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Transcript of Eric D. Donnenfeld, M.D.

Date: January 21, 2024

Case: Lumify, In Re:

Planet Depos

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WORLDWIDE COURT REPORTING & LITIGATION TECHNOLOGY

Conducted on January 21, 2024

1	1	3
1	IN THE UNITED STATES DISTRICT COURT	1 APPEARANCES:
2	DISTRICT OF NEW JERSEY	2 FINNEGAN, LLP
3	-----	3 BY: JUSTIN J. HASFORD, ESQUIRE
4		4 justin.hasford@finnegan.com
5	IN RE LUMIFY Civil Action No.	5 901 New York Avenue, NW
6	21-16766 (RK) (RLS)	6 Washington, DC 2001
7	(CONSOLIDATED)	7 202.408.4175
8	-----	8 Counsel for Plaintiffs
9		9 and the Witness
10	EXPERT VIDEOCONFERENCE DEPOSITION TESTIMONY OF	10
11	ERIC D. DONNENFELD, M.D.	11 GOODWIN PROCTER, LLP
12	SUNDAY, JANUARY 21, 2024	12 BY: CHRISTOPHER J. CASSELLA, ESQUIRE
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17		17 Counsel for Defendants
18		18
19		19 ALSO PRESENT:
20		20 Alan Ross, videographer
21		21 Erin Schuppert, exhibit technician
22	Job No.: 522606	22 * * *
23	Pages 1 - 175	23 (All present appeared via remote communication.)
24	Reported by:	24 * * *
25	Rebecca Klanderud, RPR, CSR	25
2	2	4
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2		2 EXAMINATION: PAGE
3	Expert Videoconference Deposition Testimony	3 By Mr. Cassella 7
4	of ERIC D. DONNENFELD, M.D. taken via remote	4 By Mr. Hasford. 168
5	communication with the witness being located in	5 * * *
6	Roslyn, New York on Sunday, January 21, 2024,	6 EXHIBITS:
7	commencing at approximately 3:04 p.m. EST before	7 DONNENFELD EXHIBITS: PAGE MARKED
8	Rebecca L. Klanderud, a Registered Professional	8 Exhibit 600 Declaration of Eric D. 23
9	Reporter and Certified Shorthand Reporter.	9 Donnenfeld, M.D.
10		10 Exhibit 601 Belmonte - Neurobiology of 139
11		11 Ocular Pain
12		12 Exhibit 602 Blephex Pain Point Markman order 33
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5 1 THE VIDEO TECHNICIAN: Good 2 afternoon. 3 We are on the record in the 4 videotaped deposition of Dr. Eric Donnenfeld in 5 the matter of Lumify in re before the United 6 States District Court for the District of New 7 Jersey, Case Number 21-16766 (RK) (RLS) 8 (Consolidated). 9 Today's date is January 21, 2024, the 10 time on the video monitor is 15:04 Eastern. 11 The videographer today is Alan Ross 12 representing Planet Depos, and this video 13 deposition is taking place remotely. 14 Will counsel please state their 15 appearances for the record? 16 MR. CASSELLA: Good morning. 17 This is Christopher Cassella from the 18 law firm Goodwin Procter representing the 19 defendants in this matter. 20 MR. HASFORD: Justin Hasford of 21 Finnegan on behalf of the plaintiffs. 22 THE VIDEO TECHNICIAN: The court 23 reporter today is Rebecca Klanderud, 24 representing Planet Depos. 25 The witness will now be sworn.	7 1 having been first duly sworn, 2 testified on his oath as follows: 3 * * * 4 EXAMINATION 5 * * * 6 BY MR. CASSELLA: 7 Q. Good morning or good afternoon, 8 Dr. Donnenfeld. 9 A. Yes. 10 Q. As you just heard, my name is 11 Christopher Cassella. I represent the 12 defendants in this litigation, and I'll be 13 taking your deposition this afternoon. 14 Could you please state and spell your 15 full name for the record? 16 A. My name is Eric Donnenfeld, E-r-i-c, 17 D-o-n-n-e-n-f-e-l-d. 18 Q. And where are you located today? 19 A. Today I'm at my home which is 5 20 Verity Lane, Roslyn, New York. 21 Q. Is there anyone else in the room with 22 you? 23 A. No, there is not. 24 Q. Do you have any applications open on 25 your computer other than the Zoom application?
6 1 THE COURT REPORTER: Good afternoon, 2 everyone. This is Rebecca, the court reporter 3 for today's deposition. 4 Do counsel stipulate and agree that I 5 may administer the oath remotely, and that the 6 oath so given is valid for purposes of this 7 deposition, please? 8 Mr. Cassella? 9 MR. CASSELLA: I do. 10 THE COURT REPORTER: Thank you, sir. 11 Mr. Hasford? 12 MR. HASFORD: So stipulated. 13 THE COURT REPORTER: Thank you, sir. 14 Doctor, would you kindly raise your 15 right hand, sir? 16 (The court reporter administered the 17 oath to ERIC D. DONNENFELD, M.D.) 18 THE WITNESS: Yes, I do. 19 THE COURT REPORTER: Thank you, sir. 20 THE WITNESS: Thank you. 21 THE COURT REPORTER: Counsel, you may 22 proceed. 23 MR. CASSELLA: Thank you. 24 ERIC D. DONNENFELD, M.D., 25 a witness in the above-entitled matter,	8 1 A. I do not. 2 Q. Do you have your cell phone near you? 3 A. I do. 4 Q. Is it turned on or off? 5 A. It's on, but it's muted. 6 Q. Okay. If you get any text messages 7 related to the substance of your testimony 8 today, will you please alert me to that fact? 9 A. Yes, I will. 10 Q. You've been deposed before, correct? 11 A. Yes, I have. 12 Q. About how many times? 13 A. I would guess around a dozen. 14 Q. When was the last time? 15 A. Um, a year and a half ago. 16 Q. Okay. So you're probably pretty 17 familiar with the way depositions work. Uh, 18 nonetheless, I'm going to go over just a few 19 ground rules just to make sure we're on the same 20 page today. 21 During the course of your deposition, 22 your counsel may make objections. 23 You understand that unless you've 24 been instructed specifically not to answer, you 25 must answer my questions to the best of your

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9 1 ability? 2 A. Yes, I do. 3 Q. And as you know, we have a court 4 reporter transcribing everything that's being 5 said today. This means that you and I must both 6 make an effort to speak slowly and clearly so 7 that the court reporter can transcribe every 8 word. 9 Do you understand? 10 A. Yes, I do. 11 Q. And we also need to be sure to give 12 verbal answers to make sure we have a clear 13 written record. So no head nods or hand 14 gestures. 15 Do you understand? 16 A. Yes. 17 Q. I will try to take a five- to 18 ten-minute break every hour or so. We can take 19 a longer break if you need it. We can take, uh, 20 breaks more frequently than that if you'd like. 21 Just let me know. Uh, the only thing that I ask 22 is that if there's a question pending, please 23 answer the question before we break. 24 Do you understand? 25 A. Yes.	11 1 cases, um, as an expert and as a defendant. I 2 have been, uh, deposed in several cases 3 involving product litigation as well. 4 BY MR. CASSELLA: 5 Q. Have you ever been deposed in a 6 patent case? 7 A. Yes, I have been. 8 Q. What did those patents involve? 9 MR. HASFORD: Same caution. 10 THE WITNESS: Yeah. 11 One patent was regarding, um, a 12 Femtosecond laser, and one patent was regarding 13 a device for treating lid margin disease. 14 BY MR. CASSELLA: 15 Q. So two patent cases to the best of 16 your recollection? 17 A. Correct. 18 Q. And both of those patent cases 19 involved, um, devices? 20 A. Yes, they did. 21 Q. They did not involve methods of 22 treatment? 23 A. Correct. 24 Q. Which side did you represent in those 25 cases, the patentee or the patent challenger?
10 1 Q. Please listen carefully to my 2 questions, and let me know if you don't 3 understand them. If you answer my question, I 4 will assume that you understood it. 5 Is that fair? 6 A. Yes, it is. 7 Q. And do you understand that you're not 8 permitted to discuss the substance of your 9 testimony with counsel during the breaks in the 10 deposition today? 11 A. Yes, I do. 12 Q. Is there any reason you can't testify 13 truthfully and completely today? 14 A. No, there is not. 15 Q. You just said you've been deposed 16 about a dozen times before, correct? 17 A. Yes. 18 Q. What did those cases involve? 19 MR. HASFORD: And I'll just caution 20 you, Eric. Don't disclose the details of 21 anything that would have been under an 22 obligation of confidentiality in any of those 23 cases. 24 THE WITNESS: Of course. 25 I've been deposed in malpractice	12 1 A. The patentee. 2 Q. In both? 3 A. Yes. 4 Q. And did you testify at trial in those 5 patent cases? 6 A. No, I did not. 7 Q. Have you ever testified at trial? 8 A. Yes, I have. 9 Q. And would that have been related to 10 one of your medical malpractice cases? 11 A. Correct. 12 Q. And when you said you were a 13 defendant in a med- -- med-mal case, does that 14 mean you were accused of medical malpractice? 15 A. That's correct. 16 Q. What was the outcome of that 17 litigation? 18 A. Um, I had one verdict against me, and 19 I was found not guilty in the other four. 20 Q. So were there multiple, uh, cases 21 consolidated? 22 A. No. 23 MR. HASFORD: Object to the extent it 24 mischaracterizes the witness's testimony. 25 THE WITNESS: No.

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13	1 BY MR. CASSELLA: 2 Q. Can you explain what you mean by 3 there was one verdict against you and four, uh, 4 had found you not guilty? 5 A. There were four cases I was involved 6 in that went to trial in which I was found not 7 guilty. 8 Q. So those were all stemming from 9 different incidents? 10 A. Yes. 11 Q. And the one that you were found 12 guilty in, do you remember the name of that 13 case? 14 MR. HASFORD: Objection, 15 mischaracterizes the witness's testimony. 16 THE WITNESS: I don't recall. It was 17 over -- over 25 years ago. 18 BY MR. CASSELLA: 19 Q. Did it relate to your practice as an 20 ophthalmologist? 21 A. Yes, it did. 22 Q. Do you recall which jurisdiction that 23 case was filed in? 24 A. I don't recall specifically, no. 25 Q. Would it have been in the State of	15	1 Q. And you say you met with counsel to 2 prepare for your deposition today? 3 A. We spoke by Zoom. 4 Q. Thank you for that clarification. 5 Who did you meet with over Zoom? 6 A. I met with, uh, Justin. 7 Q. And when did you meet? 8 A. Um, this morning. 9 Q. For how long did you meet? 10 A. Oh, two and a half hours. 11 Q. Did you review any documents in 12 preparation for your deposition, other than the 13 ones you mentioned a few minutes ago? 14 A. No. 15 Q. So you did not review any of 16 plaintiffs' experts' declarations other than 17 your own? 18 A. I did not. 19 Q. Have you ever reviewed any of 20 plaintiffs' declarations? 21 A. I have not. 22 Q. Other than Mr. Hasford, did you 23 discuss the substance of your testimony with 24 anyone else? 25 MR. HASFORD: Objection,
14	1 New York? 2 A. Yes, it was. 3 Q. Okay. Dr. Donnenfeld, did you do 4 anything to prepare for your deposition today? 5 A. Yes, I did. 6 Q. What did you do to prepare for your 7 deposition today? 8 MR. HASFORD: I'll just caution you, 9 Eric. Don't disclose the substance of any 10 communications you had with counsel. 11 THE WITNESS: Okay. Yeah. 12 I reviewed my notes -- um, well, not 13 my notes. I reviewed the, um, depositions of 14 Dr. Dana. I reviewed, um, my review of some of 15 the records that were involved, and I did speak 16 with counsel. 17 BY MR. CASSELLA: 18 Q. You reviewed some of the records that 19 were involved. 20 Can you explain what you mean by 21 that? 22 A. I reviewed the papers that were 23 referenced in the trial such as the Norden 24 paper, and I reviewed, um, my declaration and 25 Dr. Dana's deposition as well.	16	1 mischaracterizes the witness's testimony. 2 THE WITNESS: I only discussed it 3 with, uh, Justin. There was another lawyer on 4 the line, uh, I believe Ryan, but, um, really 5 did not discuss anything with him. 6 BY MR. CASSELLA: 7 Q. Would that have been Mr. O'Quinn? 8 A. I don't recall his last name. 9 Q. Did you speak with anyone at Eye 10 Therapies or Bausch & Lomb in preparation for 11 your deposition today? 12 A. No. 13 Q. What about in preparing your 14 declaration? 15 A. No. 16 Q. Have you ever spoken with any of 17 plaintiffs' other experts in this litigation? 18 A. No. 19 Q. Do you know any of the plaintiffs' 20 other experts in this litigation? 21 A. Yes, I do. 22 Q. Who do you know? 23 A. Dr. Noecker. 24 Q. And how do you know him? 25 A. He's one of my partners.

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17	19
1 Q. How?	1 Have you ever served as an expert
2 Can you explain what you mean by	2 with the firm, Finnegan, before?
3 that?	3 A. Oh, no.
4 A. We practice in the same group of	4 Q. Have you ever served as an expert for
5 ophthalmologists in Connecticut. I was not able	5 Bausch & Lomb before?
6 aware he was involved in this however, and I	6 A. No.
7 have not spoken with him about this.	7 Q. Have you ever received any sort of
8 Q. So when did you first learn that	8 financial compensation from Bausch?
9 Dr. Noecker was involved with this litigation?	9 A. I have received compensation from
10 A. About a week ago.	10 them for, um, uh, consulting.
11 Q. And you've never spoken to	11 Q. Can you explain what you mean by
12 Dr. Noecker about this litigation?	12 that?
13 MR. HASFORD: Objection, asked and	13 A. Um, I've been involved in advising
14 answered.	14 Bausch & Lomb in, uh, ophthalmic matters and
15 THE WITNESS: That's correct. I have	15 have met with many members of Bausch & Lomb to
16 not spoken with him about this.	16 discuss, um, opportunities in ophthalmology, and
17 BY MR. CASSELLA:	17 I've also been involved in consulting in a
18 Q. Dr. Donnenfeld, when were you first	18 similar fashion with 50 other companies.
19 contacted regarding this matter?	19 Q. And so Bausch & Lomb has paid you to
20 A. I would estimate about 10 days ago.	20 work as a consultant in connection with a
21 Q. And so that would have been around	21 drug-development program.
22 January 10th?	22 Is that fair?
23 A. I don't recall specifically. I could	23 MR. HASFORD: Object to the extent it
24 check my notes if you'd like an exact date.	24 mischaracterizes the witness's testimony.
25 Q. Do you recall who first contacted	25 THE WITNESS: I've been involved in
18	20
1 you?	1 Bausch -- with Bausch & Lomb in working on both
2 A. I do not.	2 pharmaceutical and surgical devices.
3 Q. Do you recall what you were asked to	3 BY MR. CASSELLA:
4 do when you were first contacted about this	4 Q. Has Bausch ever funded any of your
5 matter?	5 research?
6 MR. HASFORD: Uh, you can answer that	6 A. No.
7 question yes or no, but don't disclose the	7 Q. Has Bausch ever paid you to do a
8 substance of any communications you had with	8 promotional presentation or a talk?
9 counsel.	9 MR. HASFORD: Object to the form of
10 THE WITNESS: Yes. I was asked to	10 the question.
11 review a --	11 THE WITNESS: Yes, they have, as well
12 MR. HASFORD: Whoa, whoa, whoa.	12 as 50 other companies have done the same.
13 You -- Eric, you can't disclose the	13 BY MR. CASSELLA:
14 substance of any communications you had with	14 Q. Approximately how much money have you
15 attorneys.	15 received from Bausch in total?
16 THE WITNESS: Yes.	16 A. It would be difficult to estimate,
17 BY MR. CASSELLA:	17 but I would guess around \$15,000.00 over the
18 Q. Did counsel ask you to prepare a	18 course of my career.
19 declaration when they first contacted you?	19 Q. Have you ever moderated a panel for
20 MR. HASFORD: You can answer that yes	20 Bausch?
21 or no.	21 A. Yes.
22 THE WITNESS: Yes.	22 Q. How many times?
23 BY MR. CASSELLA:	23 A. Six.
24 Q. Have you ever served as an expert --	24 Q. When was the last one?
25 um, sorry. Let me rephrase that.	25 A. I did a panel discussion on Friday in

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21	1 Hawaii for Bausch & Lomb. 2 Q. This past Friday, as in two days ago? 3 A. Yes. 4 Q. In Hawaii? 5 A. Yeah. I take it back. Actually, it 6 was Thursday, three days ago. 7 Q. And that was in Hawaii? 8 A. Yes, it was. We have a national 9 meeting there called Hawaiian Eye Meeting, and 10 it's attended by approximately 700 11 ophthalmologists. 12 Q. Lucky you. 13 What was the subject of the panel 14 that you moderated for Bausch at that meeting in 15 Hawaii? 16 A. It involved dry eye. 17 Q. Did it involve treatments for dry 18 eye? 19 A. Yes, it did. 20 Q. Did you or anyone on the panel 21 discuss using brimonidine to treat dry eye 22 during that panel? 23 MR. HASFORD: Object to the form. 24 THE WITNESS: No, I did not. 25 BY MR. CASSELLA:	23
22	1 Q. You did not. 2 Did anyone on the panel? 3 MR. HASFORD: Same objection. 4 THE WITNESS: No. No one discussed 5 brimonidine. 6 BY MR. CASSELLA: 7 Q. Do you recall whether any of the 8 panels that you've moderated for Bausch 9 discussed brimonidine or its uses? 10 MR. HASFORD: Object to the form of 11 the question. 12 THE WITNESS: To my knowledge, I've 13 never discussed brimonidine with Bausch & Lomb. 14 BY MR. CASSELLA: 15 Q. Did Bausch & Lomb pay for your travel 16 to Hawaii for this meeting? 17 A. No, they did not. 18 Q. Dr. Donnenfeld, you're here to 19 testify as an expert witness on behalf of the 20 plaintiffs in this litigation, correct? 21 A. Yes. 22 Q. And you submitted a declaration in 23 support of plaintiffs' motion for a preliminary 24 injunction. 25 Is that right?	24
	1 A. That is correct. 2 Q. Okay. 3 MR. CASSELLA: Erin, could we please 4 display -- I've marked it as Exhibit 600. It's 5 Declaration of Eric D. Donnenfeld, M.D., is the 6 file name. 7 * * * 8 (Whereupon, Deposition Exhibit 600 was 9 marked for identification.) 10 * * * 11 BY MR. CASSELLA: 12 Q. Do you see a document displayed on 13 your screen, Dr. Donnenfeld? 14 A. Yes, I do. 15 Q. And do you recognize this document? 16 A. Yes, I do. 17 Q. What is this document? 18 A. Uh, this is the first page of what I 19 believe to be, um, a deposition -- I'm sorry -- 20 a, uh, um, declaration, uh, by me -- thank you. 21 I can read it better. I appreciate that -- um, 22 in support of plaintiffs' motion. 23 Q. Just for your benefit, 24 Dr. Donnenfeld, if you'd like to request control 25 of the screen, I believe you can, you know,	

