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Transcript of Robert Noecker, M.D.

Date: November 13, 2022
Case: Slayback Pharma LLC -v- Eye Therapies LLC (PTAB)

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WORLDWIDE COURT REPORTING & LITIGATION TECHNOLOGY

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SLAYBACK PHARMA LLC, Petitioner,
v.
EYE THERAPIES LLC Patent Owner

Case No.: IPR2022-00142
U.S. Patent No. 8,293,742

Deposition of Dr. Robert Noecker
Norwalk, Connecticut
Sunday, November 13, 2022
9:25 a.m.

Job No.: 468951
Pages 1-122
Reported by: Angela (Angie) Shaw-Crockett, CRR, RMR

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Deposition of Dr. Robert Noecker, held at:

Residence Inn Norwalk
45 South Main Street
Norwalk, Connecticut 06845

Pursuant to Notice, before Angela (Angie) Shaw-Crockett, CRR, RMR, Notary Public in and for the states of New York, New Jersey and Connecticut.

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A P P E A R A N C E S

ON BEHALF OF THE PETITIONER, SLAYBACK PHARMA LLC:
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ON BEHALF OF THE PATENT OWNER, EYE THERAPIES LLC:
CHRISTINA YANG, ESQUIRE
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202-408-4004

ALSO PRESENT:
Rocco Mercurio, The Videographer

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I N D E X

Examination of: Page
Dr. Robert Noecker

C O N T E N T S

MS. CIPRIANO 6
MR. DINER 118

E X H I B I T S

(Retained by the court reporter)

DEPOSITION EXHIBIT PAGE
Exhibit 1046 Figure 2 of '742 patent 80

5

1 THE VIDEOGRAPHER: We are now going on the
2 record. Today is November 13, 2022, and the time is
3 approximately 9:25.
4 This is media 1 of the video deposition of
5 Dr. Robert Noecker in the matter of Slayback Pharma
6 LLC v. Eye Therapies LLC, filed in the U.S. Patent and
7 Trademark Office, case number IPR2022-00142.
8 My name is Rocco Mercurio, and the court
9 reporter is Angie Shaw-Crockett, and we're with Planet
10 Depos.
11 Would counsel please introduce yourselves
12 and who you represent for the record.
13 MS. CIPRIANO: My name is Linnea Cipriano
14 of Goodwin, representing Petitioner.
15 MR. DINER: My name is Bryan Diner of the
16 Finnegan firm, representing the patent owner, with my
17 colleagues Christina Yang and Jason Zhang.
18 THE VIDEOGRAPHER: The court reporter will
19 now swear in the witness, and we can now proceed.
20 Dr. Robert Noecker, having been duly sworn, testified
21 as follows:
22 EXAMINATION

6

1 BY MS. CIPRIANO:
2 Q Good morning.
3 **A Good morning.**
4 Q Would you please state your name for the
5 record?
6 **A Robert Noecker.**
7 Q Have you been deposed before?
8 **A Yes.**
9 Q How many times?
10 **A Eight, ten.**
11 Q Okay. And what was the most recent time?
12 **A The most recent time was in conjunction**
13 **with a medicolegal thing.**
14 Q Okay. How long ago was that?
15 **A A year ago. During COVID.**
16 Q Okay. Have you ever served as an expert
17 witness in a patent case before?
18 **A Yes.**
19 Q And when was that?
20 **A The last one was two years ago.**
21 Q And what product -- at a high level, what
22 product was that involved with?

7

1 **A It was for Combigan.**
2 Q And was this the only time you served as an
3 expert witness in a patent case?
4 **A No.**
5 Q How many other times?
6 **A About six.**
7 Q Have you always represented the patent
8 owner in those proceedings?
9 **A I've -- you know, these things come to**
10 **different levels. So it's -- sometimes it's --**
11 **it's -- I've had all-different-level discussions with**
12 **defendants, plaintiffs, two branded product against**
13 **each other.**
14 Q So this will probably proceed as your other
15 depositions, but I'd like to go over some ground rules
16 to make sure we're on the same page.
17 I'll be asking you questions, and you'll be
18 answering them today. Your answers will be -- you've
19 just been put under oath. You understand that your
20 answers are as if you were testifying in court.
21 Do you understand that?
22 **A Yes.**

8

1 Q During the course of the deposition, your
2 counsel may make objections, but unless you've been
3 instructed by your counsel not to answer, I will
4 expect you to answer my questions.
5 Do you understand that?
6 **A Yes.**
7 Q As you know, we have a court reporter here,
8 taking down everything we say. That means that you
9 and I both must make an effort to speak slowly and
10 clearly. And I'll try not to speak over you if you
11 try not to speak over me.
12 Do you understand?
13 **A Yes.**
14 Q We'll be taking breaks from time to time,
15 and if you can please let me know if you need a break
16 at any point. I'll just ask that we finish a question
17 and answer before we take a break.
18 Does that make sense?
19 **A Yes.**
20 Q Can you -- I will ask you today to listen
21 carefully to my questions, and if there's something
22 that you don't understand, please let me know. I'm

9

1 sure that I will not be as clear as I intend to be at
2 times during the day. But if you do answer my
3 question, I'll assume that you understood the
4 question.
5 Does that make sense?
6 **A Yes.**
7 Q And you understand that while I'm asking
8 you questions today, you're not to permitted to
9 discuss the substance of your testimony with your
10 counsel.
11 Do you understand that?
12 **A Yes.**
13 Q Is there any reason that you will not be
14 able to answer my questions fully and truthfully
15 today?
16 **A No.**
17 Q Did you prepare for today's deposition?
18 **A Yes.**
19 Q So without revealing any privileged
20 communications with your counsel, at a high level,
21 what did you do to prepare for today's deposition?
22 **A I read my expert report multiple times, and**

10

1 **related materials, and met with the attorneys.**
2 Q With whom did you speak concerning this
3 deposition?
4 MR. DINER: Vague.
5 **A What do you mean by that?**
6 **BY MS. CIPRIANO:**
7 Q Who did you talk to in preparation for the
8 deposition?
9 **A So in preparation, I met with the three**
10 **attorneys here.**
11 Q Anyone else?
12 **A No.**
13 Q Have you had conversations with any of the
14 other people who submitted declarations in this IPR?
15 **A No.**
16 Q Did you review any documents other than
17 your expert declaration to prepare for this
18 deposition?
19 **A Well, as I always do, I review my own**
20 **personal experiences as well as the relevant**
21 **literature.**
22 Q Do you recall any specific documents you

11

1 looked at in preparation for the deposition?
2 **A None specifically. Most that are related**
3 **to the expert report.**
4 Q I'm going to hand you a copy of your
5 declaration, which is marked Exhibit 2020 in the IPR.
6 Do you recognize this as being the
7 declaration that you submitted in IPR2022-00142.
8 **A Yes, it appears to be.**
9 Q And at a high level, how did you prepare
10 your declaration?
11 **A Basically, read the issues at hand in the**
12 **case, reviewed the literature, started composing the**
13 **document, met, at times, with the attorneys to fill in**
14 **the blanks, edited extensively.**
15 Q Did you review any of the declarations from
16 the other experts in this case?
17 **A Yes.**
18 Q At what point did you review those in your
19 preparation?
20 **A At some point in the last year.**
21 Q Before you signed your declaration?
22 **A I believe so. The time is a little vague**

