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Transcript of Eric D. Donnenfeld, M.D.

Date: January 21, 2024
Case: Lumify, In Re:

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WORLDWIDE COURT REPORTING & LITIGATION TECHNOLOGY

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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE LUMIFY | Civil Action No. 21-16766 (RK) (RLS) (CONSOLIDATED)

EXPERT VIDEOCONFERENCE DEPOSITION TESTIMONY OF
ERIC D. DONNENFELD, M.D.
SUNDAY, JANUARY 21, 2024
ROSLYN, NEW YORK

* * *

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Job No.: 522606
Pages 1 - 175
Reported by:
Rebecca Klanderud, RPR, CSR

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Expert Videoconference Deposition Testimony of ERIC D. DONNENFELD, M.D. taken via remote communication with the witness being located in Roslyn, New York on Sunday, January 21, 2024, commencing at approximately 3:04 p.m. EST before Rebecca L. Klanderud, a Registered Professional Reporter and Certified Shorthand Reporter.

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ALSO PRESENT:

Alan Ross, videographer
Erin Schuppert, exhibit technician

* * *

(All present appeared via remote communication.)

* * *

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THE VIDEO TECHNICIAN: Good afternoon.

We are on the record in the videotaped deposition of Dr. Eric Donnenfeld in the matter of Lumify in re before the United States District Court for the District of New Jersey, Case Number 21-16766 (RK) (RLS) (Consolidated).

Today's date is January 21, 2024, the time on the video monitor is 15:04 Eastern.

The videographer today is Alan Ross representing Planet Depos, and this video deposition is taking place remotely.

Will counsel please state their appearances for the record?

MR. CASSELLA: Good morning.

This is Christopher Cassella from the law firm Goodwin Procter representing the defendants in this matter.

MR. HASFORD: Justin Hasford of Finnegan on behalf of the plaintiffs.

THE VIDEO TECHNICIAN: The court reporter today is Rebecca Klanderud, representing Planet Depos.

The witness will now be sworn.

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THE COURT REPORTER: Good afternoon, everyone. This is Rebecca, the court reporter for today's deposition.

Do counsel stipulate and agree that I may administer the oath remotely, and that the oath so given is valid for purposes of this deposition, please?

Mr. Cassella?

MR. CASSELLA: I do.

THE COURT REPORTER: Thank you, sir.

Mr. Hasford?

MR. HASFORD: So stipulated.

THE COURT REPORTER: Thank you, sir.

Doctor, would you kindly raise your right hand, sir?

(The court reporter administered the. oath to ERIC D. DONNENFELD, M.D.)

THE WITNESS: Yes, I do.

THE COURT REPORTER: Thank you, sir.

THE WITNESS: Thank you.

THE COURT REPORTER: Counsel, you may proceed.

MR. CASSELLA: Thank you.

ERIC D. DONNENFELD, M.D.,
a witness in the above-entitled matter,

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having been first duly sworn,
testified on his oath as follows:

* * *

EXAMINATION

* * *

BY MR. CASSELLA:

Q. Good morning or good afternoon, Dr. Donnenfeld.

A. Yes.

Q. As you just heard, my name is Christopher Cassella. I represent the defendants in this litigation, and I'll be taking your deposition this afternoon.

Could you please state and spell your full name for the record?

A. My name is Eric Donnenfeld, E-r-i-c, D-o-n-n-e-n-f-e-l-d.

Q. And where are you located today?

A. Today I'm at my home which is 5 Verity Lane, Roslyn, New York.

Q. Is there anyone else in the room with you?

A. No, there is not.

Q. Do you have any applications open on your computer other than the Zoom application?

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A. I do not.

Q. Do you have your cell phone near you?

A. I do.

Q. Is it turned on or off?

A. It's on, but it's muted.

Q. Okay. If you get any text messages related to the substance of your testimony today, will you please alert me to that fact?

A. Yes, I will.

Q. You've been deposed before, correct?

A. Yes, I have.

Q. About how many times?

A. I would guess around a dozen.

Q. When was the last time?

A. Um, a year and a half ago.

Q. Okay. So you're probably pretty familiar with the way depositions work. Uh, nonetheless, I'm going to go over just a few ground rules just to make sure we're on the same page today.

During the course of your deposition, your counsel may make objections.

You understand that unless you've been instructed specifically not to answer, you must answer my questions to the best of your

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ability?
A. Yes, I do.
Q. And as you know, we have a court reporter transcribing everything that's being said today. This means that you and I must both make an effort to speak slowly and clearly so that the court reporter can transcribe every word.
Do you understand?
A. Yes, I do.
Q. And we also need to be sure to give verbal answers to make sure we have a clear written record. So no head nods or hand gestures.
Do you understand?
A. Yes.
Q. I will try to take a five- to ten-minute break every hour or so. We can take a longer break if you need it. We can take, uh, breaks more frequently than that if you'd like. Just let me know. Uh, the only thing that I ask is that if there's a question pending, please answer the question before we break.
Do you understand?
A. Yes.

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Q. Please listen carefully to my questions, and let me know if you don't understand them. If you answer my question, I will assume that you understood it.
Is that fair?
A. Yes, it is.
Q. And do you understand that you're not permitted to discuss the substance of your testimony with counsel during the breaks in the deposition today?
A. Yes, I do.
Q. Is there any reason you can't testify truthfully and completely today?
A. No, there is not.
Q. You just said you've been deposed about a dozen times before, correct?
A. Yes.
Q. What did those cases involve?
MR. HASFORD: And I'll just caution you, Eric. Don't disclose the details of anything that would have been under an obligation of confidentiality in any of those cases.
THE WITNESS: Of course.
I've been deposed in malpractice

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cases, um, as an expert and as a defendant. I have been, uh, deposed in several cases involving product litigation as well.
BY MR. CASSELLA:
Q. Have you ever been deposed in a patent case?
A. Yes, I have been.
Q. What did those patents involve?
MR. HASFORD: Same caution.
THE WITNESS: Yeah.
One patent was regarding, um, a Femtosecond laser, and one patent was regarding a device for treating lid margin disease.
BY MR. CASSELLA:
Q. So two patent cases to the best of your recollection?
A. Correct.
Q. And both of those patent cases involved, um, devices?
A. Yes, they did.
Q. They did not involve methods of treatment?
A. Correct.
Q. Which side did you represent in those cases, the patentee or the patent challenger?

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A. The patentee.
Q. In both?
A. Yes.
Q. And did you testify at trial in those patent cases?
A. No, I did not.
Q. Have you ever testified at trial?
A. Yes, I have.
Q. And would that have been related to one of your medical malpractice cases?
A. Correct.
Q. And when you said you were a defendant in a med- -- med-mal case, does that mean you were accused of medical malpractice?
A. That's correct.
Q. What was the outcome of that litigation?
A. Um, I had one verdict against me, and I was found not guilty in the other four.
Q. So were there multiple, uh, cases consolidated?
A. No.
MR. HASFORD: Object to the extent it mischaracterizes the witness's testimony.
THE WITNESS: No.

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BY MR. CASSELLA:
Q. Can you explain what you mean by there was one verdict against you and four, uh, had found you not guilty?
A. There were four cases I was involved in that went to trial in which I was found not guilty.
Q. So those were all stemming from different incidents?
A. Yes.
Q. And the one that you were found guilty in, do you remember the name of that case?
MR. HASFORD: Objection, mischaracterizes the witness's testimony.
THE WITNESS: I don't recall. It was over -- over 25 years ago.
BY MR. CASSELLA:
Q. Did it relate to your practice as an ophthalmologist?
A. Yes, it did.
Q. Do you recall which jurisdiction that case was filed in?
A. I don't recall specifically, no.
Q. Would it have been in the State of

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New York?
A. Yes, it was.
Q. Okay. Dr. Donnenfeld, did you do anything to prepare for your deposition today?
A. Yes, I did.
Q. What did you do to prepare for your deposition today?
MR. HASFORD: I'll just caution you, Eric. Don't disclose the substance of any communications you had with counsel.
THE WITNESS: Okay. Yeah.
I reviewed my notes -- um, well, not my notes. I reviewed the, um, depositions of Dr. Dana. I reviewed, um, my review of some of the records that were involved, and I did speak with counsel.
BY MR. CASSELLA:
Q. You reviewed some of the records that were involved.
Can you explain what you mean by that?
A. I reviewed the papers that were referenced in the trial such as the Norden paper, and I reviewed, um, my declaration and Dr. Dana's deposition as well.

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Q. And you say you met with counsel to prepare for your deposition today?
A. We spoke by Zoom.
Q. Thank you for that clarification.
Who did you meet with over Zoom?
A. I met with, uh, Justin.
Q. And when did you meet?
A. Um, this morning.
Q. For how long did you meet?
A. Oh, two and a half hours.
Q. Did you review any documents in preparation for your deposition, other than the ones you mentioned a few minutes ago?
A. No.
Q. So you did not review any of plaintiffs' experts' declarations other than your own?
A. I did not.
Q. Have you ever reviewed any of plaintiffs' declarations?
A. I have not.
Q. Other than Mr. Hasford, did you discuss the substance of your testimony with anyone else?
MR. HASFORD: Objection,

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mischaracterizes the witness's testimony.
THE WITNESS: I only discussed it with, uh, Justin. There was another lawyer on the line, uh, I believe Ryan, but, um, really did not discuss anything with him.
BY MR. CASSELLA:
Q. Would that have been Mr. O'Quinn?
A. I don't recall his last name.
Q. Did you speak with anyone at Eye Therapies or Bausch & Lomb in preparation for your deposition today?
A. No.
Q. What about in preparing your declaration?
A. No.
Q. Have you ever spoken with any of plaintiffs' other experts in this litigation?
A. No.
Q. Do you know any of the plaintiffs' other experts in this litigation?
A. Yes, I do.
Q. Who do you know?
A. Dr. Noecker.
Q. And how do you know him?
A. He's one of my partners.

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Q. How?
Can you explain what you mean by that?
A. We practice in the same group of ophthalmologists in Connecticut. I was not able aware he was involved in this however, and I have not spoken with him about this.
Q. So when did you first learn that Dr. Noecker was involved with this litigation?
A. About a week ago.
Q. And you've never spoken to Dr. Noecker about this litigation?
MR. HASFORD: Objection, asked and answered.
THE WITNESS: That's correct. I have not spoken with him about this.
BY MR. CASSELLA:
Q. Dr. Donnenfeld, when were you first contacted regarding this matter?
A. I would estimate about 10 days ago.
Q. And so that would have been around January 10th?
A. I don't recall specifically. I could check my notes if you'd like an exact date.
Q. Do you recall who first contacted

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you?
A. I do not.
Q. Do you recall what you were asked to do when you were first contacted about this matter?
MR. HASFORD: Uh, you can answer that question yes or no, but don't disclose the substance of any communications you had with counsel.
THE WITNESS: Yes. I was asked to review a --
MR. HASFORD: Whoa, whoa, whoa.
You -- Eric, you can't disclose the substance of any communications you had with attorneys.
THE WITNESS: Yes.
BY MR. CASSELLA:
Q. Did counsel ask you to prepare a declaration when they first contacted you?
MR. HASFORD: You can answer that yes or no.
THE WITNESS: Yes.
BY MR. CASSELLA:
Q. Have you ever served as an expert -- um, sorry. Let me rephrase that.

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Have you ever served as an expert with the firm, Finnegan, before?
A. Oh, no.
Q. Have you ever served as an expert for Bausch & Lomb before?
A. No.
Q. Have you ever received any sort of financial compensation from Bausch?
A. I have received compensation from them for, um, uh, consulting.
Q. Can you explain what you mean by that?
A. Um, I've been involved in advising Bausch & Lomb in, uh, ophthalmic matters and have met with many members of Bausch & Lomb to discuss, um, opportunities in ophthalmology, and I've also been involved in consulting in a similar fashion with 50 other companies.
Q. And so Bausch & Lomb has paid you to work as a consultant in connection with a drug-development program.
Is that fair?
MR. HASFORD: Object to the extent it mischaracterizes the witness's testimony.
THE WITNESS: I've been involved in

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Bausch -- with Bausch & Lomb in working on both pharmaceutical and surgical devices.
BY MR. CASSELLA:
Q. Has Bausch ever funded any of your research?
A. No.
Q. Has Bausch ever paid you to do a promotional presentation or a talk?
MR. HASFORD: Object to the form of the question.
THE WITNESS: Yes, they have, as well as 50 other companies have done the same.
BY MR. CASSELLA:
Q. Approximately how much money have you received from Bausch in total?
A. It would be difficult to estimate, but I would guess around $15,000.00 over the course of my career.
Q. Have you ever moderated a panel for Bausch?
A. Yes.
Q. How many times?
A. Six.
Q. When was the last one?
A. I did a panel discussion on Friday in

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Hawaii for Bausch & Lomb.
Q. This past Friday, as in two days ago?
A. Yes.
Q. In Hawaii?
A. Yeah. I take it back. Actually, it was Thursday, three days ago.
Q. And that was in Hawaii?
A. Yes, it was. We have a national meeting there called Hawaiian Eye Meeting, and it's attended by approximately 700 ophthalmologists.
Q. Lucky you.
What was the subject of the panel that you moderated for Bausch at that meeting in Hawaii?
A. It involved dry eye.
Q. Did it involve treatments for dry eye?
A. Yes, it did.
Q. Did you or anyone on the panel discuss using brimonidine to treat dry eye during that panel?
MR. HASFORD: Object to the form.
THE WITNESS: No, I did not.
BY MR. CASSELLA:

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Q. You did not.
Did anyone on the panel?
MR. HASFORD: Same objection.
THE WITNESS: No. No one discussed brimonidine.
BY MR. CASSELLA:
Q. Do you recall whether any of the panels that you've moderated for Bausch discussed brimonidine or its uses?
MR. HASFORD: Object to the form of the question.
THE WITNESS: To my knowledge, I've never discussed brimonidine with Bausch & Lomb.
BY MR. CASSELLA:
Q. Did Bausch & Lomb pay for your travel to Hawaii for this meeting?
A. No, they did not.
Q. Dr. Donnenfeld, you're here to testify as an expert witness on behalf of the plaintiffs in this litigation, correct?
A. Yes.
Q. And you submitted a declaration in support of plaintiffs' motion for a preliminary injunction.
Is that right?

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A. That is correct.
Q. Okay.
MR. CASSELLA: Erin, could we please display -- I've marked it as Exhibit 600. It's Declaration of Eric D. Donnenfeld, M.D., is the file name.
* * *
(Whereupon, Deposition Exhibit 600 was marked for identification.)
* * *
BY MR. CASSELLA:
Q. Do you see a document displayed on your screen, Dr. Donnenfeld?
A. Yes, I do.
Q. And do you recognize this document?
A. Yes, I do.
Q. What is this document?
A. Uh, this is the first page of what I believe to be, um, a deposition -- I'm sorry -- a, uh, um, declaration, uh, by me -- thank you. I can read it better. I appreciate that -- um, in support of plaintiffs' motion.
Q. Just for your benefit, Dr. Donnenfeld, if you'd like to request control of the screen, I believe you can, you know,

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manipulate the document as we're discussing it. You can scroll and kind of, you know, work -- work the document yourself, if you'd like, or the technician can, uh, do it for you. Just whatever's -- whatever's easiest for you. I just wanted to let you know that you have that option available.
A. Thank you. I'm in control now.
Q. Okay. Perfect.
Could you please go to page 18 of Exhibit 600, which is your declaration?
A. Page 18?
Q. Yes, please.
A. Unfortunately, there is no page 18.
MR. HASFORD: Eric, I think it was right there on your screen for a second.
THE WITNESS: Is this page 17?
BY MR. HASFORD:
Q. The one you're --
THE WITNESS: Okay.
MR. CASSELLA: Erin, can we make the document to, like, enable scrolling instead of the --
THE WITNESS: There we go. Okay. Page 18, yes.

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BY MR. CASSELLA:
Q. Okay. We got there eventually.
Uh, is this your signature on page 18, Dr. Donnenfeld?
A. Yes, it is.
Q. And by affixing your signature to this declaration, were you attesting that the contents of the declaration were truthful?
A. Yes.
Q. Do you have any corrections to your declaration that you'd like to make?
A. No, I do not.
Q. Who drafted this declaration?
A. Um, the law firm interviewed me. We spoke at great length. They drafted the declaration. I reviewed it. I made many changes and sent it back to them.
Q. So Finnegan provided you the first draft of this declaration.
Is that fair?
A. Correct.
MR. HASFORD: Objection.
He said -- it mischaracterizes the witness's testimony.
THE WITNESS: The first written draft

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was -- was given to me by them, yes.
BY MR. CASSELLA:
Q. Did you draft any first draft of any portions of this declaration?
A. I did a verbal discussion with them, but did not draft anything in the first draft that was written.
Q. Okay. If we could go to -- I believe the next page will be Exhibit A to your declaration or I'm sorry. I guess it's Appendix A.
And is this Appendix A, the following page, is that a copy of your CV?
A. Yes, it is.
Q. Okay. Do you have any updates to your CV since you submitted this declaration?
A. I've had a new paper accepted, but it's not relevant.
Q. What was the subject of the paper?
A. Um, it was, uh, a new drug for dry eye.
Q. Was that drug a redness reliever?
A. Uh, no, it was not.
Q. Now, this declaration relates to U.S. Patent number 11,833,245.