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25 1 BY MR. CASSELLA: 2 Q. Okay. We got there eventually. 3 Uh, is this your signature on page 4 18, Dr. Donnenfeld? 5 A. Yes, it is. 6 Q. And by affixing your signature to 7 this declaration, were you attesting that the 8 contents of the declaration were truthful? 9 A. Yes. 10 Q. Do you have any corrections to your 11 declaration that you'd like to make? 12 A. No, I do not. 13 Q. Who drafted this declaration? 14 A. Um, the law firm interviewed me. We 15 spoke at great length. They drafted the 16 declaration. I reviewed it. I made many 17 changes and sent it back to them. 18 Q. So Finnegan provided you the first 19 draft of this declaration. 20 Is that fair? 21 A. Correct. 22 MR. HASFORD: Objection. 23 He said -- it mischaracterizes the 24 witness's testimony. 25 THE WITNESS: The first written draft	27 1 Is that right? 2 A. I don't know for certain. I trust 3 that is correct, though. 4 Q. I -- I will represent to you that 5 that is the full, uh, number of the patent. 6 Do you mind if we refer to that in 7 the shorthand as the '245 patent? 8 A. That would be fine. 9 Q. Okay. The '245 patent is the subject 10 of your declaration? 11 A. That is correct. 12 Q. Can we go to paragraph 14 of your 13 declaration, please? 14 A. I have it. 15 Please, if you could magnify that, 16 that would be helpful, or if I can magnify that. 17 That's great. Thank you. 18 MR. CASSELLA: Could we enable the 19 scrolling on the document so that it doesn't 20 flip to the next page every -- like, so that he 21 can, you know, the bottom -- the top of one page 22 at the same time as the bottom of another? 23 Do you know what I'm saying, Erin? 24 THE EXHIBIT TECHNICIAN: Yes, I 25 understand. That's enabled. It's right here.
26 1 was -- was given to me by them, yes. 2 BY MR. CASSELLA: 3 Q. Did you draft any first draft of any 4 portions of this declaration? 5 A. I did a verbal discussion with them, 6 but did not draft anything in the first draft 7 that was written. 8 Q. Okay. If we could go to -- I believe 9 the next page will be Exhibit A to your 10 declaration or I'm sorry. I guess it's 11 Appendix A. 12 And is this Appendix A, the following 13 page, is that a copy of your CV? 14 A. Yes, it is. 15 Q. Okay. Do you have any updates to 16 your CV since you submitted this declaration? 17 A. I've had a new paper accepted, but 18 it's not relevant. 19 Q. What was the subject of the paper? 20 A. Um, it was, uh, a new drug for dry 21 eye. 22 Q. Was that drug a redness reliever? 23 A. Uh, no, it was not. 24 Q. Now, this declaration relates to U.S. 25 Patent number 11,833,245.	28 1 I'm sorry. 2 MR. CASSELLA: Okay. Okay. 3 THE EXHIBIT TECHNICIAN: Um, right 4 there, do you see that? 5 MR. CASSELLA: Okay. I was 6 looking -- I just want him -- I just want him to 7 be able to, you know, see two pages at once if 8 he needs to. 9 Okay. Thank you. 10 BY MR. CASSELLA: 11 Q. Uh, so paragraph 14, Dr. Donnenfeld, 12 that's the beginning of the subsection of your 13 declaration entitled Person of Ordinary Skill in 14 the Art? 15 A. Yes. 16 Q. Did you come up with the definition 17 of the person of ordinary skill in the art? 18 A. I did this in conjunction -- 19 MR. HASFORD: Object to the form of 20 the question. 21 THE WITNESS: I did this in 22 conjunction with the law firm. 23 BY MR. CASSELLA: 24 Q. Did Finnegan provide the definition 25 of the person of ordinary skill in the art, to

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1 you? 2 MR. HASFORD: Objection, 3 mischaracterizes the witness's testimony. 4 THE WITNESS: Uh, they assisted me, 5 as I'm not a lawyer. They provided me with the 6 legal terms that needed to be applied. 7 BY MR. CASSELLA: 8 Q. Okay. For purposes of your 9 deposition today, can we refer in the shorthand 10 as person of ordinary skill in the art as POSA, 11 P-O-S-A? 12 A. Yes. 13 Q. Okay. If you could flip to Exhibit 14 [sic] B to your declaration, which looks like it 15 begins on page 58 of the PDF, maybe page 59 of 16 the PDF. 17 Okay. Here we are, Appendix B. 18 What is Appendix B to your 19 declaration, Dr. Donnenfeld? 20 A. This is a study that was performed 21 that documents that, um, with topical 22 anesthesia, there can still be redness. 23 Q. Uh, I'm sorry. 24 I was asking, what -- what is 25 Appendix B to your declaration?	29	1 A. Those are listed. I don't believe I 2 reviewed the Galanis deposition, however. 3 Q. Okay. So you've never seen the 4 transcript of the deposition of Dr. Galanis? 5 MR. HASFORD: Objection, 6 mischaracterizes the witness's testimony, 7 mischaracterizes the document. 8 THE WITNESS: That's correct. I 9 don't believe that I have reviewed the Galanis 10 deposition. 11 BY MR. CASSELLA: 12 Q. Okay. But you did review the 13 deposition transcript of Dr. Dana; is that 14 correct? 15 A. That's correct. 16 Q. Okay. Under Expert Declarations, 17 then, you list the declaration of Dr. Galanis 18 and the declaration of Dr. Dana. 19 Is that right? 20 A. Yes. 21 Q. Did you review the declaration of 22 Dr. Galanis? 23 A. I don't believe so. 24 Q. Okay. Did you review the declaration 25 of Dr. Dana?	31
1 A. Uh, this is a supporting document, 2 um, for my declaration. 3 Q. And this lists the materials that you 4 considered in preparing your declaration; is 5 that correct? 6 A. Yes. 7 Q. So you consider the '245 patent. 8 Is that right? 9 A. Yes. 10 Q. And under the heading, Production 11 Documents, you've got Exhibit 18 and Exhibit 36. 12 Do you recognize those as the Norden 13 and Gil references respectively? 14 A. Yes, I do. 15 Q. And if you could scroll down just a 16 little bit under Other Materials? 17 A. Thank you. 18 Q. So you've listed there the Huang 19 reference, Middleton reference, Doshi, two 20 Aslanides references, and a picture of an eye 21 with hemorrhage, correct? 22 A. Yes. 23 Q. And you've also listed under 24 Deposition Transcripts, the depositions of 25 Dr. Galanis and Dr. Dana, correct?	30	1 A. Yes, I did. 2 Q. Are there any materials that you 3 considered in preparing your declaration, that 4 are not listed in Appendix B? 5 A. No. 6 Q. So you've not reviewed any of 7 defendants' other experts' declarations? 8 A. Correct. 9 Q. Same for plaintiffs' other experts' 10 declarations? 11 A. Correct. 12 Q. Okay. If you could go to -- I 13 believe it's the next page, Appendix C to your 14 declaration? 15 And does Appendix C to your 16 declaration list the test- -- the previous 17 testimony from the last four years? 18 A. That's correct. 19 Q. Okay. Are there any updates to this 20 list of previous testimony? 21 A. No. 22 Q. Dr. Donnenfeld, to the best of your 23 recollection, has any court ever discounted your 24 opinions? 25 MR. HASFORD: Object to the form of	32

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1 the question, assumes facts not in evidence. 2 THE WITNESS: Not to my knowledge, 3 no. 4 BY MR. CASSELLA: 5 Q. Okay. 6 MR. CASSELLA: And could we please 7 display -- it's Blephex v Pain Point, Exhibit 8 602, please? 9 * * * 10 (Whereupon, Deposition Exhibit 602 was 11 marked for identification.) 12 * * * 13 BY MR. CASSELLA: 14 Q. And just before we turn to that, 15 Dr. Donnenfeld, is the first, uh, case listed in 16 your Appendix C to your declaration is Blephex v 17 Pain Point Medical Systems, number 18 3:16-cv-00410; is that correct? 19 A. Correct. 20 Q. Okay. 21 MR. CASSELLA: And if we could 22 display Exhibit 602? 23 BY MR. CASSELLA: 24 Q. Have you ever seen this document, 25 Dr. Donnenfeld?	1 Q. Did you opine on matters relating to 2 claim construction in that case? 3 A. I don't recall specifically, no. 4 Q. Okay. 5 MR. CASSELLA: Could we go to page 6 nine of the order, Erin, or if Dr. Donnenfeld 7 has control, whoever could flip to page nine, 8 please? 9 BY MR. CASSELLA: 10 Q. Do you see at the top of page nine of 11 Exhibit 602 the first sentence says: "Blephex 12 primarily relies on the declaration of Dr. Eric 13 Donnenfeld, an ophthalmologist"? 14 A. Yes. 15 Q. Is that you, sir? 16 A. Yes. 17 Q. Okay. And then it -- the opinion -- 18 the order lists -- describes the main point that 19 you were making in the -- uh, sorry. Let me 20 rephrase that. 21 The next sentence of the order 22 references your expert testimony that you 23 provided to the court in that case, correct? 24 A. Uh, I believe so, but I don't recall 25 it specifically.
1 A. Not that I recall, no. 2 Q. Do you see in the upper left-hand 3 corner the case caption which is Blephex v Pain 4 Point Medical Systems, and do you see the case 5 number in the upper right-hand side 16-cv-0410? 6 A. Yes, I do. 7 Q. Okay. Is this the same Blephex v 8 Pain Point case that was listed in exhibit -- or 9 Appendix C to your declaration? 10 MR. HASFORD: Objection, no 11 foundation. 12 THE WITNESS: Yeah. I don't know. 13 Um, I've been involved with one case with 14 Blephex versus Pain Point, but I don't recognize 15 this document. 16 BY MR. CASSELLA: 17 Q. Do you recall whether you testified 18 in the Blephex v Pain Point case? 19 A. Yes, I did. 20 Q. Okay. You were serving as an expert 21 in that case? 22 A. Yes. 23 Q. Did you submit an expert report in 24 connection with that case? 25 A. I don't recall.	1 Q. Okay. And do you see a few sentences 2 in the middle of the -- of page nine here, it 3 says: "The Court, therefore, discounts 4 Donnenfeld's opinion that a POSITA would not 5 understand 'swab' to be absorbent"? 6 A. I see that, yes. 7 Q. Okay. And then the court cites the 8 SkinMedica v the Histogen case and quotes that 9 case as saying, "conclusory, unsupported 10 assertions by experts as to the definition of a 11 claim term are not useful to a court." 12 Do you see that? 13 A. I do. 14 Q. So does this document refresh your 15 recollection as to whether any court has 16 discounted your opinions, Dr. Donnenfeld? 17 MR. HASFORD: Objection, no 18 foundation, assumes facts not in evidence. 19 THE WITNESS: Um, I stand by what is 20 written here. What is written is correct, and I 21 don't recall ever hearing this before. Uh, this 22 is new information for me, but the statement is 23 correct. Whether POSITA would understand that, 24 um, is a different matter that I can't really, 25 uh, relate to, but, uh, the facts are correct,

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1 and I've never seen this document before. 2 BY MR. CASSELLA: 3 Q. Okay. Why don't we go back to your 4 declaration now, and specifically at paragraph 5 22? 6 MR. CASSELLA: Is someone -- oh, 7 sorry. Okay. 8 BY MR. CASSELLA: 9 Q. Okay. In paragraph 22 of your 10 declaration, you state that: "The claims of the 11 '245 patent are directed, generally speaking, to 12 methods for reducing eye redness in a human 13 subject having ocular hyperemia, consisting of 14 topically administering an ocular drop 15 consisting of 0.025% weight by volume of 16 brimonidine as the sole active ingredient." 17 Do you see that sentence in paragraph 18 22? 19 A. Yes, I do. 20 Q. And it's your understanding that the 21 '245 patent generally -- generally relates to 22 methods of reducing eye redness? 23 A. Yes, I do. 24 Q. But you state in paragraph 22 that 25 the claims are directed to methods for reducing	1 drop this in the upload folder, probably, for 2 you to be able to display it? 3 THE EXHIBIT TECHNICIAN: That's 4 correct, um, unless you wanted to share it from 5 your computer. 6 MR. CASSELLA: I'll just upload it 7 really quickly. 8 Yeah. It should be uploaded. 9 THE EXHIBIT TECHNICIAN: Great. One 10 moment. 11 BY MR. CASSELLA: 12 Q. Okay. So you reviewed Exhibit 1, 13 which is the '245 patent, correct, 14 Dr. Donnenfeld? 15 A. Yes, I have. 16 Q. Okay. And do you see Exhibit 1, the 17 '245 patent displayed here on the screen? 18 A. Yes, I do. 19 Q. Okay. 20 MR. CASSELLA: Erin, could we go to 21 the very last page, I believe, which shows the 22 claims of the '245 patent? 23 Uh, maybe the previous page so that 24 we can see claim one. And maybe zoom in a 25 little bit so that we can see the text a little
1 eye redness consisting of administering 2 brimonidine, correct? 3 MR. HASFORD: Object to the extent it 4 mischaracterizes the document. 5 THE WITNESS: Yeah. 6 I state it re- -- it -- it's relevant 7 to using brimonidine as an ocular drop of 0.025% 8 percent as the sole active ingredient. 9 Q. Are you aware of the phrase 10 "consisting of" appearing in the claims of the 11 '245 patent? 12 MR. HASFORD: Object to the extent 13 it's calling for a legal conclusion. 14 THE WITNESS: Um, could you repeat 15 the question again, please? 16 BY MR. CASSELLA: 17 Q. Yeah. Sure. I'm not -- let me try 18 to do this another way. 19 You reviewed the '245 patent, 20 correct? 21 A. Yes, I did. 22 Q. Why don't we just make this easy? 23 I'm going to display the '245 patent. 24 Just one moment. 25 MR. CASSELLA: Erin, do I need to	1 easier. 2 Um, it must be further down. Um, 3 further down. Sorry. It's probably below 4 Example 5 there. Yeah. Okay. 5 BY MR. CASSELLA: 6 Q. Do you see the line beginning around 7 line 35 on the right-hand side that says: "The 8 invention claimed is," Dr. Donnenfeld? 9 A. Yes. 10 Q. Okay. And do you understand -- 11 A. Yes, I do. 12 Q. Oop. Sorry. 13 A. Yes, I do. 14 Q. Do you understand that the patent 15 claims are what follow that sentence? 16 A. Yes. 17 Q. And you reviewed these claims in 18 connection with your declaration? 19 A. Yes, I did. 20 Q. Or at least you reviewed claims 1, 2, 21 and 15? 22 A. Correct. 23 Q. Okay. In claim 1, do you see that 24 the phrase "consisting of" appears twice in the 25 claim?

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41 1 A. Yes. 2 Q. Okay. And has counsel instructed you 3 as to the meaning of the phrase "consisting of" 4 in patent law? 5 MR. HASFORD: Object to the extent 6 it, uh, calls for a legal conclusion. 7 And, um, I'll object and caution you, 8 Eric, don't disclose the substance of any 9 specific communications you may have had with 10 counsel. 11 THE WITNESS: I don't recall 12 specifically any discussion regarding 13 "consisting of," other than that it's a legal, 14 uh, decision, but I'm not aware of exactly the 15 legal meaning of that word in this patent. 16 BY MR. CASSELLA: 17 Q. So is it fair to say, Dr. Donnenfeld, 18 you have no opinions as to the meaning of the 19 phrase "consisting of" as that appears in 20 claim 1? 21 MR. HASFORD: Same objections. 22 THE WITNESS: Nothing that I'm 23 certain of. 24 BY MR. CASSELLA: 25 Q. And so you have no opinions as to the	43 1 Q. Your declaration is responding to the 2 declaration of Dr. Dana, correct? 3 A. Um, I'd have to look at exactly what 4 was written by Dr. Dana to see how I responded. 5 Q. Can you point me to where in your 6 declaration you stated that the claims of the 7 '245 patent would not have been obvious to a 8 person of ordinary skill in the art? 9 MR. HASFORD: Object to the form of 10 the question. 11 THE WITNESS: I believe that it is 12 obvious to a POSA that the patent, um, is 13 applicable. I don't believe I had said anything 14 differently. 15 Could we review my declaration, 16 please? 17 BY MR. CASSELLA: 18 Q. Sure. I just want to -- I'm just 19 asking where in your declaration you make that 20 conclusion, because I don't see that conclusion 21 explicitly stated in your declaration. 22 A. That's -- that's why I'd have to 23 review my declaration. 24 MR. HASFORD: I'll -- I'll just 25 object to the extent it mischaracterizes.
42 1 impact of that phrase "consisting of" on the 2 scope of the claims? 3 MR. HASFORD: Objection to the extent 4 it calls for a legal conclusion. 5 THE WITNESS: Again, not being a 6 lawyer, um, I don't recall exactly what the 7 significance of that word means in this patent 8 claim. 9 BY MR. CASSELLA: 10 Q. Okay. Um, Dr. Donnenfeld, you were 11 not asked to opine on the ultimate question of 12 obviousness of the '245 patent. 13 Is that right? 14 A. Could you rephrase that? 15 I don't understand what you're 16 saying. 17 Q. Do you have any opinions in your 18 declaration on whether the claims of the '245 19 patent would have been obvious to a POSA? 20 MR. HASFORD: Object to the form. 21 THE WITNESS: Um, I believe it is 22 obvious to a POSA that the patent, uh, here was 23 for using this medication to treat ocular 24 redness. 25 BY MR. CASSELLA:	44 1 THE WITNESS: I don't recall 2 specifically. I'd have to review my declaration 3 to look for this. 4 BY MR. CASSELLA: 5 Q. Okay. Dr. Donnenfeld, are you aware 6 that a different U.S. Patent was asserted 7 against defendants in this litigation? 8 A. Um, are you speaking to the 9 defendant? 10 Q. Are you aware that plaintiffs have 11 asserted a different patent other than the '245 12 patent against the defendants in this 13 litigation? 14 A. I was not aware specifically of 15 another patent. I have not -- not seen another 16 patent. 17 Q. Okay. So you've reviewed no other 18 patents other than the '245 patent in connection 19 with your declaration or your deposition today? 20 A. That's correct. 21 MR. HASFORD: Objection, 22 mischaracterizes. 23 BY MR. CASSELLA: 24 Q. So you've never reviewed U.S. Patent 25 number 8,293,742?