12

1 **at this point.**
2 Q Are there any corrections or changes you'd
3 like to make to this declaration at this point?
4 **A No.**
5 Q You're currently employed, correct?
6 **A That's correct.**
7 Q What is to your current title?
8 **A I'm an ophthalmologist with Ophthalmic**
9 **Consultants of Connecticut.**
10 Q And you understand you're being presented
11 as an expert in this proceeding, correct?
12 **A That's correct.**
13 Q What is your area of expertise?
14 **A It's treatment of conditions of the --**
15 **diagnosis and treatment of conditions of the eye.**
16 Q And you're not a chemist, right?
17 **A I'm not a chemist myself.**
18 Q You're not an expert in the formulation of
19 eye drops?
20 **A I'm familiar and I've done formulation**
21 **work, but I'm not an expert.**
22 Q What do you mean by "done formulation

13

1 work"?
2 **A I've performed research in which we need to**
3 **formulate compounds.**
4 Q Have you ever manufactured a formulation of
5 an eye drop?
6 **A I have not.**
7 Q Have you ever been involved in determining
8 which excipients will be used in the formulation of an
9 eye drop?
10 **A For experimental purposes, not for**
11 **commercial purposes.**
12 Q And when was that?
13 **A Several years ago at the**
14 **University of Arizona.**
15 Q And what product was that for?
16 **A We were -- well, several glaucoma**
17 **medications.**
18 Q What drugs?
19 **A One called "latanoprost," another one**
20 **called "latanoprost 1," another one for some**
21 **antibiotics.**
22 Q And what was your role in?

14

1 **A We were doing experiments, so we were**
2 **basically developing these drugs to look at stability**
3 **and things like that.**
4 Q And your input was on the clinical side?
5 **A Well, some of these are rabbit studies, so**
6 **I was the guy who did stuff to the rabbits.**
7 **Depended -- yeah, I was basically the clinical**
8 **advisor, had to put things in clinical perspective.**
9 Q You're not an economist, right?
10 **A I am not.**
11 Q And you're not an expert in commercial
12 marketing, correct?
13 THE VIDEOGRAPHER: Hold on. Your mic just
14 went out.
15 We're now going off the record. The time
16 is now 9:35.
17 (Recess.)
18 THE VIDEOGRAPHER: Now going back on the
19 record. The time is 9:44.
20 BY MS. CIPRIANO:
21 Q I might repeat some of the questions. I'm
22 not sure we got all of the answers to my last round,

15

1 so just so we're on the same page.
2 You are not an expert in commercial
3 marketing, correct?
4 **A That's correct.**
5 Q So throughout your declaration, you make
6 statements that refer to what you understand other
7 experts or declarants in this proceeding will say.
8 Do you recall that?
9 **A Yes.**
10 Q And when you make those statements, you're
11 not offering independent opinions on what those other
12 experts said, correct?
13 **A Correct.**
14 Q So you're relying on the expertise of
15 others?
16 **A That's correct.**
17 Q I'd like to turn now to some vocabulary to
18 make sure that we're speaking the same language.
19 So let's turn to page 14 of your
20 declaration.
21 **A (Witness complies.)**
22 Q Are you there?

16

1 **A Yes.**
2 Q Okay. And here you have a diagram of two
3 pictures of the eye, right?
4 **A Yes.**
5 Q And the bottom diagram, it's a
6 cross-section, and the front of the eye is facing
7 left, correct?
8 **A Yes.**
9 Q And that front section is called the
10 "anterior portion" of the eye, correct?
11 MR. DINER: Objection, vague.
12 **A You have to be more specific.**
13 **BY MS. CIPRIANO:**
14 Q Okay. Can you explain to me what's
15 referred to as the anterior portion of the eye?
16 **A Well, it will depend on the context, but we**
17 **frequently refer to the "anterior chamber," so talking**
18 **about the inside of the eye, the anterior chamber is**
19 **divided from the post chamber -- in the side view,**
20 **we're speaking.**
21 **So everything kind of from the iris, the**
22 **colored part, forward, to the front -- toward the**

17

1 **front of the eye is anterior chamber. Everything**
2 **behind the iris is the posterior chamber.**
3 Q So the lens is in the posterior chamber; am
4 I understanding?
5 **A That's correct.**
6 Q Okay. You also have a diagram on page 16
7 of your declaration. And I'd like to take a look at
8 what's labeled "sclera" in this figure.
9 So the sclera label points to two different
10 things.
11 Do you see that?
12 **A Yes.**
13 Q One is pointing to the front picture of the
14 eye. And that's pointing to the white that surrounds
15 the iris, right?
16 **A The sclera is dense connective tissue**
17 **that's kind of the back -- it's 80 percent of the eye.**
18 **The outside of the shell of the eye is the way to**
19 **think about it.**
20 Q And what you can see of the sclera in the
21 picture of the front of a person's eye is the white
22 part, correct?

18

1 **A The sclera is all white; it's collagen.**
2 Q Maybe we're speaking past each other.
3 Where it points to -- where sclera points
4 to a section of the person's eye that you can see the
5 brown eye with the eyelashes and the eyebrow, there,
6 the arrow is pointing to the white space around the
7 iris, correct?
8 **A Yeah. That -- that's part of it.**
9 Q Okay. And the other line from the word
10 "sclera" goes to a box that's near the back of the eye
11 in the bottom diagram, correct?
12 **A It's a cross-section, yes.**
13 Q And that's because the sclera, as you said,
14 surrounds the entire part of the eye, not just the
15 part of the eye you can see, correct?
16 **A It's the back. It's approximately**
17 **80 percent of the shell, the outside of the eye,**
18 **the -- it provides structural support to the eye.**
19 Q So that square that the sclera line points
20 to is then magnified in a cross -- further
21 cross-section on the left of that diagram?
22 **A It's a cross-section of the sclera in that**

19

1 **part.**
2 Q Okay. So the sclera -- just so I
3 understand this correctly, the sclera is what's
4 pointed to in that -- in the blue triangle, if you
5 will, that includes the episclera, stroma, lamina
6 fusca, and endothelium?
7 **A In that cross-section.**
8 Q Okay. You agree that the blood vessels
9 that cause eye redness are the blood vessels that
10 reside in the sclera, correct?
11 MR. DINER: Objection, vague.
12 **A No. I disagree with that.**
13 **BY MS. CIPRIANO:**
14 Q Where are the blood vessels that cause eye
15 redness?
16 **A If we're talking about eye redness as**
17 **relevant to this case, so we're talking about**
18 **hyperemia mostly, predominantly, those are**
19 **conjunctival blood vessels.**
20 Q And they're not in the sclera?
21 MR. DINER: Objection. Mischaracterizes
22 testimony.