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Is that right?
A. I don't know for certain. I trust that is correct, though.
Q. I -- I will represent to you that that is the full, uh, number of the patent.
Do you mind if we refer to that in the shorthand as the '245 patent?
A. That would be fine.
Q. Okay. The '245 patent is the subject of your declaration?
A. That is correct.
Q. Can we go to paragraph 14 of your declaration, please?
A. I have it.
Please, if you could magnify that, that would be helpful, or if I can magnify that.
That's great. Thank you.
MR. CASSELLA: Could we enable the scrolling on the document so that it doesn't flip to the next page every -- like, so that he can, you know, the bottom -- the top of one page at the same time as the bottom of another?
Do you know what I'm saying, Erin?
THE EXHIBIT TECHNICIAN: Yes, I understand. That's enabled. It's right here.

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I'm sorry.
MR. CASSELLA: Okay. Okay.
THE EXHIBIT TECHNICIAN: Um, right there, do you see that?
MR. CASSELLA: Okay. I was looking -- I just want him -- I just want him to be able to, you know, see two pages at once if he needs to.
Okay. Thank you.
BY MR. CASSELLA:
Q. Uh, so paragraph 14, Dr. Donnenfeld, that's the beginning of the subsection of your declaration entitled Person of Ordinary Skill in the Art?
A. Yes.
Q. Did you come up with the definition of the person of ordinary skill in the art?
A. I did this in conjunction --
MR. HASFORD: Object to the form of the question.
THE WITNESS: I did this in conjunction with the law firm.
BY MR. CASSELLA:
Q. Did Finnegan provide the definition of the person of ordinary skill in the art, to

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you?
MR. HASFORD: Objection, mischaracterizes the witness's testimony.
THE WITNESS: Uh, they assisted me, as I'm not a lawyer. They provided me with the legal terms that needed to be applied.
BY MR. CASSELLA:
Q. Okay. For purposes of your deposition today, can we refer in the shorthand as person of ordinary skill in the art as POSA, P-O-S-A?
A. Yes.
Q. Okay. If you could flip to Exhibit [sic] B to your declaration, which looks like it begins on page 58 of the PDF, maybe page 59 of the PDF.
Okay. Here we are, Appendix B.
What is Appendix B to your declaration, Dr. Donnenfeld?
A. This is a study that was performed that documents that, um, with topical anesthesia, there can still be redness.
Q. Uh, I'm sorry.
I was asking, what -- what is Appendix B to your declaration?

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A. Uh, this is a supporting document, um, for my declaration.
Q. And this lists the materials that you considered in preparing your declaration; is that correct?
A. Yes.
Q. So you consider the '245 patent.
Is that right?
A. Yes.
Q. And under the heading, Production Documents, you've got Exhibit 18 and Exhibit 36.
Do you recognize those as the Norden and Gil references respectively?
A. Yes, I do.
Q. And if you could scroll down just a little bit under Other Materials?
A. Thank you.
Q. So you've listed there the Huang reference, Middleton reference, Doshi, two Aslanides references, and a picture of an eye with hemorrhage, correct?
A. Yes.
Q. And you've also listed under Deposition Transcripts, the depositions of Dr. Galanis and Dr. Dana, correct?

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A. Those are listed. I don't believe I reviewed the Galanis deposition, however.
Q. Okay. So you've never seen the transcript of the deposition of Dr. Galanis?
MR. HASFORD: Objection, mischaracterizes the witness's testimony, mischaracterizes the document.
THE WITNESS: That's correct. I don't believe that I have reviewed the Galanis deposition.
BY MR. CASSELLA:
Q. Okay. But you did review the deposition transcript of Dr. Dana; is that correct?
A. That's correct.
Q. Okay. Under Expert Declarations, then, you list the declaration of Dr. Galanis and the declaration of Dr. Dana.
Is that right?
A. Yes.
Q. Did you review the declaration of Dr. Galanis?
A. I don't believe so.
Q. Okay. Did you review the declaration of Dr. Dana?

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A. Yes, I did.
Q. Are there any materials that you considered in preparing your declaration, that are not listed in Appendix B?
A. No.
Q. So you've not reviewed any of defendants' other experts' declarations?
A. Correct.
Q. Same for plaintiffs' other experts' declarations?
A. Correct.
Q. Okay. If you could go to -- I believe it's the next page, Appendix C to your declaration?
And does Appendix C to your declaration list the test- -- the previous testimony from the last four years?
A. That's correct.
Q. Okay. Are there any updates to this list of previous testimony?
A. No.
Q. Dr. Donnenfeld, to the best of your recollection, has any court ever discounted your opinions?
MR. HASFORD: Object to the form of

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the question, assumes facts not in evidence.
THE WITNESS: Not to my knowledge, no.
BY MR. CASSELLA:
Q. Okay.
MR. CASSELLA: And could we please display -- it's Blephex v Pain Point, Exhibit 602, please?
* * *
(Whereupon, Deposition Exhibit 602 was marked for identification.)
* * *
BY MR. CASSELLA:
Q. And just before we turn to that, Dr. Donnenfeld, is the first, uh, case listed in your Appendix C to your declaration is Blephex v Pain Point Medical Systems, number 3:16-cv-00410; is that correct?
A. Correct.
Q. Okay.
MR. CASSELLA: And if we could display Exhibit 602?
BY MR. CASSELLA:
Q. Have you ever seen this document, Dr. Donnenfeld?

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A. Not that I recall, no.
Q. Do you see in the upper left-hand corner the case caption which is Blephex v Pain Point Medical Systems, and do you see the case number in the upper right-hand side 16-cv-0410?
A. Yes, I do.
Q. Okay. Is this the same Blephex v Pain Point case that was listed in exhibit -- or Appendix C to your declaration?
MR. HASFORD: Objection, no foundation.
THE WITNESS: Yeah. I don't know. Um, I've been involved with one case with Blephex versus Pain Point, but I don't recognize this document.
BY MR. CASSELLA:
Q. Do you recall whether you testified in the Blephex v Pain Point case?
A. Yes, I did.
Q. Okay. You were serving as an expert in that case?
A. Yes.
Q. Did you submit an expert report in connection with that case?
A. I don't recall.

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Q. Did you opine on matters relating to claim construction in that case?
A. I don't recall specifically, no.
Q. Okay.
MR. CASSELLA: Could we go to page nine of the order, Erin, or if Dr. Donnenfeld has control, whoever could flip to page nine, please?
BY MR. CASSELLA:
Q. Do you see at the top of page nine of Exhibit 602 the first sentence says: "Blephex primarily relies on the declaration of Dr. Eric Donnenfeld, an ophthalmologist"?
A. Yes.
Q. Is that you, sir?
A. Yes.
Q. Okay. And then it -- the opinion -- the order lists -- describes the main point that you were making in the -- uh, sorry. Let me rephrase that.
The next sentence of the order references your expert testimony that you provided to the court in that case, correct?
A. Uh, I believe so, but I don't recall it specifically.

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Q. Okay. And do you see a few sentences in the middle of the -- of page nine here, it says: "The Court, therefore, discounts Donnenfeld's opinion that a POSITA would not understand 'swab' to be absorbent"?
A. I see that, yes.
Q. Okay. And then the court cites the SkinMedica v the Histogen case and quotes that case as saying, "conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court."
Do you see that?
A. I do.
Q. So does this document refresh your recollection as to whether any court has discounted your opinions, Dr. Donnenfeld?
MR. HASFORD: Objection, no foundation, assumes facts not in evidence.
THE WITNESS: Um, I stand by what is written here. What is written is correct, and I don't recall ever hearing this before. Uh, this is new information for me, but the statement is correct. Whether POSITA would understand that, um, is a different matter that I can't really, uh, relate to, but, uh, the facts are correct,

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and I've never seen this document before.
BY MR. CASSELLA:
Q. Okay. Why don't we go back to your declaration now, and specifically at paragraph 22?
MR. CASSELLA: Is someone -- oh, sorry. Okay.
BY MR. CASSELLA:
Q. Okay. In paragraph 22 of your declaration, you state that: "The claims of the '245 patent are directed, generally speaking, to methods for reducing eye redness in a human subject having ocular hyperemia, consisting of topically administering an ocular drop consisting of 0.025% weight by volume of brimonidine as the sole active ingredient."
Do you see that sentence in paragraph 22?
A. Yes, I do.
Q. And it's your understanding that the '245 patent generally -- generally relates to methods of reducing eye redness?
A. Yes, I do.
Q. But you state in paragraph 22 that the claims are directed to methods for reducing

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eye redness consisting of administering brimonidine, correct?
MR. HASFORD: Object to the extent it mischaracterizes the document.
THE WITNESS: Yeah.
I state it re- -- it -- it's relevant to using brimonidine as an ocular drop of 0.025% percent as the sole active ingredient.
Q. Are you aware of the phrase "consisting of" appearing in the claims of the '245 patent?
MR. HASFORD: Object to the extent it's calling for a legal conclusion.
THE WITNESS: Um, could you repeat the question again, please?
BY MR. CASSELLA:
Q. Yeah. Sure. I'm not -- let me try to do this another way.
You reviewed the '245 patent, correct?
A. Yes, I did.
Q. Why don't we just make this easy?
I'm going to display the '245 patent. Just one moment.
MR. CASSELLA: Erin, do I need to

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drop this in the upload folder, probably, for you to be able to display it?
THE EXHIBIT TECHNICIAN: That's correct, um, unless you wanted to share it from your computer.
MR. CASSELLA: I'll just upload it really quickly.
Yeah. It should be uploaded.
THE EXHIBIT TECHNICIAN: Great. One moment.
BY MR. CASSELLA:
Q. Okay. So you reviewed Exhibit 1, which is the '245 patent, correct, Dr. Donnenfeld?
A. Yes, I have.
Q. Okay. And do you see Exhibit 1, the '245 patent displayed here on the screen?
A. Yes, I do.
Q. Okay.
MR. CASSELLA: Erin, could we go to the very last page, I believe, which shows the claims of the '245 patent?
Uh, maybe the previous page so that we can see claim one. And maybe zoom in a little bit so that we can see the text a little

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easier.
Um, it must be further down. Um, further down. Sorry. It's probably below Example 5 there. Yeah. Okay.
BY MR. CASSELLA:
Q. Do you see the line beginning around line 35 on the right-hand side that says: "The invention claimed is," Dr. Donnenfeld?
A. Yes.
Q. Okay. And do you understand --
A. Yes, I do.
Q. Oop. Sorry.
A. Yes, I do.
Q. Do you understand that the patent claims are what follow that sentence?
A. Yes.
Q. And you reviewed these claims in connection with your declaration?
A. Yes, I did.
Q. Or at least you reviewed claims 1, 2, and 15?
A. Correct.
Q. Okay. In claim 1, do you see that the phrase "consisting of" appears twice in the claim?

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A. Yes.
Q. Okay. And has counsel instructed you as to the meaning of the phrase "consisting of" in patent law?
MR. HASFORD: Object to the extent it, uh, calls for a legal conclusion.
And, um, I'll object and caution you, Eric, don't disclose the substance of any specific communications you may have had with counsel.
THE WITNESS: I don't recall specifically any discussion regarding "consisting of," other than that it's a legal, uh, decision, but I'm not aware of exactly the legal meaning of that word in this patent.
BY MR. CASSELLA:
Q. So is it fair to say, Dr. Donnenfeld, you have no opinions as to the meaning of the phrase "consisting of" as that appears in claim 1?
MR. HASFORD: Same objections.
THE WITNESS: Nothing that I'm certain of.
BY MR. CASSELLA:
Q. And so you have no opinions as to the

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impact of that phrase "consisting of" on the scope of the claims?
MR. HASFORD: Objection to the extent it calls for a legal conclusion.
THE WITNESS: Again, not being a lawyer, um, I don't recall exactly what the significance of that word means in this patent claim.
BY MR. CASSELLA:
Q. Okay. Um, Dr. Donnenfeld, you were not asked to opine on the ultimate question of obviousness of the '245 patent.
Is that right?
A. Could you rephrase that?
I don't understand what you're saying.
Q. Do you have any opinions in your declaration on whether the claims of the '245 patent would have been obvious to a POSA?
MR. HASFORD: Object to the form.
THE WITNESS: Um, I believe it is obvious to a POSA that the patent, uh, here was for using this medication to treat ocular redness.
BY MR. CASSELLA:

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Q. Your declaration is responding to the declaration of Dr. Dana, correct?
A. Um, I'd have to look at exactly what was written by Dr. Dana to see how I responded.
Q. Can you point me to where in your declaration you stated that the claims of the '245 patent would not have been obvious to a person of ordinary skill in the art?
MR. HASFORD: Object to the form of the question.
THE WITNESS: I believe that it is obvious to a POSA that the patent, um, is applicable. I don't believe I had said anything differently.
Could we review my declaration, please?
BY MR. CASSELLA:
Q. Sure. I just want to -- I'm just asking where in your declaration you make that conclusion, because I don't see that conclusion explicitly stated in your declaration.
A. That's -- that's why I'd have to review my declaration.
MR. HASFORD: I'll -- I'll just object to the extent it mischaracterizes.

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THE WITNESS: I don't recall specifically. I'd have to review my declaration to look for this.
BY MR. CASSELLA:
Q. Okay. Dr. Donnenfeld, are you aware that a different U.S. Patent was asserted against defendants in this litigation?
A. Um, are you speaking to the defendant?
Q. Are you aware that plaintiffs have asserted a different patent other than the '245 patent against the defendants in this litigation?
A. I was not aware specifically of another patent. I have not -- not seen another patent.
Q. Okay. So you've reviewed no other patents other than the '245 patent in connection with your declaration or your deposition today?
A. That's correct.
MR. HASFORD: Objection, mischaracterizes.
BY MR. CASSELLA:
Q. So you've never reviewed U.S. Patent number 8,293,742?