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45 1 A. Correct. I have not reviewed that 2 patent. 3 Q. And so you're not aware that the 4 defendants' petitioned the USPTO for inter 5 partes review of that '742 patent? 6 A. I was not aware of that, no. I was 7 aware that they were contesting this patent. 8 That's all I am aware of. 9 Q. Okay. Fair enough. 10 And so you're not aware that the PTAB 11 invalidated that '742 patent? 12 MR. HASFORD: Objection, 13 mischaracterizes the record. 14 Object to the form of the question. 15 THE WITNESS: I'm not aware of any 16 other patents that are involved. 17 BY MR. CASSELLA: 18 Q. And so you're not aware that the 19 PTAB, in its final written decision invalidating 20 the '742 patent, discussed several prior art 21 references? 22 MR. HASFORD: Objection, 23 mischaracterizes the record, no foundation. 24 THE WITNESS: I am aware that there 25 are several papers that have been published	47 1 point. 2 MR. HASFORD: That's fine. 3 THE WITNESS: Fine with me. I'm 4 ready to go, but I'm also fine to stop. 5 MR. CASSELLA: Let's take just five 6 minutes, then. 7 THE VIDEO TECHNICIAN: We're off the 8 record at 15:56. 9 * * * 10 (Whereupon, a short recess was taken.) 11 * * * 12 THE VIDEO TECHNICIAN: Back on record 13 16:03. 14 BY MR. CASSELLA: 15 Q. Welcome back, Dr. Donnenfeld. 16 A. Thank you. 17 Q. If we could please turn to Section II 18 B of your declaration, which begins on page 19 seven and paragraph 26. 20 Do you see Section II B displayed on 21 your screen? 22 A. I see that now, yes. 23 Q. Okay. And in Section II B of your 24 declaration, you state that "A POSA Would Have 25 Understood that Eye Redness and Eye Pain Are
46 1 that, um, the, uh, defendant is using to try and 2 invalidate this patent, which I find not -- not 3 rational. 4 BY MR. CASSELLA: 5 Q. But you're not aware, sir, that the 6 PTAB discussed some of those references in its 7 final written decision invalidating the '742 8 patent; is that correct? 9 MR. HASFORD: Objection. Objection. 10 Mischaracterizes the record, asked and answered, 11 no foundation. 12 THE WITNESS: I'm not aware. 13 BY MR. CASSELLA: 14 Q. Okay. So you have not reviewed the 15 PTAB's final written decision; is that correct? 16 MR. HASFORD: Same objections. 17 BY MR. CASSELLA: 18 Q. I don't think I heard an answer, 19 Dr. Donnenfeld. 20 A. That's correct. I'm not aware of 21 this document. 22 Q. Okay. 23 MR. CASSELLA: Uh, would now be a 24 good time for a break? 25 I'm sort of at a natural stopping	48 1 Different." 2 Is that correct? 3 A. That's correct. 4 Q. In paragraph 27 of your declaration, 5 you say: "Eye redness, also known as ocular 6 hyperemia, is a common ophthalmic condition 7 caused by vasodilation of conjunctival blood 8 vessels or the accumulation of red blood cells 9 in the conjunctiva." 10 Do you see that? 11 A. Yes, I do. 12 Q. Dr. Donnenfeld, are you aware that 13 this definition of ocular hyperemia is different 14 from the definition of ocular hyperemia that 15 Dr. Noecker provided in his declaration? 16 MR. HASFORD: Objection, no 17 foundation, assumes facts not in evidence. 18 Object to the extent it 19 mischaracterizes the materials. 20 THE WITNESS: Uh, I'm not aware of 21 that. I have not reviewed Dr. Noecker's 22 deposition, but it's very common for, uh, 23 clinicians to view hyperemia as redness, uh, due 24 to either vasodilation or red blood cells. 25 BY MR. CASSELLA:

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49 1 Q. And so you're not aware that 2 Dr. Noecker defined hyperemia as only 3 vasodilation? 4 You do not mention the accumulation 5 of red blood cells? 6 A. It doesn't surprise me -- 7 MR. HASFORD: Same -- same 8 objections. 9 THE WITNESS: It doesn't surprise me 10 that Dr. Noecker says that. That's the 11 scientific destin- -- uh, definition, uh, used 12 by many scientists, which Dr. Noecker is one of 13 them, but it's not what's done clinically in 14 ophthalmology, and it's certainly what 15 Dr. Norden states in his paper. 16 BY MR. CASSELLA: 17 Q. So you're applying a different 18 definition of ocular hyperemia than Dr. Noecker? 19 MR. HASFORD: Objection, 20 mischaracterizes the witness's testimony and the 21 documents. 22 Objection, no foundation. 23 THE WITNESS: I'm not aware of 24 Dr. Noecker's deposition. 25 BY MR. CASSELLA:	51 1 Q. So, originally, the accumulation of 2 red blood cells was not part of the definition 3 of ocular hyperemia in your declaration? 4 MR. HASFORD: Object. Object to the 5 extent it mischaracterizes the witness's 6 testimony, um, no foundation. 7 THE WITNESS: In the first draft, um, 8 after my discussion, this was not included, and 9 I thought that that was something that needed to 10 be added as it's very relevant to this case. 11 BY MR. CASSELLA: 12 Q. And so the addition to the definition 13 that you propose, "the accumulation of red blood 14 cells," that was your original, um, opinion? 15 A. That's always been my opinion, yes. 16 Q. And that addition, "the accumulation 17 of red blood cells," that is what you say in 18 your declaration is what Dr. Norden was 19 referring to when he referred to hyperemia in 20 his paper? 21 A. Um, I believe very strongly that 22 Dr. Norden was talking about red blood cells 23 when he talked about hyperemia, as it's, uh, 24 implicit in his title of his paper. 25 Q. And so you're not aware, sir, because
50 1 Q. Are you aware of when Dr. Noecker 2 submitted his declaration in connection with 3 this preliminary injunction proceeding? 4 A. No. 5 Q. Are you aware of when Dr. Galanis and 6 Dr. Dana submitted their declarations in 7 response to Dr. Noecker's declaration? 8 A. No, I'm not. 9 Q. Who proposed the definition of ocular 10 hyperemia in paragraph 27 of your declaration? 11 A. I did. 12 Q. Did you draft that sentence in 13 paragraph 27? 14 A. Yes. 15 Q. Are you aware of how similar it is to 16 Dr. Noecker's definition? 17 MR. HASFORD: Objection, no 18 foundation, assumes facts not in evidence. 19 THE WITNESS: Um, no, I'm not, but 20 I'm certain that the, uh, accumulation of red 21 blood cells in the conjunctiva was stated by me. 22 Um, at the discussion, uh, I added that to what 23 was, uh, written the first time around, after my 24 discussion. 25 BY MR. CASSELLA:	52 1 you have not read Dr. Noecker's declaration, 2 you're not aware that Dr. Noecker has never 3 asserted that the noted reference in referring 4 to hyperemia was referring to the accumulation 5 of red blood cells, correct? 6 MR. HASFORD: Object to the form. 7 Object to the extent it 8 mischaracterizes, argumentative. 9 THE WITNESS: Yeah. I would, um, say 10 that he did not include that. As Dr. Noecker 11 doesn't perform LASIK, I wouldn't think he would 12 be knowledgeable on the subject. This is my 13 area of expertise. 14 BY MR. CASSELLA: 15 Q. So is it your opinion, sir, that one 16 would have to have knowledge of LASIK or have 17 experience performing LASIK in order to 18 understand that hyperemia means the accumulation 19 of red blood cells? 20 MR. HASFORD: Objection, 21 mischaracterizes the witness's testimony, 22 argumentative, assumes facts not in evidence. 23 THE WITNESS: No. I don't think you 24 have to have that -- that basis, but I think 25 it's very helpful to have that information.

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53 1 BY MR. CASSELLA: 2 Q. So is it your opinion, sir, that 3 Dr. Noecker did not have that information when 4 he formed his opinions in this case? 5 MR. HASFORD: Objection, no 6 foundation, assumes facts not in evidence. 7 THE WITNESS: I don't know what -- 8 what Dr. Noecker's thought process was here, but 9 as a scientist, Dr. Noecker was following the 10 traditional, uh, definition of hyperemia. So 11 he's accurate in, uh, saying that hyperemia can 12 be caused by vasodilation of conjunctival 13 vessels, but it, uh, also does not include the 14 hyperemia definition used by the majority of 15 clinicians, including Dr. Norden, that red blood 16 cells can produce hyperemia, and most 17 ophthalmologists view hyperemia as simple 18 redness. 19 BY MR. CASSELLA: 20 Q. You don't cite any evidence in 21 paragraph 27 of your declaration to support that 22 most ophthalmologists view hyperemia as simple 23 redness; is that correct? 24 MR. HASFORD: Object to the extent it 25 mischaracterizes the declaration, argumentative.	55 1 It's on page ten of the document, 2 page 15 of the PDF. 3 BY MR. CASSELLA: 4 Q. And do you see in paragraph 43 of 5 Dr. Noecker's declaration, he states that: "Red 6 eye, also known as ocular hyperemia, refers to a 7 common ophthalmic condition caused by 8 vasodilation - an increase in the diameter of 9 blood vessels on the eye and the influx of blood 10 that 'congests' the vessel." 11 Do you see that sentence? 12 A. I do. 13 Q. And so you would agree with me, 14 Dr. Donnenfeld, that Dr. Noecker, in paragraph 15 43 of his declaration, does not mention the 16 accumulation of red blood cells? 17 MR. HASFORD: Objection, no 18 foundation. 19 Object to the extent it 20 mischaracterizes the document. 21 THE WITNESS: Uh, I agree he does not 22 mention red blood cells, uh, but what he writes 23 here is correct. It's just a limited 24 definition. I don't think he goes far enough to 25 describe, uh, other causes -- uh, other causes
54 1 THE WITNESS: Uh, I do not have a 2 reference in that paragraph that states that 3 fact. However, um, being a clinician, speaking 4 on the podium on LASIK for 30 years, and being 5 one of the inventors of the procedure, I've been 6 involved in multiple discussions regarding 7 redness and LASIK surgery. And, um, in 8 conversations, overwhelmingly, ophthalmologists 9 view red blood cells under the conjunctiva that 10 makes the eye appear red, as hyperemia. 11 MR. CASSELLA: Okay. Can we please 12 display the exhibit that I just uploaded? 13 It's the declaration of Robert J. 14 Noecker, M.D., MBA. 15 BY MR. CASSELLA: 16 Q. And you have never seen this document 17 before, correct? 18 A. My answer's still no. 19 Q. So I will represent to you that this 20 is a complete copy of the declaration of 21 Dr. Noecker that was submitted in connection 22 with this preliminary conjunction proceeding, 23 specifically, his opening declaration. 24 MR. CASSELLA: If we can go to 25 paragraph 43?	56 1 or other diagnoses of ocular hyperemia. 2 BY MR. CASSELLA: 3 Q. Okay. If we could flip back to your 4 declaration, specifically in paragraph 29, and 5 do you see in paragraph 29 the first sentence 6 there: "Eye pain, also known as ocular pain, is 7 caused by damage or inflammation to pain 8 receptors in the eye - i.e., nerves, which are 9 completely different anatomical structures from 10 blood vessels." 11 Do you see that sentence? 12 A. Yes. 13 Q. Would you agree, Dr. Donnenfeld, that 14 inflammation can cause pain? 15 A. Yes, I -- 16 MR. HASFORD: Objection -- 17 THE WITNESS: I agree. Yes. I agree 18 that inflammation is one of the causes of pain. 19 BY MR. CASSELLA: 20 Q. And specifically ocular inflammation 21 can cause ocular pain; is that correct? 22 MR. HASFORD: Same objection. 23 THE WITNESS: Yes. That's true. 24 BY MR. CASSELLA: 25 Q. And would you agree with me,

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57 1 Dr. Donnenfeld, that ocular inflammation can 2 also cause ocular redness? 3 MR. HASFORD: Same objection. 4 THE WITNESS: Yes. Ocular 5 inflammation can cause redness. 6 BY MR. CASSELLA: 7 Q. And so you would agree that ocular 8 inflammation can cause ocular hyperemia? 9 MR. HASFORD: Same objection. 10 THE WITNESS: Yes. Ocular 11 inflammation can cause hyperemia. 12 BY MR. CASSELLA: 13 Q. Okay. In a few sentences down in 14 sort of the middle-ish of paragraph 29 of your 15 declaration, you write that: "Inflammation of 16 nerves in the eye can lead to eye redness by 17 causing adjacent blood vessels to become 18 inflamed. Inflammation of nerves in the eye 19 themselves, however, do not cause eye redness." 20 Do you see those two sentences there? 21 A. Yes. 22 Q. Okay. So you would agree that 23 inflammation of nerves in the eye can lead to 24 eye redness, correct? 25 A. Yes. Inflammation of the nerves can	59 1 cause redness. 2 Q. So is it fair to say that your 3 opinion is that the inflammation of nerves in 4 the eye does not directly cause eye redness? 5 MR. HASFORD: Object to the extent 6 that it mischaracterizes the witness's 7 testimony. 8 THE WITNESS: Yeah. I would say very 9 strongly that if there was no blood vessels 10 available, even with inflammation, there would 11 be no redness. 12 For example, in the case of ischemia, 13 which is a common cause of pain, you can have 14 inflammation and not have redness at all. As a 15 matter of fact, the eye is extremely white. 16 BY MR. CASSELLA: 17 Q. Would you agree that inflammation of 18 nerves in the eye can indirectly cause eye 19 redness by causing adjacent blood vessels to 20 become inflamed? 21 MR. HASFORD: Object to the form of 22 the question. 23 THE WITNESS: Yes. 24 Inflammation, um, can have a 25 secondary effect of causing, uh, blood vessels
58 1 lead to eye redness, but there are many causes 2 of eye redness. 3 Q. But in the next sentence you say: 4 "Inflammation of nerves in the eye themselves, 5 however, do not cause eye redness." 6 A. Yes. 7 Q. Can you explain what you mean by that 8 second sentence which follows the one where you 9 said, "Inflammation of nerves in the eye can 10 lead to eye redness"? 11 A. Yes. Inflammation of the nerves that 12 are not adjacent, uh, or has synaptic 13 connections to red blood cells -- to, um, um, 14 vessels, does not necessarily cause redness. 15 You can have inflammation and not have eye 16 redness. 17 Q. So how does inflammation of nerves 18 lead to eye redness? 19 A. Um, there are multiple mechanisms in 20 which inflammation can lead to eye redness, um, 21 but, um, they can be due to the release of 22 different chemical mediators, um, but that's, 23 um, kind of beyond the scope of my description 24 here. You know, the fact is that inflammation 25 can cause redness, or it does not necessarily	60 1 to become inflamed and red. 2 BY MR. CASSELLA: 3 Q. Are you familiar with the term 4 "allergic conjunctivitis"? 5 A. Yes, I am. 6 Q. What is allergic conjunctivitis? 7 A. Allergic, uh, conjunctivitis is 8 generally a, uh, um, antigen antibody, um, um, 9 reaction in which, um, the conjunctiva becomes 10 inflamed. 11 Q. And does the inflammation associated 12 with allergic conjunctivitis cause eye redness? 13 MR. HASFORD: Objection, incomplete 14 hypothetical. 15 THE WITNESS: Yes. The inflammation 16 associated with, um, um, allergic conjunctivitis 17 can cause eye redness, assuming that there are 18 vessels there that can become inflamed. 19 BY MR. CASSELLA: 20 Q. You've written about allergic 21 conjunctivitis before, correct? 22 A. Yes, I have. 23 MR. CASSELLA: Erin, could we please 24 display -- it's, um, Exhibit 603. Uh, it's -- 25 the file name is Carr, C-a-r-r, Exhibit 603.

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1 * * * 2 (Whereupon, Deposition Exhibit 603 was 3 marked for identification.) 4 * * * 5 BY MR. CASSELLA: 6 Q. Is the text size big enough for you, 7 Dr. Donnenfeld? 8 A. Unfortunately, no. 9 Q. It's barely -- barely big enough for 10 me, so -- 11 A. Okay. Now -- 12 Q. Okay. Um, do you recognize this 13 document which we've marked as Exhibit 603, 14 Dr. Donnenfeld? 15 A. Yes, I do. 16 Q. What is this document? 17 A. This is a paper that I, uh, was a 18 co-author on that, um, looked at treating 19 allergic conjunctivitis with, I think, 20 olopatadine. 21 Q. Would you agree, Dr. Donnenfeld, that 22 seasonal and perennial allergies are a common 23 medical problem in the United States? 24 A. Yes, I do. 25 Q. And you write that -- in the first	61	1 which produces the ocular signs and symptoms 2 associated with allergic conjunctivitis? 3 MR. HASFORD: Object to -- 4 BY MR. CASSELLA: 5 Q. Is that correct? 6 MR. HASFORD: Object to the form of 7 the question. 8 THE WITNESS: Yes. That is true. 9 BY MR. CASSELLA: 10 Q. And the signs and symptoms associated 11 with allergic conjunctivitis are exemplified by 12 redness and itching; is that correct? 13 A. Uh, those are very common signs and 14 symptoms, yes. 15 Q. If we could go to page e108, uh, it 16 should be page 2 of the PDF, the bottom 17 right-hand corner, do you see the heading, 18 Current Treatment Options? 19 A. Yes, I see that. 20 Q. Okay. And underneath that heading, 21 you wrote that: Optimal management of allergic 22 conjunctivitis necessitates a broad approach 23 that involves allergen avoidance, symptomatic 24 relief, and pharmacologic suppression of 25 inflammatory responses. (As read)	63
1 paragraph, um, the left-hand column of this 2 page -- 3 MR. CASSELLA: If we can scroll down 4 a little bit, in the middle of that paragraph -- 5 yeah, right there. 6 BY MR. CASSELLA: 7 Q. In the middle of that paragraph, you 8 write that: "As much as 40% of the population 9 is affected by symptoms of AC," which I 10 understand you mean allergic conjunctivitis? 11 A. Yes. 12 Q. Do you see that sentence? 13 A. Yes. I agree with that statement. 14 Q. Do you stand by that sentence today? 15 A. I haven't reviewed the literature 16 recently, so I can't, uh, be absolutely certain 17 it's 40 percent, but it's very common. 18 Q. Is the inflammation associated with 19 allergic conjunctivitis characterized by 20 itching, conjunctival hyperemia, excessive 21 tearing, and conjunctival and eyelid swelling? 22 A. Those are very common signs and 23 symptoms of allergic conjunctivitis, yes. 24 Q. So in allergic conjunctivitis, 25 there's an inflammatory response to allergens	62	1 Do you see that sentence? 2 A. Yes, I do. 3 Q. But can you explain a little bit more 4 what you mean by the optimal management 5 necessitates a broad approach that involves 6 allergens avoidance, symptomatic relief, and 7 pharmacologic suppression of inflammatory 8 responses? 9 A. What we're saying there is that the 10 treatment of allergic conjunctivitis can many 11 times be multifactorial and may necessitate 12 changing the environment, avoiding allergens, 13 and there are medications that can be used to 14 suppress the allergic response, but all three 15 are not required in every case, but in -- in 16 many cases you do require all three of these 17 treatment options. 18 Q. So that first option for optimal 19 management would be allergen avoidance? 20 A. That's the -- 21 MR. HASFORD: Objection, 22 mischaracterizes the witness's testimony. 23 THE WITNESS: That's the first that's 24 listed there, but they're all important. 25 BY MR. CASSELLA:	64

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65 1 Q. Okay. And then another prong of the 2 optimal management is symptomatic relief; is 3 that correct? 4 A. Yes. 5 Q. And to state the obvious, that means 6 treating the symptoms of allergic 7 conjunctivitis; is that correct? 8 A. Yes. 9 Q. Okay. And then the third, uh, 10 category listed in that sentence, pharmacologic 11 suppression of inflammatory responses. 12 Is it fair to say that that is the 13 treatment of the underlying cause of the, uh, 14 inflammatory response? 15 MR. HASFORD: Object to the form. 16 THE WITNESS: No. It wouldn't be 17 treating the underlying cause. It would be 18 treating the inflammatory result, um, of -- of 19 the, uh, antigen antibody deposition. Uh, 20 treating the cause is really avoidance. If you 21 can avoid the antigen, you would be treating it, 22 uh, significantly. 23 Pharmacologic suppression is really 24 nonspecific in general. It just involves 25 therapies that reduce inflammation, not	67 1 1, you identified some drug classes that are 2 pharmacologic treatments for allergic 3 conjunctivitis; is that correct? 4 A. Yes. 5 Q. And so that would include 6 antihistamines, vasoconstrictors, mast cell 7 stabilizers, leukotriene receptor antagonists, 8 NSAIDs, corticosteroids, and single-agent 9 antihistamine-mast cell stabilizers; is that 10 correct? 11 A. Correct. 12 Q. And in the next column over in Table 13 1, you've listed the mechanism of action for 14 each of these drug classes; is that correct? 15 A. Yes. 16 Q. Okay. Is it fair to say that the 17 mechanism of action for each of these drug 18 classes is different? 19 A. Um, some of them overlap, but some of 20 them are different. 21 Q. So it would be fair to say that 22 antihistamines work via a different mechanism of 23 action than vasoconstrictors? 24 A. Yes. That would be accurate. 25 Q. And so going back to that sentence we
66 1 necessarily that specific antigen. 2 BY MR. CASSELLA: 3 Q. So do I understand you to mean that 4 the allergen avoidance would be to treat the 5 cause, the symptomatic relief would be to treat 6 the symptoms of the inflammatory response, and 7 the pharmacologic suppression would be to treat 8 the -- the underlying cause of the inflammation? 9 A. No, not that -- 10 MR. HASFORD: Object to the extent -- 11 object to the extent it mischaracterizes the 12 witness's testimony. 13 THE WITNESS: It's not treating the 14 underlying cause. It's treating the 15 inflammatory sequelae. 16 BY MR. CASSELLA: 17 Q. If we could go to the next page, 18 there's a Table 1 on page e109. 19 Do you see Table 1 displayed on your 20 screen, Dr. Donnenfeld? 21 A. I do. 22 Q. And Table 1 lists pharmacologic 23 treatments for allergic conjunctivitis, correct? 24 A. Yes. 25 Q. And in the left-hand column of Table	68 1 were just reviewing about optimal management of 2 allergic conjunctivitis, would the use of an 3 antihistamine fall under the category of 4 pharmacologic suppression of inflammatory 5 responses? 6 MR. HASFORD: Object to the extent it 7 mischaracterizes. 8 THE WITNESS: Uh, yeah. An 9 antihistamine would be a pharmacologic, um, 10 technique to reduce the inflammation, yes. 11 BY MR. CASSELLA: 12 Q. And the use of a vasoconstrictor, 13 would that fall into the category of symptomatic 14 relief? 15 A. Um -- 16 MR. HASFORD: Same objection. 17 THE WITNESS: It would not be, um, 18 symptomatic relief, no. 19 BY MR. CASSELLA: 20 Q. Why not? 21 A. Because it treats redness which is a 22 sign, not a symptom. 23 Q. Can you explain the difference 24 between sign and symptom? 25 A. A sign -- a symptom is something that

