, 120:8 part 16:22, 17:22, 18:8, 18:14, 18:15, 19:1, 20:8, 35:1, 46:11, 47:1, 55:18, 58:16, 58:19, 66:1, 66:19, 67:2, 73:16, 74:7, 78:17, 101:9	particular 42:9, 63:5 particularly 21:10, 22:2, 22:7, 22:18, 23:5 parties 121:21, 122:1 parts 34:14 party 121:10 past 18:2, 74:7 patent 1:1, 1:3, 1:11, 1:12, 3:11, 4:12, 5:6, 5:16, 6:17, 7:3, 7:7, 79:20, 79:22, 80:15, 80:18, 81:2, 81:8, 81:12, 83:9, 83:19, 89:12, 89:15, 93:20, 94:1, 94:6, 95:17, 106:11, 106:17 patentee 89:16 patient 39:10, 40:6, 54:7, 65:19, 72:7, 94:20, 95:8, 95:9, 95:13, 106:15, 106:16 patient's 27:10, 68:4 patients 23:2, 33:22, 37:1, 38:4, 38:17, 39:2, 39:18, 40:15, 41:2, 54:4, 54:6, 60:13, 62:20, 63:14, 75:12, 79:12,
---	--	---	---

98:22, 99:7, 107:15, 111:22, 112:20 peaks 86:1 people 10:14, 23:14, 23:17, 23:19, 100:18, 110:12, 112:22 people's 101:6 percent 17:17, 18:17, 28:21, 29:5, 33:3, 33:4, 33:7, 33:9, 33:15, 34:15, 38:13, 38:14, 50:13, 50:14, 50:15, 50:22, 51:9, 51:11, 52:4, 52:15, 52:20, 53:3, 54:4, 56:1, 56:3, 57:11, 58:14, 59:3, 59:15, 59:22, 60:4, 60:5, 60:6, 60:12, 60:13, 61:2, 61:5, 62:4, 62:6, 62:8, 62:21, 63:8, 63:12, 63:14, 69:7, 75:3, 75:4, 75:12, 75:14, 77:3, 77:5, 77:17, 77:22, 78:1, 78:2, 78:5, 86:2, 86:11, 86:16, 86:20, 86:21, 88:3, 88:4, 88:8, 88:17, 93:12, 110:12, 117:12, 117:20, 117:21	percentage 75:14, 76:6 percentages 93:15 perfect 23:1, 23:9 performed 13:2, 38:4, 65:12, 70:21, 74:6, 94:20, 95:1 periods 39:17 peripheral 67:14 periphery 44:13, 44:19, 45:2 permitted 9:8 person 23:17, 26:21, 28:1, 28:2, 41:19, 50:6, 51:3, 55:10, 55:11, 109:17, 113:3, 115:12 person's 17:21, 18:4 personal 10:20 personally 116:11 perspective 14:8 petitioner 1:6, 3:2, 5:14 ph 115:9, 115:13, 115:16, 115:17, 116:3, 116:8, 116:10, 116:12, 116:16, 117:1, 117:4, 117:5 pharma 1:5, 3:2, 5:5 phase 29:16	phrase 22:9, 47:6 physician 39:9 physiologic 115:17 picture 17:13, 17:21, 25:19 pictures 16:3 piece 65:15 place 108:13 placebo 38:22 placed 80:13 plaintiffs 7:12 planet 5:9 play 46:11, 47:1 please 5:11, 6:4, 8:15, 8:22, 64:18, 119:14, 119:18 plexuses 119:22 plotted 84:1, 84:6, 84:7 plusses 82:8 point 8:16, 11:18, 11:20, 12:1, 12:3, 53:10, 56:13, 59:14, 60:8, 68:6, 68:8, 73:10, 73:22, 94:4, 95:19, 108:16, 111:16 pointed 19:4, 36:1	pointing 17:13, 17:14, 18:6 points 17:9, 18:3, 18:19, 32:17 pooled 64:9 population 100:4, 100:7 portion 16:10, 16:15, 20:9, 28:10 position 22:10, 31:16, 51:2, 110:20 positive 60:20, 88:21 possible 23:12, 23:13, 24:3, 42:2, 43:11, 45:4 post 16:19, 54:8 posterior 17:2, 17:3, 24:19 practicing 40:5 pre-study 65:4, 67:17 predominantly 19:18 preparation 10:7, 10:9, 11:1, 11:19, 48:22, 49:4, 58:4 prepare 9:17, 9:21, 10:17, 11:9, 73:17 present 3:21, 42:9, 44:6 presented 12:10 pressure 24:13, 24:14,
--	---	---	---