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A. Correct. I have not reviewed that patent.
Q. And so you're not aware that the defendants' petitioned the USPTO for inter partes review of that '742 patent?
A. I was not aware of that, no. I was aware that they were contesting this patent. That's all I am aware of.
Q. Okay. Fair enough.
And so you're not aware that the PTAB invalidated that '742 patent?
MR. HASFORD: Objection, mischaracterizes the record.
Object to the form of the question.
THE WITNESS: I'm not aware of any other patents that are involved.
BY MR. CASSELLA:
Q. And so you're not aware that the PTAB, in its final written decision invalidating the '742 patent, discussed several prior art references?
MR. HASFORD: Objection, mischaracterizes the record, no foundation.
THE WITNESS: I am aware that there are several papers that have been published

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that, um, the, uh, defendant is using to try and invalidate this patent, which I find not -- not rational.
BY MR. CASSELLA:
Q. But you're not aware, sir, that the PTAB discussed some of those references in its final written decision invalidating the '742 patent; is that correct?
MR. HASFORD: Objection. Objection. Mischaracterizes the record, asked and answered, no foundation.
THE WITNESS: I'm not aware.
BY MR. CASSELLA:
Q. Okay. So you have not reviewed the PTAB's final written decision; is that correct?
MR. HASFORD: Same objections.
BY MR. CASSELLA:
Q. I don't think I heard an answer, Dr. Donnenfeld.
A. That's correct. I'm not aware of this document.
Q. Okay.
MR. CASSELLA: Uh, would now be a good time for a break?
I'm sort of at a natural stopping

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point.
MR. HASFORD: That's fine.
THE WITNESS: Fine with me. I'm ready to go, but I'm also fine to stop.
MR. CASSELLA: Let's take just five minutes, then.
THE VIDEO TECHNICIAN: We're off the record at 15:56.
* * *
(Whereupon, a short recess was taken.)
* * *
THE VIDEO TECHNICIAN: Back on record 16:03.
BY MR. CASSELLA:
Q. Welcome back, Dr. Donnenfeld.
A. Thank you.
Q. If we could please turn to Section II B of your declaration, which begins on page seven and paragraph 26.
Do you see Section II B displayed on your screen?
A. I see that now, yes.
Q. Okay. And in Section II B of your declaration, you state that "A POSA Would Have Understood that Eye Redness and Eye Pain Are

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Different."
Is that correct?
A. That's correct.
Q. In paragraph 27 of your declaration, you say: "Eye redness, also known as ocular hyperemia, is a common ophthalmic condition caused by vasodilation of conjunctival blood vessels or the accumulation of red blood cells in the conjunctiva."
Do you see that?
A. Yes, I do.
Q. Dr. Donnenfeld, are you aware that this definition of ocular hyperemia is different from the definition of ocular hyperemia that Dr. Noecker provided in his declaration?
MR. HASFORD: Objection, no foundation, assumes facts not in evidence.
Object to the extent it mischaracterizes the materials.
THE WITNESS: Uh, I'm not aware of that. I have not reviewed Dr. Noecker's deposition, but it's very common for, uh, clinicians to view hyperemia as redness, uh, due to either vasodilation or red blood cells.
BY MR. CASSELLA:

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Q. And so you're not aware that Dr. Noecker defined hyperemia as only vasodilation?
You do not mention the accumulation of red blood cells?
A. It doesn't surprise me --
MR. HASFORD: Same -- same objections.
THE WITNESS: It doesn't surprise me that Dr. Noecker says that. That's the scientific destin- -- uh, definition, uh, used by many scientists, which Dr. Noecker is one of them, but it's not what's done clinically in ophthalmology, and it's certainly what Dr. Norden states in his paper.
BY MR. CASSELLA:
Q. So you're applying a different definition of ocular hyperemia than Dr. Noecker?
MR. HASFORD: Objection, mischaracterizes the witness's testimony and the documents.
Objection, no foundation.
THE WITNESS: I'm not aware of Dr. Noecker's deposition.
BY MR. CASSELLA:

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Q. Are you aware of when Dr. Noecker submitted his declaration in connection with this preliminary injunction proceeding?
A. No.
Q. Are you aware of when Dr. Galanis and Dr. Dana submitted their declarations in response to Dr. Noecker's declaration?
A. No, I'm not.
Q. Who proposed the definition of ocular hyperemia in paragraph 27 of your declaration?
A. I did.
Q. Did you draft that sentence in paragraph 27?
A. Yes.
Q. Are you aware of how similar it is to Dr. Noecker's definition?
MR. HASFORD: Objection, no foundation, assumes facts not in evidence.
THE WITNESS: Um, no, I'm not, but I'm certain that the, uh, accumulation of red blood cells in the conjunctiva was stated by me. Um, at the discussion, uh, I added that to what was, uh, written the first time around, after my discussion.
BY MR. CASSELLA:

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Q. So, originally, the accumulation of red blood cells was not part of the definition of ocular hyperemia in your declaration?
MR. HASFORD: Object. Object to the extent it mischaracterizes the witness's testimony, um, no foundation.
THE WITNESS: In the first draft, um, after my discussion, this was not included, and I thought that that was something that needed to be added as it's very relevant to this case.
BY MR. CASSELLA:
Q. And so the addition to the definition that you propose, "the accumulation of red blood cells," that was your original, um, opinion?
A. That's always been my opinion, yes.
Q. And that addition, "the accumulation of red blood cells," that is what you say in your declaration is what Dr. Norden was referring to when he referred to hyperemia in his paper?
A. Um, I believe very strongly that Dr. Norden was talking about red blood cells when he talked about hyperemia, as it's, uh, implicit in his title of his paper.
Q. And so you're not aware, sir, because

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you have not read Dr. Noecker's declaration, you're not aware that Dr. Noecker has never asserted that the noted reference in referring to hyperemia was referring to the accumulation of red blood cells, correct?
MR. HASFORD: Object to the form.
Object to the extent it mischaracterizes, argumentative.
THE WITNESS: Yeah. I would, um, say that he did not include that. As Dr. Noecker doesn't perform LASIK, I wouldn't think he would be knowledgeable on the subject. This is my area of expertise.
BY MR. CASSELLA:
Q. So is it your opinion, sir, that one would have to have knowledge of LASIK or have experience performing LASIK in order to understand that hyperemia means the accumulation of red blood cells?
MR. HASFORD: Objection, mischaracterizes the witness's testimony, argumentative, assumes facts not in evidence.
THE WITNESS: No. I don't think you have to have that -- that basis, but I think it's very helpful to have that information.

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BY MR. CASSELLA:
Q. So is it your opinion, sir, that Dr. Noecker did not have that information when he formed his opinions in this case?
MR. HASFORD: Objection, no foundation, assumes facts not in evidence.
THE WITNESS: I don't know what -- what Dr. Noecker's thought process was here, but as a scientist, Dr. Noecker was following the traditional, uh, definition of hyperemia. So he's accurate in, uh, saying that hyperemia can be caused by vasodilation of conjunctival vessels, but it, uh, also does not include the hyperemia definition used by the majority of clinicians, including Dr. Norden, that red blood cells can produce hyperemia, and most ophthalmologists view hyperemia as simple redness.
BY MR. CASSELLA:
Q. You don't cite any evidence in paragraph 27 of your declaration to support that most ophthalmologists view hyperemia as simple redness; is that correct?
MR. HASFORD: Object to the extent it mischaracterizes the declaration, argumentative.

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THE WITNESS: Uh, I do not have a reference in that paragraph that states that fact. However, um, being a clinician, speaking on the podium on LASIK for 30 years, and being one of the inventors of the procedure, I've been involved in multiple discussions regarding redness and LASIK surgery. And, um, in conversations, overwhelmingly, ophthalmologists view red blood cells under the conjunctiva that makes the eye appear red, as hyperemia.
MR. CASSELLA: Okay. Can we please display the exhibit that I just uploaded?
It's the declaration of Robert J. Noecker, M.D., MBA.
BY MR. CASSELLA:
Q. And you have never seen this document before, correct?
A. My answer's still no.
Q. So I will represent to you that this is a complete copy of the declaration of Dr. Noecker that was submitted in connection with this preliminary conjunction proceeding, specifically, his opening declaration.
MR. CASSELLA: If we can go to paragraph 43?

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It's on page ten of the document, page 15 of the PDF.
BY MR. CASSELLA:
Q. And do you see in paragraph 43 of Dr. Noecker's declaration, he states that: "Red eye, also known as ocular hyperemia, refers to a common ophthalmic condition caused by vasodilation - an increase in the diameter of blood vessels on the eye and the influx of blood that 'congests' the vessel."
Do you see that sentence?
A. I do.
Q. And so you would agree with me, Dr. Donnenfeld, that Dr. Noecker, in paragraph 43 of his declaration, does not mention the accumulation of red blood cells?
MR. HASFORD: Objection, no foundation.
Object to the extent it mischaracterizes the document.
THE WITNESS: Uh, I agree he does not mention red blood cells, uh, but what he writes here is correct. It's just a limited definition. I don't think he goes far enough to describe, uh, other causes -- uh, other causes

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or other diagnoses of ocular hyperemia.
BY MR. CASSELLA:
Q. Okay. If we could flip back to your declaration, specifically in paragraph 29, and do you see in paragraph 29 the first sentence there: "Eye pain, also known as ocular pain, is caused by damage or inflammation to pain receptors in the eye - i.e., nerves, which are completely different anatomical structures from blood vessels."
Do you see that sentence?
A. Yes.
Q. Would you agree, Dr. Donnenfeld, that inflammation can cause pain?
A. Yes, I --
MR. HASFORD: Objection --
THE WITNESS: I agree. Yes. I agree that inflammation is one of the causes of pain.
BY MR. CASSELLA:
Q. And specifically ocular inflammation can cause ocular pain; is that correct?
MR. HASFORD: Same objection.
THE WITNESS: Yes. That's true.
BY MR. CASSELLA:
Q. And would you agree with me,

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Dr. Donnenfeld, that ocular inflammation can also cause ocular redness?
MR. HASFORD: Same objection.
THE WITNESS: Yes. Ocular inflammation can cause redness.
BY MR. CASSELLA:
Q. And so you would agree that ocular inflammation can cause ocular hyperemia?
MR. HASFORD: Same objection.
THE WITNESS: Yes. Ocular inflammation can cause hyperemia.
BY MR. CASSELLA:
Q. Okay. In a few sentences down in sort of the middle-ish of paragraph 29 of your declaration, you write that: "Inflammation of nerves in the eye can lead to eye redness by causing adjacent blood vessels to become inflamed. Inflammation of nerves in the eye themselves, however, do not cause eye redness."
Do you see those two sentences there?
A. Yes.
Q. Okay. So you would agree that inflammation of nerves in the eye can lead to eye redness, correct?
A. Yes. Inflammation of the nerves can

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lead to eye redness, but there are many causes of eye redness.
Q. But in the next sentence you say: "Inflammation of nerves in the eye themselves, however, do not cause eye redness."
A. Yes.
Q. Can you explain what you mean by that second sentence which follows the one where you said, "Inflammation of nerves in the eye can lead to eye redness"?
A. Yes. Inflammation of the nerves that are not adjacent, uh, or has synaptic connections to red blood cells -- to, um, um, vessels, does not necessarily cause redness. You can have inflammation and not have eye redness.
Q. So how does inflammation of nerves lead to eye redness?
A. Um, there are multiple mechanisms in which inflammation can lead to eye redness, um, but, um, they can be due to the release of different chemical mediators, um, but that's, um, kind of beyond the scope of my description here. You know, the fact is that inflammation can cause redness, or it does not necessarily

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cause redness.
Q. So is it fair to say that your opinion is that the inflammation of nerves in the eye does not directly cause eye redness?
MR. HASFORD: Object to the extent that it mischaracterizes the witness's testimony.
THE WITNESS: Yeah. I would say very strongly that if there was no blood vessels available, even with inflammation, there would be no redness.
For example, in the case of ischemia, which is a common cause of pain, you can have inflammation and not have redness at all. As a matter of fact, the eye is extremely white.
BY MR. CASSELLA:
Q. Would you agree that inflammation of nerves in the eye can indirectly cause eye redness by causing adjacent blood vessels to become inflamed?
MR. HASFORD: Object to the form of the question.
THE WITNESS: Yes.
Inflammation, um, can have a secondary effect of causing, uh, blood vessels

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to become inflamed and red.
BY MR. CASSELLA:
Q. Are you familiar with the term "allergic conjunctivitis"?
A. Yes, I am.
Q. What is allergic conjunctivitis?
A. Allergic, uh, conjunctivitis is generally a, uh, um, antigen antibody, um, um, reaction in which, um, the conjunctiva becomes inflamed.
Q. And does the inflammation associated with allergic conjunctivitis cause eye redness?
MR. HASFORD: Objection, incomplete hypothetical.
THE WITNESS: Yes. The inflammation associated with, um, um, allergic conjunctivitis can cause eye redness, assuming that there are vessels there that can become inflamed.
BY MR. CASSELLA:
Q. You've written about allergic conjunctivitis before, correct?
A. Yes, I have.
MR. CASSELLA: Erin, could we please display -- it's, um, Exhibit 603. Uh, it's -- the file name is Carr, C-a-r-r, Exhibit 603.

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* * *
(Whereupon, Deposition Exhibit 603 was marked for identification.)
* * *
BY MR. CASSELLA:
Q. Is the text size big enough for you, Dr. Donnenfeld?
A. Unfortunately, no.
Q. It's barely -- barely big enough for me, so --
A. Okay. Now --
Q. Okay. Um, do you recognize this document which we've marked as Exhibit 603, Dr. Donnenfeld?
A. Yes, I do.
Q. What is this document?
A. This is a paper that I, uh, was a co-author on that, um, looked at treating allergic conjunctivitis with, I think, olopatadine.
Q. Would you agree, Dr. Donnenfeld, that seasonal and perennial allergies are a common medical problem in the United States?
A. Yes, I do.
Q. And you write that -- in the first

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paragraph, um, the left-hand column of this page --
MR. CASSELLA: If we can scroll down a little bit, in the middle of that paragraph -- yeah, right there.
BY MR. CASSELLA:
Q. In the middle of that paragraph, you write that: "As much as 40% of the population is affected by symptoms of AC," which I understand you mean allergic conjunctivitis?
A. Yes.
Q. Do you see that sentence?
A. Yes. I agree with that statement.
Q. Do you stand by that sentence today?
A. I haven't reviewed the literature recently, so I can't, uh, be absolutely certain it's 40 percent, but it's very common.
Q. Is the inflammation associated with allergic conjunctivitis characterized by itching, conjunctival hyperemia, excessive tearing, and conjunctival and eyelid swelling?
A. Those are very common signs and symptoms of allergic conjunctivitis, yes.
Q. So in allergic conjunctivitis, there's an inflammatory response to allergens

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which produces the ocular signs and symptoms associated with allergic conjunctivitis?
MR. HASFORD: Object to --
BY MR. CASSELLA:
Q. Is that correct?
MR. HASFORD: Object to the form of the question.
THE WITNESS: Yes. That is true.
BY MR. CASSELLA:
Q. And the signs and symptoms associated with allergic conjunctivitis are exemplified by redness and itching; is that correct?
A. Uh, those are very common signs and symptoms, yes.
Q. If we could go to page e108, uh, it should be page 2 of the PDF, the bottom right-hand corner, do you see the heading, Current Treatment Options?
A. Yes, I see that.
Q. Okay. And underneath that heading, you wrote that: Optimal management of allergic conjunctivitis necessitates a broad approach that involves allergen avoidance, symptomatic relief, and pharmacologic suppression of inflammatory responses. (As read)

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Do you see that sentence?
A. Yes, I do.
Q. But can you explain a little bit more what you mean by the optimal management necessitates a broad approach that involves allergens avoidance, symptomatic relief, and pharmacologic suppression of inflammatory responses?
A. What we're saying there is that the treatment of allergic conjunctivitis can many times be multifactorial and may necessitate changing the environment, avoiding allergens, and there are medications that can be used to suppress the allergic response, but all three are not required in every case, but in -- in many cases you do require all three of these treatment options.
Q. So that first option for optimal management would be allergen avoidance?
A. That's the --
MR. HASFORD: Objection, mischaracterizes the witness's testimony.
THE WITNESS: That's the first that's listed there, but they're all important.
BY MR. CASSELLA:

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Q. Okay. And then another prong of the optimal management is symptomatic relief; is that correct?
A. Yes.
Q. And to state the obvious, that means treating the symptoms of allergic conjunctivitis; is that correct?
A. Yes.
Q. Okay. And then the third, uh, category listed in that sentence, pharmacologic suppression of inflammatory responses.
Is it fair to say that that is the treatment of the underlying cause of the, uh, inflammatory response?
MR. HASFORD: Object to the form.
THE WITNESS: No. It wouldn't be treating the underlying cause. It would be treating the inflammatory result, um, of -- of the, uh, antigen antibody deposition. Uh, treating the cause is really avoidance. If you can avoid the antigen, you would be treating it, uh, significantly.
Pharmacologic suppression is really nonspecific in general. It just involves therapies that reduce inflammation, not

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necessarily that specific antigen.
BY MR. CASSELLA:
Q. So do I understand you to mean that the allergen avoidance would be to treat the cause, the symptomatic relief would be to treat the symptoms of the inflammatory response, and the pharmacologic suppression would be to treat the -- the underlying cause of the inflammation?
A. No, not that --
MR. HASFORD: Object to the extent -- object to the extent it mischaracterizes the witness's testimony.
THE WITNESS: It's not treating the underlying cause. It's treating the inflammatory sequelae.
BY MR. CASSELLA:
Q. If we could go to the next page, there's a Table 1 on page e109.
Do you see Table 1 displayed on your screen, Dr. Donnenfeld?
A. I do.
Q. And Table 1 lists pharmacologic treatments for allergic conjunctivitis, correct?
A. Yes.
Q. And in the left-hand column of Table

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1, you identified some drug classes that are pharmacologic treatments for allergic conjunctivitis; is that correct?
A. Yes.
Q. And so that would include antihistamines, vasoconstrictors, mast cell stabilizers, leukotriene receptor antagonists, NSAIDs, corticosteroids, and single-agent antihistamine-mast cell stabilizers; is that correct?
A. Correct.
Q. And in the next column over in Table 1, you've listed the mechanism of action for each of these drug classes; is that correct?
A. Yes.
Q. Okay. Is it fair to say that the mechanism of action for each of these drug classes is different?
A. Um, some of them overlap, but some of them are different.
Q. So it would be fair to say that antihistamines work via a different mechanism of action than vasoconstrictors?
A. Yes. That would be accurate.
Q. And so going back to that sentence we

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were just reviewing about optimal management of allergic conjunctivitis, would the use of an antihistamine fall under the category of pharmacologic suppression of inflammatory responses?
MR. HASFORD: Object to the extent it mischaracterizes.
THE WITNESS: Uh, yeah. An antihistamine would be a pharmacologic, um, technique to reduce the inflammation, yes.
BY MR. CASSELLA:
Q. And the use of a vasoconstrictor, would that fall into the category of symptomatic relief?
A. Um --
MR. HASFORD: Same objection.
THE WITNESS: It would not be, um, symptomatic relief, no.
BY MR. CASSELLA:
Q. Why not?
A. Because it treats redness which is a sign, not a symptom.
Q. Can you explain the difference between sign and symptom?
A. A sign -- a symptom is something that

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you experience or feel, and a sign is something that you see.
Q. So is it your opinion that because -- sorry. Let me rephrase that.
So is it your opinion that eye redness cannot be felt?
A. Uh, on certain --
MR. HASFORD: Object -- object to the extent it mischaracterizes the witness's testimony.
THE WITNESS: Um, yes. Eye redness, uh, in general, cannot be felt.
BY MR. CASSELLA:
Q. So the use of a vasoconstrictor, in your opinion, would be treatment of a sign of inflammation; is that correct?
MR. HASFORD: Same objection.
THE WITNESS: Um, in this case, yes. It would be a treatment of one of the signs of inflammation.
BY MR. CASSELLA:
Q. Okay. I'd like you to -- if we could go back -- we're on Table 1 there. Great.
Um, so we -- I think we said antihistamines or -- excuse me. Let me

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rephrase.
So you testified that antihistamines would fall into the category of pharmacologic suppression of inflammation responses, correct?
A. That's correct.
Q. And vasoconstrictors, I believe you testified, would be a treatment of a sign of the inflammation; is that correct?
MR. HASFORD: Object to the extent it mischaracterizes.
THE WITNESS: Well, it's a -- it's a sign of redness, not necessarily inflammation, but it's a sign -- it's a sign of the redness associated with inflammation.
BY MR. CASSELLA:
Q. Okay. What about the next category of drug class, mast cell stabilizers?
Would that also be a pharmacologic suppression of inflammatory responses?
A. Yes.
MR. HASFORD: Same objection.
THE WITNESS: Yes, it would.
BY MR. CASSELLA:
Q. And what about leukotriene receptor antagonists?