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69 1 you experience or feel, and a sign is something 2 that you see. 3 Q. So is it your opinion that because -- 4 sorry. Let me rephrase that. 5 So is it your opinion that eye 6 redness cannot be felt? 7 A. Uh, on certain -- 8 MR. HASFORD: Object -- object to the 9 extent it mischaracterizes the witness's 10 testimony. 11 THE WITNESS: Um, yes. Eye redness, 12 uh, in general, cannot be felt. 13 BY MR. CASSELLA: 14 Q. So the use of a vasoconstrictor, in 15 your opinion, would be treatment of a sign of 16 inflammation; is that correct? 17 MR. HASFORD: Same objection. 18 THE WITNESS: Um, in this case, yes. 19 It would be a treatment of one of the signs of 20 inflammation. 21 BY MR. CASSELLA: 22 Q. Okay. I'd like you to -- if we could 23 go back -- we're on Table 1 there. Great. 24 Um, so we -- I think we said 25 antihistamines or -- excuse me. Let me	71 1 MR. HASFORD: Same objection. 2 THE WITNESS: Yes. 3 BY MR. CASSELLA: 4 Q. What about NSAIDs? 5 MR. HASFORD: Same objection. 6 THE WITNESS: Um, NSAIDs treat, um, 7 the symptom of itching, but, um, they don't 8 really do it in this circumstance as an 9 anti-inflammatory. They do it more as an 10 anesthetic effect, which NSAIDs have. And for 11 that reason, NSAIDs are not very commonly used 12 in treating allergy any longer but it's -- it 13 doesn't really affect the mechanism of itching, 14 more it's a -- it's just an anesthetic that 15 makes the patients feel better, but it 16 doesn't -- it doesn't treat the inflammatory 17 cascade. 18 BY MR. CASSELLA: 19 Q. So is it fair to say that an NSAID, 20 um, blocks the sensation of itching? 21 MR. HASFORD: Object to the form. 22 THE WITNESS: It -- no. I don't 23 think that would be a correct definition. I 24 would say it just anesthetizes the cornea and 25 makes the cornea less receptive to symptoms
70 1 rephrase. 2 So you testified that antihistamines 3 would fall into the category of pharmacologic 4 suppression of inflammation responses, correct? 5 A. That's correct. 6 Q. And vasoconstrictors, I believe you 7 testified, would be a treatment of a sign of the 8 inflammation; is that correct? 9 MR. HASFORD: Object to the extent it 10 mischaracterizes. 11 THE WITNESS: Well, it's a -- it's a 12 sign of redness, not necessarily inflammation, 13 but it's a sign -- it's a sign of the redness 14 associated with inflammation. 15 BY MR. CASSELLA: 16 Q. Okay. What about the next category 17 of drug class, mast cell stabilizers? 18 Would that also be a pharmacologic 19 suppression of inflammatory responses? 20 A. Yes. 21 MR. HASFORD: Same objection. 22 THE WITNESS: Yes, it would. 23 BY MR. CASSELLA: 24 Q. And what about leukotriene receptor 25 antagonists?	72 1 like -- like itching or pain. 2 BY MR. CASSELLA: 3 Q. Okay. Okay. Now, under this 4 heading, Current Treatment Options, which begins 5 on page e108, you've got a few different 6 subsections. One is Allergen-Specific 7 Immunotherapy appearing on page e109. Another 8 is Topical Antihistamines, appearing on page 9 e110; Antihistamine-Vasoconstrictor 10 Combinations, Leukotriene Receptor Antagonists; 11 NSAIDs; Corticosteroids, Mast Cell Stabilizers 12 on page e111, and Dual-Acting Antihistamine-Mast 13 Cell Stabilizing Agents on -- also on page e111. 14 Do you see those categories that I 15 just mentioned? 16 A. They're a little blurry, but I do see 17 them, yes. 18 MR. CASSELLA: Maybe we could make 19 the text just a little -- just a little bit 20 bigger. 21 Okay. Could we go up one page to 22 e- -- page e110? 23 BY MR. CASSELLA: 24 Q. And do you see the heading there, 25 Antihistamine-Vasoconstrictor Combinations?

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73 1 A. Yes. 2 Q. And so combinations of antihistamines 3 with a vasoconstrictor can treat allergic 4 conjunctivitis; is that correct? 5 A. Um, they can be helpful, uh, for 6 treating the -- the symptoms and the signs of 7 allergic conjunctivitis, yes. 8 Q. Okay. And you wrote in that first 9 sentence there the: "Topical vasoconstrictors 10 are highly effective at reducing ocular and 11 conjunctival hyperemia through stimulation of 12 vascular a-adrenergic receptors." 13 Is that correct? 14 A. Yes. 15 Q. Okay. And you -- do you stand by 16 that sentence today? 17 A. Um, a-adrenergic receptor agonists 18 can reduce conjunctival hyperemia. Yes. I 19 stand by that. 20 Q. In the next sentence you write the 21 "Vasoconstrictors are commonly available in 22 nonprescription combination formulations that 23 contain an antihistamine (e.g., 24 naphazoline-antazoline, 25 naphazoline-pheniramine)."	75 1 is the active ingredient in the drug product 2 Alaway? 3 A. I don't recall. 4 Q. Are you aware that Bausch is 5 currently sponsoring a phase three clinical 6 trial to evaluate the efficacy of the 7 combination of brimonidine 0.025 percent and 8 ketotifen 0.035 percent? 9 MR. HASFORD: Objection, no 10 foundation. 11 THE WITNESS: I am not. 12 BY MR. CASSELLA: 13 Q. Okay. 14 MR. CASSELLA: And could we please 15 display the document titled Clinical Trial 16 Number NCT05579730? 17 Okay. If we could please mark this 18 exhibit as Exhibit 604? 19 * * * 20 (Whereupon, Deposition Exhibit 604 was 21 marked for identification.) 22 * * * 23 BY MR. CASSELLA: 24 Q. Have you ever seen this document, 25 Dr. Donnenfeld?
74 1 Do you see that sentence? 2 A. Yes. 3 Q. Are there any other combinations of, 4 uh, antihistamine vasoconstrictors that you're 5 aware of today? 6 A. Uh, I'm not aware, no. There might 7 be, but I -- I'm not aware of any. 8 Q. These combination, uh, treatments 9 relieve redness and itchiness associated with 10 allergic conjunctivitis, correct? 11 A. That is correct. 12 Q. Are you aware of the drug ketotifen? 13 A. Yes, I am. 14 Q. What is ketotifen? 15 A. Uh, ketotifen is a -- um, I believe 16 it's an antihistamine. I'd actually have to 17 review that to be certain. 18 Q. Okay. Do you recall what ketotifen 19 is used to treat? 20 A. Um, allergic conjunctivitis, I 21 believe. 22 Q. Are you aware of the branded drug 23 products called Alaway? 24 A. Yes, I am. 25 Q. And do you recall whether ketotifen	76 1 A. Not to my knowledge, no. 2 Q. Do you see at the top of the page 3 there, the title of the document is Evaluation 4 of Brimonidine Tartrate/Ketotifen Fumarate 5 Combination for the Treatment of Allergic 6 Conjunctivitis? 7 A. I do read that, yes. 8 Q. Okay. And the sponsor -- did -- 9 sorry. Let me rephrase. 10 Do you understand that this is a 11 ClinicalTrials.gov printout for the clinical 12 trial number NCT 05579730? 13 MR. HASFORD: Objection, no 14 foundation. 15 THE WITNESS: Yeah. I have not 16 rela- -- no understanding of this. I've not 17 seen the document. I'm not aware of the trial 18 previously, but if you report that this is 19 accurate, then I -- I will take your word for 20 it. 21 BY MR. CASSELLA: 22 Q. Have you ever viewed the website 23 ClinicalTrials.gov? 24 A. Yes. 25 Q. Are you generally aware of

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1 ClinicalTrials.gov providing details about 2 clinical trials? 3 A. Yes, I am. 4 MR. HASFORD: Objection. 5 BY MR. CASSELLA: 6 Q. Do you see the sponsor for this 7 clinical trial is Bausch & Lomb, Incorporated? 8 MR. HASFORD: Objection, no 9 foundation. 10 THE WITNESS: I see that on the 11 document you're showing me. I do see that 12 written. 13 BY MR. CASSELLA: 14 Q. Okay. And then under Study Overview, 15 in the middle of the page, the first page here, 16 do you see the Brief Summary, that sentence: 17 "To evaluate the efficacy of Combo (Drug Product 18 Brimonidine Tartrate 0.025%/Ketotifen Fumarate 19 0.035% Ophthalmic Solution) compared to its 20 individual components and vehicle in a 21 population of subjects with allergic 22 conjunctivitis"? 23 Do you see that sentence? 24 A. I do. 25 Q. So do you have any understanding as	77	1 Time Frame? 2 A. Yes. 3 Q. Okay. So one of the outcome measures 4 in this clinical study is: "Ocular itching 5 measured by Conjunctival Allergen Challenge 6 Ocular Itching Scale." 7 Do you see that? 8 MR. HASFORD: Objection, no 9 foundation. 10 THE WITNESS: Yes, I see that. 11 BY MR. CASSELLA: 12 Q. And the other outcome measure of this 13 clinical study is "Conjunctival Redness measured 14 by Ocular Hyperemia Scale." 15 Do you see that? 16 MR. HASFORD: Same objection. 17 THE WITNESS: Yes, I see that. 18 BY MR. CASSELLA: 19 Q. So are the primary outcomes of this 20 clinical study the measurement of ocular itching 21 and conjunctival redness? 22 MR. HASFORD: Objection, no 23 foundation. 24 THE WITNESS: It doesn't say that 25 they're the primary outcome, so I can't -- I	79
1 to whether Bausch & Lomb is currently sponsoring 2 a clinical trial aimed at evaluating the 3 efficacy of brimonidine with ketotifen to treat 4 allergic conjunctivitis? 5 MR. HASFORD: Objection, asked and 6 answered, no foundation. 7 THE WITNESS: Um, I just read what 8 you're showing me right here for the first time, 9 and, um, it does appear that they are evaluating 10 those two drugs together. 11 BY MR. CASSELLA: 12 Q. Okay. 13 MR. CASSELLA: If we could scroll 14 to -- it's going to be page, uh, seven of the 15 PDF? 16 It looks like also page seven of the 17 document, 7 of 9. 18 Then can we blow that text up a 19 little bit so Dr. Donnenfeld could read it? 20 BY MR. CASSELLA: 21 Q. Do you see the heading there, What is 22 the study measuring? 23 A. Yes. 24 Q. And do you see the table listed below 25 there, Outcome Measure, Measure Description, and	78	1 can't assume that. 2 BY MR. CASSELLA: 3 Q. Are those two outcome measures of 4 this clinical study? 5 A. Yes, they -- 6 MR. HASFORD: Same objection. 7 THE WITNESS: Yes, they are. 8 BY MR. CASSELLA: 9 Q. Okay. If we could go back to your 10 declaration? 11 Um, there's a subsection C that 12 begins at paragraph 30 on page nine of your 13 declaration, and I'll just pause until the -- 14 that paragraph's displayed on your screen. 15 Okay. Can you see the subsection C 16 on page nine? 17 It's titled Clinical Studies Contain 18 Uniform Protocols for Reporting Adverse Events? 19 Do you see that? 20 A. Yes. 21 Q. And this section -- subsection of 22 your declaration has two paragraphs, correct? 23 A. Yes. 24 Q. And in neither of those paragraphs do 25 you cite the Alphan protocol; is that correct?	80

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1 A. I believe you are correct. 2 MR. HASFORD: It's argumentative. 3 BY MR. CASSELLA: 4 Q. Have you ever seen the protocols for 5 adverse event reporting that were used in the 6 Alphagan clinical trials? 7 A. I've seen the adverse events, but I 8 haven't seen the protocol, no. 9 Q. So you have no direct evidence of a 10 uniform protocol being used in the Alphagan 11 clinical trials, correct? 12 MR. HASFORD: Objection, 13 mischaracterizes the witness's testimony, 14 argumentative. 15 THE WITNESS: I'm aware of the, um, 16 adverse events that were stated. I'm not aware 17 of how they were ascertained. 18 BY MR. CASSELLA: 19 Q. You have not provided a definition of 20 conjunctival blanching in your declaration, have 21 you? 22 A. I have not. 23 Q. What definition of conjunctival 24 blanching did the Alphagan clinical trials use? 25 A. I don't recall. I'd have to review	1 down a page? 2 BY MR. CASSELLA: 3 Q. Do you recognize this document? 4 A. I can't -- I can't be certain. It 5 looks familiar, but I -- I can't recall. 6 Q. Does Exhibit 63 appear to be the 7 label for Alphagan 0.5 percent? 8 MR. HASFORD: Objection, no 9 foundation. 10 THE WITNESS: Possibly. 11 MR. CASSELLA: Can we go to page four 12 of Exhibit 63? 13 Uh, one page up. It's page five. 14 BY MR. CASSELLA: 15 Q. Do you see the section titled 16 Clinical Studies? 17 A. Yes, I do. 18 Q. And do you see that the -- the 19 sentence in the second paragraph: In two 20 controlled, multi-center studies, ALPHAGAN 0.5% 21 ophthalmic solution was significantly more 22 effective in decreasing the incidence of 23 post-operative IOP elevations, um, than was the 24 vehicle at one, two, and three hours post-argon 25 laser trabeculoplasty. (As read)
1 that. 2 Q. You'd have to review what? 3 A. Um, I'd have to view what the 4 definition was. 5 Q. In the clinical trial protocol? 6 A. Yes. 7 Q. And you've never seen that protocol, 8 correct? 9 A. Correct. 10 MR. CASSELLA: Okay. Erin, I just 11 added an exhibit, um, to the portal, if you 12 don't mind displaying it? 13 It's Exhibit 63. 14 THE EXHIBIT TECHNICIAN: My 15 apologies, Counsel. It's not showing up. I 16 keep refreshing. 17 MR. CASSELLA: Uh, it looks like it's 18 uploaded on my end. I don't know if -- 19 THE EXHIBIT TECHNICIAN: There we go. 20 We have it now. Thank you. 21 MR. CASSELLA: Okay. Thank you. 22 BY MR. CASSELLA: 23 Q. Dr. Donnenfeld, have you ever seen 24 Exhibit 63, which -- 25 MR. CASSELLA: If we could scroll	1 And apologies if I butchered that 2 last word. 3 A. You said it beautifully. 4 Q. Do you see that sentence there? 5 A. I do. 6 Q. So is it your understanding that 7 there were two controlled clinical trials of 8 Alphagan 0.5 percent, evaluating the drug 9 Alphagan 0.5 percent com- -- uh, compared to the 10 vehicle at one, two, and three hours post-argon 11 laser trabeculoplasty? 12 A. That's correct. 13 MR. HASFORD: Objection, foundation. 14 BY MR. CASSELLA: 15 Q. Do you have any understanding as to 16 how long these studies lasted? 17 MR. HASFORD: Same objection. 18 THE WITNESS: What's stated here is 19 they were tested at one, two, and three hours 20 post-argon laser trabeculoplasty. That's the 21 only information that I have, based on this 22 document. 23 BY MR. CASSELLA: 24 Q. But is it possible, Dr. Donnenfeld, 25 that this study could be studies of Alphagan 0.5

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1 percent were conducted in the course of a single 2 day? [sic] 3 MR. HASFORD: Object, no foundation. 4 THE WITNESS: I would assume that 5 they were conducted on an individual patient 6 over the course of one day, yes. 7 BY MR. CASSELLA: 8 Q. Okay. Um, page six of Exhibit 63, 9 there's a heading called Adverse Reactions. 10 And do you see there that the -- 11 Exhibit 63 states that: "The most common 12 adverse events reported in association with the 13 use of ALPHAGAN 0.5% in conjunction with ALT was 14 transient conjunctival blanching in 50% of 15 patients and upper lid retraction in 30% of 16 patients?" 17 A. I can -- 18 Q. Do you see that sentence? 19 A. Yes. 20 Q. So do you have any understanding as 21 to whether the adverse reaction of transient 22 conjunctival blanching was measured over the 23 course of a single day for each patient in these 24 clinical studies? 25 MR. HASFORD: Objection, no	1 Do you see that sentence? 2 A. Yes. I do see that. 3 Q. Okay. And then the next sentence: 4 In these studies, both patients -- patient 5 groups were dosed BID; however, due to the 6 duration of action of ALPHAGAN, it is 7 recommended that ALPHAGAN be dosed TID. (As 8 read) 9 Do you see that sentence? 10 A. Yes. 11 Q. Do you have any understanding as to 12 what those terms "BID" and "TID" refer to? 13 A. Yes. BID is twice a day, and TID is 14 three times a day. 15 Q. Okay. And do you have any 16 understanding as to whether the clinical trials 17 for Alphagan 0.2% lasted up to one year? 18 MR. HASFORD: Objection, no 19 foundation. 20 THE WITNESS: Yeah. I -- I don't 21 know. 22 BY MR. CASSELLA: 23 Q. Are the -- is -- sorry. Let me 24 rephrase. 25 Is the Alphagan 0.2% being measured
1 foundation. 2 THE WITNESS: I don't know. 3 BY MR. CASSELLA: 4 Q. Okay. If we could go to page eight 5 of Exhibit 63? 6 And on page eight of Exhibit 63, the 7 title is ALPHAGAN (brimonidine tartrate 8 ophthalmic solution) 0.2%. 9 Do you see that? 10 A. Uh, you'll have to blow that up for 11 me, please. I see that, yes. 12 Q. Do you have any understanding as to 13 whether this is the label for Alphagan 0.2%? 14 A. I don't know. 15 MR. HASFORD: Objection, foundation. 16 THE WITNESS: Again, I don't know. 17 BY MR. CASSELLA: 18 Q. Okay. If we could go to page nine, 19 there's a heading, Clinical Evaluations, and in 20 the second paragraph under Clinical Evaluations, 21 it states: In comparative clinical studies with 22 timolol 0.5%, lasting up to one year, the IOP 23 lowering effect of ALPHAGAN was approximately 24 4-6 mm of mercury compared with approximately 6 25 mm of mercury for timolol. (As read)	1 in a different -- well, I'm sorry. Let me 2 rephrase. 3 The Alphagan 0.5% that we just 4 reviewed, that was, um, studied in connection 5 with ALT, correct? 6 MR. HASFORD: Object, no foundation. 7 THE WITNESS: In the one example you 8 showed me, that's how it was evaluated, yes. 9 BY MR. CASSELLA: 10 Q. Okay. And here on page nine of 11 Exhibit 63, Alphagan 0.2% is being measured, uh, 12 for its IOP-lowering effects over the course of 13 one year; is that correct? 14 MR. HASFORD: Same objection. 15 THE WITNESS: Um, it says up to one 16 year. 17 BY MR. CASSELLA: 18 Q. So you don't have any understanding 19 as to how long the clinical trials for Alphagan 20 0.2% lasted? 21 A. I do not. 22 MR. HASFORD: Objection. Objection, 23 no foundation, argumentative. 24 BY MR. CASSELLA: 25 Q. On page 11 of Exhibit 63, there's a