24:15, 24:17, 25:3, 25:4, 25:7, 25:10, 25:12, 25:13, 26:3, 26:4, 26:7, 27:10, 27:13, 47:2, 55:20, 65:7, 65:14, 65:16, 68:11, 68:12, 70:5 presumably 70:3 prevent 95:7, 95:9, 95:12 primarily 24:12 primary 54:21, 68:10, 68:13 principles 58:1 prior 20:13, 23:20, 28:4, 28:8, 32:6, 49:2, 50:5, 70:17, 92:20 privileged 9:19 probably 7:14, 23:17, 32:13, 69:6, 99:10, 116:10 problem 55:2, 110:1, 110:11, 112:3, 112:6 problems 115:1 procedure 94:17, 95:5, 95:14, 106:21 proceed 5:19, 7:14 proceeding 12:11, 15:7,	38:8, 51:2, 94:2, 94:5 proceedings 7:8 procter 3:5 produce 47:22 produced 80:18 produces 97:1 product 6:21, 6:22, 7:12, 13:15, 22:5, 24:7, 32:22, 33:11, 59:22, 60:1 production 67:10, 67:12, 116:4 products 21:20, 22:16, 22:18, 23:1, 23:3, 23:8, 23:10, 24:6, 33:18, 33:21, 104:20 proper 58:7, 111:17 properties 31:3 property 50:17, 51:5 prospective 107:18 protocol 30:6, 38:5, 39:15, 39:16, 40:15, 40:19, 40:22, 41:3, 59:12, 63:17, 63:21, 69:7, 71:3, 71:6, 73:12, 73:13, 73:16, 74:3, 74:14, 74:19, 78:11, 79:15,	104:1, 113:8 protocols 38:8 provide 74:16, 111:20 provider's 21:21 provides 18:18 providing 35:5, 115:11, 115:19 public 2:13, 121:1, 121:3, 122:9 published 28:8, 76:8 pulled 47:12 pump 82:18, 91:10, 91:16, 92:7, 92:11 pupil 65:11, 67:3, 67:6, 70:5 purpose 44:9 purposes 13:10, 13:11, 39:11, 83:18 pursuant 2:12 put 7:19, 14:8, 41:4, 41:6, 50:3, 79:16, 93:17, 115:4, 116:11	43:17, 58:6, 77:1, 77:8, 77:9, 77:20, 84:4, 87:6, 91:21, 99:5, 99:6, 103:17, 104:16, 105:5, 105:6, 107:3 questioned 108:5, 108:13 questions 7:17, 8:4, 8:21, 9:8, 9:14, 14:21, 37:5, 41:6, 118:10, 118:18, 118:19, 120:11, 120:12 quick 118:3 quickly 88:7 quite 28:14, 87:7 quote 45:22, 46:9, 47:5, 47:7 quoted 58:21
			R rabbit 14:5 rabbits 14:6 radial 94:13, 94:16, 95:1 randomize 113:1 rate 62:7, 70:5 rated 54:6, 98:3 ratio 71:16 reactions 60:9 read 9:22, 11:11,
		Q quarter 62:18 question 8:16, 9:3, 9:4, 26:16, 30:8, 31:10, 36:4, 37:3, 43:12,	

46:19, 49:5, 54:2, 54:17, 57:15, 65:19, 119:13, 119:17, 120:8 reading 108:6, 121:18 really 75:22, 88:16, 112:8, 118:9 reason 9:13 reasons 111:10 rebound 82:19, 83:6, 83:19, 85:17, 85:20, 86:10, 88:15, 91:14 rebound-hyperemia 84:9, 85:6, 87:4, 87:10, 87:15, 87:22, 88:1, 91:2, 91:3, 91:9, 91:15, 92:10, 92:17 recall 10:22, 15:8, 78:14, 78:16, 79:6, 79:21, 94:7, 95:18, 118:17, 118:22 received 80:7 recent 6:11, 6:12 receptor 41:10, 41:13, 41:16, 41:17, 41:21, 42:5, 43:8, 43:16, 43:19, 44:5, 45:9, 47:15 receptors 42:8, 42:16, 42:20, 44:1, 44:9, 44:11,	44:14, 44:15, 44:16, 44:22, 45:2, 46:4, 46:11, 46:22, 47:1, 48:1 recess 14:17, 61:18, 118:6 recognize 11:6, 23:1, 34:11, 45:18, 51:22, 59:21, 94:1, 98:11, 106:6 recommend 23:3, 39:10 record 5:2, 5:12, 6:5, 14:15, 14:19, 61:17, 72:13, 103:15, 118:5, 119:14, 119:17, 120:15, 121:9, 121:20 recorded 29:17, 29:21, 30:3, 30:4, 67:16, 68:1, 68:4, 72:5, 78:7, 96:4, 99:1, 99:7, 100:12, 103:13 recording 72:7 red 28:20, 32:1, 112:21, 119:2, 119:7, 119:9, 120:6 redness 19:9, 19:15, 19:16, 20:14, 21:3, 22:14, 23:15, 23:20, 29:10, 29:19, 29:22, 30:3, 50:8, 50:19, 59:10, 61:4,	67:16, 68:1, 68:3, 68:9, 68:15, 68:18, 68:21, 79:3, 79:14, 96:7, 96:10, 96:12, 96:17, 97:2, 97:20, 97:21, 97:22, 98:3, 98:16, 99:2, 99:8, 99:18, 99:22, 100:7, 101:7, 101:8, 