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MR. HASFORD: Same objection.
THE WITNESS: Yes.
BY MR. CASSELLA:
Q. What about NSAIDs?
MR. HASFORD: Same objection.
THE WITNESS: Um, NSAIDs treat, um, the symptom of itching, but, um, they don't really do it in this circumstance as an anti-inflammatory. They do it more as an anesthetic effect, which NSAIDs have. And for that reason, NSAIDs are not very commonly used in treating allergy any longer but it's -- it doesn't really affect the mechanism of itching, more it's a -- it's just an anesthetic that makes the patients feel better, but it doesn't -- it doesn't treat the inflammatory cascade.
BY MR. CASSELLA:
Q. So is it fair to say that an NSAID, um, blocks the sensation of itching?
MR. HASFORD: Object to the form.
THE WITNESS: It -- no. I don't think that would be a correct definition. I would say it just anesthetizes the cornea and makes the cornea less receptive to symptoms

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like -- like itching or pain.
BY MR. CASSELLA:
Q. Okay. Okay. Now, under this heading, Current Treatment Options, which begins on page e108, you've got a few different subsections. One is Allergen-Specific Immunotherapy appearing on page e109. Another is Topical Antihistamines, appearing on page e110; Antihistamine-Vasoconstrictor Combinations, Leukotriene Receptor Antagonists; NSAIDs; Corticosteroids, Mast Cell Stabilizers on page e111, and Dual-Acting Antihistamine-Mast Cell Stabilizing Agents on -- also on page e111.
Do you see those categories that I just mentioned?
A. They're a little blurry, but I do see them, yes.
MR. CASSELLA: Maybe we could make the text just a little -- just a little bit bigger.
Okay. Could we go up one page to e- -- page e110?
BY MR. CASSELLA:
Q. And do you see the heading there, Antihistamine-Vasoconstrictor Combinations?

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A. Yes.
Q. And so combinations of antihistamines with a vasoconstrictor can treat allergic conjunctivitis; is that correct?
A. Um, they can be helpful, uh, for treating the -- the symptoms and the signs of allergic conjunctivitis, yes.
Q. Okay. And you wrote in that first sentence there the: "Topical vasoconstrictors are highly effective at reducing ocular and conjunctival hyperemia through stimulation of vascular a-adrenergic receptors."
Is that correct?
A. Yes.
Q. Okay. And you -- do you stand by that sentence today?
A. Um, a-adrenergic receptor agonists can reduce conjunctival hyperemia. Yes. I stand by that.
Q. In the next sentence you write the "Vasoconstrictors are commonly available in nonprescription combination formulations that contain an antihistamine (e.g., naphazoline-antazoline, naphazoline-pheniramine)."

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Do you see that sentence?
A. Yes.
Q. Are there any other combinations of, uh, antihistamine vasoconstrictors that you're aware of today?
A. Uh, I'm not aware, no. There might be, but I -- I'm not aware of any.
Q. These combination, uh, treatments relieve redness and itchiness associated with allergic conjunctivitis, correct?
A. That is correct.
Q. Are you aware of the drug ketotifen?
A. Yes, I am.
Q. What is ketotifen?
A. Uh, ketotifen is a -- um, I believe it's an antihistamine. I'd actually have to review that to be certain.
Q. Okay. Do you recall what ketotifen is used to treat?
A. Um, allergic conjunctivitis, I believe.
Q. Are you aware of the branded drug products called Alaway?
A. Yes, I am.
Q. And do you recall whether ketotifen

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is the active ingredient in the drug product Alaway?
A. I don't recall.
Q. Are you aware that Bausch is currently sponsoring a phase three clinical trial to evaluate the efficacy of the combination of brimonidine 0.025 percent and ketotifen 0.035 percent?
MR. HASFORD: Objection, no foundation.
THE WITNESS: I am not.
BY MR. CASSELLA:
Q. Okay.
MR. CASSELLA: And could we please display the document titled Clinical Trial Number NCT05579730?
Okay. If we could please mark this exhibit as Exhibit 604?
* * *
(Whereupon, Deposition Exhibit 604 was marked for identification.)
* * *
BY MR. CASSELLA:
Q. Have you ever seen this document, Dr. Donnenfeld?

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A. Not to my knowledge, no.
Q. Do you see at the top of the page there, the title of the document is Evaluation of Brimonidine Tartrate/Ketotifen Fumarate Combination for the Treatment of Allergic Conjunctivitis?
A. I do read that, yes.
Q. Okay. And the sponsor -- did -- sorry. Let me rephrase.
Do you understand that this is a ClinicalTrials.gov printout for the clinical trial number NCT 05579730?
MR. HASFORD: Objection, no foundation.
THE WITNESS: Yeah. I have not rela- -- no understanding of this. I've not seen the document. I'm not aware of the trial previously, but if you report that this is accurate, then I -- I will take your word for it.
BY MR. CASSELLA:
Q. Have you ever viewed the website ClinicalTrials.gov?
A. Yes.
Q. Are you generally aware of

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ClinicalTrials.gov providing details about clinical trials?
A. Yes, I am.
MR. HASFORD: Objection.
BY MR. CASSELLA:
Q. Do you see the sponsor for this clinical trial is Bausch & Lomb, Incorporated?
MR. HASFORD: Objection, no foundation.
THE WITNESS: I see that on the document you're showing me. I do see that written.
BY MR. CASSELLA:
Q. Okay. And then under Study Overview, in the middle of the page, the first page here, do you see the Brief Summary, that sentence: "To evaluate the efficacy of Combo (Drug Product Brimonidine Tartrate 0.025%/Ketotifen Fumarate 0.035% Ophthalmic Solution) compared to its individual components and vehicle in a population of subjects with allergic conjunctivitis"?
Do you see that sentence?
A. I do.
Q. So do you have any understanding as

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to whether Bausch & Lomb is currently sponsoring a clinical trial aimed at evaluating the efficacy of brimonidine with ketotifen to treat allergic conjunctivitis?
MR. HASFORD: Objection, asked and answered, no foundation.
THE WITNESS: Um, I just read what you're showing me right here for the first time, and, um, it does appear that they are evaluating those two drugs together.
BY MR. CASSELLA:
Q. Okay.
MR. CASSELLA: If we could scroll to -- it's going to be page, uh, seven of the PDF?
It looks like also page seven of the document, 7 of 9.
Then can we blow that text up a little bit so Dr. Donnenfeld could read it?
BY MR. CASSELLA:
Q. Do you see the heading there, What is the study measuring?
A. Yes.
Q. And do you see the table listed below there, Outcome Measure, Measure Description, and

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Time Frame?
A. Yes.
Q. Okay. So one of the outcome measures in this clinical study is: "Ocular itching measured by Conjunctival Allergen Challenge Ocular Itching Scale."
Do you see that?
MR. HASFORD: Objection, no foundation.
THE WITNESS: Yes, I see that.
BY MR. CASSELLA:
Q. And the other outcome measure of this clinical study is "Conjunctival Redness measured by Ocular Hyperemia Scale."
Do you see that?
MR. HASFORD: Same objection.
THE WITNESS: Yes, I see that.
BY MR. CASSELLA:
Q. So are the primary outcomes of this clinical study the measurement of ocular itching and conjunctival redness?
MR. HASFORD: Objection, no foundation.
THE WITNESS: It doesn't say that they're the primary outcome, so I can't -- I

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can't assume that.
BY MR. CASSELLA:
Q. Are those two outcome measures of this clinical study?
A. Yes, they --
MR. HASFORD: Same objection.
THE WITNESS: Yes, they are.
BY MR. CASSELLA:
Q. Okay. If we could go back to your declaration?
Um, there's a subsection C that begins at paragraph 30 on page nine of your declaration, and I'll just pause until the -- that paragraph's displayed on your screen.
Okay. Can you see the subsection C on page nine?
It's titled Clinical Studies Contain Uniform Protocols for Reporting Adverse Events?
Do you see that?
A. Yes.
Q. And this section -- subsection of your declaration has two paragraphs, correct?
A. Yes.
Q. And in neither of those paragraphs do you cite the Alphagan protocol; is that correct?

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A. I believe you are correct.
MR. HASFORD: It's argumentative.
BY MR. CASSELLA:
Q. Have you ever seen the protocols for adverse event reporting that were used in the Alphagan clinical trials?
A. I've seen the adverse events, but I haven't seen the protocol, no.
Q. So you have no direct evidence of a uniform protocol being used in the Alphagan clinical trials, correct?
MR. HASFORD: Objection, mischaracterizes the witness's testimony, argumentative.
THE WITNESS: I'm aware of the, um, adverse events that were stated. I'm not aware of how they were ascertained.
BY MR. CASSELLA:
Q. You have not provided a definition of conjunctival blanching in your declaration, have you?
A. I have not.
Q. What definition of conjunctival blanching did the Alphagan clinical trials use?
A. I don't recall. I'd have to review

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that.
Q. You'd have to review what?
A. Um, I'd have to view what the definition was.
Q. In the clinical trial protocol?
A. Yes.
Q. And you've never seen that protocol, correct?
A. Correct.
MR. CASSELLA: Okay. Erin, I just added an exhibit, um, to the portal, if you don't mind displaying it?
It's Exhibit 63.
THE EXHIBIT TECHNICIAN: My apologies, Counsel. It's not showing up. I keep refreshing.
MR. CASSELLA: Uh, it looks like it's uploaded on my end. I don't know if --
THE EXHIBIT TECHNICIAN: There we go.
We have it now. Thank you.
MR. CASSELLA: Okay. Thank you.
BY MR. CASSELLA:
Q. Dr. Donnenfeld, have you ever seen Exhibit 63, which --
MR. CASSELLA: If we could scroll

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down a page?
BY MR. CASSELLA:
Q. Do you recognize this document?
A. I can't -- I can't be certain. It looks familiar, but I -- I can't recall.
Q. Does Exhibit 63 appear to be the label for Alphagan 0.5 percent?
MR. HASFORD: Objection, no foundation.
THE WITNESS: Possibly.
MR. CASSELLA: Can we go to page four of Exhibit 63?
Uh, one page up. It's page five.
BY MR. CASSELLA:
Q. Do you see the section titled Clinical Studies?
A. Yes, I do.
Q. And do you see that the -- the sentence in the second paragraph: In two controlled, multi-center studies, ALPHAGAN 0.5% ophthalmic solution was significantly more effective in decreasing the incidence of post-operative IOP elevations, um, than was the vehicle at one, two, and three hours post-argon laser trabeculoplasty. (As read)

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And apologies if I butchered that last word.
A. You said it beautifully.
Q. Do you see that sentence there?
A. I do.
Q. So is it your understanding that there were two controlled clinical trials of Alphagan 0.5 percent, evaluating the drug Alphagan 0.5 percent com- -- uh, compared to the vehicle at one, two, and three hours post-argon laser trabeculoplasty?
A. That's correct.
MR. HASFORD: Objection, foundation.
BY MR. CASSELLA:
Q. Do you have any understanding as to how long these studies lasted?
MR. HASFORD: Same objection.
THE WITNESS: What's stated here is they were tested at one, two, and three hours post-argon laser trabeculoplasty. That's the only information that I have, based on this document.
BY MR. CASSELLA:
Q. But is it possible, Dr. Donnenfeld, that this study could be studies of Alphagan 0.5

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percent were conducted in the course of a single day? [sic]
MR. HASFORD: Object, no foundation.
THE WITNESS: I would assume that they were conducted on an individual patient over the course of one day, yes.
BY MR. CASSELLA:
Q. Okay. Um, page six of Exhibit 63, there's a heading called Adverse Reactions.
And do you see there that the -- Exhibit 63 states that: "The most common adverse events reported in association with the use of ALPHAGAN 0.5% in conjunction with ALT was transient conjunctival blanching in 50% of patients and upper lid retraction in 30% of patients"?
A. I can --
Q. Do you see that sentence?
A. Yes.
Q. So do you have any understanding as to whether the adverse reaction of transient conjunctival blanching was measured over the course of a single day for each patient in these clinical studies?
MR. HASFORD: Objection, no

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foundation.
THE WITNESS: I don't know.
BY MR. CASSELLA:
Q. Okay. If we could go to page eight of Exhibit 63?
And on page eight of Exhibit 63, the title is ALPHAGAN (brimonidine tartrate ophthalmic solution) 0.2%.
Do you see that?
A. Uh, you'll have to blow that up for me, please. I see that, yes.
Q. Do you have any understanding as to whether this is the label for Alphagan 0.2%?
A. I don't know.
MR. HASFORD: Objection, foundation.
THE WITNESS: Again, I don't know.
BY MR. CASSELLA:
Q. Okay. If we could go to page nine, there's a heading, Clinical Evaluations, and in the second paragraph under Clinical Evaluations, it states: In comparative clinical studies with timolol 0.5%, lasting up to one year, the IOP lowering effect of ALPHAGAN was approximately 4-6 mm of mercury compared with approximately 6 mm of mercury for timolol. (As read)

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Do you see that sentence?
A. Yes. I do see that.
Q. Okay. And then the next sentence: In these studies, both patients -- patient groups were dosed BID; however, due to the duration of action of ALPHAGAN, it is recommended that ALPHAGAN be dosed TID. (As read)
Do you see that sentence?
A. Yes.
Q. Do you have any understanding as to what those terms "BID" and "TID" refer to?
A. Yes. BID is twice a day, and TID is three times a day.
Q. Okay. And do you have any understanding as to whether the clinical trials for Alphagan 0.2% lasted up to one year?
MR. HASFORD: Objection, no foundation.
THE WITNESS: Yeah. I -- I don't know.
BY MR. CASSELLA:
Q. Are the -- is -- sorry. Let me rephrase.
Is the Alphagan 0.2% being measured

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in a different -- well, I'm sorry. Let me rephrase.
The Alphagan 0.5% that we just reviewed, that was, um, studied in connection with ALT, correct?
MR. HASFORD: Object, no foundation.
THE WITNESS: In the one example you showed me, that's how it was evaluated, yes.
BY MR. CASSELLA:
Q. Okay. And here on page nine of Exhibit 63, Alphagan 0.2% is being measured, uh, for its IOP-lowering effects over the course of one year; is that correct?
MR. HASFORD: Same objection.
THE WITNESS: Um, it says up to one year.
BY MR. CASSELLA:
Q. So you don't have any understanding as to how long the clinical trials for Alphagan 0.2% lasted?
A. I do not.
MR. HASFORD: Objection. Objection, no foundation, argumentative.
BY MR. CASSELLA:
Q. On page 11 of Exhibit 63, there's a

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heading, Adverse Reactions, and do you see in the second paragraph there: "Events occurring in approximately 3-9% of the subjects, in descending order included," and there's a long list of, uh, adverse events, and on the last line, "conjunctival blanching" is listed.
Do you see that?
A. Yes.
Q. So do you have any understanding as to whether conjunctival blanching was measured in this clinical trial of Alphagan 0.2% over the course of one year?
MR. HASFORD: Objection, no foundation.
THE WITNESS: I -- I don't know when it was evaluated, and it doesn't say one year, which is up to one year, so I -- I really can't state with certainty when it was measured.
BY MR. CASSELLA:
Q. So you don't know whether the conjunctival blanching would have been measured immediately after the first dose of Alphagan 0.2% was administered?
MR. HASFORD: Same objection.
THE WITNESS: I don't know for

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certain when this was measured, but in clinical trials, there are generally multiple time frames in which a patient is evaluated, and adverse events are evaluated on each visit.
BY MR. CASSELLA:
Q. The patients in the Alphagan 0.2% clinical studies were dosed twice per day; is that correct?
A. That's correct.
MR. HASFORD: Objection.
BY MR. CASSELLA:
Q. Okay. On page 13 then of Exhibit 63, the title's ALPHAGAN P (brimonidine tartrate ophthalmic solution) 0.15%.
Can you see that?
A. Uh, not yet.
Yes. I see it now.
Q. And do you understand whether this is the label for Alphagan P 0.15%?
MR. HASFORD: Object, no foundation.
THE WITNESS: Uh, I don't know for certain, but I -- I would assume that it is.
BY MR. CASSELLA:
Q. Okay. On page 14, there's a heading, Clinical Evaluations, and the second paragraph

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there states: Two clinical studies were conducted to evaluate the safety, efficacy, and acceptability of ALPHAGAN P 0.15% compared to ALPHAGAN administered three-times-daily in patients with open-angle glaucoma or ocular hypertension. (As read)
Do you see that?
A. Yes, I do.
Q. Is there any indication as to how long the clinical studies of Alphagan P were conducted?
MR. HASFORD: Object, foundation.
THE WITNESS: Not in this paragraph that you've showed me, no.
BY MR. CASSELLA:
Q. And in these Alphagan P clinical studies, the patients were dosed three times daily, correct?
A. Yes.
Q. And in the Alphagan 0.2% clinical studies, which we just discussed, those patients were dosed twice per day; is that correct?
A. That's correct.
Q. Okay. I think we've been going about an hour.