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89 1 heading, Adverse Reactions, and do you see in 2 the second paragraph there: "Events occurring 3 in approximately 3-9% of the subjects, in 4 descending order included," and there's a long 5 list of, uh, adverse events, and on the last 6 line, "conjunctival blanching" is listed. 7 Do you see that? 8 A. Yes. 9 Q. So do you have any understanding as 10 to whether conjunctival blanching was measured 11 in this clinical trial of Alphagan 0.2% over the 12 course of one year? 13 MR. HASFORD: Objection, no 14 foundation. 15 THE WITNESS: I -- I don't know when 16 it was evaluated, and it doesn't say one year, 17 which is up to one year, so I -- I really can't 18 state with certainty when it was measured. 19 BY MR. CASSELLA: 20 Q. So you don't know whether the 21 conjunctival blanching would have been measured 22 immediately after the first dose of Alphagan 23 0.2% was administered? 24 MR. HASFORD: Same objection. 25 THE WITNESS: I don't know for	91 1 there states: Two clinical studies were 2 conducted to evaluate the safety, efficacy, and 3 acceptability of ALPHAGAN P 0.15% compared to 4 ALPHAGAN administered three-times-daily in 5 patients with open-angle glaucoma or ocular 6 hypertension. (As read) 7 Do you see that? 8 A. Yes, I do. 9 Q. Is there any indication as to how 10 long the clinical studies of Alphagan P were 11 conducted? 12 MR. HASFORD: Object, foundation. 13 THE WITNESS: Not in this paragraph 14 that you've showed me, no. 15 BY MR. CASSELLA: 16 Q. And in these Alphagan P clinical 17 studies, the patients were dosed three times 18 daily, correct? 19 A. Yes. 20 Q. And in the Alphagan 0.2% clinical 21 studies, which we just discussed, those patients 22 were dosed twice per day; is that correct? 23 A. That's correct. 24 Q. Okay. I think we've been going about 25 an hour.
90 1 certain when this was measured, but in clinical 2 trials, there are generally multiple time frames 3 in which a patient is evaluated, and adverse 4 events are evaluated on each visit. 5 BY MR. CASSELLA: 6 Q. The patients in the Alphagan 0.2% 7 clinical studies were dosed twice per day; is 8 that correct? 9 A. That's correct. 10 MR. HASFORD: Objection. 11 BY MR. CASSELLA: 12 Q. Okay. On page 13 then of Exhibit 63, 13 the title's ALPHAGAN P (brimonidine tartrate 14 ophthalmic solution) 0.15%. 15 Can you see that? 16 A. Uh, not yet. 17 Yes. I see it now. 18 Q. And do you understand whether this is 19 the label for Alphagan P 0.15%? 20 MR. HASFORD: Object, no foundation. 21 THE WITNESS: Uh, I don't know for 22 certain, but I -- I would assume that it is. 23 BY MR. CASSELLA: 24 Q. Okay. On page 14, there's a heading, 25 Clinical Evaluations, and the second paragraph	92 1 Um, would you like to take a break, 2 or would you like to keep going? 3 MR. HASFORD: We can take a break 4 now. 5 THE WITNESS: Okay. 6 MR. CASSELLA: Okay. 7 THE VIDEO TECHNICIAN: Okay. 8 Off record, 5:06. 9 * * * 10 (Whereupon, a short recess was taken.) 11 * * * 12 THE VIDEO TECHNICIAN: Back on record 13 17:17. 14 BY MR. CASSELLA: 15 Q. Could we turn to paragraph 33 of your 16 declaration, Dr. Donnenfeld? 17 Do you see the sentence, you wrote in 18 paragraph 33 of your declaration: "First, a 19 POSA would have concluded that Norden left 20 unanswered the question of whether brimonidine 21 alone could be used to reduce eye redness"? 22 Do you see that sentence? 23 A. Yes. 24 Q. And then a few sentence down, you 25 say: "Because other eye redness relieving drugs

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93 1 were administered before brimonidine, a POSA 2 would have been unable to determine whether 3 Norden's observed reduction in hyperemia, due 4 solely to brimonidine, or if it was due to a 5 synergistic effect of administering brimonidine 6 with an NSAID and corticosteroid, such as 7 diclofenac and prednisolone acetate." 8 A. Correct. 9 Q. Do you see that? 10 And then at the end of that sentence 11 that I just read, you have a footnote, Footnote 12 2, and in that footnote, you cite Exhibit 502, 13 the Middleton reference, uh, which refers to the 14 drug Auvelity, A-u-v-e-l-i-t-y? 15 A. Yes. 16 Q. Correct? 17 A. Yes. 18 Q. The -- oh, sorry. 19 MR. CASSELLA: Eric, could we 20 display -- display Exhibit 502, Middleton? 21 BY MR. CASSELLA: 22 Q. And do you see Exhibit 502 displayed 23 on your screen, Dr. Donnenfeld? 24 A. Yes, I do. 25 Q. And is this the Middleton reference?	95 1 Q. That drug does not treat eye redness, 2 correct? 3 A. Correct. 4 Q. Are either of these two drugs in 5 Auvelity vasoconstrictors? 6 A. Not to my knowledge. 7 Q. Are either of the drugs in Auvelity 8 an Alpha-1 or Alpha-2 agonist? 9 A. Not to my knowledge again. 10 Q. What is your basis for your statement 11 in paragraph 33 that a POSA would have been 12 unable to determine whether Norden's observed 13 reduction in hyperemia was due solely to 14 brimonidine or if it was due to a synergistic 15 effect of administering brimonidine with an 16 NSAID or a corticosteroid? 17 A. Well, again, as I've stated before, 18 the Norden study was poorly controlled. It 19 would never be accepted today into a journal. 20 Um, the statement that I make here is 21 that when you're studying a drug, you don't want 22 to have secondary drugs that may influence the 23 outcome. And in this case, the patient received 24 two other medications that are known 25 anti-inflammatory -- actually, very potent
94 1 A. Um, I can't tell. 2 MR. CASSELLA: Um, maybe, could we go 3 down one more page? 4 THE WITNESS: Yes. 5 BY MR. CASSELLA: 6 Q. Do you see the title there is, Meet 7 the newest antidepressant: 8 dextromethorphan/bupropion (Auvelity)? 9 A. Yes. 10 Q. Okay. And this article was published 11 in October of 2022, correct? 12 A. Yes. 13 Q. So this article would not have been 14 available to a POSA in 2008, correct? 15 A. That's correct. 16 Q. And the Middleton reference discusses 17 the drug Auvelity, correct? 18 A. Yes. 19 Q. That drug, Auvelity, is a combination 20 of dextromethorphan and bupropion, correct? 21 A. Yes. 22 Q. And that drug, Auvelity is, uh, 23 indicated for the treatment of depression; is 24 that correct? 25 A. Yes, it is.	96 1 anti-inflammatories, and the question remained 2 unanswered based on the study on whether or not 3 the brimonidine would have had the same effect 4 if the other two drugs had not been available. 5 Q. Is it your opinion, sir, that 6 brimonidine requires the presence of an NSAID or 7 a corticosteroid to reduce redness? 8 A. No. I just state that this study did 9 not provide that information. 10 Q. Why would a POSA reading Norden have 11 thought that an NSAID or a corticosteroid would 12 have been necessary for brimonidine to reduce 13 redness? 14 A. Um, they would not have known whether 15 or not the brimonidine alone would have been 16 effective unless it was in the setting of two 17 other very well known anti-inflammatories. 18 Q. Would a person of ordinary skill in 19 2008 have any reason to believe that the 20 activity of a vasoconstrictor depended upon the 21 presence of an NSAID or a corticosteroid? 22 A. Um, they would not have known the 23 efficacy, the side effects, the duration of 24 action, um, um, of the, uh, medication in the 25 setting of using other medications that would

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97 1 have had a similar synergistic effect. 2 Q. I'm not sure that was responsive to 3 my question. 4 I asked, would a person of ordinary 5 skill in 2008 have had any reason to believe 6 that the activity of a vasoconstrictor depended 7 upon the presence of an NSAID or a 8 corticosteroid? 9 MR. HASFORD: Objection, 10 argumentative. 11 I'll move to strike the colloquy at 12 the beginning of the question. 13 THE WITNESS: Um, a POSA would have 14 accepted that a, um, vasoconstrictor did not 15 necessar- -- necessarily require other 16 medications to be effective, but a POSA would 17 have discounted the results of this trial 18 because it would not have answered the question 19 on whether the brimonidine played a role in 20 preventing these complications, unless the other 21 medications were -- were present at the same 22 time. 23 MR. CASSELLA: Uh, Erin, could we 24 display -- it's Exhibit 18, Norden? 25 I just, uh, uploaded it.	99 1 there. Good. 2 BY MR. CASSELLA: 3 Q. Okay. So is this the beginning of 4 the Norden reference that's discussed in your 5 declaration? 6 A. Yes, it is. 7 MR. CASSELLA: And if we could go 8 to -- it's page 471. Um, it's the last page of 9 the document. There's a heading, Discussion. 10 BY MR. CASSELLA: 11 Q. And do you see the first sentence 12 under the heading, Discussion, in the Norden 13 reference, Norden states: "These data 14 demonstrate that brimonidine administered before 15 LASIK can significantly reduce subconjunctival 16 hemorrhage as well as the amount of hyperemia"? 17 Do you see that sentence? 18 A. I do see that sentence, yes. 19 Q. Okay. In this sentence, Norden does 20 not say that brimonidine can significantly 21 reduce subconjunctival hemorrhage, as well as 22 the amount of hyperemia in the presence of an 23 NSAID or a corticosteroid, correct? 24 MR. HASFORD: Objection to the extent 25 it mischaracterizes the document.
98 1 THE EXHIBIT TECHNICIAN: My 2 apologies. It's taking a moment. 3 MR. CASSELLA: That's okay. The 4 Internet in this conference room is a little 5 wonky, so I'm not positive that it goes through 6 very quickly. 7 THE EXHIBIT TECHNICIAN: Okay. 8 We have it. One moment. 9 BY MR. CASSELLA: 10 Q. Do you see Exhibit 18 displayed on 11 your screen, Dr. Donnenfeld? 12 A. I do. 13 Q. And do you recognize this exhibit? 14 A. Yes, I do. 15 Q. This is the Norden reference that is 16 discussed in your declaration? 17 A. Well, that's coming up. I believe 18 this is just the table of contents I'm looking 19 at right now. 20 Q. Oh, I'm sorry. 21 MR. CASSELLA: Could we scroll down 22 just one or two pages, uh, to the beginning of 23 the article? 24 Uh, one more page. 25 THE WITNESS: Next page. Next --	100 1 THE WITNESS: Yeah. That -- that's 2 correct. He doesn't mention that. I think if 3 he, uh, considered that, he would have changed 4 the study. 5 BY MR. CASSELLA: 6 Q. Can you point me to any language or 7 paragraph in Norden where he -- it states that 8 the presence of an NSAID or a corticosteroid 9 would be required for brimonidine to reduce 10 redness? 11 A. No. 12 MR. HASFORD: Same objection. 13 THE WITNESS: He -- he certainly 14 doesn't -- does not state that anywhere in the 15 paper, which is, you know, a problem with the 16 paper. Um, I'm certain that a good paper today 17 would contain that information. 18 BY MR. CASSELLA: 19 Q. Are you aware that certain 20 vasoconstrictors were approved by the FDA as 21 redness relievers in 2008? 22 MR. HASFORD: Objection, no 23 foundation. 24 THE WITNESS: I was aware that other 25 medications were used for redness relievers,

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101 1 yes. 2 BY MR. CASSELLA: 3 Q. Do you recall which vasoconstrictors 4 were approved by the FDA for redness relief in 5 2008? 6 MR. HASFORD: Same objection. 7 THE WITNESS: Um, tetrahydrozoline 8 and, uh, hydralazine. 9 BY MR. CASSELLA: 10 Q. What about naphazoline? 11 A. I'm sorry. Naphazoline, yes. 12 Q. What about oxymetazoline? 13 A. I believe so. I'm not certain when 14 that was approved, but certainly that is a 15 redness reliever, yes. 16 Q. And I believe you mentioned the 17 tetrahydrozoline? 18 A. Yes. 19 Q. And those are all vasoconstrictors, 20 correct? 21 A. Yes, they are. 22 Q. And do you have any understanding as 23 to whether those drugs are alpha agonists? 24 A. Uh, they're all alpha-1 agonists, 25 yes.	103 1 redness. 2 Q. And these prior art vasoconstrictors 3 that were approved for the relief of ocular 4 redness worked through alpha agonism? 5 A. Yes. 6 Q. And just to be clear, these prior art 7 redness relievers did not require 8 co-administration of an NSAID or a 9 corticosteroid to achieve this effect, correct? 10 MR. HASFORD: Objection, asked and 11 answered. 12 THE WITNESS: Correct. They were 13 approved in studies in which there was no NSAID 14 or no penicillin use in the studies. They would 15 never have done a study of these medications 16 with -- with those medications available. 17 BY MR. CASSELLA: 18 Q. Can we return to paragraph 35 of your 19 declaration? 20 Do you see in paragraph 35 the 21 sentence, uh: "Second, a POSA would have 22 recognized that, while Norden states that 23 brimonidine was shown to reduce hyperemia, 24 Norden does not differentiate between hyperemia 25 caused by vasodilation as opposed to surgical
102 1 Q. Are they all collective alpha-1 2 agonists? 3 A. Um, I'm not certain, but I believe 4 that they are. 5 Q. Do you have any understanding as to 6 whether some of them were mixed alpha-1, alpha-2 7 agonists? 8 A. I'm not aware. 9 Q. And all of these vasoconstrictors 10 that we just mentioned, naphazoline, 11 oxymetazoline and tetrahydrozoline, those were 12 approved to treat eye redness, correct? 13 A. Yes, they were. 14 Q. And they were approved to treat eye 15 redness alone, correct? 16 MR. HASFORD: Object to the form. 17 THE WITNESS: Um, yes, they were. 18 BY MR. CASSELLA: 19 Q. So for all of those prior art 20 vasoconstrictors, no other active ingredient was 21 required for them to reduce redness; is that 22 correct? 23 A. I believe some of them were used in, 24 uh, combinations, but as stand-alone drugs, yes, 25 they were all approved for the relief of ocular	104 1 trauma causing a small number of red blood cells 2 to enter the subconjunctival space, which would 3 make the eye appear hyperemic." 4 Do you see that sentence? 5 A. Yes, I do. 6 Q. And in the following paragraph -- I'm 7 sorry. 8 In the next sentence, you state: 9 "Based on Norden's disclosure, a POSA would have 10 understood Norden's reference to hyperemia to 11 refer to micro-vessel hemorrhage in the 12 conjunctiva." 13 Do you see that? 14 A. Yes. 15 Q. And then in the following paragraph, 16 paragraph 37, you state that: Hyperemia can 17 refer to either vasodilation or micro-vessel 18 hemorrhaging," and you cite Exhibit 500 Doshi. 19 Is that correct? 20 A. Yes. 21 Q. And the -- your support for that 22 sentence is Doshi's, uh, statement that 23 "Subconjunctival Hemorrhage is generally 24 painless but can appear as diffusely hyperemic." 25 Do you see that?

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105 1 A. Yes. 2 Q. Does Doshi mention micro-vessel 3 hemorrhaging? 4 A. Um, she does not specifically use the 5 word micro-vessel hemorrhages, but she does 6 refer to conjunctival hemorrhages as being 7 hyperemic, and she does differentiate between 8 classic conjunctival hemorrhages, which are very 9 red and very specific versus just ocular redness 10 which she defines as hyperemia. 11 But regardless, this is common 12 nomenclature used by ophthalmologists all over 13 the world that small red blood cells 14 subconjunctivally are viewed hyperemia. The 15 average ophthalmologist says hyperemia is a red 16 eye, and they don't differentiate the cause of 17 the red eye. 18 MR. CASSELLA: Could we display 19 Exhibit, um, 500 Doshi, please? 20 If we could go to the next page and 21 maybe blow up the text a little bit? 22 BY MR. CASSELLA: 23 Q. Do you recognize this document, 24 Dr. Donnenfeld? 25 A. Yes, I do.	107 1 hyperemic? 2 A. Yes. 3 Q. It does not say that subconjunctival 4 hemorrhage always appears as hyperemic, correct? 5 MR. HASFORD: Objection to the extent 6 it mischaracterizes the document. 7 THE WITNESS: No. Subconjunctival 8 hemorrhages are not always hyperemic, um, but 9 they can be. 10 BY MR. CASSELLA: 11 Q. I believe you testified previously 12 that this document, Exhibit 500, Doshi is 13 directed to Subconjunctival Hemorrhage, which is 14 the title of the document, correct? 15 A. Yes. 16 Q. And nowhere in this document does it 17 mention micro-vessel hemorrhaging, correct? 18 MR. HASFORD: Objection to the extent 19 it mischaracterizes the document. 20 THE WITNESS: It doesn't refer to 21 that. It just basically says, is what I just 22 said is, that hemorrhages under the conjunctiva 23 are hyperemia. 24 BY MR. CASSELLA: 25 Q. So is it your opinion,
106 1 Q. Can you point me to where in -- I'm 2 sorry. 3 Let me ask an additional question. 4 What is this document? 5 A. This is an article written by two 6 authors, regarding subconjunctival hemorrhage. 7 Q. Okay. And this is the Doshi 8 reference that you cite in paragraph 36 of your 9 declaration, correct? 10 A. Yes. This is just a reference that 11 documents that clinicians view hemorrhages as 12 hyperemia. 13 Q. And where in this document does it 14 support that statement? 15 A. I'd have to scroll through the 16 article and look at it. 17 Q. Okay. That's fine. 18 MR. CASSELLA: Can you, uh, give 19 Dr. Donnenfeld control? 20 THE WITNESS: "Subconjunctival 21 Hemorrhage is generally painless but can appear 22 as diffusely hyperemic," the fourth line down. 23 BY MR. CASSELLA: 24 Q. So that sentence states that 25 subconjunctival hemorrhage can appear as	108 1 Dr. Donnenfeld, that subconjunctival hemorrhage 2 is the same as hyperemia? 3 MR. HASFORD: Object to the extent it 4 mischaracterizes the witness's testimony. 5 THE WITNESS: Subconjunctival 6 hemorrhages can be differentiated in that they 7 are diffusely or very violaceous red, um, but 8 they don't have to be. They can be just pinkish 9 and appear hyperemic. 10 Um, she describes, um, them as being 11 diffusely hyperemic. That would imply it's, you 12 know, over -- over the entire eye, which is what 13 hyperemia is. It's a -- it's generally a red 14 eye. 15 BY MR. CASSELLA: 16 Q. So, in your opinion, sir, what is the 17 difference between subconjunctival hemorrhage 18 and micro-vessel hemorrhaging? 19 A. Just -- just simply magnitude. The 20 difference between the two of them is the degree 21 of red blood cells. A large amount of blood 22 cells will appear as a very sub-classic 23 subconjunctival hemorrhage. Whereas a small 24 amount of red blood cells will appear to be less 25 red and will be -- and will be kind of just a