101:17, 101:21, 102:2, 102:10, 102:11, 102:16, 102:17, 103:5, 103:9, 103:15, 103:19, 103:21, 104:3, 104:13, 105:1, 105:13, 109:11, 109:19, 110:9, 110:21, 111:22, 112:1, 112:12, 112:13, 113:15, 114:12, 114:19, 116:5, 116:9, 120:2 reduce 26:7, 27:9, 27:12, 50:8, 50:19, 109:19, 111:21, 113:14 reducers 20:14, 22:14 reduction 82:18 refer 15:6, 16:17, 41:12, 64:6, 81:10, 97:9, 115:20, 118:14 reference 20:21, 37:15, 47:14, 49:13, 55:21, 56:15, 80:5 referred 16:15, 24:19,	27:5, 45:19, 51:17, 93:19, 106:7 referring 28:17, 46:15, 59:2, 70:3, 98:6, 104:21, 108:10 refers 60:3 refrain 39:10 refresh 47:18 regard 118:18 related 10:1, 11:2, 62:3, 78:5, 97:22, 104:20, 121:20 relatedly 86:8 relation 20:3, 20:6, 68:21, 85:5 relative 40:13, 85:1 relaxing 48:2 release 48:2 relevant 10:20, 19:17, 47:12 reliance 74:3 relied 34:12, 57:21, 74:4 relief 21:3 relievers 23:15, 23:20 rely 46:2 relying 15:14, 48:9,
---	--	---	---

57:15, 57:17, 74:11, 74:15 remember 29:14, 30:7, 49:8, 68:22, 74:17, 74:20 repeat 14:21 rephrase 25:11 report 9:22, 11:3, 55:10, 72:3, 84:19, 85:1, 86:17, 98:12, 98:17, 100:6, 100:15, 101:16, 102:15, 103:12, 105:2 reported 1:26, 54:5, 57:10, 60:11, 60:17, 79:4, 98:5, 99:8, 100:14, 102:11, 113:20 reporter 4:10, 5:9, 5:18, 8:7, 45:16, 121:1, 121:3 reporting 60:16, 61:9, 61:11, 85:20 reports 52:3, 57:10, 101:21, 108:17 represent 5:12, 37:19, 89:3, 90:5 represented 7:7, 35:18, 93:4, 121:11 representing 5:14, 5:16, 92:7 represents 83:5, 89:9	reproduced 81:7 reproduction 90:17, 90:21 research 13:2 reside 19:10 residence 2:4, 121:15 respect 75:3 responding 67:7 responses 49:13 rest 46:10, 47:7 result 42:8, 45:12 results 52:12, 53:1, 72:2, 112:8 retained 4:10 returned 69:18, 71:9 revealing 9:19 review 10:16, 10:19, 11:15, 11:18, 36:1, 48:8, 48:11, 48:21, 73:21 reviewed 11:12, 37:18, 73:17 reviews 37:12, 52:5, 98:8, 99:4 right 12:16, 14:9, 16:3, 17:15, 20:16, 26:4, 26:7, 26:12, 35:20, 41:10, 47:8, 52:14,	57:11, 57:16, 59:9, 61:1, 61:10, 65:1, 69:4, 73:14, 74:20, 79:1, 79:14, 80:1, 82:1, 82:13, 82:19, 83:16, 83:19, 84:2, 84:9, 84:15, 84:20, 85:6, 87:10, 88:17, 89:3, 90:18, 92:12, 97:22, 100:8, 103:22, 110:22, 112:1, 114:2, 115:9 right-hand 35:13, 46:1, 70:1, 81:6, 107:7 risk 22:13 risk-benefit 22:10 rmr 1:26, 2:13 robert 1:16, 2:1, 4:3, 5:5, 5:20, 6:6, 121:5, 121:14 rocco 3:22, 5:8 role 13:22, 47:1 root 27:20 rough 120:18, 120:19 round 14:22 row 38:13, 56:16, 59:2 rule 44:1 rules 7:15	s s 40:11 s- 56:15, 58:4 safe 21:10, 22:2, 22:7, 22:19, 23:6, 33:21, 35:19, 36:14 safety 71:19 said 15:12, 18:13, 21:15, 21:17, 24:21, 57:13, 78:4, 86:8, 90:14, 121:19 same 7:16, 15:1, 15:18, 26:4, 30:19, 32:2, 34:5, 54:2, 58:20, 58:21, 60:17, 66:2, 71:4, 79:9, 80:10, 80:22, 81:18, 85:18, 92:1, 92:2, 120:8 saw 28:20, 89:15 say 8:8, 15:7, 21:19, 22:12, 23:5, 23:8, 24:14, 24:17, 27:14, 30:3, 31:20, 32:14, 44:1, 49:19, 52:19, 65:2, 67:18, 72:18, 76:6, 76:11, 87:18, 87:20, 99:17, 111:16, 114:10 saying 26:21, 40:18,
---	--	--	---