20

1 **A They are not in the sclera.**
2 **BY MS. CIPRIANO:**
3 Q In relation to the sclera, where is the --
4 where are the conjunctival blood vessels?
5 **A They're in the conjunctiva.**
6 Q And where is that in relation to the
7 sclera?
8 **A It's superficial, in part, to the eye.**
9 **It's superficial in the portion.**
10 Q Okay. And superficial meaning it's on top
11 of the episclera?
12 **A Correct.**
13 Q Prior to Lumify, there were a number of
14 over-the-counter eye redness reducers on the
15 commercial market.
16 You agree with that, right?
17 **A Yes.**
18 Q So if we could turn to page 25 of your
19 declaration --
20 **A (Witness complies.)**
21 Q -- just for reference.
22 You list a few in the chart that's at the

21

1 bottom of that page. And some examples that you list
2 are Naphcon, Naphcon-A, All Clear, Ocu-Clear, Visine,
3 and Visine Advanced Redness Relief.
4 Do you see that?
5 **A Yes.**
6 Q And these were all FDA approved as
7 over-the-counter treatments, correct?
8 **A Yes.**
9 Q So you'd agree that all of these were
10 considered by the FDA to be particularly safe,
11 correct?
12 MR. DINER: Objection, vague. Lacks
13 foundation.
14 **A I'd have to look at that closer -- what the**
15 **FDA said.**
16 **BY MS. CIPRIANO:**
17 Q Well, let's look at what you said in
18 paragraph 61 of your declaration.
19 In -- starting four lines down, you say
20 "Because OTC products treat self-diagnoseable
21 conditions without a health care provider's
22 instructions, they are susceptible to misuse through

22

1 overuse. Therefore, they must not only be
2 efficacious, but they must also be particularly safe."
3 Do you see that?
4 **A I do.**
5 Q So you'd agree that if a product is
6 approved to be over-the-counter, it must be
7 particularly safe?
8 **A Yeah. The context of that -- of that**
9 **phrase, or the sentence is -- is always -- in**
10 **medicine, we always take this risk-benefit position.**
11 **So the more bad your condition is or more serious,**
12 **say, in our field, glaucoma blinds you, so we'll**
13 **accept more risk.**
14 Q Okay. But for redness reducers that are --
15 were commercially available as over-the-counter
16 products, you'd agree that the products that are
17 listed in the charts on page 25 of your declaration --
18 that those products were deemed to be particularly
19 safe, correct?
20 MR. DINER: Objection. Mischaracterizes
21 his testimony. Lack of foundation.
22 **A No. I mean, these -- and we certainly**

23

1 **recognize these products are certainly not perfect.**
2 **And frequently, there's many patients sometimes we**
3 **recommend that they don't use these products.**
4 **So it depends on the context, depends on**
5 **the clinical scenario, what we say is particularly**
6 **safe or not.**
7 **BY MS. CIPRIANO:**
8 Q When you say these products are not --
9 certainly not perfect, you'd agree that all of these
10 products had side effects like hyperemia,
11 conjunctivitis, and medicamentosa?
12 **A Those are possible. Don't happen every**
13 **time, but they're possible, yes.**
14 Q You agree some people misused or overused
15 over-the-counter redness relievers, correct?
16 **A I mean, generally, I think any therapy**
17 **people -- somebody, some person, has probably overused**
18 **or improperly used. We see that all the time.**
19 Q And you agree that some people had to stop
20 using prior over-the-counter redness relievers because
21 either of the side effects or because they stopped
22 working, correct?

24

1 MR. DINER: Objection. Incomplete
2 hypothetical. Lacks foundation.
3 **A For any specific, there's always a possible**
4 **scenario where that's true. And I think there's**
5 **certainly individual anecdotal cases where that's**
6 **happened with, once again, these products and every**
7 **other product that's ever been used to treat a human.**
8 **BY MS. CIPRIANO:**
9 Q Let's talk a little bit about brimonidine.
10 You'd agree that brimonidine is known to
11 have ocular hypertensive effects, correct?
12 **A We primarily use brimonidine to lower eye**
13 **pressure.**
14 Q And when you say "lowering eye pressure,"
15 that's lowering the intraocular pressure, correct?
16 **A That's correct.**
17 Q And when we say "intraocular pressure,"
18 that's the fluid inside what -- I think what we
19 referred to as the posterior segment of the eye?
20 MR. DINER: Objection, vague.
21 **A I don't exactly understand what you said**
22 **that last time.**

25

1 **BY MS. CIPRIANO:**
2 Q Okay. So when we talk about lowering
3 intraocular pressure, the pressure that we're talking
4 about is the pressure of the fluid that's inside the
5 eye, correct?
6 MR. DINER: Objection, vague.
7 **A Well, intraocular pressure is the pressure**
8 **inside the eye.**
9 **BY MS. CIPRIANO:**
10 Q And what is causing that pressure?
11 Let me rephrase that.
12 What is exerting the pressure in the eye?
13 **A Well, the eye always has a pressure. And**
14 **so there's this fluid aqueous which the eye makes and**
15 **drains it away.**
16 Q And what I'm trying to get at is where that
17 fluid is held in the eye.
18 And is that in the -- if we need to go back
19 to the picture, maybe that would be helpful.
20 Is that in the section of the eye that's
21 behind the lens?
22 **A Well, it circulates around the eye.**

26

1 Q It's everywhere in the eye?
2 **A It's -- it's moving.**
3 Q Okay. So intraocular pressure is not the
4 same as blood pressure, right?
5 **A Correct.**
6 Q So brimonidine hasn't ever been used to
7 reduce systemic blood pressure, right?
8 **A I don't know if it's been attempted.**
9 Q You're not aware?
10 **A I'm not aware.**
11 Q Okay. But you agree it's not known to be a
12 systemic hypotensive agent, right?
13 **A On average -- once again, it depends how**
14 **you administer it.**
15 Q I'm not sure I understand.
16 **A How are -- the question is, how are you**
17 **administering it?**
18 Q Systemically?
19 **A Systemically.**
20 MR. DINER: Objection, vague.
21 **A So you're saying to give it to a person,**
22 **like, intravenously or --**

27

1 **BY MS. CIPRIANO:**
2 Q Yeah, let's step back.
3 What I'm trying to understand is, there
4 are -- "hypotensive" can have a couple of different
5 meanings in medicine. It's referred to a couple of
6 different ways.
7 There are agents that are characterized, at
8 least in my understanding of the literature, as
9 hypotensive agents that are administered to reduce a
10 patient's blood pressure.
11 You agree with that?
12 **A Yes, there's some agents we use to reduce**
13 **blood pressure, yes.**
14 Q Okay. But when you say that brimonidine is
15 known to have hypotensive effects, that's limited to
16 the fact that it's known to have ocular hypotensive
17 effects, correct?
18 MR. DINER: Objection. Mischaracterizes
19 the document.
20 **A It depends on the root of administration.**
21 **BY MS. CIPRIANO:**
22 Q And what do you mean by that?

28

1 **A How are you giving it to the person?**
2 Q Is it your opinion that a person of
3 ordinary skill in the art would understand that
4 brimonidine was known prior to 2008 to have systemic
5 hypotensive effects?
6 **A Brimonidine? Depending how you administer,**
7 **it could.**
8 Q Are you aware of any study published prior
9 to August of 2008 that showed brimonidine to be a
10 vasodilator in the anterior portion of the eye?
11 **A I'm not sure exactly what -- those terms**
12 **aren't as specific as I'd like, but I think there's**
13 **certainly, from our clinical studies we've seen, blood**
14 **vessels on the surface of the eye get quite dilated**
15 **with the use of brimonidine, yes.**
16 Q And in what -- strike that.
17 And what clinical studies are you referring
18 to?
19 **A So Alphagan eye drop study used for**
20 **glaucoma, we saw significant red eyes or hyperemias**
21 **when used in eye-drop form at 0.2 percent.**
22 Q Okay. So you're talking about the adverse

29

1 event of hyperemia that is seen after administration
2 with brimonidine, correct?
3 MR. DINER: Objection to the extent it
4 mischaracterizes testimony.
5 **A The -- well, it was 0.2 percent Alphagan**
6 **used. It was a glaucoma study, and that was one of**
7 **the endpoints that were measured.**
8 **BY MS. CIPRIANO:**
9 Q What was an endpoint?
10 **A Eye redness, hyperemia.**
11 Q And what study is this?
12 **A 1996. I'm trying to think of the first**
13 **author.**
14 **I can look it up. I can't remember off the**
15 **top of my head the author. But it was the**
16 **FDA-approval studies, the phase III trials submitted**
17 **for approval of Alphagan, that hyperemia was recorded**
18 **in that.**
19 Q Do they measure redness?
20 **A I'm sorry. What do you mean by "measure"?**
21 Q Did -- was there a scale that was recorded
22 that measured redness in those studies?