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109 1 mildly red eye, which is what we describe as 2 hyperemia. 3 Q. So, again, Doshi states that 4 subconjunctival hemorrhage can appear as 5 hyperemic, correct? 6 MR. HASFORD: Object to the extent it 7 mischaracterizes the document. 8 THE WITNESS: Yes. It -- I agree 9 with the statement. Um, the hemorrhages that 10 I'm talking about, whether they be very overt, 11 large amount of blood, which is a classic 12 subconjunctival hemorrhage, or they can be just 13 a small amount of blood, which is also 14 subconjunctival hemorrhage, but it doesn't have 15 the classic appearance of very violaceous, uh, 16 red eyes. They just appear to be pinkish or 17 hyperemic, and we're talking about exactly the 18 same disease process here. Um, in most cases, 19 they're trauma related, and it's just blood in 20 the subconjunctival hemorrhage space, and the 21 only difference here is the degree of magnitude 22 of the disease. 23 BY MR. CASSELLA: 24 Q. So the larger magnitude is 25 subconjunctival hemorrhage, and the smaller	111 1 cells as hyperemia, which he describes in the 2 very title of his paper, bleeding. He doesn't 3 describe vasodilation anywhere in that paper. 4 He only describes bleeding in the paper. It's 5 actually right in the title that -- that it's -- 6 that it's bleeding, and he describes hyperemia 7 later on in the paper, but nowhere does he 8 mention or describe vasodilation. He only 9 describes hemorrhage, and it's in the title 10 again, itself. 11 BY MR. CASSELLA: 12 Q. And nowhere does Norden reference 13 micro-vessel hemorrhaging, correct? 14 A. Um, he actually does mention 15 micro-vessel hemorrhaging, uh, at the limbus but 16 in a different context. 17 Q. Nowhere does Norden equate 18 micro-vessel hemorrhaging with hyperemia, 19 correct? 20 MR. HASFORD: Object to the extent it 21 mischaracterizes the witness's testimony. 22 THE WITNESS: Um, Norden does not 23 call hyperemia small amounts of red blood cells 24 in the subconjunctival space, but he does define 25 it as -- as bleeding, and bleeding is different
110 1 magnitude is hyperemia? 2 Is that your opinion, sir? 3 A. They're both subconjunctival 4 hemorrhages, but a large amount of hemorrhage is 5 termed a subconjunctival hemorrhage, but a small 6 amount of subconjunctival hemorrhage is also 7 subconjunctival hemorrhage, but it's termed 8 hyperemic, which it appears different. 9 Q. And is this based on your definition 10 of hyperemia as including the accumulation of 11 red blood cells? 12 A. It's not only my definition, it's the 13 definition of most ophthalmologists. 14 Q. And you haven't provided any 15 reference demonstrating that that is the 16 definition used by most ophthalmologists, 17 correct? 18 MR. HASFORD: Objection, 19 mischaracterizes the witness's testimony, 20 argumentative. 21 THE WITNESS: I -- I have no 22 documents that describe this, other than what's 23 written in the Norden article, which is a 24 classic representation of an ophthalmologist 25 causing -- calling small amounts of red blood	112 1 than vasodilation. 2 BY MR. CASSELLA: 3 Q. Are you aware that Dr. Noecker has 4 opined that subconjunctival hemorrhage is unlike 5 hyperemia? 6 MR. HASFORD: Objection, no 7 foundation. 8 THE WITNESS: Yeah. I -- I'm not 9 aware of that. 10 MR. CASSELLA: Can we go back to 11 Dr. Noecker's declaration? 12 It's Exhibit, um, 204. I think it's 13 displayed -- oh, I think it's mislabeled at 024 14 in -- in the PDF viewer. 15 And could we go to paragraph 202, 16 which is on page 72 of the declaration? 17 BY MR. CASSELLA: 18 Q. And do you see that first sentence: 19 "Moreover, unlike hyperemia, which occurs due to 20 the dilation of the intact blood vessels, 21 hemorrhage occurs when a blood vessel ruptures 22 and bleeds." 23 Do you see that sentence? 24 A. Yes, I do. 25 Q. And so in this sentence, Dr. Noecker

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113 1 says that hyperemia is unlike hemorrhage, 2 correct? 3 MR. HASFORD: Objection, no 4 foundation. 5 THE WITNESS: Uh, in reading that 6 sentence, what Dr. Noecker is describing is the 7 dictionary diagnosis of what hyperemia is, what 8 the dictionary description of what hyperemia is, 9 but not the clinical application used by 10 clinicians, especially clinicians who perform 11 LASIK. 12 BY MR. CASSELLA: 13 Q. Have you cited any references in your 14 declaration to support that clinicians 15 performing LASIK use the term hyperemia in the 16 way you've described? 17 A. I'm not aware of any articles that 18 describe this. 19 Q. And, in fact, the only reference that 20 you cite in support of your, uh, definition of 21 hyperemia as referring to either vasodilation or 22 micro-vessel hemorrhaging is Doshi, which is 23 related to subconjunctival hemorrhage, correct? 24 MR. HASFORD: Object to the extent it 25 mischaracterizes.	115 1 And if we could make the text a little bigger. 2 BY MR. CASSELLA: 3 Q. And, um, do you see on page 468 of 4 Norden, under the Conclusion portion of the 5 abstract, Norden states that: "This study 6 suggests that brimonidine administered before 7 LASIK may significantly reduce subconjunctival 8 hemorrhage and reduce the amount of hyperemia." 9 Correct? 10 A. That's exactly what he says, yes. 11 Q. So in that sentence, he refers to 12 subconjunctival hemorrhage and hyperemia 13 separately, correct? 14 MR. HASFORD: Object to the extent it 15 mischaracterizes. 16 THE WITNESS: Um, he refers to 17 subconjunctival hemorrhage, um, and hyperemia as 18 being different, and they are different. They 19 look different, but they're the same disease 20 process, and they're both bleeding, and that's 21 the premise of his article. The title is 22 bleeding. The title is not, uh, vasodilation. 23 These are bleeding abnormalities occurring in 24 patients having LASIK, and they do look 25 different. I do agree with that, but they're
114 1 THE WITNESS: Yeah. That -- that's 2 the only reference that I looked -- I only 3 looked for one, and I'm sure if I looked for 4 others, I might find more, but I actually asked 5 this question of a group of ophthalmologists who 6 perform LASIK, and they uniformly described 7 hyperemia as, um, leaking blood vessels in the 8 subconjunctival space in the setting of LASIK. 9 BY MR. CASSELLA: 10 Q. But you have not provided that 11 information in your declaration, correct? 12 A. I have not. 13 MR. HASFORD: Objection, 14 argumentative. 15 THE WITNESS: Um-huh. 16 BY MR. CASSELLA: 17 Q. Now, Norden actually refers to 18 subconjunctival hemorrhage and hyperemia 19 independently of one another, correct? 20 A. He refers to them actually both as 21 bleeding. 22 MR. CASSELLA: Can we go back to 23 Exhibit 18, Norden? 24 And when we get there, go to page 25 468, which is the first page of the article.	116 1 the same underlying disease process, just 2 different magnitudes of order. 3 BY MR. CASSELLA: 4 Q. And as we had saw earlier in 5 Dr. Noecker's declaration, Dr. Noecker refers to 6 hyperemia as vasodilation and not bleeding, 7 correct? 8 MR. HASFORD: Objection, no 9 foundation. 10 THE WITNESS: What you showed me is 11 exactly what you stated here. Dr. Noecker 12 describes hyperemia according to the dictionary 13 definition of hyperemia, uh, used by scientists, 14 uh, not by clinicians and especially not by 15 LASIK surgeons. 16 BY MR. CASSELLA: 17 Q. If we go to page 469 of Norden, uh, 18 just the next page down, it's the beginning of 19 the Results section, and then -- let me know 20 when you can see that. 21 Okay. Do you see the Results section 22 beginning on page 469, Dr. Donnenfeld? 23 A. Yes, I do. 24 Q. Okay. And then the next page 470 has 25 a Table 1, Table 2 figure and a couple of

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117	1 subsections titled Subconjunctival Hemorrhage, 2 Hyperemia, Superior Micropannus Bleed, and Flap 3 Slippage. 4 Do you see those sections? 5 A. Uh, yes, I do. 6 Q. And so Norden has a separate table 7 for the results related to subconjunctival 8 hemorrhage, correct? 9 A. Yes, he does. 10 MR. HASFORD: Objection, form. 11 BY MR. CASSELLA: 12 Q. And he has a separate table for 13 superior micropannus bleed, correct? 14 A. Yes, he does. 15 Q. And then a separate figure for 16 hyperemia, correct? 17 A. Yes, he does. 18 Q. And he has an individual subsection 19 in this, uh, Results section for each of those, 20 uh, three categories, Subconjunctival 21 Hemorrhage, Hyperemia, and Superior Micropannus 22 Bleed? 23 MR. HASFORD: Object to the form. 24 THE WITNESS: Yes, he does. 25 BY MR. CASSELLA:	119	1 to differentiate between hyperemia caused by 2 vasodilation and the pinkness caused by 3 scattered red blood cells in subconjunctival 4 space due to micro-vessel hemorrhaging," and you 5 cite Exhibit 562, correct? 6 A. Yes. 7 MR. CASSELLA: Could we please 8 display Exhibit 562, which is -- uh, it's titled 9 Picture of Hemorrhage, Exhibit 562? 10 BY MR. CASSELLA: 11 Q. And do you recognize Exhibit 562, 12 Dr. Donnenfeld? 13 A. Yes, I do. 14 Q. Okay. Where did this image come 15 from? 16 A. Um, I just Googled subconjunctival 17 hemorrhage, and I took this off the Internet. 18 Q. So you don't recall what specific 19 website it came from? 20 A. Uh, I do not. 21 Q. And so you provided this image to 22 counsel for purposes of inclusion in your 23 declaration? 24 A. Yes, I did. 25 MR. HASFORD: Object to the question.
118	1 Q. On page 468, uh, just two pages up, 2 under -- or just above the Patients and Methods 3 section, there's a paragraph that begins: This 4 prospective, double-masked trial was designed -- 5 uh, designed to objectively assess the effect of 6 brimonidine administration before LASIK on 7 subconjunctival hemorrhage, hyperemia, and 8 micropannus bleeding. 9 Correct? 10 A. Yes. Three different forms of 11 bleeding. 12 Q. Do you have any understanding as to 13 what, uh, grading scale was used to evaluate the 14 hyperemia in the Norden reference? 15 A. He did not use a grading scale. He 16 just arbitrarily created one of his own without 17 visual representation. He didn't use a -- 18 pictures, which most people use. He didn't 19 describe the location of the, um, hyperemia, 20 and, uh, didn't describe the presence or absence 21 of vasodilation. 22 Q. If we go to paragraph 36 of your 23 declaration, do you see at the end of this 24 paragraph, which ends on the next page, uh, you 25 state that: "Notably, the naked eye is unable	120	1 BY MR. CASSELLA: 2 Q. Okay. Paragraph 37 of your 3 declaration, um, you state that: "Norden 4 indicates that LASIK patients were examined 5 5 minutes post-operatively and again the next 6 morning, which would have been at least 12 hours 7 after surgery and likely longer." 8 And then you state: "Norden's 9 results, however, state that 'the amount of 10 hyperemia. . . was notably lower in patients 11 treated prophylactically with brimonidine' when 12 evaluated the next morning after surgery," 13 correct? 14 A. That's what I said, yes. 15 Q. And you quote Norden in that second 16 sentence that I just recited, correct? 17 A. "Notably lower"? Yes. I -- that's 18 what I was -- that was his description. 19 Q. Yeah. You quote Norden as stating 20 the amount of hyperemia is notably lower in 21 patients treated prophylactically with 22 brimonidine, end quote, correct? 23 A. Yes. 24 Q. The words following that quote do not 25 appear in Norden, "when evaluated the next

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121 1 morning after surgery," correct? 2 MR. HASFORD: Objection, 3 argumentative, and objection to the extent it 4 mischaracterizes the documents. 5 THE WITNESS: No. That was not his 6 writing. That's my interpretation of him 7 describing seeing patients the day following 8 surgery. 9 MR. CASSELLA: Can we go back to 10 Exhibit 18, please, page 469? 11 BY MR. CASSELLA: 12 Q. Do you recall, Dr. Donnenfeld, how 13 many eye examinations Dr. Norden performed? 14 A. I believe he described, uh, two 15 examinations. 16 Q. And on page 469, in the -- uh, one of 17 the middle paragraphs there, Norden states: 18 "Slit-lamp microscopy was performed 5 minutes 19 postoperatively." 20 Correct? 21 A. Uh, if you could just blow that up 22 for me, I'd appreciate it. 23 Yes. 24 Q. And then, uh, a few sentences down in 25 that same paragraph, it states: "For purposes	123 1 examined again the next day. He examined the 2 next day for the study. The study was on 3 hemorrhages. Therefore, a POSA would know that 4 the patient examined the next day had an 5 examination of the hemorrhages that occurred. 6 Q. That sentence does not state that, 7 though, correct? 8 MR. HASFORD: Objection, 9 argumentative. 10 Objection to the extent it 11 mischaracterizes the document. 12 THE WITNESS: It says: For purposes 13 of the study, eyes were examined again the next 14 morning. (As read) 15 BY MR. CASSELLA: 16 Q. It doesn't say whether hyperemia, 17 hemorrhage or bleeding were measured in the 18 five-minute post-op examination, or in the 19 morning-after examination, correct? 20 A. It does not. 21 MR. HASFORD: Objection to the extent 22 it mischaracterizes. 23 THE WITNESS: Yeah. 24 BY MR. CASSELLA: 25 Q. So it's entirely possible that the,
122 1 of this study, eyes were examined again the next 2 morning." 3 Do you see that? 4 A. Yes. 5 Q. So it's -- Norden performed two eye 6 examinations, correct? 7 A. That's what I believe, yes. 8 Q. One was five minutes post-op, and the 9 other was the next morning, correct? 10 A. Correct. 11 Q. In the following paragraph, it 12 states: "The operating surgeon (R.N.) performed 13 the post-operative examinations and recorded the 14 amount of subconjunctival hemorrhage, hyperemia, 15 bleeding from the micropannus, and flap 16 slippage/wrinkling." 17 Do you see that? 18 A. Yes. 19 Q. Where in Norden does it state that 20 the data related to the amount of 21 subconjunctival hemorrhage, hyperemia, and 22 bleeding from the micropannus came from the 23 examination the morning after the operation? 24 A. It says for purposes of the study, 25 which means for the study, the eyes were	124 1 uh, amount of subconjunctival hemorrhage, 2 hyperemia, and bleeding from the micropannus 3 were measured in the five-minute post-op 4 examination, correct? 5 MR. HASFORD: Object. Objection to 6 the extent it mischaracterizes the document. 7 THE WITNESS: No. I mean, that's 8 very bluntly a silly thought; that when you do a 9 study and you say you're examining the patient, 10 you do the same examination on both days unless 11 you differentiate between them -- between them. 12 Um, it said the operating surgeon 13 performed the postoperative examinations, not 14 examination, and recorded the amount of 15 subconjunctival hemorrhage, hyperemia, bleeding 16 from the micropannus, and flap slippage. Uh, 17 that means that he recorded the exact same thing 18 on both examinations. 19 BY MR. CASSELLA: 20 Q. And so it's your opinion, 21 Dr. Donnenfeld, that the results reported in 22 Norden are the results from only a morning-after 23 examination and did not contain any data from 24 the five-minute post-op examination? 25 A. Uh, I don't know the answer to that

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125 1 question. That really is a good question, and 2 it should be in a good paper. It should be 3 there, but it's not written in this paper on 4 whether the results were described for that day 5 or the next day or whether you assume that they 6 were the same. 7 Q. I'm sorry. Could you -- I didn't 8 catch the last part about you're -- 9 A. Sure. 10 Q. -- assuming they were the same. 11 A. Yeah. The -- the surgeon performed 12 two examinations, examining hemorrhages on both 13 examinations. It is not written whether the 14 findings that he presents here are recorded from 15 five minutes postoperatively or the next day or 16 a mean of both examinations or whether the 17 examinations were the same. 18 It's, again, an intrinsic, uh, lack 19 of evidence in the study that basically is a -- 20 is a fairly poor design. You're absolutely 21 right. They should have described what it was 22 like five minutes post-op, and they should have 23 described it the next day, but examinations were 24 performed both days, and they were looking at 25 bleeding. And I cannot tell you exactly what	127 1 mischaracterizes the documents. 2 THE WITNESS: I don't recall 3 specifically whether he -- whether he called it 4 eye redness or not, but by definition, a 5 subconjunctival hemorrhage is redness, but I 6 don't recall him saying specifically redness. 7 BY MR. CASSELLA: 8 Q. So would you agree that the reduction 9 of hemorrhage is a reduction of redness? 10 MR. HASFORD: Same objections. 11 THE WITNESS: A reduction in 12 hemorrhage would be a smaller hemorrhage, but it 13 also could be a larger -- it could be -- the 14 hemorrhage could either be smaller, or it could 15 be less blood in a small amount of area so that 16 a reduction in hemorrhage could mean that the 17 area of the hemorrhage was smaller, or it could 18 also mean that the amount of blood in one space 19 was lower. 20 BY MR. CASSELLA: 21 Q. Would the administration of a 22 vasoconstrictor -- excuse me. 23 Would the administration of a 24 vasoconstrictor before LASIK cause less 25 subconjunctival hemorrhage because the blood
126 1 the bleeding that took place here, whether it 2 took place or was described at five-day or the 3 next day. It just -- that data is just not 4 there. 5 Q. Would a reduction of subconjunctival 6 hemorrhage reduce redness? 7 MR. HASFORD: Objection to the form 8 of the question, incomplete hypothetical. 9 THE WITNESS: I'm sorry. 10 Could you just repeat that one more 11 time, please? 12 BY MR. CASSELLA: 13 Q. Sure. I'll make it more specific. 14 In Norden, he concludes that 15 brimonidine reduced the amount of 16 subconjunctival hemorrhage, correct? 17 A. Yes, he did. 18 Q. If there -- in -- sorry. Let me 19 rephrase. 20 Is the reduction of subconjunctival 21 hemorrhage described in Norden a reduction in 22 eye redness? 23 MR. HASFORD: Object to the form of 24 the question. 25 Object to the extent it	128 1 vessels themselves are smaller? 2 MR. HASFORD: Object to the form of 3 the question, incomplete hypothetical. 4 THE WITNESS: Um, the answer is, that 5 a vasoconstrictor, um, could cause less 6 hemorrhage because the vessels are smaller. It 7 also could mean that the, um, junctions between 8 the, um, endothelial cells are tightened so that 9 there's less leakage of blood out of the eye. 10 So it could be several mechanisms of 11 action, but one of them could certainly be that 12 the vessels were smaller. 13 BY MR. CASSELLA: 14 Q. Okay. I'd like to turn to paragraph 15 40 of your declaration. 16 And do you see paragraph, uh, 40 of 17 your declaration displayed on the screen, 18 Dr. Donnenfeld? 19 A. Yes. 20 Q. And in the last sentence of this 21 paragraph on your declaration, you state that, 22 uh: "Gil focuses on the use of brimonidine to 23 treat ocular pain." 24 Correct? 25 A. Correct.