47:5, 73:15, 74:15, 85:10, 91:6, 100:11, 111:3, 113:19, 114:6 says 46:20, 52:14, 53:19, 57:7, 57:8, 60:10, 62:20, 64:15, 65:4, 70:3, 70:11, 70:20, 71:8, 71:14, 83:14, 99:16, 101:3, 104:2 scale 29:21, 30:2, 30:7, 55:13, 59:11, 61:5, 68:21, 79:14, 97:20, 97:21, 98:3, 98:16, 98:18, 99:2, 99:8, 100:1, 113:11, 113:15, 114:5, 114:12, 114:18 scenario 23:5, 24:4, 32:10, 32:12, 39:14, 43:4, 43:12, 45:3, 96:15, 96:20, 101:12, 117:9 schirmer 65:11, 67:8, 67:11, 70:21, 71:20 scientific 49:5 scientists 42:7 sclera 17:8, 17:9, 17:16, 17:20, 18:1, 18:3, 18:10, 18:13, 18:19, 18:22,	19:2, 19:3, 19:10, 19:20, 20:1, 20:3, 20:7, 66:16, 118:20, 119:20, 120:3, 120:5 scope 106:17 score 99:22, 100:7 scores 101:2, 104:3 second 54:8, 58:12, 65:3, 69:11, 69:12, 86:7, 96:1, 107:6, 110:16, 110:17, 111:15, 111:16 secondary 68:13, 68:15 section 16:9, 18:4, 25:20, 53:13, 57:8, 64:15, 64:19, 71:8, 90:17, 103:19, 108:1, 108:7, 108:21 sedative 45:6, 45:11 see 17:11, 17:20, 18:4, 18:15, 21:4, 22:3, 23:18, 31:20, 34:20, 34:21, 35:2, 35:11, 35:15, 37:17, 38:9, 38:15, 46:5, 46:6, 46:12, 47:4, 48:3, 48:5, 48:8, 48:19, 48:20, 49:12, 50:16, 50:20, 51:18, 52:9, 52:11, 52:17,	53:16, 53:19, 53:21, 54:10, 55:19, 56:4, 56:8, 56:19, 59:4, 59:17, 60:14, 62:9, 64:16, 69:11, 69:20, 69:21, 70:7, 71:11, 71:17, 71:22, 75:15, 81:4, 86:13, 86:14, 86:18, 87:19, 88:1, 88:9, 96:5, 96:6, 97:4, 97:11, 98:18, 100:16, 101:2, 101:18, 104:5, 107:12, 107:19, 109:13, 111:18, 116:6 seeing 52:10, 76:6, 101:1 seems 60:1 seen 28:13, 29:1, 86:11, 90:3, 93:11 segment 24:19 self-diagnoseable 21:20 sense 8:18, 9:5 sensitive 115:16 sentence 22:9, 36:12, 46:2, 46:6, 46:10, 46:20, 47:4, 47:7, 47:11, 47:21, 48:6, 49:11, 54:10, 56:2, 58:11, 58:20, 69:16, 69:22,	72:22, 86:7, 96:1, 108:3 sentences 53:22, 54:11, 70:11 separately 101:20 serious 22:11 served 6:16, 7:2 set 112:18, 121:6, 122:4 sets 98:15 several 13:13, 13:16, 41:21, 60:3, 81:13 severe 54:7, 54:14, 55:6, 59:8 severity 61:1 shape 91:7 sharply 62:8 shaw-crockett 1:26, 2:13, 5:9, 121:2 shell 17:18, 18:17 short-term 50:21 shorthand 64:7, 121:1 should 36:1, 37:4 showed 28:9 showing 30:9, 31:13 sic 30:15, 62:21, 79:20 side 14:4, 16:19,
--	--	---	--

23:10, 23:21, 35:13, 40:13, 53:18, 70:1, 80:11, 80:13, 81:6, 81:11 sign 31:8, 96:8, 96:17 signature-plkal 122:7 signed 11:21 significance 77:3, 77:10 significant 28:20, 77:18, 87:3, 104:3 significantly 57:8, 58:15, 58:22, 76:20 signing 121:19 similar 90:11, 91:8 since 36:6 single 113:4 sit 120:7 situations 67:6 six 7:6 size 65:11, 67:3, 70:5 skew 112:8 skill 28:3, 41:20, 50:6, 51:3, 109:18, 115:12 slayback 1:5, 3:2, 5:5 slope 87:18, 88:3, 88:6, 88:21	sloppiness 112:4 slowly 8:9 solicited 106:2 some 7:15, 11:20, 13:20, 14:5, 14:21, 15:17, 21:1, 23:14, 23:17, 23:19, 27:12, 32:18, 38:21, 40:15, 45:22, 50:20, 51:9, 61:11, 68:3, 73:22, 79:7, 79:8, 85:20, 99:20, 101:6, 110:22, 114:6, 114:17, 119:8 somebody 23:17, 100:21, 101:6 someone 104:12, 105:13 something 8:21, 37:4, 37:13, 74:4, 103:13 sometimes 7:10, 23:2, 100:18 somewhere 73:1, 100:12 