30

1 **A In that study, I'm not sure if there was a**
2 **scale, no.**
3 Q So when you say recorded "redness," they
4 recorded whether hyperemia was observed, correct?
5 **A I'd have to go back and look at the study**
6 **protocol, which we did. I'm not sure if there was a**
7 **grading scale. I can't remember.**
8 Q To go back to my question about studies
9 showing brimonidine to be a vasodilator.
10 You agree that even -- well, strike that.
11 Let me back up a little bit.
12 You'd agree that alpha 1 agonist drugs are
13 accepted to be vasoconstrictors in the eye, correct?
14 **A So I'll -- so to answer that, I'll assume**
15 **that you're -- that topically administrated [sic] in**
16 **the form of an eye drop that, applied to the eye, that**
17 **you can have -- you'll have a vasoconstrictive effect**
18 **on the surface blood vessels of the eye, yes.**
19 Q And those same alpha 1 agonist drugs that
20 are applied topically in the form of an eye drop also
21 can cause hyperemia, correct?
22 MR. DINER: Objection. Incomplete

31

1 hypothetical.
2 **A I think what you're asking me is, can**
3 **these -- can drugs with alpha 1 properties cause**
4 **hyperemia, which is yes.**
5 **BY MS. CIPRIANO:**
6 Q So hyperemia is not necessarily a -- strike
7 that.
8 So hyperemia is not necessarily a sign that
9 a drug is a vasodilator, correct?
10 **A I don't understand the question.**
11 Q Okay. Let's take it step by step.
12 You -- so I asked you whether you were
13 aware of any studies showing that brimonidine was a
14 vasodilator in the eye when applied topically -- let
15 me start over.
16 So it's your position that because
17 brimonidine causes hyperemia, that it can be a
18 vasodilator when applied topically to the eye; is that
19 correct?
20 **A I think what we can say is that when we see**
21 **that the blood vessels on the surface of the eye are**
22 **engorged, they're vasodilators; the blood vessels are**

32

1 **dilated. If they're red and engorged, hyperemia.**
2 Q And that same type of hyperemia where when
3 the blood vessels of the eye are engorged occurs after
4 a topical administration of alpha 1 agonists, correct?
5 MR. DINER: Objection. Mischaracterizes
6 prior testimony.
7 **A The answer is, it depends.**
8 **BY MS. CIPRIANO:**
9 Q But it can?
10 **A In a very specific scenario, based on the**
11 **timing when you're measuring these things. If you**
12 **give me a specific clinical scenario, we can address**
13 **whether or not it probably happens.**
14 Q So when you say that brimonidine causes
15 hyperemia, what was the timing of measuring that
16 hyperemia?
17 **A There are many time points.**
18 Q Okay. Let's look at -- we'll look at some
19 specific studies a little bit later, maybe to get to
20 the bottom of that.
21 So we talked a little bit about the
22 Alphagan product. You mentioned that.

33

1 **A I did mention that, yes.**
2 Q And Alphagan, I understand, was available
3 in concentrations of 0.5 percent brimonidine and
4 0.2 percent brimonidine; is that correct?
5 **A What do you mean by "available"?**
6 Q It was marketed in those strengths.
7 **A It was never marketed in 0.5 percent.**
8 Q Okay. So original Alphagan was marketed at
9 0.2 percent?
10 **A That was the original Alphagan, yes.**
11 Q And another product called "Alphagan P" was
12 also marketed in that family, correct?
13 **A That's correct.**
14 Q And that was available, commercially
15 available, at 0.15 percent and 0.1 percent?
16 **A Yes.**
17 Q And those Alphagan and Alphagan P were both
18 Alphagan products, correct?
19 **A Yes.**
20 Q And Alphagan concluded that all -- that the
21 Alphagan and Alphagan P products were safe and
22 comfortable for patients, correct?

34

1 MR. DINER: Objection. No foundation.
2 **A What's the context of that statement?**
3 **BY MS. CIPRIANO:**
4 Q Do you disagree?
5 MR. DINER: Same objection. No foundation.
6 **A I mean, they're approved by the FDA.**
7 **BY MS. CIPRIANO:**
8 Q Let's take it a look at another exhibit.
9 I'm going to hand you what's been marked as
10 1031 in the IPR.
11 Do you recognize this as one of the
12 documents you relied on in your declaration?
13 **A Yes.**
14 Q And this is parts of the NDA that was
15 submitted for Alphagan at 0.2 percent, correct?
16 **A Yes.**
17 Q So if we could turn to page 12 of the
18 document.
19 **A (Witness complies.)**
20 Q So it's page 12 of 286, if you see that.
21 **A I see it.**
22 Q So here on page 12, this is a list of

35

1 clinical studies that were part of the NDA.
2 Do you see that?
3 **A Yes.**
4 Q Okay. And then on page 13, this is, if you
5 will, an expanded chart, providing a little more
6 information about the clinical studies that were
7 listed in on page 12; is that correct?
8 **A Yes.**
9 Q And the clinical studies listed on page 13
10 are categorized as "early dose tolerance studies."
11 Do you see that?
12 **A Yes.**
13 Q Okay. And then on the right-hand side,
14 there's a "study conclusions" column.
15 Do you see that?
16 **A Yes.**
17 Q And for all of these studies, Alphagan
18 represented to the FDA that brimonidine, at all the
19 concentrations tested, was safe and comfortable,
20 right?
21 MR. DINER: Objection, foundation.
22 Dr. Noecker, it is a large document. You

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1 should take the time to review the pages she pointed
2 to and any other information in this document you
3 think would be helpful to inform you in order to
4 answer her question.
5 **A I have to look into -- it's been a long**
6 **time since I've looked at these.**
7 **BY MS. CIPRIANO:**
8 Q You're welcome to look at whatever you need
9 to in this document.
10 But if you could just look at the "study
11 conclusions" column here and look at the first
12 sentence in every box here, Alphagan stated
13 "brimonidine concentrations of," and it lists the
14 concentrations that were studied "is safe and
15 comfortable," correct?
16 MR. DINER: Objection. Document speaks for
17 itself.
18 **A Those words are there but, once again, it**
19 **all depends on the context of what we're talking**
20 **about. This is a glaucoma medication.**
21 **BY MS. CIPRIANO:**
22 Q Were these studies administered to glaucoma