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Um, would you like to take a break, or would you like to keep going?
MR. HASFORD: We can take a break now.
THE WITNESS: Okay.
MR. CASSELLA: Okay.
THE VIDEO TECHNICIAN: Okay.
Off record, 5:06.
* * *
(Whereupon, a short recess was taken.)
* * *
THE VIDEO TECHNICIAN: Back on record 17:17.
BY MR. CASSELLA:
Q. Could we turn to paragraph 33 of your declaration, Dr. Donnenfeld?
Do you see the sentence, you wrote in paragraph 33 of your declaration: "First, a POSA would have concluded that Norden left unanswered the question of whether brimonidine alone could be used to reduce eye redness"?
Do you see that sentence?
A. Yes.
Q. And then a few sentence down, you say: "Because other eye redness relieving drugs

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were administered before brimonidine, a POSA would have been unable to determine whether Norden's observed reduction in hyperemia, due solely to brimonidine, or if it was due to a synergistic effect of administering brimonidine with an NSAID and corticosteroid, such as diclofenac and prednisolone acetate."

A. Correct.

Q. Do you see that?

And then at the end of that sentence that I just read, you have a footnote, Footnote 2, and in that footnote, you cite Exhibit 502, the Middleton reference, uh, which refers to the drug Auvelity, A-u-v-e-l-i-t-y?

A. Yes.

Q. Correct?

A. Yes.

Q. The -- oh, sorry.

MR. CASSELLA: Eric, could we display -- display Exhibit 502, Middleton?

BY MR. CASSELLA:

Q. And do you see Exhibit 502 displayed on your screen, Dr. Donnenfeld?

A. Yes, I do.

Q. And is this the Middleton reference?

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A. Um, I can't tell.

MR. CASSELLA: Um, maybe, could we go down one more page?

THE WITNESS: Yes.

BY MR. CASSELLA:

Q. Do you see the title there is, Meet the newest antidepressant: dextromethorphan/bupropion (Auvelity)?

A. Yes.

Q. Okay. And this article was published in October of 2022, correct?

A. Yes.

Q. So this article would not have been available to a POSA in 2008, correct?

A. That's correct.

Q. And the Middleton reference discusses the drug Auvelity, correct?

A. Yes.

Q. That drug, Auvelity, is a combination of dextromethorphan and bupropion, correct?

A. Yes.

Q. And that drug, Auvelity is, uh, indicated for the treatment of depression; is that correct?

A. Yes, it is.

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Q. That drug does not treat eye redness, correct?

A. Correct.

Q. Are either of these two drugs in Auvelity vasoconstrictors?

A. Not to my knowledge.

Q. Are either of the drugs in Auvelity an Alpha-1 or Alpha-2 agonist?

A. Not to my knowledge again.

Q. What is your basis for your statement in paragraph 33 that a POSA would have been unable to determine whether Norden's observed reduction in hyperemia was due solely to brimonidine or if it was due to a synergistic effect of administering brimonidine with an NSAID or a corticosteroid?

A. Well, again, as I've stated before, the Norden study was poorly controlled. It would never be accepted today into a journal.

Um, the statement that I make here is that when you're studying a drug, you don't want to have secondary drugs that may influence the outcome. And in this case, the patient received two other medications that are known anti-inflammatory -- actually, very potent

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anti-inflammatories, and the question remained unanswered based on the study on whether or not the brimonidine would have had the same effect if the other two drugs had not been available.

Q. Is it your opinion, sir, that brimonidine requires the presence of an NSAID or a corticosteroid to reduce redness?

A. No. I just state that this study did not provide that information.

Q. Why would a POSA reading Norden have thought that an NSAID or a corticosteroid would have been necessary for brimonidine to reduce redness?

A. Um, they would not have known whether or not the brimonidine alone would have been effective unless it was in the setting of two other very well known anti-inflammatories.

Q. Would a person of ordinary skill in 2008 have any reason to believe that the activity of a vasoconstrictor depended upon the presence of an NSAID or a corticosteroid?

A. Um, they would not have known the efficacy, the side effects, the duration of action, um, um, of the, uh, medication in the setting of using other medications that would

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have had a similar synergistic effect.
Q. I'm not sure that was responsive to my question.
I asked, would a person of ordinary skill in 2008 have had any reason to believe that the activity of a vasoconstrictor depended upon the presence of an NSAID or a corticosteroid?
MR. HASFORD: Objection, argumentative.
I'll move to strike the colloquy at the beginning of the question.
THE WITNESS: Um, a POSA would have accepted that a, um, vasoconstrictor did not necessar- -- necessarily require other medications to be effective, but a POSA would have discounted the results of this trial because it would not have answered the question on whether the brimonidine played a role in preventing these complications, unless the other medications were -- were present at the same time.
MR. CASSELLA: Uh, Erin, could we display -- it's Exhibit 18, Norden?
I just, uh, uploaded it.

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THE EXHIBIT TECHNICIAN: My apologies. It's taking a moment.
MR. CASSELLA: That's okay. The Internet in this conference room is a little wonky, so I'm not positive that it goes through very quickly.
THE EXHIBIT TECHNICIAN: Okay.
We have it. One moment.
BY MR. CASSELLA:
Q. Do you see Exhibit 18 displayed on your screen, Dr. Donnenfeld?
A. I do.
Q. And do you recognize this exhibit?
A. Yes, I do.
Q. This is the Norden reference that is discussed in your declaration?
A. Well, that's coming up. I believe this is just the table of contents I'm looking at right now.
Q. Oh, I'm sorry.
MR. CASSELLA: Could we scroll down just one or two pages, uh, to the beginning of the article?
Uh, one more page.
THE WITNESS: Next page. Next --

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there. Good.
BY MR. CASSELLA:
Q. Okay. So is this the beginning of the Norden reference that's discussed in your declaration?
A. Yes, it is.
MR. CASSELLA: And if we could go to -- it's page 471. Um, it's the last page of the document. There's a heading, Discussion.
BY MR. CASSELLA:
Q. And do you see the first sentence under the heading, Discussion, in the Norden reference, Norden states: "These data demonstrate that brimonidine administered before LASIK can significantly reduce subconjunctival hemorrhage as well as the amount of hyperemia"?
Do you see that sentence?
A. I do see that sentence, yes.
Q. Okay. In this sentence, Norden does not say that brimonidine can significantly reduce subconjunctival hemorrhage, as well as the amount of hyperemia in the presence of an NSAID or a corticosteroid, correct?
MR. HASFORD: Objection to the extent it mischaracterizes the document.

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THE WITNESS: Yeah. That -- that's correct. He doesn't mention that. I think if he, uh, considered that, he would have changed the study.
BY MR. CASSELLA:
Q. Can you point me to any language or paragraph in Norden where he -- it states that the presence of an NSAID or a corticosteroid would be required for brimonidine to reduce redness?
A. No.
MR. HASFORD: Same objection.
THE WITNESS: He -- he certainly doesn't -- does not state that anywhere in the paper, which is, you know, a problem with the paper. Um, I'm certain that a good paper today would contain that information.
BY MR. CASSELLA:
Q. Are you aware that certain vasoconstrictors were approved by the FDA as redness relievers in 2008?
MR. HASFORD: Objection, no foundation.
THE WITNESS: I was aware that other medications were used for redness relievers,

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yes.
BY MR. CASSELLA:
Q. Do you recall which vasoconstrictors were approved by the FDA for redness relief in 2008?
MR. HASFORD: Same objection.
THE WITNESS: Um, tetrahydrolozine and, uh, hydralazine.
BY MR. CASSELLA:
Q. What about naphazoline?
A. I'm sorry. Naphazoline, yes.
Q. What about oxymetazoline?
A. I believe so. I'm not certain when that was approved, but certainly that is a redness reliever, yes.
Q. And I believe you mentioned the tetrahydrozoline?
A. Yes.
Q. And those are all vasoconstrictors, correct?
A. Yes, they are.
Q. And do you have any understanding as to whether those drugs are alpha agonists?
A. Uh, they're all alpha-1 agonists, yes.

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Q. Are they all collective alpha-1 agonists?
A. Um, I'm not certain, but I believe that they are.
Q. Do you have any understanding as to whether some of them were mixed alpha-1, alpha-2 agonists?
A. I'm not aware.
Q. And all of these vasoconstrictors that we just mentioned, naphazoline, oxymetazoline and tetrahydrozoline, those were approved to treat eye redness, correct?
A. Yes, they were.
Q. And they were approved to treat eye redness alone, correct?
MR. HASFORD: Object to the form.
THE WITNESS: Um, yes, they were.
BY MR. CASSELLA:
Q. So for all of those prior art vasoconstrictors, no other active ingredient was required for them to reduce redness; is that correct?
A. I believe some of them were used in, uh, combinations, but as stand-alone drugs, yes, they were all approved for the relief of ocular redness.

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Q. And these prior art vasoconstrictors that were approved for the relief of ocular redness worked through alpha agonism?
A. Yes.
Q. And just to be clear, these prior art redness relievers did not require co-administration of an NSAID or a corticosteroid to achieve this effect, correct?
MR. HASFORD: Objection, asked and answered.
THE WITNESS: Correct. They were approved in studies in which there was no NSAID or no penicillin use in the studies. They would never have done a study of these medications with -- with those medications available.
BY MR. CASSELLA:
Q. Can we return to paragraph 35 of your declaration?
Do you see in paragraph 35 the sentence, uh: "Second, a POSA would have recognized that, while Norden states that brimonidine was shown to reduce hyperemia, Norden does not differentiate between hyperemia caused by vasodilation as opposed to surgical

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trauma causing a small number of red blood cells to enter the subconjunctival space, which would make the eye appear hyperemic."
Do you see that sentence?
A. Yes, I do.
Q. And in the following paragraph -- I'm sorry.
In the next sentence, you state: "Based on Norden's disclosure, a POSA would have understood Norden's reference to hyperemia to refer to micro-vessel hemorrhage in the conjunctiva."
Do you see that?
A. Yes.
Q. And then in the following paragraph, paragraph 37, you state that: Hyperemia can refer to either vasodilation or micro-vessel hemorrhaging," and you cite Exhibit 500 Doshi.
Is that correct?
A. Yes.
Q. And the -- your support for that sentence is Doshi's, uh, statement that "Subconjunctival Hemorrhage is generally painless but can appear as diffusely hyperemic."
Do you see that?

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A. Yes.
Q. Does Doshi mention micro-vessel hemorrhaging?
A. Um, she does not specifically use the word micro-vessel hemorrhages, but she does refer to conjunctival hemorrhages as being hyperemic, and she does differentiate between classic conjunctival hemorrhages, which are very red and very specific versus just ocular redness which she defines as hyperemia.
But regardless, this is common nomenclature used by ophthalmologists all over the world that small red blood cells subconjunctivally are viewed hyperemia. The average ophthalmologist says hyperemia is a red eye, and they don't differentiate the cause of the red eye.
MR. CASSELLA: Could we display Exhibit, um, 500 Doshi, please?
If we could go to the next page and maybe blow up the text a little bit?
BY MR. CASSELLA:
Q. Do you recognize this document, Dr. Donnenfeld?
A. Yes, I do.

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Q. Can you point me to where in -- I'm sorry.
Let me ask an additional question.
What is this document?
A. This is an article written by two authors, regarding subconjunctival hemorrhage.
Q. Okay. And this is the Doshi reference that you cite in paragraph 36 of your declaration, correct?
A. Yes. This is just a reference that documents that clinicians view hemorrhages as hyperemia.
Q. And where in this document does it support that statement?
A. I'd have to scroll through the article and look at it.
Q. Okay. That's fine.
MR. CASSELLA: Can you, uh, give Dr. Donnenfeld control?
THE WITNESS: "Subconjunctival Hemorrhage is generally painless but can appear as diffusely hyperemic," the fourth line down.
BY MR. CASSELLA:
Q. So that sentence states that subconjunctival hemorrhage can appear as

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hyperemic?
A. Yes.
Q. It does not say that subconjunctival hemorrhage always appears as hyperemic, correct?
MR. HASFORD: Objection to the extent it mischaracterizes the document.
THE WITNESS: No. Subconjunctival hemorrhages are not always hyperemic, um, but they can be.
BY MR. CASSELLA:
Q. I believe you testified previously that this document, Exhibit 500, Doshi is directed to Subconjunctival Hemorrhage, which is the title of the document, correct?
A. Yes.
Q. And nowhere in this document does it mention micro-vessel hemorrhaging, correct?
MR. HASFORD: Objection to the extent it mischaracterizes the document.
THE WITNESS: It doesn't refer to that. It just basically says, is what I just said is, that hemorrhages under the conjunctiva are hyperemia.
BY MR. CASSELLA:
Q. So is it your opinion,

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Dr. Donnenfeld, that subconjunctival hemorrhage is the same as hyperemia?
MR. HASFORD: Object to the extent it mischaracterizes the witness's testimony.
THE WITNESS: Subconjunctival hemorrhages can be differentiated in that they are diffusely or very violaceously red, um, but they don't have to be. They can be just pinkish and appear hyperemic.
Um, she describes, um, them as being diffusely hyperemic. That would imply it's, you know, over -- over the entire eye, which is what hyperemia is. It's a -- it's generally a red eye.
BY MR. CASSELLA:
Q. So, in your opinion, sir, what is the difference between subconjunctival hemorrhage and micro-vessel hemorrhaging?
A. Just -- just simply magnitude. The difference between the two of them is the degree of red blood cells. A large amount of blood cells will appear as a very sub-classic subconjunctival hemorrhage. Whereas a small amount of red blood cells will appear to be less red and will be -- and will be kind of just a

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mildly red eye, which is what we describe as hyperemia.

Q. So, again, Doshi states that subconjunctival hemorrhage can appear as hyperemic, correct?

MR. HASFORD: Object to the extent it mischaracterizes the document.

THE WITNESS: Yes. It -- I agree with the statement. Um, the hemorrhages that I'm talking about, whether they be very overt, large amount of blood, which is a classic subconjunctival hemorrhage, or they can be just a small amount of blood, which is also subconjunctival hemorrhage, but it doesn't have the classic appearance of very violaceous, uh, red eyes. They just appear to be pinkish or hyperemic, and we're talking about exactly the same disease process here. Um, in most cases, they're trauma related, and it's just blood in the subconjunctival hemorrhage space, and the only difference here is the degree of magnitude of the disease.

BY MR. CASSELLA:

Q. So the larger magnitude is subconjunctival hemorrhage, and the smaller

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magnitude is hyperemia?

Is that your opinion, sir?

A. They're both subconjunctival hemorrhages, but a large amount of hemorrhage is termed a subconjunctival hemorrhage, but a small amount of subconjunctival hemorrhage is also subconjunctival hemorrhage, but it's termed hyperemic, which it appears different.