sorry 29:20, 44:14, 46:15, 50:17, 56:14, 63:2, 87:6, 87:20, 97:12, 97:16, 99:5, 100:19 sort 66:9, 68:21, 79:9 sound 109:3	sources 49:6 south 2:5, 121:15 space 18:6 speak 8:9, 8:10, 8:11, 10:2 speaking 15:18, 16:20, 18:2 speaks 36:16, 92:20 specific 10:22, 16:12, 24:3, 28:12, 32:10, 32:12, 32:19, 37:14, 43:3, 43:12, 45:3, 84:20, 84:21, 105:22, 115:13 specifically 11:2, 49:4, 95:19, 105:4 speculation 72:12, 73:7, 84:11, 89:11 square 18:19 stability 14:2 stand 86:17 standard 39:15, 40:14, 40:18, 90:1 standardized 55:5 start 31:15, 81:16, 88:16, 90:5, 105:11, 112:21 started 11:12 starting 21:19, 53:18,	60:4, 60:5, 108:21, 113:6 starts 37:10, 46:3, 69:12, 88:14, 88:20 state 6:4, 96:22, 108:2, 109:10, 113:7, 116:2 stated 36:12, 59:1 statement 34:2, 48:9, 53:2, 53:14, 57:4, 58:21, 62:5, 90:16, 97:6, 97:7 statements 15:6, 15:10, 115:20 states 1:1, 2:14, 107:5, 107:8, 108:3, 121:3 statistical 68:18, 77:2, 77:10 statistically 76:19, 104:2 status 66:15, 66:19 steeper 87:17, 88:7 step 27:2, 31:11, 63:3, 85:13, 85:22, 87:9, 91:20 still 40:11, 40:14, 95:4, 95:6, 105:14 sting 116:13 stinging 96:3, 116:4, 116:9, 116:16,
---	---	---	--

117:4 stop 23:19 stopped 23:21 street 2:5, 121:15 strengths 33:6 strike 28:16, 30:10, 31:6, 38:1, 43:17, 68:1, 102:1, 105:10, 119:4 stroma 19:5 structural 18:18 structures 49:15, 66:12 studied 36:14, 103:12 studies 14:5, 28:13, 28:17, 29:16, 29:22, 30:8, 31:13, 32:19, 35:1, 35:6, 35:9, 35:10, 35:17, 36:22, 38:3, 38:12, 38:22, 39:22, 57:14, 59:11, 61:5, 61:13, 63:22, 64:6, 64:7, 64:9, 68:16, 72:3, 72:6, 73:5, 74:3, 74:7, 74:9, 74:12, 75:5, 76:12, 78:5, 78:8, 93:14, 101:20, 105:19, 106:1 stuff 14:6 subarticle 47:13	subconjunctival 107:10 subject 71:4 subject's 65:13 subjective 57:9, 114:18 subjects 69:17, 71:9 submitted 10:14, 11:7, 29:16, 34:15 substance 9:9 subtype 42:5, 42:9, 42:13 subtypes 41:21, 42:16, 43:8, 43:16, 43:19, 44:5, 67:11 success 112:18 summary 57:15, 57:22, 58:17 sunday 1:18, 121:16 superficial 20:8, 20:9, 20:10, 119:21 support 18:18, 74:16 sure 7:16, 9:1, 14:22, 15:18, 26:15, 28:11, 30:1, 30:6, 37:7, 41:1, 42:13, 46:17, 49:19, 55:1, 58:7, 58:13, 59:13, 69:7, 70:9, 73:15, 79:7, 81:17, 83:10, 84:12,	87:21, 95:20, 100:11, 107:2, 107:21, 109:7, 114:22 surface 28:14, 30:18, 31:21, 102:20, 103:3, 120:2 surgeon 94:17 surgeons 108:17 surgery 94:13, 94:16, 109:12 surprise 49:20, 49:22 surprised 50:1, 50:2 surprises 50:1 surrounds 17:14, 18:14 susceptible 21:22 swear 5:19 swelling 97:2 switching 79:18 sworn 5:20, 121:6 symptoms 96:2, 97:2 system 44:12, 44:19, 45:1, 45:13 systemic 26:7, 26:12, 28:4 systemically 26:18, 26:19 T table 56:17, 98:20, 100:16, 100:19,	100:20, 101:1 tables 101:16, 102:12 take 8:17, 17:7, 22:10, 31:11, 34:8, 36:1, 45:15, 45:21, 47:18, 48:13, 59:20, 61:15, 63:3, 80:12, 86:4, 98:7, 107:6, 108:22, 112:8, 112:9, 118:3, 119:10 taken 70:6, 70:11, 121:8 takes 83:15 taking 8:8, 8:14, 111:22 talk 10:7, 24:9, 25:2, 41:15, 45:5, 47:20, 55:21, 60:22, 64:6, 65:1, 78:18, 79:19, 81:14, 97:20, 106:9, 113:10 talked 32:21, 94:10, 95:16 talking 16:17, 19:16, 19:17, 25:3, 28:22, 36:19, 41:13, 50:10, 50:18, 56:2, 60:17, 79:8, 79:9, 83:10, 83:16, 84:12, 84:15, 87:11, 98:4, 102:9, 104:19, 105:4, 105:9, 108:2,