37

1 patients?
2 MR. DINER: Again, Dr. Noecker, it's a
3 large document. The question is vague. If you need
4 to look at something, you should look at something.
5 And feel free to ask counsel any questions you may
6 have.
7 THE WITNESS: Sure.
8 BY MS. CIPRIANO:
9 Q To the extent it's helpful, the study -- a
10 narrative about the study design starts on page 20 of
11 the exhibit, if that's helpful.
12 **A (Witness reviews document.)**
13 Q Doctor, are you looking for something
14 specific in the document?
15 **A Yes. I'm looking for the study reference**
16 **numbers A342-105-8042, 106-7831 119-7831, 120-8042.**
17 **So I don't see those in here.**
18 Q I've reviewed the document as well, and I
19 can represent to you that they are not in -- the data
20 from that is not in this document.
21 **A Okay.**
22 Q Without looking at the study, do you have

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1 any information that would give you -- strike that.
2 Do you have any information that would tell
3 you whether or not these early dose tolerance studies
4 were performed on glaucoma patients?
5 **A I'd like to look at the study protocol.**
6 Q Okay. Can we look at the information
7 that's actually on this page, because I don't think we
8 have the study protocols in this proceeding. But --
9 but let's look and see if we can come up with any kind
10 of conclusions based on the data that's here.
11 The treatment in these -- at least the four
12 studies that are listed on page 13 of Exhibit 1031 --
13 the treatment is in that first row, 0.02 percent,
14 0.8 percent, and "vehicle."
15 Do you see that?
16 **A Yes.**
17 Q If these were glaucoma patients, would you
18 expect vehicle to be administered?
19 MR. DINER: Objection, vague. Incomplete
20 hypothetical.
21 **A There are some -- there are some clinical**
22 **studies in which vehicle or placebo is administered.**

39

1 **BY MS. CIPRIANO:**
2 Q For glaucoma patients?
3 **A Yes.**
4 Q And in what circumstances is that?
5 **A Depending what you -- you have an**
6 **intervention, and then you have kind of a control arm.**
7 Q So glaucoma can cause blindness, correct?
8 **A That's correct.**
9 Q As a treating physician, would you
10 recommend that a glaucoma patient refrain from
11 glaucoma medication for the purposes of a study?
12 MR. DINER: Objection, vague.
13 **A Well, the answer is, it always depends. It**
14 **depends on the exact clinical scenario, but it is**
15 **not -- it is standard study protocol to do what we**
16 **call "washout." And it's actually clinical protocol,**
17 **as well, where we have periods of time we have**
18 **patients go without their medications.**
19 **BY MS. CIPRIANO:**
20 Q Okay. Let's look at the dose column here.
21 And the dose column in each of these
22 studies, the four studies on page 13, lists that -- my

40

1 understanding from what's noted here -- that the study
2 drug was administered to one eye; is that how you
3 interpret this?
4 **A I think so.**
5 Q As a practicing clinician, would you advise
6 your patient to administer a glaucoma medication to
7 only one eye?
8 MR. DINER: Objection. Incomplete
9 hypothetical.
10 **A I typically don't, but especially back in**
11 **the '90s and even still today, it's called what's**
12 **called a "one-eye trial." So frequently, to**
13 **distinguish side effects, relative efficacy, it's**
14 **standard. It's still deemed standard clinical**
15 **protocol to do this at times in some patients,**
16 **depending on the circumstances.**
17 **BY MS. CIPRIANO:**
18 Q So you're saying that it's standard
19 protocol to administer glaucoma medication to one eye
20 and vehicle to the other eye?
21 **A It could be.**
22 Q But without the study protocol, you can't

41

1 be sure that these were administered to glaucoma
2 patients, correct?
3 **A I'd need to look at the protocol.**
4 Q Do you agree that -- we can put this
5 document away. I think I may have a couple more
6 questions about it to come later, but we can put it
7 away for now.
8 **A (Witness complies.)**
9 Q You would agree that brimonidine is known
10 to be an alpha-2 receptor agonist, right?
11 **A Yes.**
12 Q And when we refer to "alpha" here, we're
13 talking about alpha adrenergic receptor, correct?
14 **A Yes.**
15 Q In your declaration you talk about two
16 types: An alpha 1 adrenergic receptor and an alpha-2
17 adrenergic receptor, correct?
18 **A Yes.**
19 Q You agree that as of August 2008, a person
20 of ordinary skill in the art would have known that
21 there are several subtypes of each of these receptor
22 types, correct?

42

1 MR. DINER: Objection, vague.
2 **A It's possible.**
3 **BY MS. CIPRIANO:**
4 Q You're aware there's an alpha-2A and
5 alpha-2B and an alpha-2C receptor subtype?
6 **A Yes.**
7 Q Scientists in 2008 would have understood
8 that the result of activating these receptors would
9 depend on the particular subtype that was present.
10 Do you agree with that?
11 MR. DINER: Objection, vague. Incomplete
12 hypothetical.
13 **A I'm not sure what you mean by "subtype."**
14 **BY MS. CIPRIANO:**
15 Q You just -- you're aware that there are
16 subtypes of alpha-2 receptors?
17 **A There are, yes, and they have been**
18 **discovered.**
19 Q And you agree that activating -- activating
20 alpha-2A versus alpha-2B versus alpha-2C receptors
21 could have different effects, correct?
22 MR. DINER: Objection. Incomplete

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1 hypothetical.
2 **A You'd have -- the answer, it would depend,**
3 **and it's unclear. So I'd have to know the specific**
4 **kind of scenario and what we were trying to**
5 **accomplish.**
6 **BY MS. CIPRIANO:**
7 Q But you agree that in certain
8 circumstances, these receptor subtypes do different
9 things?
10 MR. DINER: Objection, vague.
11 **A It's possible, but it would depend on the**
12 **scenario what question we're -- specific question**
13 **we're trying to ask.**
14 **BY MS. CIPRIANO:**
15 Q You'd also agree that the different
16 receptor subtypes are known to be located -- let me
17 strike that and ask a better question.
18 Do you know if the different alpha-2
19 receptor subtypes are located in a homogenous manner
20 throughout the body?
21 MR. DINER: Objection, vague.
22 **A It's a little bit difficult. What I can**

44

1 **say as a general rule, all receptors are not**
2 **distributed homogeneously throughout the body.**
3 **BY MS. CIPRIANO:**
4 Q So different tissues in the body have
5 different receptor subtypes of any type that are
6 present, correct?
7 MR. DINER: Objection, vague.
8 **A It will depend on the organ and its**
9 **purpose, what receptors are there.**
10 **BY MS. CIPRIANO:**
11 Q These alpha adrenergic receptors are found
12 in both the central nervous system and in the
13 periphery, correct?
14 **A I'm sorry. Which receptors?**
15 Q The alpha adrenergic receptors.
16 **A Adrenergic receptors are found throughout**
17 **the body.**
18 Q And that includes both on the central
19 nervous system and in the periphery?
20 **A Yes.**
21 Q Would you agree that the effect of
22 activating alpha adrenergic receptors in the central

45

1 nervous system can exert a different effect than
2 activating these receptors in the periphery?
3 **A It will depend on the specific scenario,**
4 **but it's possible, yes.**
5 Q So in your declaration, you talk about
6 clonidine having a sedative effect, correct?
7 **A Correct.**
8 Q And clonidine is known to have alpha-2
9 adrenergic receptor activity, correct?
10 **A Yes.**
11 Q Would you agree that the sedative effect of
12 clonidine is a result of its effect on the central
13 nervous system?
14 **A That's what's believed.**
15 Q I'd like to take a look at an article. The
16 court reporter is going to hand you a document that's
17 been marked Exhibit 1019.
18 Do you recognize this as the document that
19 we referred to as "Lachkar" in your declaration?
20 **A Yes.**
21 Q So I'd like to take a look at page 3. And
22 in your declaration, you quote some language that's in