Q. And is this based on your definition of hyperemia as including the accumulation of red blood cells?

A. It's not only my definition, it's the definition of most ophthalmologists.

Q. And you haven't provided any reference demonstrating that that is the definition used by most ophthalmologists, correct?

MR. HASFORD: Objection, mischaracterizes the witness's testimony, argumentative.

THE WITNESS: I -- I have no documents that describe this, other than what's written in the Norden article, which is a classic representation of an ophthalmologist causing -- calling small amounts of red blood

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cells as hyperemia, which he describes in the very title of his paper, bleeding. He doesn't describe vasodilation anywhere in that paper. He only describes bleeding in the paper. It's actually right in the title that -- that it's -- that it's bleeding, and he describes hyperemia later on in the paper, but nowhere does he mention or describe vasodilation. He only describes hemorrhage, and it's in the title again, itself.

BY MR. CASSELLA:

Q. And nowhere does Norden reference micro-vessel hemorrhaging, correct?

A. Um, he actually does mention micro-vessel hemorrhaging, uh, at the limbus but in a different context.

Q. Nowhere does Norden equate micro-vessel hemorrhaging with hyperemia, correct?

MR. HASFORD: Object to the extent it mischaracterizes the witness's testimony.

THE WITNESS: Um, Norden does not call hyperemia small amounts of red blood cells in the subconjunctival space, but he does define it as -- as bleeding, and bleeding is different

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than vasodilation.

BY MR. CASSELLA:

Q. Are you aware that Dr. Noecker has opined that subconjunctival hemorrhage is unlike hyperemia?

MR. HASFORD: Objection, no foundation.

THE WITNESS: Yeah. I -- I'm not aware of that.

MR. CASSELLA: Can we go back to Dr. Noecker's declaration?

It's Exhibit, um, 204. I think it's displayed -- oh, I think it's mislabeled at 024 in -- in the PDF viewer.

And could we go to paragraph 202, which is on page 72 of the declaration?

BY MR. CASSELLA:

Q. And do you see that first sentence: "Moreover, unlike hyperemia, which occurs due to the dilation of the intact blood vessels, hemorrhage occurs when a blood vessel ruptures and bleeds."

Do you see that sentence?

A. Yes, I do.

Q. And so in this sentence, Dr. Noecker

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says that hyperemia is unlike hemorrhage, correct?
MR. HASFORD: Objection, no foundation.
THE WITNESS: Uh, in reading that sentence, what Dr. Noecker is describing is the dictionary diagnosis of what hyperemia is, what the dictionary description of what hyperemia is, but not the clinical application used by clinicians, especially clinicians who perform LASIK.
BY MR. CASSELLA:
Q. Have you cited any references in your declaration to support that clinicians performing LASIK use the term hyperemia in the way you've described?
A. I'm not aware of any articles that describe this.
Q. And, in fact, the only reference that you cite in support of your, uh, definition of hyperemia as referring to either vasodilation or micro-vessel hemorrhaging is Doshi, which is related to subconjunctival hemorrhage, correct?
MR. HASFORD: Object to the extent it mischaracterizes.

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THE WITNESS: Yeah. That -- that's the only reference that I looked -- I only looked for one, and I'm sure if I looked for others, I might find more, but I actually asked this question of a group of ophthalmologists who perform LASIK, and they uniformly described hyperemia as, um, leaking blood vessels in the subconjunctival space in the setting of LASIK.
BY MR. CASSELLA:
Q. But you have not provided that information in your declaration, correct?
A. I have not.
MR. HASFORD: Objection, argumentative.
THE WITNESS: Um-huh.
BY MR. CASSELLA:
Q. Now, Norden actually refers to subconjunctival hemorrhage and hyperemia independently of one another, correct?
A. He refers to them actually both as bleeding.
MR. CASSELLA: Can we go back to Exhibit 18, Norden?
And when we get there, go to page 468, which is the first page of the article.

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And if we could make the text a little bigger.
BY MR. CASSELLA:
Q. And, um, do you see on page 468 of Norden, under the Conclusion portion of the abstract, Norden states that: "This study suggests that brimonidine administered before LASIK may significantly reduce subconjunctival hemorrhage and reduce the amount of hyperemia."
Correct?
A. That's exactly what he says, yes.
Q. So in that sentence, he refers to subconjunctival hemorrhage and hyperemia separately, correct?
MR. HASFORD: Object to the extent it mischaracterizes.
THE WITNESS: Um, he refers to subconjunctival hemorrhage, um, and hyperemia as being different, and they are different. They look different, but they're the same disease process, and they're both bleeding, and that's the premise of his article. The title is bleeding. The title is not, uh, vasodilation. These are bleeding abnormalities occurring in patients having LASIK, and they do look different. I do agree with that, but they're

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the same underlying disease process, just different magnitudes of order.
BY MR. CASSELLA:
Q. And as we had saw earlier in Dr. Noecker's declaration, Dr. Noecker refers to hyperemia as vasodilation and not bleeding, correct?
MR. HASFORD: Objection, no foundation.
THE WITNESS: What you showed me is exactly what you stated here. Dr. Noecker describes hyperemia according to the dictionary definition of hyperemia, uh, used by scientists, uh, not by clinicians and especially not by LASIK surgeons.
BY MR. CASSELLA:
Q. If we go to page 469 of Norden, uh, just the next page down, it's the beginning of the Results section, and then -- let me know when you can see that.
Okay. Do you see the Results section beginning on page 469, Dr. Donnenfeld?
A. Yes, I do.
Q. Okay. And then the next page 470 has a Table 1, Table 2 figure and a couple of

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subsections titled Subconjunctival Hemorrhage, Hyperemia, Superior Micropannus Bleed, and Flap Slippage.
Do you see those sections?
A. Uh, yes, I do.
Q. And so Norden has a separate table for the results related to subconjunctival hemorrhage, correct?
A. Yes, he does.
MR. HASFORD: Objection, form.
BY MR. CASSELLA:
Q. And he has a separate table for superior micropannus bleed, correct?
A. Yes, he does.
Q. And then a separate figure for hyperemia, correct?
A. Yes, he does.
Q. And he has an individual subsection in this, uh, Results section for each of those, uh, three categories, Subconjunctival Hemorrhage, Hyperemia, and Superior Micropannus Bleed?
MR. HASFORD: Object to the form.
THE WITNESS: Yes, he does.
BY MR. CASSELLA:

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Q. On page 468, uh, just two pages up, under -- or just above the Patients and Methods section, there's a paragraph that begins: This prospective, double-masked trial was designed -- uh, designed to objectively assess the effect of brimonidine administration before LASIK on subconjunctival hemorrhage, hyperemia, and micropannus bleeding.
Correct?
A. Yes. Three different forms of bleeding.
Q. Do you have any understanding as to what, uh, grading scale was used to evaluate the hyperemia in the Norden reference?
A. He did not use a grading scale. He just arbitrarily created one of his own without visual representation. He didn't use a -- pictures, which most people use. He didn't describe the location of the, um, hyperemia, and, uh, didn't describe the presence or absence of vasodilation.
Q. If we go to paragraph 36 of your declaration, do you see at the end of this paragraph, which ends on the next page, uh, you state that: "Notably, the naked eye is unable

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to differentiate between hyperemia caused by vasodilation and the pinkness caused by scattered red blood cells in subconjunctival space due to micro-vessel hemorrhaging," and you cite Exhibit 562, correct?
A. Yes.
MR. CASSELLA: Could we please display Exhibit 562, which is -- uh, it's titled Picture of Hemorrhage, Exhibit 562?
BY MR. CASSELLA:
Q. And do you recognize Exhibit 562, Dr. Donnenfeld?
A. Yes, I do.
Q. Okay. Where did this image come from?
A. Um, I just Googled subconjunctival hemorrhage, and I took this off the Internet.
Q. So you don't recall what specific website it came from?
A. Uh, I do not.
Q. And so you provided this image to counsel for purposes of inclusion in your declaration?
A. Yes, I did.
MR. HASFORD: Object to the question.

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BY MR. CASSELLA:
Q. Okay. Paragraph 37 of your declaration, um, you state that: "Norden indicates that LASIK patients were examined 5 minutes post-operatively and again the next morning, which would have been at least 12 hours after surgery and likely longer."
And then you state: "Norden's results, however, state that 'the amount of hyperemia. . .was notably lower in patients treated prophylactically with brimonidine' when evaluated the next morning after surgery," correct?
A. That's what I said, yes.
Q. And you quote Norden in that second sentence that I just recited, correct?
A. "Notably lower"? Yes. I -- that's what I was -- that was his description.
Q. Yeah. You quote Norden as stating the amount of hyperemia is notably lower in patients treated prophylactically with brimonidine, end quote, correct?
A. Yes.
Q. The words following that quote do not appear in Norden, "when evaluated the next

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morning after surgery," correct?
MR. HASFORD: Objection, argumentative, and objection to the extent it mischaracterizes the documents.
THE WITNESS: No. That was not his writing. That's my interpretation of him describing seeing patients the day following surgery.
MR. CASSELLA: Can we go back to Exhibit 18, please, page 469?
BY MR. CASSELLA:
Q. Do you recall, Dr. Donnenfeld, how many eye examinations Dr. Norden performed?
A. I believe he described, uh, two examinations.
Q. And on page 469, in the -- uh, one of the middle paragraphs there, Norden states: "Slit-lamp microscopy was performed 5 minutes postoperatively."
Correct?
A. Uh, if you could just blow that up for me, I'd appreciate it.
Yes.
Q. And then, uh, a few sentences down in that same paragraph, it states: "For purposes

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of this study, eyes were examined again the next morning."
Do you see that?
A. Yes.
Q. So it's -- Norden performed two eye examinations, correct?
A. That's what I believe, yes.
Q. One was five minutes post-op, and the other was the next morning, correct?
A. Correct.
Q. In the following paragraph, it states: "The operating surgeon (R.N.) performed the post-operative examinations and recorded the amount of subconjunctival hemorrhage, hyperemia, bleeding from the micropannus, and flap slippage/wrinkling."
Do you see that?
A. Yes.
Q. Where in Norden does it state that the data related to the amount of subconjunctival hemorrhage, hyperemia, and bleeding from the micropannus came from the examination the morning after the operation?
A. It says for purposes of the study, which means for the study, the eyes were

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examined again the next day. He examined the next day for the study. The study was on hemorrhages. Therefore, a POSA would know that the patient examined the next day had an examination of the hemorrhages that occurred.
Q. That sentence does not state that, though, correct?
MR. HASFORD: Objection, argumentative.
Objection to the extent it mischaracterizes the document.
THE WITNESS: It says: For purposes of the study, eyes were examined again the next morning. (As read)
BY MR. CASSELLA:
Q. It doesn't say whether hyperemia, hemorrhage or bleeding were measured in the five-minute post-op examination, or in the morning-after examination, correct?
A. It does not.
MR. HASFORD: Objection to the extent it mischaracterizes.
THE WITNESS: Yeah.
BY MR. CASSELLA:
Q. So it's entirely possible that the,

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uh, amount of subconjunctival hemorrhage, hyperemia, and bleeding from the micropannus were measured in the five-minute post-op examination, correct?
MR. HASFORD: Object. Objection to the extent it mischaracterizes the document.
THE WITNESS: No. I mean, that's very bluntly a silly thought; that when you do a study and you say you're examining the patient, you do the same examination on both days unless you differentiate between them -- between them.
Um, it said the operating surgeon performed the postoperative examinations, not examination, and recorded the amount of subconjunctival hemorrhage, hyperemia, bleeding from the micropannus, and flap slippage. Uh, that means that he recorded the exact same thing on both examinations.
BY MR. CASSELLA:
Q. And so it's your opinion, Dr. Donnenfeld, that the results reported in Norden are the results from only a morning-after examination and did not contain any data from the five-minute post-op examination?
A. Uh, I don't know the answer to that

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question. That really is a good question, and it should be in a good paper. It should be there, but it's not written in this paper on whether the results were described for that day or the next day or whether you assume that they were the same.

Q. I'm sorry. Could you -- I didn't catch the last part about you're --

A. Sure.

Q. -- assuming they were the same.

A. Yeah. The -- the surgeon performed two examinations, examining hemorrhages on both examinations. It is not written whether the findings that he presents here are recorded from five minutes postoperatively or the next day or a mean of both examinations or whether the examinations were the same.

It's, again, an intrinsic, uh, lack of evidence in the study that basically is a -- is a fairly poor design. You're absolutely right. They should have described what it was like five minutes post-op, and they should have described it the next day, but examinations were performed both days, and they were looking at bleeding. And I cannot tell you exactly what

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the bleeding that took place here, whether it took place or was described at five-day or the next day. It just -- that data is just not there.

Q. Would a reduction of subconjunctival hemorrhage reduce redness?

MR. HASFORD: Objection to the form of the question, incomplete hypothetical.

THE WITNESS: I'm sorry.

Could you just repeat that one more time, please?

BY MR. CASSELLA:

Q. Sure. I'll make it more specific.

In Norden, he concludes that brimonidine reduced the amount of subconjunctival hemorrhage, correct?

A. Yes, he did.

Q. If there -- in -- sorry. Let me rephrase.

Is the reduction of subconjunctival hemorrhage described in Norden a reduction in eye redness?

MR. HASFORD: Object to the form of the question.

Object to the extent it

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mischaracterizes the documents.

THE WITNESS: I don't recall specifically whether he -- whether he called it eye redness or not, but by definition, a subconjunctival hemorrhage is redness, but I don't recall him saying specifically redness.

BY MR. CASSELLA:

Q. So would you agree that the reduction of hemorrhage is a reduction of redness?

MR. HASFORD: Same objections.

THE WITNESS: A reduction in hemorrhage would be a smaller hemorrhage, but it also could be a larger -- it could be -- the hemorrhage could either be smaller, or it could be less blood in a small amount of area so that a reduction in hemorrhage could mean that the area of the hemorrhage was smaller, or it could also mean that the amount of blood in one space was lower.

BY MR. CASSELLA:

Q. Would the administration of a vasoconstrictor -- excuse me.

Would the administration of a vasoconstrictor before LASIK cause less subconjunctival hemorrhage because the blood

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vessels themselves are smaller?

MR. HASFORD: Object to the form of the question, incomplete hypothetical.

THE WITNESS: Um, the answer is, that a vasoconstrictor, um, could cause less hemorrhage because the vessels are smaller. It also could mean that the, um, junctions between the, um, endothelial cells are tightened so that there's less leakage of blood out of the eye.

So it could be several mechanisms of action, but one of them could certainly be that the vessels were smaller.

BY MR. CASSELLA:

Q. Okay. I'd like to turn to paragraph 40 of your declaration.

And do you see paragraph, uh, 40 of your declaration displayed on the screen, Dr. Donnenfeld?

A. Yes.

Q. And in the last sentence of this paragraph on your declaration, you state that, uh: "Gil focuses on the use of brimonidine to treat ocular pain."

Correct?

A. Correct.

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Q. Is there a relationship between ocular pain and ocular redness?
A. Um, yes.
MR. HASFORD: Object to the form of the question.
THE WITNESS: Okay.
The answer is that, uh, pain can be associated with redness, or pain could be associated with a lack of redness.
As a matter of fact, that's exactly the statement that, uh, Gil makes in the third paragraph of his, um, um, paper. He says that pain can be related to inflammation or ischemia, so that you can have pain with redness or pain without redness.
BY MR. CASSELLA:
Q. When pain occurs with redness, do you have any understanding as to how that -- sorry. Let me rephrase.
So pain can occur with redness, correct?
A. That's one of the ways that pain can occur, yes.
Q. And can you just explain what -- um, what is happening in the eye when pain occurs

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with redness?
A. Well, when pain occurs with redness, very commonly it's associated with inflammation, and inflammation can, um, cause pain receptors to be activated, um, and, uh, create a -- create -- and create discomfort.
Q. So the inflammation can cause both the pain and the redness?
MR. HASFORD: Object to the extent it mischaracterizes the witness's testimony.
THE WITNESS: Yeah. Inflammation can cause redness, and inflammation can cause pain. That -- that is correct.
BY MR. CASSELLA:
Q. Okay.
MR. CASSELLA: Could we display Exhibit 36, please, which is the Gil reference?
BY MR. CASSELLA:
Q. Do you see Exhibit 36 displayed on your screen, Dr. Donnenfeld?
A. Yes, I do.
Q. And that's U.S. Patent Number 6,294,553 to inventor Daniel W. Gil, correct?
A. Yes.
Q. And this is the Gil reference that

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you discuss in your declaration?
A. Yes, it is.
MR. CASSELLA: Now, if we could go to column one of Gil. It's, um, just a couple pages down, I think.
BY MR. CASSELLA:
Q. Do you see in column one of Gil, right around line 10, it says that the "invention relates to the topical application of brimonidine for treating ocular pain and neurogenic inflammation and compositions useful for such application"?
A. Yes. I do see that.
Q. So Gil says that the invention is -- relates to treatment of both ocular pain and neurogenic information?
A. Well, what -- what Gil's describing here is a model of pain or trauma. Um, the model here is a trauma model. Um, I think all the models he has here are trauma models, and the, uh, thought that trauma can be applied to the use of a medication to reduce redness is not applicable. Uh, trauma is something that is -- that we don't use, um, redness relievers for. Trauma is a whole different entity, and all of

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the descriptions he has here are related to pain, and pain, uh, is not the model that we look for when we look at the invention of a medication used for treating redness.
So all the -- you know, all -- everything that's described in the Gil patent relates to pain, and you cannot read anything regarding hyperemia or redness from this patent. Um, hyperemia can be seen with pain, but, um, treating hyperemia in clinical application using, um, vasoconstrictors is not done in the setting of pain. As a matter of fact, it's specifically not supposed to be used in the setting of trauma.
So, um, everything here I discounted as not being applicable, uh, to -- to hyperemia.
Q. Okay. That was, uh, not related to my question.
My question was just in this column one, around line 10, Gil says that the invention relates to the topical application of brimonidine to treat pain and neurogenic inflammation, correct?
MR. HASFORD: I'll -- I'll object. I'll move to strike the colloquy at the

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beginning once again, um, and I'll object as argumentative.