--	--	---	---

110:18, 115:8, 118:22 talks 47:14, 65:5, 105:20 target 115:12 tartrate 47:22 teaches 86:8 tear 65:11, 66:13, 67:8, 67:10, 67:11, 67:12, 70:21, 71:20, 116:4 tearing 96:3, 116:9 tell 38:2, 53:17, 114:7 tells 75:21 ten 6:10 tend 92:5, 116:12 tendency 86:10 term 102:10 terms 28:11 test 65:11, 67:8, 67:12, 70:21, 71:20, 110:22 tested 35:19 testified 5:20 testifying 7:20 testimony 9:9, 19:22, 22:21, 29:4, 32:6, 49:2,	85:8, 90:9, 90:20, 92:20, 93:7, 103:1, 111:2, 111:12, 114:21, 121:9 th 122:5 therapies 1:10, 3:11, 5:6, 121:11 therapy 23:16 thereby 47:1 therefore 22:1 thick 82:11, 83:6, 86:11, 86:16 thicker 82:21 thin 82:17 thing 6:13, 50:17, 59:14, 66:2, 83:12, 83:16, 83:18 things 7:9, 14:3, 14:8, 17:10, 32:11, 43:9, 58:1, 58:11, 65:5, 66:8, 66:9, 67:20, 94:10, 95:16, 102:6, 117:1 think 17:19, 23:16, 24:4, 24:18, 28:12, 29:12, 31:2, 31:20, 36:3, 38:7, 40:4, 41:5, 49:5, 50:10, 75:1, 80:1, 85:1, 90:11, 91:14, 99:10,	99:15, 110:16 thinner 82:16, 87:16 third 56:16, 71:7, 95:20, 96:1, 113:6, 113:7 thought 80:10 three 10:9, 109:2 through 21:22, 62:1, 64:11, 64:20, 72:9, 101:16, 102:12, 109:7 throughout 15:5, 43:20, 44:2, 44:16, 88:20, 88:22 time 5:2, 6:11, 6:12, 7:2, 8:14, 11:22, 14:15, 14:19, 23:13, 23:18, 24:22, 32:17, 36:1, 36:6, 39:17, 49:5, 61:14, 61:17, 61:20, 62:13, 71:1, 87:20, 118:5, 118:8, 118:10, 118:11, 120:14, 120:21 times 6:9, 7:5, 9:2, 9:22, 11:13, 40:15, 62:13 timing 32:11, 32:15 timolol 75:6, 75:9, 75:13, 77:5 tissue 17:16, 47:2 tissues 44:4	title 12:7 titled 103:19 titles 49:12 titrate 52:16 today 5:2, 7:18, 8:20, 9:8, 9:15, 40:11, 104:20, 120:7 today's 9:17, 9:21, 120:13 together 90:12, 92:5, 92:22 tolerance 35:10, 38:3, 57:14 top 20:10, 29:15, 74:21, 79:6, 117:18, 118:2 topical 32:4, 50:11, 116:3 topically 30:15, 30:20, 31:14, 31:18 toward 16:22 trademark 1:1, 5:7 transient 60:12 treat 21:20, 24:7 treated 112:22 treating 39:9 treatment 12:14, 12:15, 38:11, 38:13, 70:15, 104:4,
---	--	---	---

117:15, 117:22 treatments 21:7 trial 1:3, 40:12, 56:3, 107:18 trials 29:16, 79:4 triangle 19:4 triggering 120:2 true 24:4, 71:4, 121:8 truthfully 9:14 try 8:10, 8:11, 65:9 trying 25:16, 27:3, 29:12, 43:4, 43:13, 58:9, 74:2, 77:1, 87:21, 88:13, 90:16, 93:3, 105:12, 109:16, 112:16, 114:3 turn 15:17, 15:19, 20:18, 34:17, 62:3, 62:13, 78:17, 93:19, 115:5 turning 111:15 twice 109:20, 111:11 two 6:20, 7:12, 16:2, 17:9, 41:15, 48:5, 58:11, 64:7, 66:22, 70:15, 70:17, 84:1, 93:14, 108:15 type 32:2, 44:5	types 41:16, 41:22 typically 40:10, 94:22, 103:9 U uh-huh 65:10, 69:15 ultrasonic 66:2 unable 110:9 unclear 43:3 under 7:19, 52:14, 65:3, 66:7, 67:6, 96:2 underlying 49:6, 57:22, 73:19 understand 7:19, 7:21, 8:5, 8:12, 8:22, 9:7, 9:11, 12:10, 15:6, 19:3, 24:21, 26:15, 27:3, 28:3, 31:10, 33:2, 54:18, 55:16, 58:9, 70:10, 