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1 kind of the middle of the right-hand column on page 3
2 of the exhibit. And you rely on the sentence that
3 starts "Vasoconstriction is mediated mainly via
4 alpha 1 adrenergic receptors."
5 Do you see that?
6 **A I see the sentence.**
7 Q And you cite that in your declaration?
8 **A Yes.**
9 Q In your declaration you don't quote the
10 rest of that sentence, but it continues "although
11 alpha-2 adrenergic receptors may play a part."
12 Do you see that?
13 MR. DINER: Objection. Mischaracterizes
14 the document.
15 **A I'm sorry. Where are you referring to?**
16 **BY MS. CIPRIANO:**
17 Q Sure.
18 Just the next couple of words after what I
19 just read.
20 So the whole sentence says
21 "Vasoconstriction is mediated mainly via alpha 1
22 adrenergic receptors, although alpha-2 adrenergic

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1 receptors may play a part and, thereby, have a role in
2 the autoregulation of capillary pressure and tissue
3 oxygen delivery."
4 **A Yes, I see that sentence.**
5 Q Okay. And I was just saying that you quote
6 the first phrase to the first comma, but you don't
7 quote the rest of that sentence in your declaration,
8 right?
9 MR. DINER: Objection. Mischaracterizes
10 the document.
11 **A Well, I mean, this whole sentence, yeah, is**
12 **relevant. It's based on -- it's actually pulled from**
13 **this subarticle. It's cited from the Hoffmann article**
14 **Reference 30, which talks about adrenergic and**
15 **receptor antagonists.**
16 **BY MS. CIPRIANO:**
17 Q So then you also in your declaration -- and
18 we can take a look. Feel free, if you need to refresh
19 your memory.
20 You also talk about that -- the next
21 sentence in that paragraph, "On the other hand,
22 brimonidine tartrate may also produce vasodilation via

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1 the alpha-2 adrenergic receptors on endothelial cells
2 which release endothelial-derived relaxing factor."
3 Do you see that?
4 **A Yes.**
5 Q You see the article has two footnotes at
6 the end of that sentence?
7 **A Yes, yes.**
8 Q Did you review those articles to see what
9 the author was relying on for that statement?
10 **A I believe so. It's been a while.**
11 Q You did review them?
12 **A I believe so, yes.**
13 Q Can we take a look at your declaration,
14 Appendix B?
15 **A (Witness complies.)**
16 **Yes.**
17 Q And you'd agree that the articles by Angus
18 and the article by Bockman are not on your list of
19 materials considered? I don't see them.
20 **A I don't see them.**
21 Q So does that mean you did not review them
22 in preparation for this declaration?

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1 MR. DINER: Objection, vague.
2 Mischaracterizes his prior testimony.
3 **A Well, I mean, just -- did I do it**
4 **specifically in preparation for this? No, I don't**
5 **think so. But any time you read a scientific article,**
6 **it's good to know what the underlying sources are.**
7 **BY MS. CIPRIANO:**
8 Q Do you remember what is discussed in the
9 Angus and Bockman articles cited in Lachkar?
10 **A It discusses what's alluded to in this**
11 **sentence, that there's vasodilation effects. You can**
12 **see -- you can see from the titles of the articles in**
13 **the reference that there's responses in the**
14 **circulation. So they're evaluating vascular**
15 **structures and the effect of alpha-2 agonists.**
16 Q But you agree that the Angus and Bockman
17 articles don't discuss anything about the eye,
18 correct?
19 **A I can't say for sure.**
20 Q Would it surprise you that they don't
21 mention anything about the eye?
22 **A Would it surprise me? To the extent**

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1 **anything else surprises me, would I be surprised? No,**
2 **I would not be surprised.**
3 Q We can put that away for now.
4 **A (Witness complies.)**
5 Q So it is your opinion that prior to
6 August 2008, a person of ordinary skill in the art
7 would have understood that brimonidine's ability to
8 reduce eye redness was concentration dependent; is
9 that accurate?
10 **A Well, I think when we're talking about the**
11 **topical administration of brimonidine, our experience**
12 **is largely with the Alphagan formulation, so the**
13 **0.2 percent formulation, which is commercially**
14 **available, and then the 0.15 percent formulation and**
15 **the 0.1 percent formulation. So at those levels,**
16 **those concentrations we're finding, we see that -- I'm**
17 **sorry. What was the thing -- what was the property we**
18 **were talking about?**
19 Q Ability to reduce eye redness.
20 **A Yeah. So we could see some blanching,**
21 **short-term blanching, that was noted, especially at**
22 **the highest concentration, the 0.2 percent formulation**

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1 **of Alphagan.**
2 Q But your position in this proceeding is
3 that a person of ordinary skill in the arts would have
4 understood from the Alphagan and Alphagan P labels
5 that this property of brimonidine was
6 concentration-dependent, correct?
7 **A Conjunctival blanching happened with the**
8 **highest concentration that was available, the**
9 **0.2 percent. It was -- that happened with some**
10 **frequency at the highest concentration, the**
11 **0.2 percent.**
12 Q We can look at paragraph 77 of your
13 declaration, but I'd like to look at the articles that
14 are cited in that paragraph.
15 So the first article that you cite in
16 paragraph 77 of your declaration is what's -- what you
17 referred to as "David, 1993."
18 Do you see that?
19 **A Yes.**
20 Q I'm going to hand you a document that's
21 been marked Exhibit 1029 in the IPR.
22 Do you recognize this as the article by

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1 David that you cite in your declaration?
2 **A Yes, it appears to be.**
3 Q And this reports on a study that was done
4 with 0.5 percent brimonidine, correct?
5 **A (Witness reviews document.)**
6 Q Where I got the concentration was just in
7 the abstract at the beginning, where I list the
8 objective and the conclusion on the first page.
9 **A I see that. I'd just like to confirm the**
10 **methods. I'm not seeing the methods, which is**
11 **interesting. I don't see the concentration listed in**
12 **the methods or the results.**
13 Q If we look on the first page, in
14 "Objective," right under the list of authors, it says
15 "to evaluate the efficacy of 0.5 percent brimonidine
16 titrate."
17 Do you see that?
18 **A I do.**
19 Q So is it accurate to say that you agree
20 that this study was done with 0.5 percent brimonidine?
21 **A I guess we have to assume that. It's a**
22 **little disturbing it's not in the methods or the**

53

1 **results, but...**
2 Q But you cite -- for the statement about --
3 excuse me -- 0.5 percent brimonidine, this is the
4 article that you cite in your declaration?
5 **A Yes.**
6 MR. DINER: Objection. Mischaracterizes
7 his declaration.
8 BY MS. CIPRIANO:
9 Q So if we look at the conclusion in your
10 declaration, you point to page 3, correct?
11 **A Yes.**
12 Q In about the middle, a couple of lines up
13 from the comment section on page 3 in the left-hand
14 column, there's a statement about conjunctival
15 blanching.
16 Do you see that?
17 You can tell me when you're there. It's in
18 the paragraph starting "ocular side effects."
19 Do you see where it says "conjunctival
20 blanching"?
21 **A I see the paragraph.**
22 Q So I'm interested in the sentences that are