THE WITNESS: Um, the field of the invention does state that it is for treating ocular pain and neurogenic inflammation, yes. That -- that is what is stated here, but it's a model that does not apply to ocular redness.

BY MR. CASSELLA:

Q. And inflammation, specifically neurogenic inflammation, can cause redness, correct?

MR. HASFORD: Objection, incomplete hypothetical, and object to the extent it mischaracterizes the document.

THE WITNESS: Um, neurogenic inflammation occurs when you have pain, and with pain you can have inflammation.

BY MR. CASSELLA:

Q. Gil said in column one that pain is "an indicator of injury or tissue damage due to inflammation, ischemia, mechanical or other irritation."

Correct?

A. Yes. That's true.

Q. So pain can be an indicator of damage

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due to inflammation, correct?

A. Yes, or ischemia or mechanical or other irritation.

Q. In the next paragraph, beginning around line 20, Gil describes how the, uh, sensation of pain happens in the body; is that correct?

I should say -- sorry. Let me just be more clear.

In that column one, beginning around line 20, Gil describes how the sensation of pain occurs in the eye, correct?

A. Yes, he does.

Q. Okay. And the first step leading to the sensation of pain as taught by Gil is the activation of nociceptive primary afferents by some sort of stimuli, correct?

A. That -- that is what he states, yes.

Q. And primary afferents are nerves or neurons?

A. Yes.

Q. And this stimulation leads to action potentials in their axons which propagate to the spinal cord?

A. Um, you know, pain -- pain receptors don't necessarily go to the spinal cord, but the statement you made is accurate that there are neurons that are -- um, uh, that are initiated, and they go to a, um, tissue, um, that does respond by creating the sensation of pain. It can go to the brainstem. It can go to the spinal cord. It can go to the brain itself, um, but yes. Um, there has to be a neuron that fires, that goes to a target tissue.

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Q. I'm looking at, um, column one of Gil around line 35. It just says: "The stimulation of primary afferents leads to action potentials in their axons which propagate to the spinal cord."

Correct?

A. Yes. That's exactly what he states.

Q. Okay. And do you agree with that statement?

A. Um, I'm really not a neurologist, so I'm not an expert in, um, um, the neurologic spinal cord basis of pain. I do know a great deal about, uh, pain in the eye itself, but, um, I can't say whether it goes to the spinal cord or elsewhere.

Q. Okay. That's fair.

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Now, the next sentence in Gil, he states that the "excited primary afferents release neuropeptides," including substance P, calcitonin gene-related peptide, and neurokinin A at their peripheral terminals.

Do you see that?

A. Yeah. I do see that.

Q. And these "Neuropeptides enhance inflammatory reactions in the injured tissue, contributing to vasoconstrictor, edema, and increased vascular permeability, this phenomena is called 'neurogenic inflammation,'" correct?

A. Um, he describes neurogenic inflammation this way. Again, I'm not an expert in substance P, calcitonin gene-related peptides, neurokinin A's, uh, at their peripheral terminals.

I do know a great deal about pain, uh, at the ocular surface, but I can't really say the role of these different neuropeptides in causing pain. It's not my area of expertise.

Q. So the activation of these primary afferents that we just discussed leads to both the sensation of pain and the release of neuropeptides that cause neurogenic

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inflammation?
A. Um --
MR. HASFORD: Objection that it mischaracterizes the document.
THE WITNESS: Yeah.
You know, for purposes of what we're speaking here today, I'll define neurogenic inflammation as inflammation of the nerves that go on to cause, uh, additional inflammation which could include, uh, vascular permeability or -- vascular permeability or redness.
MR. HASFORD: It does look like we've been going a little over an hour.
Would this be a good time for a break?
THE WITNESS: Can I --
MR. CASSELLA: Yeah. Why don't we -- we can break, and I don't have too much longer, but it would probably be good to just, uh, take a break now.
MR. HASFORD: Okay. That's fine.
THE VIDEO TECHNICIAN: We're off the record at 18:19.
* * *
(Whereupon, a short recess was taken.)

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* * *
THE VIDEO TECHNICIAN: Back on record 18:28.
BY MR. CASSELLA:
Q. So, Dr. Donnenfeld, I think we were just discussing the -- well, actually, why don't we just turn to your declaration, paragraph 40. Uh, it's on page 14.
And you -- this is the beginning of a subsection E where you state that: A POSA Would Not Have Understood Gil (Ex. 36) to Teach That Topical Administration of 0.2% Brimonidine Reduces Eye Redness.
Correct?
A. Correct.
Q. And we were just discussing the Gil reference, and we were discussing the activation of the primary afferents, correct?
A. Yes.
Q. And I believe you testified that the activation of the primary afferents leads to the sensation of pain; is that correct?
A. That's correct.
Q. And the activation of the primary afferents also leads to the release of

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neuropeptides, correct?
A. Yeah. That -- that -- that I would say is yes, but, again, especially in the setting of a trauma model like this, um, there should be additional neuropeptides that are released.
Q. Okay.
MR. CASSELLA: Can we please display, um, it's Exhibit 601, and it's titled Belmonte.
BY MR. CASSELLA:
Q. And just let me know when you can see Exhibit 601 displayed on your screen.
MR. CASSELLA: I think we -- uh, could we mark it, Erin, as -- uh, with just like a sticker or something 601?
* * *
(Whereupon, Deposition Exhibit 601 was marked for identification.)
* * *
MR. CASSELLA: And maybe make the text a little bigger for Dr. Donnenfeld.
BY MR. CASSELLA:
Q. Okay. Dr. Donnenfeld, do you see Exhibit 601, a reference titled Neurobiology of Ocular Pain, displayed on your screen?

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A. Yes, I do.
Q. Have you ever seen this document?
A. I have not.
MR. CASSELLA: Could we go to page 119 of Exhibit 601, which, uh, begins on -- it's page three of the PDF?
BY MR. CASSELLA:
Q. And on the left-hand column --
MR. CASSELLA: Uh, make the text a little bigger, please.
BY MR. CASSELLA:
Q. Uh, towards the top of the page on the left-hand column, can you read that size text or --
A. I have to go a little larger.
All right. That's good.
Q. Okay. So the left-hand column on page 119 of Exhibit 601, which, uh, I'll refer to as Belmonte, it states that "ocular pain is an immediate consequence of the activation of trigeminal sensory neurons by various forms of energy (mechanical, thermal and chemical), acting at injurious or near injurious levels."
Do you see that?
A. Yes, I do.

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Q. And then the next sentence: "The front of the eye is abundantly innervated by the terminal processes of nociceptive nerve cells. There, noxious stimuli are readily detected, and distinct pain sensations are subsequently evoked."

Do you see those sentences?

A. Yes, I do.

Q. Do you agree with the -- these statements in Belmonte, Exhibit 601?

A. No. I -- you know, I really think that they need to be discussed. Uh, when you -- when they speak to the front of the eye, uh, you're speaking of the conjunctival, sclera, and cornea. The cornea is the most innervated portion of the body. It has the most pain receptors and is extraordinarily sensitive to pain.

Uh, the conjunctiva, on the other hand has very few pain receptors and is really, uh, a very different tissue than the cornea. The cornea also has no blood supply, whereas the conjunctiva does have blood supply, and the sclera has actually less pain receptors than -- than both of them.

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So they are really putting all three parts of the front of the eye together and lumping them together, whereas they're really very different.

Q. I see.

It's -- uh, so you're -- you're saying that the front of the eye, as used in this paragraph, is, um, somewhat vague?

MR. HASFORD: Object to the extent it mischaracterizes the witness's testimony.

THE WITNESS: Yeah. I would say it's just not accurate.

BY MR. CASSELLA:

Q. Do you see the next paragraph: "In addition to signaling injury, primary sensory neurons innervating the eye play other roles in the injury response: they enhance local inflammatory reactions caused by tissue damage through the release of mediators such as neuropeptides from their peripheral nerve endings (neurogenic inflammation)"?

A. Yes.

Q. And sitting here today, do you have any reason to disagree with that statement in Belmonte?

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A. I have no reason to doubt this, but, again, uh, I'm not a neurobiologist, so this is not really my area of expertise.

Q. Okay. I -- I understand.

Um, I just want to look at a few more paragraphs then, and just you can tell me whether you have an understanding as to what they disclose or not.

MR. CASSELLA: Could we go to paragraph -- I'm sorry -- page 138?

Uh, it's going to be, uh, 22, page 22 of the PDF. Yep. There it is.

BY MR. CASSELLA:

Q. And do you see up at the top of the page on page 138 of Belmonte there's a section entitled: Changes in Ocular Sensory Neurons Secondary to Ocular Injury and Inflammation, and the subsection immediately, uh, underneath that is subsection 5.1, Inflammatory Mediators Released by Ocular Injury?

Do you see that?

A. Yes.

Q. And in the first sentence underneath that heading, it states that: "Injurious forces acting on body issues, cause cell damage and

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destruction and excite nociceptive endings of the affected tissues. Inflammation is a localized protective response that serves to destroy, dilute or wall-off the injurious agent and the injured tissues. It is a complex process involving pain, dilation of peripheral blood vessels, increased vascular permeability, plasma extravasation and migration of leukocytes into the inflamed area."

Do you see that sentence or couple of sentences on page 138 of Belmonte?

MR. HASFORD: Object to the form.

THE WITNESS: I do see that, yes.

BY MR. CASSELLA:

Q. Okay. And sitting here today, do you have any reason to dispute the -- uh, these statements in Belmonte?

MR. HASFORD: Objection, no foundation.

THE WITNESS: Uh, actually, I do.

And, um, when you speak of injurious forces to the, um, uh, front of the eye, um, they're really talking about acute traumatic injuries to the eye, um, where I believe this would be accurate to go -- again, not my area of

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expertise. However, it's very well described that chronic injury to the cornea, uh, and front of the eye actually causes anesthesia, and there's a loss of response, and that's one of the very common sequelae to dry eye in that not only does the eye become dry, but it becomes less sensitive to pain and it releases less inflammatory mediators.

So the description they have here I think would apply to an acute traumatic injury such as the trauma models that were described by Gil, but it wouldn't apply to a chronic red eye due to chronic irritation such as dry eye which, uh, your expert described as the most common cause of red eye where there's actually a loss of sensation, and the eye actually produces less inflammation than it would if it was an acute injury.

BY MR. CASSELLA:

Q. Okay. I appreciate the clarification there.

Do you see the next paragraph then: "An initial step in the inflammatory response to injury is the release of neuropeptides from sensory nerve fibers excited by the noxious

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stimulation. Neuropeptides in turn initiate local responses acting directly on target cells, or indirectly through the release of other chemical mediators. This phenomenon, called 'neurogenic inflammation,' constitutes the first line of defense of the immediate response to injury."

Do you see that?

A. Yes, I do.

Q. Okay. And do you have any reason to dispute these statements from Belmonte?

MR. HASFORD: Objection, no foundation.

THE WITNESS: Again, not my true area of expertise, but, you know, I do agree that in an acute injury, which is being described here, they are describing an acute injury that these things occur. However, in -- and that's what occurs with pain in general. However, in a chronic irritation, I don't believe that these same issues would apply, uh, such as a chronically red eye.

BY MR. CASSELLA:

Q. Does Gil relate to chronic injuries?

A. No. Gil actually speaks to acute

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injuries. He -- he speaks to trauma. I think in trauma, um, these steps that are described here are probably fairly accurate, but a trauma model of red eye is something that should not be applied to medications. There's no use of trauma in evaluating a, um, medication for the treatment of red eye. Trauma is a separate tissue and as a matter of fact, trauma is an exclusion for evaluating a medication for the treatment of dry eye or -- or -- I'm sorry, or redness.

Q. In the next paragraph of Belmonte it states: In the eye, the inflammatory response consecutive to injury includes dilation of blood vessels which causes increased blood flow, plasma extravasation, breakdown of the blood-aqueous humor barrier, miosis and infiltration of inflammatory cells. Most of the known inflammatory mediators have been found in the conjunctiva and anterior, uh, uveal tissues and in a lesser degree in the retina, during the development of local inflammation. (As read)

Do you see that sentence there?

A. I do, yes.

Q. Do you have any reason to dispute

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those statements from Belmonte?

MR. HASFORD: Objection, no foundation.

THE WITNESS: Um, yeah. Yeah. The inflammatory response here is in relation to injury, and I think in response to injury, which is trauma, um, uh, most of these findings I would agree with, but, again, I preface my remarks by saying this is not truly my area of expertise.

BY MR. CASSELLA:

Q. Okay. Fair enough.

A. Um-huh.

Q. Um, on page 146, I just want to look at a couple more passages from Belmonte. Page 146, there's a heading: Other Protective Mechanisms Mediated by Ocular Sensory Neurons.

That's the heading of section seven, and then immediately underneath that is a subsection 7.1 entitled Neurogenic Inflammation.

Do you see this subsection on page 146 of Belmonte?

A. Yes.

Q. And Belmonte states: As described in Section 5, neurogenic inflammation constitutes

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the first line of defense of the eye against acute injury. Topical application to the eye of capsaicin or nitrogen mustard or anterior segment mechanical or thermal injury evokes an irritative response characterized by corneal edema, miosis, aqueous humor flare, photophobia, conjunctival vasodilatation -- excuse me -- lid edema and lacrimation, which can be attenuated by denervation or blockade of corneal nerves with local anesthetics or tetrodotoxin. (As read)

Do you see that sentence?

A. I do.

Q. Okay. Do you have any reason to dispute those statements from Belmonte?

MR. HASFORD: Objection, no foundation.

THE WITNESS: Um, again, what they're describing here is an acute injury. Uh, an acute injury has absolutely nothing to do with management of chronically red eye. So what's being described here is reasonable in the setting of an acute trauma or application of a, uh, toxic substance, but it doesn't really apply to using vasoconstrictors to treat red eyes.

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BY MR. CASSELLA:

Q. Do you see a couple sentences down Belmonte says the: Selective blockade of the responsiveness of corneal sensor -- sensory fibers to chemical irritants with diltiazem also reduces ocular neurogenic inflammation. (As read)

And the next sentence: Neurogenic inflammation is attributable to antidromic release of ocular -- by ocular nerves of neuropeptides (substance P and related tachykinins; CGRP) and perhaps to still unknown mediators released by sensory nerves, which enhance local inflammatory processes. (As read)

Do you see those sentences?

A. I do.

Q. And do you have any reason to dispute those statements from Belmonte?

MR. HASFORD: Objection, no foundation.

THE WITNESS: Um, I'm not familiar with many of these, um, topics being discussed, so I -- I really don't have an informed decision to give you on this.

BY MR. CASSELLA:

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Q. Okay. Do you understand CGRP in the sentence that I just read to refer to calcitonin gene-related peptide?

A. I'm -- I -- I am familiar with what that -- that says. I'm not that familiar with what it does.

Q. Okay. And Gil mentions substance P and CGRP, correct?

A. Yes.

Q. And those are the same neuropeptides that Gil says are released upon activation of the primary afferents; is that correct?

A. Associated with trauma, yes.

Q. Okay.

MR. CASSELLA: Could we go back to Gil for just a minute, uh, column three of Gil?

It's Exhibit 36.

Uh, can we make the text a little bigger?

And actually, can we display just the -- the very last paragraph in column two?

It's the page above, and kind of display both the end of the previous page and the beginning of the next page.

BY MR. CASSELLA:

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Q. So in column two on the right-hand side of Gil, it states: "The sites of action are presumed to be in the spinal cord and in the brain, where they can reduce the perception of pain."