77:20, 81:18, 84:4, 85:9, 87:21, 90:16, 91:6, 93:2, 104:16, 105:12, 107:2, 107:21, 109:1, 109:16, 110:9, 110:20, 114:3 understanding 17:4, 27:8, 40:1, 54:13, 58:13, 64:18, 69:5, 70:16, 72:4, 81:17 understood 9:3, 42:7,	50:7, 51:4, 82:5, 101:4 united 1:1 units 81:22, 82:4 university 13:14 unless 8:2 until 88:4, 88:17 untreated 112:22 use 23:3, 24:12, 27:12, 28:15, 57:10, 60:11, 92:5, 92:21, 92:22, 93:2 uses 94:17 using 23:20, 106:2 usually 84:14 V vacuum 102:10 vague 10:4, 11:22, 16:11, 19:11, 21:12, 24:20, 25:6, 26:20, 37:3, 38:19, 39:12, 42:1, 42:11, 43:10, 43:21, 44:7, 49:1, 60:19, 73:6, 76:15, 77:19, 84:3, 84:16, 84:22, 85:7, 87:5, 89:4, 93:5, 96:9, 96:13, 100:2, 100:9, 101:11, 104:14,	105:3, 105:15, 109:4, 110:10, 112:2, 112:14, 114:20, 116:17, 117:14 value 75:17, 75:20, 75:21, 76:2, 76:3, 76:12, 76:21, 85:5, 85:6 values 75:18, 84:8, 84:12, 84:15, 84:20, 85:1 variable 72:17, 90:1 variables 112:9, 113:8 various 66:14, 67:11, 104:20 vascular 49:14 vasoconstriction 46:3, 46:21, 82:13, 83:1, 83:4, 83:5, 83:11, 83:15, 83:22, 84:7, 84:8, 85:4, 85:5, 85:12, 85:15, 85:16, 85:21, 86:1, 86:9, 86:19, 87:2, 88:14 vasoconstrictive 30:17 vasoconstrictors 30:13 vasodilation 47:22, 49:11 vasodilator 28:10, 30:9, 31:9, 31:14, 31:18 vasodilators 31:22
---	---	--	--

vehicle 38:14, 38:18, 38:22, 40:20, 57:11, 59:6 version 80:14, 80:17, 90:15 versus 42:20, 77:4, 83:12 vessel 99:19 vessels 19:8, 19:9, 19:14, 19:19, 20:4, 28:14, 30:18, 31:21, 31:22, 32:3, 102:19, 103:3, 103:10, 114:8, 119:1, 119:6, 119:8, 119:20, 119:21, 120:1, 120:4 via 46:3, 46:21, 47:22 video 5:4 videographer 3:22, 5:1, 5:18, 14:13, 14:18, 61:16, 61:19, 118:4, 118:7, 120:13 view 16:19, 77:2, 109:15, 109:17, 111:20, 113:13 vigorous 55:13 visible 120:2 visine 21:2, 21:3 vision 67:14 visit 63:17, 64:21,	65:4, 67:17, 69:3, 69:4, 69:10, 69:18, 70:2, 70:3, 70:4, 72:8, 103:16, 103:22, 104:8 visits 65:2, 104:4, 104:7 visual 65:8, 65:12, 65:17, 67:13, 70:4, 71:15 vitreous 66:19 vocabulary 15:17 W walk 109:7 walks 64:20 want 58:7, 58:13, 70:9, 77:13, 80:19, 81:11, 98:7, 107:6, 107:21, 108:22, 110:19, 114:11 washington 3:19 washout 39:16, 69:14, 69:17 way 17:18, 92:4, 122:1 ways 27:6 we'll 8:14, 22:12, 32:18, 58:11, 62:14, 76:5, 87:18, 98:10 we're 5:9, 7:16,	14:15, 15:1, 15:18, 16:20, 18:2, 19:16, 19:17, 25:3, 36:19, 41:12, 43:12, 43:13, 50:10, 50:16, 54:2, 61:16, 61:19, 76:6, 77:1, 80:10, 80:22, 81:17, 81:18, 105:9, 118:4, 118:7, 120:14 we've 28:13, 62:12, 80:13, 104:19, 104:20 weeks 71:9 welcome 36:8, 61:22 went 14:14 whatever 36:8 whereof 122:4 whether 30:4, 31:12, 32:13, 38:3, 81:11, 113:14, 119:5 white 17:14, 17:21, 18:1, 18:6, 101:9 whole 46:20, 47:11, 58:5, 72:3, 88:22 williams 115:21 winging 112:6 within 106:17, 121:3 without 9:19, 21:21,	37:22, 39:18, 40:22, 71:3, 110:8 witness 5:19, 6:17, 7:3, 15:21, 20:20, 34:19, 37:7, 37:12, 41:8, 48:15, 50:4, 52:5, 56:12, 62:15, 79:17, 86:6, 93:18, 95:22, 97:15, 98:8, 99:4, 107:16, 118:16, 121:5, 121:9, 122:4 word 18:9 words 36:18, 46:18, 96:6 work 12:21, 13:1, 74:9, 115:17 working 23:22 worse 111:5 wrong 64:19 Y yang 3:13, 5:17 yeah 14:7, 18:8, 22:8, 27:2, 47:11, 50:20, 61:15, 63:16, 64:2, 64:3, 89:12, 92:4, 98:21, 99:13, 101:2 year 6:15, 11:20 years 6:20, 13:13