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1 kind of in the middle of that paragraph. And just so
2 we're on the same page, they read:
3 "Conjunctival blanching was noted in 75
4 (40.9 percent) of 183 brimonidine-treated patients.
5 Again, the majority of these cases were reported as
6 mild. Blanching was rated as moderate in 16 patients
7 and severe in one patient in the B/B group (at the
8 first post ALT examination, one hour after the second
9 drop of brimonidine)."
10 Do you see that sentence -- those couple of
11 sentences?
12 **A Yes.**
13 Q In your understanding, what is the
14 difference between mild, moderate, and severe
15 blanching?
16 **A Depends on the context.**
17 Q Well, as you read it here, how do you
18 understand this?
19 **A Well, I mean, this study was basically --**
20 **used a very, very high concentration of brimonidine,**
21 **which never came to market. It was a primary study to**
22 **look at IOP lowering. So that's the endpoint that was**

55

1 **measured. I'm not sure how conjunctival blanching was**
2 **measured. So that's the first problem, who that**
3 **information came from. It's hard for me to comment**
4 **further.**
5 Q So is there a standardized definition of
6 what "mild," "moderate," and "severe" blanching would
7 entail?
8 **A It depends on -- it depends on the study.**
9 **This is a glaucoma study. So it could be like, "Hey,**
10 **person, did you have anything to report to us?" Or it**
11 **could be, "Hey, person, do you notice blanching?" Or**
12 **it could be, "Doctor, do you notice blanching?" Or,**
13 **"Doctor, here is this very vigorous graded scale to**
14 **blanching." It depends.**
15 Q You don't have any information based on the
16 David article to understand how blanching was
17 monitored in the study; do you?
18 **A I'm not -- like, that part of the**
19 **methodology -- it was basically to see if this drug**
20 **lowered eye pressure.**
21 Q So the next reference that you talk about
22 or you cite in paragraph 77 of your declaration also

56

1 deals with 0.5 percent brimonidine in that -- in the
2 next sentence there in your paragraph 77, talking
3 about clinical trial with 0.5 percent brimonidine.
4 Do you see that?
5 **A Yes.**
6 Q And you cite to -- again, back to the
7 document that we looked at before, Exhibit 1031.
8 Do you see that?
9 **A Yes.**
10 Q Okay. If you could open that back up
11 again.
12 **A (Witness complies.)**
13 Q So you point to page 13 of Exhibit 1031.
14 **A I'm sorry. What page was it?**
15 Q Page 13, you reference study S342-108-8042,
16 which I believe is listed in the third row of the
17 table on page 13?
18 **A Okay.**
19 Q Do you see that?
20 **A Yes.**
21 Q Okay. Am I interpreting that correctly,
22 that that's the information that you were citing in

57

1 your declaration?
2 MR. DINER: Objection to the extent it
3 mischaracterizes the definition.
4 **A So it's that study. That statement comes**
5 **from that study, yes.**
6 **BY MS. CIPRIANO:**
7 Q Okay. And it says -- in the study
8 conclusion section, it says "Significantly greater
9 incidences of conjunctival blanching and subjective
10 reports of dry eye were reported with use of
11 brimonidine 0.5 percent and vehicle," right?
12 **A I need to look at this study.**
13 Q As we said before, the data from these
14 early dose tolerance studies is not in Exhibit 1031 as
15 I have read them, but you're relying on this summary,
16 right, that's listed in this document?
17 That's what you're relying on in your
18 declaration?
19 MR. DINER: Objection. Mischaracterizes
20 his declaration.
21 **A I relied on everything, not just the**
22 **summary. I mean, we need to look at the underlying**

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1 **principles behind these things.**
2 **BY MS. CIPRIANO:**
3 Q Did you look at the data from study
4 S342-108-8042 in preparation for this declaration?
5 **A I looked at the whole amount of data that**
6 **was available, so -- but to answer this question, I**
7 **want to make sure that we answer it in the proper**
8 **context.**
9 Q So I'm trying to understand your opinions
10 in this matter, and you cite this page from -- you
11 cite two things for this sentence. And we'll look at
12 the Alphagan label in a second.
13 I just want to make sure I'm understanding
14 that your comment about 0.5 percent brimonidine
15 exhibiting significantly greater incidence of
16 conjunctival blanching -- in part, that's based on the
17 summary of this study listed on page 13 of
18 Exhibit 1031, correct?
19 **A In part.**
20 Q You'd agree that the same sentence, the
21 same statement that you quoted in paragraph 77 about
22 causing significantly greater incidence of

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1 conjunctival blanching, that was also stated in the
2 next row of the chart on page 13, referring to
3 brimonidine 0.35 percent.
4 Do you see that?
5 **A Yes, the high concentration of brimonidine**
6 **had more blanching than the vehicle.**
7 Q Okay. And do you know if this blanching
8 was categorized as mild, moderate, or severe?
9 **A No. I can't comment on that right now.**
10 Q Okay. Do you know if redness was measured
11 in this -- in these studies with any scale?
12 **A We need to look at the study protocol. I'm**
13 **sure it was listed.**
14 Q The other thing you point to for this --
15 for your information about 0.5 percent brimonidine is
16 the Alphagan label, the 2001 Alphagan label.
17 Do you see that in paragraph 77 of your
18 declaration?
19 **A Yes.**
20 Q So let's take a look at Exhibit 2012.
21 Do you recognize this as the Alphagan
22 0.5 percent product label?

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1 **A Seems to be multiple product labels.**
2 Q Apologies.
3 So the first several pages is -- refers to
4 a 0.5 percent, and then, starting at page 6 is
5 Alphagan 0.2 percent, and then, starting at page 11 is
6 .15 percent.
7 **A Yes.**
8 Q So you point to page 4 of this document.
9 And in the adverse reactions at the bottom
10 of the page, it says "The most common adverse events
11 reported in association with the use of Alphagan
12 0.5 percent in conjunction with ALT was transient
13 conjunctival blanching in 50 percent of patients."
14 Do you see that?
15 **A Yes.**
16 Q Do you know if this is reporting on the
17 same study as reported that we were just talking about
18 in Exhibit 1031?
19 MR. DINER: Objection, vague.
20 **A I'm not positive.**
21 **BY MS. CIPRIANO:**
22 Q And this document doesn't talk about the

61

1 severity of the blanching, right?
2 **A This package insert of 0.5 percent**
3 **Alphagan, no.**
4 Q Do you know if redness was measured on a
5 scale in connection with the studies of 0.5 percent
6 Alphagan?
7 **A This drug never came to market, and this**
8 **document is only a package insert.**
9 Q But it's reporting on a clinical study,
10 right?
11 **A It's reporting some clinical information.**
12 **All the information on a package insert does not come**
13 **from clinical studies.**
14 MR. DINER: Is now a good time for a break?
15 MS. CIPRIANO: Yeah, we can take a break.
16 THE VIDEOGRAPHER: We're now going off the
17 record. The time is 11:05 a.m.
18 (Recess.)
19 THE VIDEOGRAPHER: We're now going back on.
20 The time is 11:15 a.m.
21 BY MS. CIPRIANO:
22 Q Welcome back.