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129 1 Q. Is there a relationship between 2 ocular pain and ocular redness? 3 A. Um, yes. 4 MR. HASFORD: Object to the form of 5 the question. 6 THE WITNESS: Okay. 7 The answer is that, uh, pain can be 8 associated with redness, or pain could be 9 associated with a lack of redness. 10 As a matter of fact, that's exactly 11 the statement that, uh, Gil makes in the third 12 paragraph of his, um, um, paper. He says that 13 pain can be related to inflammation or ischemia, 14 so that you can have pain with redness or pain 15 without redness. 16 BY MR. CASSELLA: 17 Q. When pain occurs with redness, do you 18 have any understanding as to how that -- sorry. 19 Let me rephrase. 20 So pain can occur with redness, 21 correct? 22 A. That's one of the ways that pain can 23 occur, yes. 24 Q. And can you just explain what -- um, 25 what is happening in the eye when pain occurs	131 1 you discuss in your declaration? 2 A. Yes, it is. 3 MR. CASSELLA: Now, if we could go to 4 column one of Gil. It's, um, just a couple 5 pages down, I think. 6 BY MR. CASSELLA: 7 Q. Do you see in column one of Gil, 8 right around line 10, it says that the 9 "invention relates to the topical application of 10 brimonidine for treating ocular pain and 11 neurogenic inflammation and compositions useful 12 for such application"? 13 A. Yes. I do see that. 14 Q. So Gil says that the invention is -- 15 relates to treatment of both ocular pain and 16 neurogenic information? 17 A. Well, what -- what Gil's describing 18 here is a model of pain or trauma. Um, the 19 model here is a trauma model. Um, I think all 20 the models he has here are trauma models, and 21 the, uh, thought that trauma can be applied to 22 the use of a medication to reduce redness is not 23 applicable. Uh, trauma is something that is -- 24 that we don't use, um, redness relievers for. 25 Trauma is a whole different entity, and all of
130 1 with redness? 2 A. Well, when pain occurs with redness, 3 very commonly it's associated with inflammation, 4 and inflammation can, um, cause pain receptors 5 to be activated, um, and, uh, create a -- 6 create -- and create discomfort. 7 Q. So the inflammation can cause both 8 the pain and the redness? 9 MR. HASFORD: Object to the extent it 10 mischaracterizes the witness's testimony. 11 THE WITNESS: Yeah. Inflammation can 12 cause redness, and inflammation can cause pain. 13 That -- that is correct. 14 BY MR. CASSELLA: 15 Q. Okay. 16 MR. CASSELLA: Could we display 17 Exhibit 36, please, which is the Gil reference? 18 BY MR. CASSELLA: 19 Q. Do you see Exhibit 36 displayed on 20 your screen, Dr. Donnenfeld? 21 A. Yes, I do. 22 Q. And that's U.S. Patent Number 23 6,294,553 to inventor Daniel W. Gil, correct? 24 A. Yes. 25 Q. And this is the Gil reference that	132 1 the descriptions he has here are related to 2 pain, and pain, uh, is not the model that we 3 look for when we look at the invention of a 4 medication used for treating redness. 5 So all the -- you know, all -- 6 everything that's described in the Gil patent 7 relates to pain, and you cannot read anything 8 regarding hyperemia or redness from this patent. 9 Um, hyperemia can be seen with pain, but, um, 10 treating hyperemia in clinical application 11 using, um, vasoconstrictors is not done in the 12 setting of pain. As a matter of fact, it's 13 specifically not supposed to be used in the 14 setting of trauma. 15 So, um, everything here I discounted 16 as not being applicable, uh, to -- to hyperemia. 17 Q. Okay. That was, uh, not related to 18 my question. 19 My question was just in this column 20 one, around line 10, Gil says that the invention 21 relates to the topical application of 22 brimonidine to treat pain and neurogenic 23 inflammation, correct? 24 MR. HASFORD: I'll -- I'll object. 25 I'll move to strike the colloquy at the

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133 1 beginning once again, um, and I'll object as 2 argumentative. 3 THE WITNESS: Um, the field of the 4 invention does state that it is for treating 5 ocular pain and neurogenic inflammation, yes. 6 That -- that is what is stated here, but it's a 7 model that does not apply to ocular redness. 8 BY MR. CASSELLA: 9 Q. And inflammation, specifically 10 neurogenic inflammation, can cause redness, 11 correct? 12 MR. HASFORD: Objection, incomplete 13 hypothetical, and object to the extent it 14 mischaracterizes the document. 15 THE WITNESS: Um, neurogenic 16 inflammation occurs when you have pain, and with 17 pain you can have inflammation. 18 BY MR. CASSELLA: 19 Q. Gil said in column one that pain is 20 "an indicator of injury or tissue damage due to 21 inflammation, ischemia, mechanical or other 22 irritation." 23 Correct? 24 A. Yes. That's true. 25 Q. So pain can be an indicator of damage	135 1 don't necessarily go to the spinal cord, but the 2 statement you made is accurate that there are 3 neurons that are -- um, uh, that are initiated, 4 and they go to a, um, tissue, um, that does 5 respond by creating the sensation of pain. It 6 can go to the brainstem. It can go to the 7 spinal cord. It can go to the brain itself, um, 8 but yes. Um, there has to be a neuron that 9 fires, that goes to a target tissue. 10 Q. I'm looking at, um, column one of Gil 11 around line 35. It just says: "The stimulation 12 of primary afferents leads to action potentials 13 in their axons which propagate to the spinal 14 cord." 15 Correct? 16 A. Yes. That's exactly what he states. 17 Q. Okay. And do you agree with that 18 statement? 19 A. Um, I'm really not a neurologist, so 20 I'm not an expert in, um, um, the neurologic 21 spinal cord basis of pain. I do know a great 22 deal about, uh, pain in the eye itself, but, um, 23 I can't say whether it goes to the spinal cord 24 or elsewhere. 25 Q. Okay. That's fair.
134 1 due to inflammation, correct? 2 A. Yes, or ischemia or mechanical or 3 other irritation. 4 Q. In the next paragraph, beginning 5 around line 20, Gil describes how the, uh, 6 sensation of pain happens in the body; is that 7 correct? 8 I should say -- sorry. Let me just 9 be more clear. 10 In that column one, beginning around 11 line 20, Gil describes how the sensation of pain 12 occurs in the eye, correct? 13 A. Yes, he does. 14 Q. Okay. And the first step leading to 15 the sensation of pain as taught by Gil is the 16 activation of nociceptive primary afferents by 17 some sort of stimuli, correct? 18 A. That -- that is what he states, yes. 19 Q. And primary afferents are nerves or 20 neurons? 21 A. Yes. 22 Q. And this stimulation leads to action 23 potentials in their axons which propagate to the 24 spinal cord? 25 A. Um, you know, pain -- pain receptors	136 1 Now, the next sentence in Gil, he 2 states that the "excited primary afferents 3 release neuropeptides," including substance P, 4 calcitonin gene-related peptide, and 5 neurokinin A at their peripheral terminals. 6 Do you see that? 7 A. Yeah. I do see that. 8 Q. And these "Neuropeptides enhance 9 inflammatory reactions in the injured tissue, 10 contributing to vasoconstrictor, edema, and 11 increased vascular permeability, this phenomena 12 is called 'neurogenic inflammation,'" correct? 13 A. Um, he describes neurogenic 14 inflammation this way. Again, I'm not an expert 15 in substance P, calcitonin gene-related 16 peptides, neurokinin A's, uh, at their 17 peripheral terminals. 18 I do know a great deal about pain, 19 uh, at the ocular surface, but I can't really 20 say the role of these different neuropeptides in 21 causing pain. It's not my area of expertise. 22 Q. So the activation of these primary 23 afferents that we just discussed leads to both 24 the sensation of pain and the release of 25 neuropeptides that cause neurogenic

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137 1 inflammation? 2 A. Um -- 3 MR. HASFORD: Objection that it 4 mischaracterizes the document. 5 THE WITNESS: Yeah. 6 You know, for purposes of what we're 7 speaking here today, I'll define neurogenic 8 inflammation as inflammation of the nerves that 9 go on to cause, uh, additional inflammation 10 which could include, uh, vascular permeability 11 or -- vascular permeability or redness. 12 MR. HASFORD: It does look like we've 13 been going a little over an hour. 14 Would this be a good time for a 15 break? 16 THE WITNESS: Can I -- 17 MR. CASSELLA: Yeah. Why don't we -- 18 we can break, and I don't have too much longer, 19 but it would probably be good to just, uh, take 20 a break now. 21 MR. HASFORD: Okay. That's fine. 22 THE VIDEO TECHNICIAN: We're off the 23 record at 18:19. 24 * * * 25 (Whereupon, a short recess was taken.)	139 1 neuropeptides, correct? 2 A. Yeah. That -- that -- that I would 3 say is yes, but, again, especially in the 4 setting of a trauma model like this, um, there 5 should be additional neuropeptides that are 6 released. 7 Q. Okay. 8 MR. CASSELLA: Can we please display, 9 um, it's Exhibit 601, and it's titled Belmonte. 10 BY MR. CASSELLA: 11 Q. And just let me know when you can see 12 Exhibit 601 displayed on your screen. 13 MR. CASSELLA: I think we -- uh, 14 could we mark it, Erin, as -- uh, with just like 15 a sticker or something 601? 16 * * * 17 (Whereupon, Deposition Exhibit 601 was 18 marked for identification.) 19 * * * 20 MR. CASSELLA: And maybe make the 21 text a little bigger for Dr. Donnenfeld. 22 BY MR. CASSELLA: 23 Q. Okay. Dr. Donnenfeld, do you see 24 Exhibit 601, a reference titled Neurobiology of 25 Ocular Pain, displayed on your screen?
138 1 * * * 2 THE VIDEO TECHNICIAN: Back on record 3 18:28. 4 BY MR. CASSELLA: 5 Q. So, Dr. Donnenfeld, I think we were 6 just discussing the -- well, actually, why don't 7 we just turn to your declaration, paragraph 40. 8 Uh, it's on page 14. 9 And you -- this is the beginning of a 10 subsection E where you state that: A POSA Would 11 Not Have Understood Gil (Ex. 36) to Teach That 12 Topical Administration of 0.2% Brimonidine 13 Reduces Eye Redness. 14 Correct? 15 A. Correct. 16 Q. And we were just discussing the Gil 17 reference, and we were discussing the activation 18 of the primary afferents, correct? 19 A. Yes. 20 Q. And I believe you testified that the 21 activation of the primary afferents leads to the 22 sensation of pain; is that correct? 23 A. That's correct. 24 Q. And the activation of the primary 25 afferents also leads to the release of	140 1 A. Yes, I do. 2 Q. Have you ever seen this document? 3 A. I have not. 4 MR. CASSELLA: Could we go to page 5 119 of Exhibit 601, which, uh, begins on -- it's 6 page three of the PDF? 7 BY MR. CASSELLA: 8 Q. And on the left-hand column -- 9 MR. CASSELLA: Uh, make the text a 10 little bigger, please. 11 BY MR. CASSELLA: 12 Q. Uh, towards the top of the page on 13 the left-hand column, can you read that size 14 text or -- 15 A. I have to go a little larger. 16 All right. That's good. 17 Q. Okay. So the left-hand column on 18 page 119 of Exhibit 601, which, uh, I'll refer 19 to as Belmonte, it states that "ocular pain is 20 an immediate consequence of the activation of 21 trigeminal sensory neurons by various forms of 22 energy (mechanical, thermal and chemical), 23 acting at injurious or near injurious levels." 24 Do you see that? 25 A. Yes, I do.

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141 1 Q. And then the next sentence: "The 2 front of the eye is abundantly innervated by the 3 terminal processes of nociceptive nerve cells. 4 There, noxious stimuli are readily detected, and 5 distinct pain sensations are subsequently 6 evoked." 7 Do you see those sentences? 8 A. Yes, I do. 9 Q. Do you agree with the -- these 10 statements in Belmonte, Exhibit 601? 11 A. No. I -- you know, I really think 12 that they need to be discussed. Uh, when you -- 13 when they speak to the front of the eye, uh, 14 you're speaking of the conjunctival, sclera, and 15 cornea. The cornea is the most innervated 16 portion of the body. It has the most pain 17 receptors and is extraordinarily sensitive to 18 pain. 19 Uh, the conjunctiva, on the other 20 hand has very few pain receptors and is really, 21 uh, a very different tissue than the cornea. 22 The cornea also has no blood supply, whereas the 23 conjunctiva does have blood supply, and the 24 sclera has actually less pain receptors than -- 25 than both of them.	143 1 A. I have no reason to doubt this, but, 2 again, uh, I'm not a neurobiologist, so this is 3 not really my area of expertise. 4 Q. Okay. I -- I understand. 5 Um, I just want to look at a few more 6 paragraphs then, and just you can tell me 7 whether you have an understanding as to what 8 they disclose or not. 9 MR. CASSELLA: Could we go to 10 paragraph -- I'm sorry -- page 138? 11 Uh, it's going to be, uh, 22, page 22 12 of the PDF. Yep. There it is. 13 BY MR. CASSELLA: 14 Q. And do you see up at the top of the 15 page on page 138 of Belmonte there's a section 16 entitled: Changes in Ocular Sensory Neurons 17 Secondary to Ocular Injury and Inflammation, and 18 the subsection immediately, uh, underneath that 19 is subsection 5.1, Inflammatory Mediators 20 Released by Ocular Injury? 21 Do you see that? 22 A. Yes. 23 Q. And in the first sentence underneath 24 that heading, it states that: "Injurious forces 25 acting on body issues, cause cell damage and
142 1 So they are really putting all three 2 parts of the front of the eye together and 3 lumping them together, whereas they're really 4 very different. 5 Q. I see. 6 It's -- uh, so you're -- you're 7 saying that the front of the eye, as used in 8 this paragraph, is, um, somewhat vague? 9 MR. HASFORD: Object to the extent it 10 mischaracterizes the witness's testimony. 11 THE WITNESS: Yeah. I would say it's 12 just not accurate. 13 BY MR. CASSELLA: 14 Q. Do you see the next paragraph: "In 15 addition to signaling injury, primary sensory 16 neurons innervating the eye play other roles in 17 the injury response: they enhance local 18 inflammatory reactions caused by tissue damage 19 through the release of mediators such as 20 neuropeptides from their peripheral nerve 21 endings (neurogenic inflammation)"? 22 A. Yes. 23 Q. And sitting here today, do you have 24 any reason to disagree with that statement in 25 Belmonte?	144 1 destruction and excite nociceptive endings of 2 the affected tissues. Inflammation is a 3 localized protective response that serves to 4 destroy, dilute or wall-off the injurious agent 5 and the injured tissues. It is a complex 6 process involving pain, dilation of peripheral 7 blood vessels, increased vascular permeability, 8 plasma extravasation and migration of leukocytes 9 into the inflamed area." 10 Do you see that sentence or couple of 11 sentences on page 138 of Belmonte? 12 MR. HASFORD: Object to the form. 13 THE WITNESS: I do see that, yes. 14 BY MR. CASSELLA: 15 Q. Okay. And sitting here today, do you 16 have any reason to dispute the -- uh, these 17 statements in Belmonte? 18 MR. HASFORD: Objection, no 19 foundation. 20 THE WITNESS: Uh, actually, I do. 21 And, um, when you speak of injurious 22 forces to the, um, uh, front of the eye, um, 23 they're really talking about acute traumatic 24 injuries to the eye, um, where I believe this 25 would be accurate to go -- again, not my area of

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1 expertise. However, it's very well described 2 that chronic injury to the cornea, uh, and front 3 of the eye actually causes anesthesia, and 4 there's a loss of response, and that's one of 5 the very common sequelae to dry eye in that not 6 only does the eye become dry, but it becomes 7 less sensitive to pain and it releases less 8 inflammatory mediators. 9 So the description they have here I 10 think would apply to an acute traumatic injury 11 such as the trauma models that were described by 12 Gil, but it wouldn't apply to a chronic red eye 13 due to chronic irritation such as dry eye which, 14 uh, your expert described as the most common 15 cause of red eye where there's actually a loss 16 of sensation, and the eye actually produces less 17 inflammation than it would if it was an acute 18 injury. 19 BY MR. CASSELLA: 20 Q. Okay. I appreciate the clarification 21 there. 22 Do you see the next paragraph then: 23 "An initial step in the inflammatory response to 24 injury is the release of neuropeptides from 25 sensory nerve fibers excited by the noxious	145	1 injuries. He -- he speaks to trauma. I think 2 in trauma, um, these steps that are described 3 here are probably fairly accurate, but a trauma 4 model of red eye is something that should not be 5 applied to medications. There's no use of 6 trauma in evaluating a, um, medication for the 7 treatment of red eye. Trauma is a separate 8 tissue and as a matter of fact, trauma is an 9 exclusion for evaluating a medication for the 10 treatment of dry eye or -- or -- I'm sorry, or 11 redness. 12 Q. In the next paragraph of Belmonte it 13 states: In the eye, the inflammatory response 14 consecutive to injury includes dilation of blood 15 vessels which causes increased blood flow, 16 plasma extravasation, breakdown of the 17 blood-aqueous humor barrier, miosis and 18 infiltration of inflammatory cells. Most of the 19 known inflammatory mediators have been found in 20 the conjunctiva and anterior, uh, uveal tissues 21 and in a lesser degree in the retina, during the 22 development of local inflammation. (As read) 23 Do you see that sentence there? 24 A. I do, yes. 25 Q. Do you have any reason to dispute	147
1 stimulation. Neuropeptides in turn initiate 2 local responses acting directly on target cells, 3 or indirectly through the release of other 4 chemical mediators. This phenomenon, called 5 'neurogenic inflammation,' constitutes the first 6 line of defense of the immediate response to 7 injury." 8 Do you see that? 9 A. Yes, I do. 10 Q. Okay. And do you have any reason to 11 dispute these statements from Belmonte? 12 MR. HASFORD: Objection, no 13 foundation. 14 THE WITNESS: Again, not my true area 15 of expertise, but, you know, I do agree that in 16 an acute injury, which is being described here, 17 they are describing an acute injury that these 18 things occur. However, in -- and that's what 19 occurs with pain in general. However, in a 20 chronic irritation, I don't believe that these 21 same issues would apply, uh, such as a 22 chronically red eye. 23 BY MR. CASSELLA: 24 Q. Does Gil relate to chronic injuries? 25 A. No. Gil actually speaks to acute	146	1 those statements from Belmonte? 2 MR. HASFORD: Objection, no 3 foundation. 4 THE WITNESS: Um, yeah. Yeah. The 5 inflammatory response here is in relation to 6 injury, and I think in response to injury, which 7 is trauma, um, uh, most of these findings I 8 would agree with, but, again, I preface my 9 remarks by saying this is not truly my area of 10 expertise. 11 BY MR. CASSELLA: 12 Q. Okay. Fair enough. 13 A. Um-huh. 14 Q. Um, on page 146, I just want to look 15 at a couple more passages from Belmonte. Page 16 146, there's a heading: Other Protective 17 Mechanisms Mediated by Ocular Sensory Neurons. 18 That's the heading of section seven, 19 and then immediately underneath that is a 20 subsection 7.1 entitled Neurogenic Inflammation. 21 Do you see this subsection on page 22 146 of Belmonte? 23 A. Yes. 24 Q. And Belmonte states: As described in 25 Section 5, neurogenic inflammation constitutes	148

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1 the first line of defense of the eye against 2 acute injury. Topical application to the eye of 3 capsaicin or nitrogen mustard or anterior 4 segment mechanical or thermal injury evokes an 5 irritative response characterized by corneal 6 edema, miosis, aqueous humor flare, photophobia, 7 conjunctival vasodilatation -- excuse me -- lid 8 edema and lacrimation, which can be attenuated 9 by denervation or blockade of corneal nerves 10 with local anesthetics or tetrodotoxin. (As 11 read) 12 Do you see that sentence? 13 A. I do. 14 Q. Okay. Do you have any reason to 15 dispute those statements from Belmonte? 16 MR. HASFORD: Objection, no 17 foundation. 18 THE WITNESS: Um, again, what they're 19 describing here is an acute injury. Uh, an 20 acute injury has absolutely nothing to do with 21 management of chronically red eye. So what's 22 being described here is reasonable in the 23 setting of an acute trauma or application of a, 24 uh, toxic substance, but it doesn't really apply 25 to using vasoconstrictors to treat red eyes.	1 Q. Okay. Do you understand CGRP in the 2 sentence that I just read to refer to calcitonin 3 gene-related peptide? 4 A. I'm -- I -- I am familiar with what 5 that -- that says. I'm not that familiar with 6 what it does. 7 Q. Okay. And Gil mentions substance P 8 and CGRP, correct? 9 A. Yes. 10 Q. And those are the same neuropeptides 11 that Gil says are released upon activation of 12 the primary afferents; is that correct? 13 A. Associated with trauma, yes. 14 Q. Okay. 15 MR. CASSELLA: Could we go back to 16 Gil for just a minute, uh, column three of Gil? 17 It's Exhibit 36. 18 Uh, can we make the text a little 19 bigger? 20 And actually, can we display just 21 the -- the very last paragraph in column two? 22 It's the page above, and kind of 23 display both the end of the previous page and 24 the beginning of the next page. 25 BY MR. CASSELLA:
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1 BY MR. CASSELLA: 2 Q. Do you see a couple sentences down 3 Belmonte says the: Selective blockade of the 4 responsiveness of corneal sensor -- sensory 5 fibers to chemical irritants with diltiazem also 6 reduces ocular neurogenic inflammation. (As 7 read) 8 And the next sentence: Neurogenic 9 inflammation is attributable to antidromic 10 release of ocular -- by ocular nerves of 11 neuropeptides (substance P and related 12 tachykinins; CGRP) and perhaps to still unknown 13 mediators released by sensory nerves, which 14 enhance local inflammatory processes. (As read) 15 Do you see those sentences? 16 A. I do. 17 Q. And do you have any reason to dispute 18 those statements from Belmonte? 19 MR. HASFORD: Objection, no 20 foundation. 21 THE WITNESS: Um, I'm not familiar 22 with many of these, um, topics being discussed, 23 so I -- I really don't have an informed decision 24 to give you on this. 25 BY MR. CASSELLA:	1 Q. So in column two on the right-hand 2 side of Gil, it states: "The sites of action 3 are presumed to be in the spinal cord and in the 4 brain, where they can reduce the perception of 5 pain." 6 Do you see that sentence? 7 A. Um, if you could magnify that a 8 little bit, it would be helpful for me. Thanks. 9 MR. CASSELLA: Yeah. Can we blow 10 that up just a little bit? 11 BY MR. CASSELLA: 12 Q. Do you need it to be a little bigger 13 than that or -- 14 A. No, this is fine. 15 I think you oriented me to the 16 paragraph above the -- okay. I see: The 17 sites . . . 18 Okay. Now, I'm -- I'm fine. 19 So, "The sites of action," that's the 20 sentence you're referring to? 21 Q. Yeah. Just to orient you onto where 22 I'm looking at Gil. 23 Do you see that sentence, the end of 24 column two and, uh, kind of one word into column 25 three on the next page?