---	---	--	---

yellow 82:22 york 2:14, 3:7, 3:18, 121:4 yourselves 5:11 z zero 69:19, 82:8, 85:14, 97:22, 98:3, 99:1, 99:8, 99:11, 100:21, 101:6 zeros 100:18 zhang 3:15, 5:17 . .02 86:3 .03 86:16, 86:20, 88:15 .05 87:17, 87:18, 88:3, 88:4, 88:8, 88:17 .15 60:6 .3 86:21 .838 76:3 0 0.02 38:13 0.025 93:12, 117:12, 117:20 0.03 86:11, 93:12 0.1 33:15, 50:15 0.15 33:15, 50:14	0.2 28:21, 29:5, 33:4, 33:9, 34:15, 50:13, 50:22, 51:9, 51:11, 60:5, 62:4, 62:6, 62:21, 63:8, 63:12, 75:4, 78:5, 117:12 0.3 86:2, 117:21 0.35 59:3 0.48 100:17 0.5 33:3, 33:7, 52:4, 52:15, 52:20, 53:3, 56:1, 56:3, 57:11, 58:14, 59:15, 59:22, 60:4, 60:12, 61:2, 61:5 0.61 100:17 0.8 38:14 0.838 75:20 00142 1:9, 5:7, 11:7 05 61:17 06845 2:6, 121:16 1 1 1:25, 65:4 100 69:7 10018 3:7 1004 93:22 1006 106:5	1019 45:17 1029 51:21 103 64:6 1031 34:10, 38:12, 56:7, 56:13, 57:14, 58:18, 60:18, 62:12, 63:4, 64:8 104 64:6 1046 4:12, 80:6, 80:7, 81:1, 81:7 105 37:16 106 37:16 108 56:15, 58:4 11 60:5, 61:17, 61:20, 70:14 118 4:7 119 37:16 12 34:17, 34:20, 34:22, 35:7, 71:10, 71:21, 72:9, 73:10, 101:16, 102:12, 118:5, 118:8, 120:14, 120:21, 121:17 120 37:16 122 1:25 13 1:18, 5:2, 35:4, 35:9, 38:12, 39:22, 56:13, 56:15,	56:17, 58:17, 59:2, 100:16, 100:20, 101:1, 121:16 138 115:5, 116:2 14 15:19, 75:14 146 96:21 149 97:14, 97:15, 97:19, 98:6, 98:12 15 61:20, 62:20, 63:13, 75:12 16 17:6, 54:6, 98:15, 98:16, 99:9 16.8 62:21 166 108:22 169 108:1, 108:7 170 109:9 172 111:16 174 113:7 175 108:15 18 122:5 183 54:4 1993 51:17 1996 29:12 2 2 92:2 20 37:10
--	--	---	---

20001 3:19 2001 59:16 2002 108:2, 109:10, 111:16, 113:8 2008 28:4, 28:9, 41:19, 42:7, 50:6 2012 59:20 2014 78:19, 78:21, 78:22 202 3:20 2020 11:5 2022 1:9, 1:18, 5:2, 5:7, 11:7, 121:16, 122:5 2061 81:3 21 63:22, 64:1, 64:8 212 3:8 2161 80:18, 81:8 2166 98:10 2175 108:18 2186 108:18 25 1:19, 5:3, 20:18, 22:17, 121:17 26 103:18 286 34:20, 64:1, 64:8, 75:1	3 30 47:14, 70:12, 70:14, 98:17 342 37:16, 56:15, 58:4 35 14:16 38 118:15, 118:18, 119:11, 119:17, 120:8 3b 104:4, 104:8 4 4.6 116:10 40.9 54:4 4004 3:20 408 3:20 43 118:5 44 14:19 4413 3:19 45 2:5, 86:4, 86:8, 121:15 468951 1:24 49 97:8, 97:13 4b 104:4, 104:8 5 50 60:13 52 62:14, 62:16, 63:4, 75:1,	118:8 54 120:14, 120:21, 121:17 553 93:20, 94:1, 94:6, 95:17 5b 104:4, 104:8 6 6.3 75:14, 77:5, 78:2 6.8 62:8, 63:14, 75:3, 75:12, 77:3, 78:1 6.9 116:16, 117:4 61 21:18 620 3:6 65 115:6 7 7 70:12 74 79:20 742 4:12, 79:22, 80:15, 80:18, 81:2, 81:7, 83:19, 106:11, 106:17 75 54:3 77 51:12, 51:16, 55:22, 56:2, 58:21, 59:17, 62:2, 75:2, 78:18 7831 37:16	8 8,293,742 1:13 80 4:12, 17:17, 18:17 8042 37:16, 56:15, 58:4 813 3:8 83 77:17, 77:22 8800 3:8 9 9 1:19, 5:3, 14:16, 14:19, 70:12, 70:14, 121:17 90 40:11 901 3:18 94 86:5 95 90:14, 110:12
---	---	--	---