Do you see that sentence?

A. Um, if you could magnify that a little bit, it would be helpful for me. Thanks.

MR. CASSELLA: Yeah. Can we blow that up just a little bit?

BY MR. CASSELLA:

Q. Do you need it to be a little bigger than that or --

A. No, this is fine.

I think you oriented me to the paragraph above the -- okay. I see: The sites . . .

Okay. Now, I'm -- I'm fine.

So, "The sites of action," that's the sentence you're referring to?

Q. Yeah. Just to orient you onto where I'm looking at Gil.

Do you see that sentence, the end of column two and, uh, kind of one word into column three on the next page?

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A. Yes.
Q. Okay. And then the next sentence on -- in column three says: "One potential mechanism for the alleviation of pain at the level of the spinal cord is the inhibition of the release of chemical mediators of pain, including substance P and calcitonin gene-related peptide."
Do you see that sentence?
A. I do.
Q. And do you have any reason to dispute Gil's statement in that, uh, column three?
A. No. I think that in a -- in a pain model, that this would apply, yes.
Q. Okay. And Gil says that: This mechanism has been demonstrated in vitro for the alpha-2 agonist, the dexmedetomidine and acting on rat spinal cord slices and for brimonidine (UK 14304) acting on cultured dorsal root ganglion cells. (As read).
And then it cites Supowit 1998 and provides the title Alpha-2 adrenergic receptor activation inhibits calcitonin gene-related peptide expression in cultured dorsal root ganglia neurons.

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Do you see that passage in Gil?
A. I do.
Q. And do you have any reason to dispute that statement from Gil?
A. You know, Gil is describing the use of, uh, alpha-2 agonists in reducing pain and, um, while this may apply, uh, systemically, there really has been no use of alpha-2 agonists in, uh, reduction of pain in ophthalmology. This is something that's not done, to my knowledge, by anyone, and I'm not aware of any clinical trials on patients in which this has been done, other than the RK study, which was again a trauma study, but it's certainly nothing that's done today in the management of act- -- of pain.
But as far as his description of the pathways that are here, again, not my area of expertise, but I have no reason to doubt what he says.
Q. Do you have any understanding as to what dorsal root ganglion cells are?
A. Uh, I have a broad understanding, but I really couldn't define it accurately.
Q. What is your broad understanding?

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A. They are, um, uh, neurons that go to the spinal cord, uh, that have to do with, uh, sensation of pain -- sensation and pain.
But, again, not my area of expertise. I don't really want to venture too far on this.
Q. Okay. Fair enough.
A. Um-huh.
MR. CASSELLA: Can we display the Exhibit 605 Supowit, please?
And could we mark this also, uh, just with, like, a little sticker 605?
* * *
(Whereupon, Deposition Exhibit 605 was marked for identification.)
* * *
MR. CASSELLA: Um, and please zoom in so Dr. Donnenfeld can read it.
BY MR. CASSELLA:
Q. Dr. Donnenfeld, do you see Exhibit 605 displayed on your screen right now?
A. Yes, I do.
Q. And this is a -- I'm sorry. I think -- uh, we're -- oh, okay. We're back.
Uh, this is a paper titled a2-Adrenergic receptor activation inhibits

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calcitonin gene-related peptide expression in cultured dorsal root ganglia neurons, correct?
A. That's the title, yes.
Q. And the first author is Scott C. Supowit?
A. Yep.
Q. And is this the same Supowit reference that was mentioned in Gil in column three that we just discussed?
A. I believe so.
Q. Okay. In the abstract of Supowit --
MR. CASSELLA: And maybe we could zoom in even further because the abstract text is small.
BY MR. CASSELLA:
Q. Uh, the abstract of Supowit states that: "Calcitonin gene-related peptide or CGRP, a potent vasodilator, is produced in dorsal root ganglia (DRG) neurons which extend nerves peripherally to blood vessels and centrally to the spinal cord."
Do you see that sentence?
A. I do.
Q. Okay. Do you have any reason to dispute that statement in Supowit?

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MR. HASFORD: Objection, no foundation.
THE WITNESS: Again, this is not my area of expertise, and, um, in all due respect, we're talking about a pain model here that has nothing to do with the management of red eye as we know it in ophthalmology. So it's certainly some -- some very interesting basic science, but it doesn't have anything to do with what we do clinically.
BY MR. CASSELLA:
Q. Do you see in the middle of the abstract, um, there's a reference to nerve growth factor (NGF)?
Do you see that?
A. Uh, which line down is it?
Q. Uh, it's like right in the middle, um --
A. Yeah. I see it. Yep.
Q. You know, the full sentence -- just so the record's clear, the full sentence in the abstract is: "Using the rationale in vivo DRG neurons receive a continuous supply of target tissue derived nerve growth factor (NGF), which stimulates CGRP synthesis, the cultured neurons

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were treated," and it goes on to explain the, um, methods of the study.
Do you see that sentence that I just read?
A. I do.
Q. Okay. And do you have any reason to dispute that nerve growth factor stimulates CGRP synthesis?
MR. HASFORD: Objection, no foundation.
THE WITNESS: Again, my same response. This is not my area of expertise. It has nothing to do with our clinical use of vasoconstrictors to treat red eyes and ophthalmology.
BY MR. CASSELLA:
Q. In the introduction heading, it's the --
MR. CASSELLA: On, yeah, the first page of Supowit page 184, um, just scroll down just a little bit.
BY MR. CASSELLA:
Q. The first paragraph under the Introduction, it states that: Calcitonin gene-related peptide (CGRP, and the tachykinins,

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substance P and neurokinin A) are found in a subpopulation of sensory neurons, mainly in those with small myelinated and nonmyelinated fibers which mediate nociceptive signaling. (As read)
Do you see that sentence?
A. I do.
Q. Okay. And the CGRP, substance P, and neurokinin A are the neuropeptides that were referenced in Gil, correct?
A. Yes.
Q. And Gil relates to nociceptive signaling, correct?
A. Yes, he does.
Q. Now, the next sentence in the introduction states: "The cell bodies of these neurons are located in dorsal root ganglia (DRG) and extend nerves that terminate centrally in laminae I/II of the spinal cord and in a variety of peripheral tissues including blood vessels."
Do you see that sentence?
A. Yes.
Q. And understanding that this may not be your particular area of expertise, do you have any reason to dispute this sentence in

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Supowit?
MR. HASFORD: Objection to form, no foundation.
THE WITNESS: Yeah. I -- um, I cannot confirm or deny whether this is accurate or not, and I, being an expert in managing red, eyes, don't see any role in how this applies to the routine management of red eyes with -- with vasoconstrictors.
So, you know, it -- it certainly is very good basic science. Um, I can say that a POSA in the field of ophthalmology would not have any knowledge of this.
BY MR. CASSELLA:
Q. Do you see the next sentence: Although the sensory nervous system functions to 'sense' stimuli in the periphery, and transmit the information centrally through the afferent pathway, it also possesses an efferent function through the release of neuropeptides from peripheral sensory nerve fibers in response to local stimuli. Thus the release of CGRP (and substance P) from the sensory nerve terminals in the dorsal horn of the spinal cord modulates pain transmission, while release from terminals

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in peripheral tissues plays as key role in neurogenic inflammation. (As read)
Do you see that sentence?
A. I do.
Q. Do you have any reason to dispute that sentence in Supowit?
MR. HASFORD: Objection, no foundation.
THE WITNESS: I -- I really can't comment on this. This is not my area of expertise.
BY MR. CASSELLA:
Q. Okay. Fair enough.
A. Um-huh.
Q. Um, the next page, page 185 --
MR. HASFORD: You know, I'm going to have to ask you at this point, Chris, how much more of this are you going to do based on his previous answers to these questions?
Because it's -- it's getting borderline, um, problematic here.
MR. CASSELLA: He's responded to some of them with substantive testimony. I just want to understand what his --
MR. HASFORD: You -- you've heard

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what he's been saying. I mean, you know, if -- because we're going -- we're going to have to -- to cut this off at some point.
MR. CASSELLA: Well, uh, this is my time. So unless you're trying to halt the deposition, I think we're just going to keep going.
We'll just -- I'm not trying to keep the witness here all night. I want to -- you know, I want to get this over with as quickly as possible, so we don't have that much more.
MR. HASFORD: Yeah. Okay. Well, this is a complete waste of time. I'm going to put that on the record.
So go ahead.
MR. CASSELLA: Noted for the record.
BY MR. CASSELLA:
Q. Uh, page 185, on the left-hand column, the middle paragraph states: Activation of a2-adrenoreceptors on afferent nerve terminals at the periphery can also inhibit neuropeptide release.
Do you see that?
A. Yes, I do.
Q. Okay. And do you have any reason to

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dispute that statement from Supowit?
MR. HASFORD: Objection, no foundation.
THE WITNESS: Um, actually, I believe this to be accurate, and, um, I am familiar with this, uh, again mostly applied to a pain model which, um, everything, um, in his article refers to pain and not to red eye.
BY MR. CASSELLA:
Q. Okay.
MR. CASSELLA: If we could go to page 190?
BY MR. CASSELLA:
Q. And in the discussion section, uh, it's further down on the left-hand column, it states that: "The results of the present study demonstrate that the a2-adrenergic receptor agonist UK 14,304 can attenuate the stimulatory effects of NGF on CGRP mRNA accumulation and iCGRP levels in primary cultures of adult DRG neurons."
Do you see that sentence?
A. Yes. And, uh, I have no expertise in this area and cannot comment on this as being accurate or not accurate. It has nothing to do

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with what we do to manage red eyes.
Q. Do you understand that UK 14,304 is the compound brimonidine?
A. No. Was not aware of that.
Q. Do you --
A. Still my -- my answer -- my answer's the same, though. I don't know the stimulatory effects of NGF on CGRP mRNA accumulation. Um, this is, um, in -- this is basic scientist [sic], uh, not clinical medicine.
Q. Do you recall whether Gil references UK 14,304 as brimonidine?
A. I believe he does. I'd have to go back and look again, but I do believe that's accurate.
Q. Okay. On page 191 -- oops. Sorry. I lost my column there.
Do you see on the bottom right-hand column of page 191, it states: "Therefore our observations --"
A. I'm sorry. I apologize.
Where am I looking?
MR. CASSELLA: Uh, I think we need to scroll further down on 191. It's at the very bottom of page 191 in the right-hand column.

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Uh, yeah.
BY MR. CASSELLA:
Q. Towards the very bottom there: "Therefore" -- it states: "Therefore, our observations that an a2-agonist can inhibit both the production and release of a very potent vasodilator in sensory neurons suggests one possible mechanism which could account for the reduced neuronal expression of CGRP."
Do you see that sentence?
It continues onto the next page.
A. I do.
Q. Okay. And one more time: Do you have any reason to dispute that sentence in Supowit?
MR. HASFORD: Objection, no foundation.
THE WITNESS: Um, I -- yeah. I would agree that an a2-agonist can, um, be a vasodilator or it can be a vasoconstrictor. I don't know how it applies in reference to this, uh, paper.
Again, this is a basic science paper written 25 years ago in a publication called Brain Research. Um, it's about as far away from

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what I do on a clinical basis as could possibly exist.
BY MR. CASSELLA:
Q. Do you agree that the decreased activity of CGRP-containing nerves could facilitate adrenergic vasoconstriction and thus contribute to the elevated peripheral vascular resistance?
MR. HASFORD: Objection, no foundation, incomplete hypothetical.
THE WITNESS: Yeah. I can't comment on that.
BY MR. CASSELLA:
Q. Uh, earlier, you testified that you had been found liable in a med-mal case; is that correct?
A. Yes, I was.
Q. Were you required to compensate the plaintiff in that case?
A. Uh, yes. There was a -- um, um, there was an award given. And again, um, just for the record, it was a case in which I was not guilty, but, again, a jury found differently, but there was compensation that was made, and I can't recall exactly what the number was.

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Q. Do you recall -- could you -- I'm sorry. I'm going to rephrase.
Um, what order of magnitude was the compensation?
Was it the order of hundreds of dollars?
MR. HASFORD: Objection to the form of the question.
THE WITNESS: Um, I don't recall exactly. It was, um, several hundred thousand dollars, but I can't recall directly.
BY MR. CASSELLA:
Q. Dr. Donnenfeld, do you have any notes with you?
A. No, I do not.
Q. Do you have any documents with you in the room?
A. I do not.
Q. Did you discuss the substance of your testimony at any point with counsel today?
A. Um, not subsequent to us starting this conversation today. I did before -- you know, earlier on, before we spoke to you.
Q. Okay. Fair enough. I have no further questions.

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Thank you, Dr. Donnenfeld.
A. Thank you.
MR. HASFORD: A little bit of follow-up.
* * *
EXAMINATION
* * *
BY MR. HASFORD:
Q. Um, good evening, Doctor.
A. Good evening.
Q. Earlier today, um, Mr. Cassella asked you, uh, whether you reviewed, um, Dr. Galanis's deposition transcript.
Do you remember that?
A. Yes, I do.
Q. I believe you either didn't recall or you may have answered that you didn't think you did.
Um, let me direct your attention to page five of your declaration and in particular paragraph 17.
MR. HASFORD: Let's pull that up on the screen.
BY MR. HASFORD:
Q. Take a look at paragraph 17, and then

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let me know when you're ready.
A. I am, yes.
Q. How, if at all, does paragraph 17 of your declaration refresh your recollection as to whether you reviewed Dr. Galanis's deposition transcript?
MR. CASSELLA: Objection, leading.
MR. HASFORD: What's -- what's leading about that question? "How if at all"?
That's not leading at all. I'll reask the question.
BY MR. HASFORD:
Q. How, if at all, does paragraph 17 of your declaration refresh your recollection as to whether you reviewed Dr. Galanis's deposition transcript?
A. Yeah. Now, I do -- now, I do recall reviewing it, uh, for this declaration. I can't remember the specifics of it, and I haven't reviewed it over the last couple days, but I need to go back and look at that again, but yes, I did review this.
Q. All right. Take a look now, if you would, at paragraph 30 of your declaration on page nine.

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I believe you were asked a similar question about Mr. Cassella about Dr. Galanis's declaration in addition to his deposition transcript.
Do you remember that?
A. Yes, I do.
Q. Okay. Take a look at paragraph 30, and let me know when you're ready.
A. I am ready.
Q. How, if at all, does paragraph 30 of your declaration refresh your recollection as to whether you reviewed Dr. Galanis's declaration in this matter?
A. Yes. I do recall reading about his position on conjunctival blanching, yes.
MR. HASFORD: Nothing further from us.
MR. CASSELLA: Okay.
THE VIDEO TECHNICIAN: Okay.
Anything else for the record?
MR. HASFORD: Not from me.
Thank you, Dr. Donnenfeld.
THE WITNESS: Thank you.
THE VIDEO TECHNICIAN: This concludes the videotape deposition of Dr. Eric Donnenfeld.

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We are off the record 19:09.
MR. HASFORD: So we'll take a rough as soon as you can get it to us, and then obviously a final, um, ASAP, given that we've got a hearing coming up in a little over 36 hours.
THE COURT REPORTER: Okay. Very good. Thank you, Mr. Hasford.
And how about for you, Mr. Cassella?
MR. CASSELLA: Yeah. The same, as soon as possible.
THE COURT REPORTER: Okay. I will do my best to get this to you as soon as I possibly can.
Thank you, everyone.
* * *
(Whereupon, the deposition was concluded at approximately 7:09 p.m. EST.)
* * *

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DEPOSITION ERRATA SHEET

Our Assignment No. 522606
Caption: In Re Lumify

DECLARATION UNDER PENALTY OF PERJURY
I declare under penalty of perjury that I have read the entire transcript of my Deposition taken in the captioned matter or the same has been read to me, and the same is true and accurate, save and except for changes and/or corrections, if any, as indicated by me on the DEPOSITION ERRATA SHEET hereof, with the understanding that I offer these changes as if still under oath.
Signed on the _____ day of _____, 20___.

_____
ERIC D. DONNENFELD, M.D.

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DEPOSITION ERRATA SHEET

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CERTIFICATION

I, REBECCA KLANDERUD, Registered Professional Reporter, Certified Shorthand Reporter, certify that the foregoing is a true and accurate transcript of the foregoing deposition; that the witness was first sworn by me at the time, place, and on the date herein before set forth.

I further certify that I am neither attorney nor counsel for, not related to nor employed by any of the parties to the action in which this deposition was taken; further, that I am not a relative or employee of any attorney or counsel employed in this case, nor am I financially interested in this action

_____
Rebecca Klanderud
Registered Professional Reporter
Certified Shorthand Reporter

(The foregoing certification of this transcript does not apply to any reproduction of the same by any means unless under the direct control and/or supervision of the certifying reporter.)

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