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153 1 A. Yes. 2 Q. Okay. And then the next sentence 3 on -- in column three says: "One potential 4 mechanism for the alleviation of pain at the 5 level of the spinal cord is the inhibition of 6 the release of chemical mediators of pain, 7 including substance P and calcitonin 8 gene-related peptide." 9 Do you see that sentence? 10 A. I do. 11 Q. And do you have any reason to dispute 12 Gil's statement in that, uh, column three? 13 A. No. I think that in a -- in a pain 14 model, that this would apply, yes. 15 Q. Okay. And Gil says that: This 16 mechanism has been demonstrated in vitro for the 17 alpha-2 agonist, the dexmedetomidine and acting 18 on rat spinal cord slices and for brimonidine 19 (UK 14304) acting on cultured dorsal root 20 ganglion cells. (As read). 21 And then it cites Supowit 1998 and 22 provides the title Alpha-2 adrenergic receptor 23 activation inhibits calcitonin gene-related 24 peptide expression in cultured dorsal root 25 ganglia neurons.	155 1 A. They are, um, uh, neurons that go to 2 the spinal cord, uh, that have to do with, uh, 3 sensation of pain -- sensation and pain. 4 But, again, not my area of expertise. 5 I don't really want to venture too far on this. 6 Q. Okay. Fair enough. 7 A. Um-huh. 8 MR. CASSELLA: Can we display the 9 Exhibit 605 Supowit, please? 10 And could we mark this also, uh, just 11 with, like, a little sticker 605? 12 * * * 13 (Whereupon, Deposition Exhibit 605 was 14 marked for identification.) 15 * * * 16 MR. CASSELLA: Um, and please zoom in 17 so Dr. Donnenfeld can read it. 18 BY MR. CASSELLA: 19 Q. Dr. Donnenfeld, do you see Exhibit 20 605 displayed on your screen right now? 21 A. Yes, I do. 22 Q. And this is a -- I'm sorry. I 23 think -- uh, we're -- oh, okay. We're back. 24 Uh, this is a paper titled 25 a2-Adrenergic receptor activation inhibits
154 1 Do you see that passage in Gil? 2 A. I do. 3 Q. And do you have any reason to dispute 4 that statement from Gil? 5 A. You know, Gil is describing the use 6 of, uh, alpha-2 agonists in reducing pain and, 7 um, while this may apply, uh, systemically, 8 there really has been no use of alpha-2 agonists 9 in, uh, reduction of pain in ophthalmology. 10 This is something that's not done, to my 11 knowledge, by anyone, and I'm not aware of any 12 clinical trials on patients in which this has 13 been done, other than the RK study, which was 14 again a trauma study, but it's certainly nothing 15 that's done today in the management of act- -- 16 of pain. 17 But as far as his description of the 18 pathways that are here, again, not my area of 19 expertise, but I have no reason to doubt what he 20 says. 21 Q. Do you have any understanding as to 22 what dorsal root ganglion cells are? 23 A. Uh, I have a broad understanding, but 24 I really couldn't define it accurately. 25 Q. What is your broad understanding?	156 1 calcitonin gene-related peptide expression in 2 cultured dorsal root ganglia neurons, correct? 3 A. That's the title, yes. 4 Q. And the first author is Scott C. 5 Supowit? 6 A. Yep. 7 Q. And is this the same Supowit 8 reference that was mentioned in Gil in column 9 three that we just discussed? 10 A. I believe so. 11 Q. Okay. In the abstract of Supowit -- 12 MR. CASSELLA: And maybe we could 13 zoom in even further because the abstract text 14 is small. 15 BY MR. CASSELLA: 16 Q. Uh, the abstract of Supowit states 17 that: "Calcitonin gene-related peptide or CGRP, 18 a potent vasodilator, is produced in dorsal root 19 ganglia (DRG) neurons which extend nerves 20 peripherally to blood vessels and centrally to 21 the spinal cord." 22 Do you see that sentence? 23 A. I do. 24 Q. Okay. Do you have any reason to 25 dispute that statement in Supowit?

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1 MR. HASFORD: Objection, no 2 foundation. 3 THE WITNESS: Again, this is not my 4 area of expertise, and, um, in all due respect, 5 we're talking about a pain model here that has 6 nothing to do with the management of red eye as 7 we know it in ophthalmology. So it's certainly 8 some -- some very interesting basic science, but 9 it doesn't have anything to do with what we do 10 clinically. 11 BY MR. CASSELLA: 12 Q. Do you see in the middle of the 13 abstract, um, there's a reference to nerve 14 growth factor (NGF)? 15 Do you see that? 16 A. Uh, which line down is it? 17 Q. Uh, it's like right in the middle, 18 um -- 19 A. Yeah. I see it. Yep. 20 Q. You know, the full sentence -- just 21 so the record's clear, the full sentence in the 22 abstract is: "Using the rationale in vivo DRG 23 neurons receive a continuous supply of target 24 tissue derived nerve growth factor (NGF), which 25 stimulates CGRP synthesis, the cultured neurons	157 1 substance P and neurokinin A) are found in a 2 subpopulation of sensory neurons, mainly in 3 those with small myelinated and nonmyelinated 4 fibers which mediate nociceptive signaling. (As 5 read) 6 Do you see that sentence? 7 A. I do. 8 Q. Okay. And the CGRP, substance P, and 9 neurokinin A are the neuropeptides that were 10 referenced in Gil, correct? 11 A. Yes. 12 Q. And Gil relates to nociceptive 13 signaling, correct? 14 A. Yes, he does. 15 Q. Now, the next sentence in the 16 introduction states: "The cell bodies of these 17 neurons are located in dorsal root ganglia (DRG) 18 and extend nerves that terminate centrally in 19 laminae I/II of the spinal cord and in a variety 20 of peripheral tissues including blood vessels." 21 Do you see that sentence? 22 A. Yes. 23 Q. And understanding that this may not 24 be your particular area of expertise, do you 25 have any reason to dispute this sentence in
158 1 were treated," and it goes on to explain the, 2 um, methods of the study. 3 Do you see that sentence that I just 4 read? 5 A. I do. 6 Q. Okay. And do you have any reason to 7 dispute that nerve growth factor stimulates CGRP 8 synthesis? 9 MR. HASFORD: Objection, no 10 foundation. 11 THE WITNESS: Again, my same 12 response. This is not my area of expertise. It 13 has nothing to do with our clinical use of 14 vasoconstrictors to treat red eyes and 15 ophthalmology. 16 BY MR. CASSELLA: 17 Q. In the introduction heading, it's 18 the -- 19 MR. CASSELLA: On, yeah, the first 20 page of Supowit page 184, um, just scroll down 21 just a little bit. 22 BY MR. CASSELLA: 23 Q. The first paragraph under the 24 Introduction, it states that: Calcitonin 25 gene-related peptide (CGRP, and the tachykinins,	159 1 Supowit? 2 MR. HASFORD: Objection to form, no 3 foundation. 4 THE WITNESS: Yeah. I -- um, I 5 cannot confirm or deny whether this is accurate 6 or not, and I, being an expert in managing red, 7 eyes, don't see any role in how this applies to 8 the routine management of red eyes with -- with 9 vasoconstrictors. 10 So, you know, it -- it certainly is 11 very good basic science. Um, I can say that a 12 POSA in the field of ophthalmology would not 13 have any knowledge of this. 14 BY MR. CASSELLA: 15 Q. Do you see the next sentence: 16 Although the sensory nervous system functions to 17 'sense' stimuli in the periphery, and transmit 18 the information centrally through the afferent 19 pathway, it also possesses an efferent function 20 through the release of neuropeptides from 21 peripheral sensory nerve fibers in response to 22 local stimuli. Thus the release of CGRP (and 23 substance P) from the sensory nerve terminals in 24 the dorsal horn of the spinal cord modulates 25 pain transmission, while release from terminals

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1 in peripheral tissues plays as key role in	1 dispute that statement from Supowit?
2 neurogenic inflammation. (As read)	2 MR. HASFORD: Objection, no
3 Do you see that sentence?	3 foundation.
4 A. I do.	4 THE WITNESS: Um, actually, I believe
5 Q. Do you have any reason to dispute	5 this to be accurate, and, um, I am familiar with
6 that sentence in Supowit?	6 this, uh, again mostly applied to a pain model
7 MR. HASFORD: Objection, no	7 which, um, everything, um, in his article refers
8 foundation.	8 to pain and not to red eye.
9 THE WITNESS: I -- I really can't	9 BY MR. CASSELLA:
10 comment on this. This is not my area of	10 Q. Okay.
11 expertise.	11 MR. CASSELLA: If we could go to page
12 BY MR. CASSELLA:	12 190?
13 Q. Okay. Fair enough.	13 BY MR. CASSELLA:
14 A. Um-huh.	14 Q. And in the discussion section, uh,
15 Q. Um, the next page, page 185 --	15 it's further down on the left-hand column, it
16 MR. HASFORD: You know, I'm going to	16 states that: "The results of the present study
17 have to ask you at this point, Chris, how much	17 demonstrate that the a2-adrenergic receptor
18 more of this are you going to do based on his	18 agonist UK 14,304 can attenuate the stimulatory
19 previous answers to these questions?	19 effects of NGF on CGRP mRNA accumulation and
20 Because it's -- it's getting	20 iCGRP levels in primary cultures of adult DRG
21 borderline, um, problematic here.	21 neurons."
22 MR. CASSELLA: He's responded to some	22 Do you see that sentence?
23 of them with substantive testimony. I just want	23 A. Yes. And, uh, I have no expertise in
24 to understand what his --	24 this area and cannot comment on this as being
25 MR. HASFORD: You -- you've heard	25 accurate or not accurate. It has nothing to do
162	164
1 what he's been saying. I mean, you know, if --	1 with what we do to manage red eyes.
2 because we're going -- we're going to have to --	2 Q. Do you understand that UK 14,304 is
3 to cut this off at some point.	3 the compound brimonidine?
4 MR. CASSELLA: Well, uh, this is my	4 A. No. Was not aware of that.
5 time. So unless you're trying to halt the	5 Q. Do you --
6 deposition, I think we're just going to keep	6 A. Still my -- my answer -- my answer's
7 going.	7 the same, though. I don't know the stimulatory
8 We'll just -- I'm not trying to keep	8 effects of NGF on CGRP mRNA accumulation. Um,
9 the witness here all night. I want to -- you	9 this is, um, in -- this is basic scientist
10 know, I want to get this over with as quickly as	10 [sic], uh, not clinical medicine.
11 possible, so we don't have that much more.	11 Q. Do you recall whether Gil references
12 MR. HASFORD: Yeah. Okay. Well,	12 UK 14,304 as brimonidine?
13 this is a complete waste of time. I'm going to	13 A. I believe he does. I'd have to go
14 put that on the record.	14 back and look again, but I do believe that's
15 So go ahead.	15 accurate.
16 MR. CASSELLA: Noted for the record.	16 Q. Okay. On page 191 -- oops. Sorry.
17 BY MR. CASSELLA:	17 I lost my column there.
18 Q. Uh, page 185, on the left-hand	18 Do you see on the bottom right-hand
19 column, the middle paragraph states: Activation	19 column of page 191, it states: "Therefore our
20 of a2-adrenoreceptors on afferent nerve terminals	20 observations --"
21 at the periphery can also inhibit neuropeptide	21 A. I'm sorry. I apologize.
22 release.	22 Where am I looking?
23 Do you see that?	23 MR. CASSELLA: Uh, I think we need to
24 A. Yes, I do.	24 scroll further down on 191. It's at the very
25 Q. Okay. And do you have any reason to	25 bottom of page 191 in the right-hand column.

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165	1 Uh, yeah. 2 BY MR. CASSELLA: 3 Q. Towards the very bottom there: 4 "Therefore" -- it states: "Therefore, our 5 observations that an a2-agonist can inhibit both 6 the production and release of a very potent 7 vasodilator in sensory neurons suggests one 8 possible mechanism which could account for the 9 reduced neuronal expression of CGRP." 10 Do you see that sentence? 11 It continues onto the next page. 12 A. I do. 13 Q. Okay. And one more time: Do you 14 have any reason to dispute that sentence in 15 Supowit? 16 MR. HASFORD: Objection, no 17 foundation. 18 THE WITNESS: Um, I -- yeah. I would 19 agree that an a2-agonist can, um, be a 20 vasodilator or it can be a vasoconstrictor. I 21 don't know how it applies in reference to this, 22 uh, paper. 23 Again, this is a basic science paper 24 written 25 years ago in a publication called 25 Brain Research. Um, it's about as far away from	167	1 Q. Do you recall -- could you -- I'm 2 sorry. I'm going to rephrase. 3 Um, what order of magnitude was the 4 compensation? 5 Was it the order of hundreds of 6 dollars? 7 MR. HASFORD: Objection to the form 8 of the question. 9 THE WITNESS: Um, I don't recall 10 exactly. It was, um, several hundred thousand 11 dollars, but I can't recall directly. 12 BY MR. CASSELLA: 13 Q. Dr. Donnenfeld, do you have any notes 14 with you? 15 A. No, I do not. 16 Q. Do you have any documents with you in 17 the room? 18 A. I do not. 19 Q. Did you discuss the substance of your 20 testimony at any point with counsel today? 21 A. Um, not subsequent to us starting 22 this conversation today. I did before -- you 23 know, earlier on, before we spoke to you. 24 Q. Okay. Fair enough. I have no 25 further questions.
166	1 what I do on a clinical basis as could possibly 2 exist. 3 BY MR. CASSELLA: 4 Q. Do you agree that the decreased 5 activity of CGRP-containing nerves could 6 facilitate adrenergic vasoconstriction and thus 7 contribute to the elevated peripheral vascular 8 resistance? 9 MR. HASFORD: Objection, no 10 foundation, incomplete hypothetical. 11 THE WITNESS: Yeah. I can't comment 12 on that. 13 BY MR. CASSELLA: 14 Q. Uh, earlier, you testified that you 15 had been found liable in a med-mal case; is that 16 correct? 17 A. Yes, I was. 18 Q. Were you required to compensate the 19 plaintiff in that case? 20 A. Uh, yes. There was a -- um, um, 21 there was an award given. And again, um, just 22 for the record, it was a case in which I was not 23 guilty, but, again, a jury found differently, 24 but there was compensation that was made, and I 25 can't recall exactly what the number was.	168	1 Thank you, Dr. Donnenfeld. 2 A. Thank you. 3 MR. HASFORD: A little bit of 4 follow-up. 5 * * * 6 EXAMINATION 7 * * * 8 BY MR. HASFORD: 9 Q. Um, good evening, Doctor. 10 A. Good evening. 11 Q. Earlier today, um, Mr. Cassella asked 12 you, uh, whether you reviewed, um, Dr. Galanis's 13 deposition transcript. 14 Do you remember that? 15 A. Yes, I do. 16 Q. I believe you either didn't recall or 17 you may have answered that you didn't think you 18 did. 19 Um, let me direct your attention to 20 page five of your declaration and in particular 21 paragraph 17. 22 MR. HASFORD: Let's pull that up on 23 the screen. 24 BY MR. HASFORD: 25 Q. Take a look at paragraph 17, and then

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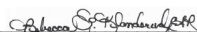
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169	171
1 let me know when you're ready. 2 A. I am, yes. 3 Q. How, if at all, does paragraph 17 of 4 your declaration refresh your recollection as to 5 whether you reviewed Dr. Galanis's deposition 6 transcript? 7 MR. CASSELLA: Objection, leading. 8 MR. HASFORD: What's -- what's 9 leading about that question? "How if at all?" 10 That's not leading at all. I'll 11 reask the question. 12 BY MR. HASFORD: 13 Q. How, if at all, does paragraph 17 of 14 your declaration refresh your recollection as to 15 whether you reviewed Dr. Galanis's deposition 16 transcript? 17 A. Yeah. Now, I do -- now, I do recall 18 reviewing it, uh, for this declaration. I can't 19 remember the specifics of it, and I haven't 20 reviewed it over the last couple days, but I 21 need to go back and look at that again, but yes, 22 I did review this. 23 Q. All right. Take a look now, if you 24 would, at paragraph 30 of your declaration on 25 page nine.	1 We are off the record 19:09. 2 MR. HASFORD: So we'll take a rough 3 as soon as you can get it to us, and then 4 obviously a final, um, ASAP, given that we've 5 got a hearing coming up in a little over 36 6 hours. 7 THE COURT REPORTER: Okay. Very 8 good. Thank you, Mr. Hasford. 9 And how about for you, Mr. Cassella? 10 MR. CASSELLA: Yeah. The same, as 11 soon as possible. 12 THE COURT REPORTER: Okay. I will do 13 my best to get this to you as soon as I possibly 14 can. 15 Thank you, everyone. 16 * * * 17 (Whereupon, the deposition was 18 concluded at approximately 7:09 19 p.m. EST.) 20 * * * 21 22 23 24 25
170	172
1 I believe you were asked a similar 2 question about Mr. Cassella about Dr. Galanis's 3 declaration in addition to his deposition 4 transcript. 5 Do you remember that? 6 A. Yes, I do. 7 Q. Okay. Take a look at paragraph 30, 8 and let me know when you're ready. 9 A. I am ready. 10 Q. How, if at all, does paragraph 30 of 11 your declaration refresh your recollection as to 12 whether you reviewed Dr. Galanis's declaration 13 in this matter? 14 A. Yes. I do recall reading about his 15 position on conjunctival blanching, yes. 16 MR. HASFORD: Nothing further from 17 us. 18 MR. CASSELLA: Okay. 19 THE VIDEO TECHNICIAN: Okay. 20 Anything else for the record? 21 MR. HASFORD: Not from me. 22 Thank you, Dr. Donnenfeld. 23 THE WITNESS: Thank you. 24 THE VIDEO TECHNICIAN: This concludes 25 the videotape deposition of Dr. Eric Donnenfeld.	1 DEPOSITION ERRATA SHEET 2 3 Our Assignment No. 522606 4 Caption: In Re Lumify 5 6 DECLARATION UNDER PENALTY OF PERJURY 7 I declare under penalty of perjury 8 that I have read the entire transcript of 9 my Deposition taken in the captioned matter 10 or the same has been read to me, and 11 the same is true and accurate, save and 12 except for changes and/or corrections, if 13 any, as indicated by me on the DEPOSITION 14 ERRATA SHEET hereof, with the understanding 15 that I offer these changes as if still under 16 oath. 17 Signed on the _____ day of 18 _____, 20____. 19 20 21 22 23 24 _____ 25 ERIC D. DONNENFELD, M.D.

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