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1 So I'd like to continue our march through
2 paragraph 77 of your declaration. And I'd like to
3 turn next to your discussion of data related to
4 0.2 percent brimonidine.
5 And the statement in your declaration is
6 that when the concentration was lowered to 0.2 percent
7 brimonidine, the rate of conjunctival blanching
8 sharply dropped to 6.8 percent.
9 Do you see that?
10 **A Yes.**
11 Q And then, so again you cite -- we cite back
12 to that Exhibit 1031 that we've looked at a couple of
13 times. So I'd like to turn to that. And this time
14 we'll look at page 52 that you cite.
15 **A (Witness complies.)**
16 Q Are you on page 52?
17 **A Yes.**
18 Q So near, I guess, in the bottom quarter of
19 the page or so, there's a line "conjunctival
20 blanching," and it says -- it lists 15 patients, which
21 was 16.8 percent [sic] of to 0.2 percent brimonidine
22 study group.

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1 Am I interpreting that correctly?
2 **A I'm sorry. Where are you?**
3 Q So I guess let's take a step back.
4 Page 52, of Exhibit 1031 lists adverse
5 events for this particular study --
6 **A Yes.**
7 Q -- correct?
8 And this study administered 0.2 percent
9 brimonidine, correct?
10 **A Yes.**
11 Q So for the study group that was
12 administered 0.2 percent brimonidine, the adverse
13 event of conjunctival blanching was listed for 15
14 patients, which was 6.8 percent of that group.
15 Am I interpreting that correctly?
16 **A Yeah, I'll have to look at the study**
17 **protocol, if that was every visit or once in a while.**
18 **But yes, that's the number.**
19 Q Okay. Let's do that.
20 **A Okay.**
21 Q I don't have the study protocol, but I
22 have -- on page 21, these studies are described.

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1 MR. DINER: That's page 21 of 286?
2 MS. CIPRIANO: Yeah.
3 MR. DINER: Yeah, he's got it.
4 BY MS. CIPRIANO:
5 Q So to be clear, in your declaration, you
6 talk about -- you refer to studies 103 and 104. And
7 that's shorthand for the two studies that are
8 discussed on page 21 of 286 of Exhibit 1031, correct?
9 **A Those are the studies for the pooled data**
10 **for the approval study?**
11 Q So let's go through a little bit of at
12 least the information that we have about the study
13 design here.
14 So about halfway down the page, there's a
15 section that says "Study Design."
16 Do you see that?
17 **A Yes.**
18 Q And my understanding -- and please correct
19 me if I'm wrong -- is this section at the bottom of
20 the page walks through what happens at each study
21 visit; is that correct?
22 **A It's not everything happens.**

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1 Q Okay. All right. Well, let's talk about
2 what it does say about the study visits.
3 So in the second line under "Study Design,"
4 it says "At the pre-study visit (visit 1)."
5 And it talks about the different things
6 that were measured. "An ophthalmic evaluation
7 consisting of assessments of intraocular pressure,
8 IOP, visual acuity, biomicroscopy" -- I'm not going to
9 try to -- "ophthalmoscopy"?
10 **A Uh-huh.**
11 Q Okay. "Pupil size, Schirmer tear test, and
12 a visual field were performed to determine the
13 subject's eligibility."
14 So assessments of intraocular pressure,
15 that's a measurement done with a piece of equipment?
16 **A It's a measurement of eye pressure.**
17 Q Okay. Visual acuity, what is that
18 measurement?
19 **A How well the patient can read the eye**
20 **chart.**
21 Q Okay. Biomicroscopy, what is that?
22 **A That's a detailed examination of the front**

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1 **part of the eye.**
2 Q Is that the same thing as ultrasonic
3 biomicroscopy?
4 **A No.**
5 Q Is this biomicroscopy done with a
6 microscope?
7 **A Yes. It's looking under the microscope at**
8 **a lot of different things.**
9 Q What sort of things are analyzed in that
10 assessment?
11 **A It's an assessment of the eyelids and**
12 **eyelashes, kind of the structures around the eye. And**
13 **then you look at the -- you assess the tear film and**
14 **all its various components, and you assess the cornea**
15 **and its different layers and status. And then the**
16 **conjunctival episclera/sclera. And then you look**
17 **deeper into the anterior chamber. And you look deeper**
18 **into the iris. You look at the angle of the eye, the**
19 **status of the lens, the anterior part of the vitreous.**
20 Q Okay. And ophthalmoscopy, what is that?
21 **A That's when you look deeper into the eye.**
22 Q Okay. Those two are done in conjunction

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1 with one another, biomicroscopy and ophthalmoscopy?
2 **A They're part of the eye exam.**
3 Q And then an assessment of pupil size, what
4 does that entail?
5 **A So it's a measurement of the diameter and,**
6 **under certain lighting situations, how the pupil is**
7 **responding.**
8 Q And then a Schirmer tear test, what is
9 that?
10 **A That's a measurement of tear production.**
11 **And there's various subtypes of the Schirmer tear**
12 **test, but it's a measurement of tear production.**
13 Q And then a visual field, what is that?
14 **A That's a measure of peripheral vision.**
15 Q Okay. Now, from the information here, do
16 you know if redness was recorded in any of these
17 assessments during the pre-study visit?
18 **A It doesn't say this explicitly, but I would**
19 **assume from my experience as a clinical investigator**
20 **it's one of the things you note, yes.**
21 Q And how would it be noted?
22 **A On the form.**

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1 Q Would redness always be recorded -- strike
2 that.
3 Would some information about redness always
4 be recorded in a patient's file?
5 **A Once again, it always depends on what the**
6 **point of the clinical study is, but in a study such as**
7 **this, yes.**
8 Q Was the point of this study to assess
9 redness?
10 **A The primary endpoint was to measure eye**
11 **pressure, the effect of this drug -- this drug -- or,**
12 **these drugs, actually -- on eye pressure that was the**
13 **primary endpoints and secondary endpoints. And then**
14 **you have extra information.**
15 Q Was an assessment of redness a secondary
16 endpoint in these studies?
17 **A The study design was not to do -- not to**
18 **evaluate or do statistical analysis on redness, but**
19 **it's information that's collected.**
20 Q Do you know if it was collected in a -- in
21 relation to a redness scale of any sort?
22 **A I don't remember.**

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1 Q Okay. So after -- those are the -- what we
2 just discussed are the assessments, if you will, that
3 occurred in visit 1 -- what they characterize as
4 visit 1, right?
5 Is that my understanding?
6 **A Probably. We'd have to look. To be**
7 **100 percent sure, we'd have to look at the protocol.**
8 Q Okay. Well, based on what information is
9 here, in the next paragraph, there's a description of
10 what happened at visit 2.
11 Do you see that? It's in the second line
12 of the next paragraph? Starts in second line of the
13 next paragraph.
14 **A "Following washout"?**
15 Q Uh-huh.
16 **A Is that the sentence you're addressing?**
17 Q Yes. "Following washout, all subjects
18 returned for a baseline examination (visit 2, day
19 zero)."
20 Do you see that?
21 **A Do I see that?**
22 Q And then in the next line, at the sentence

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1 that begins at kinda the right-hand side of the page,
2 it again lists what happened at that visit.
3 Says "At this visit," presumably referring
4 to visit 2, "baseline measurements of IOP, visual
5 acuity, pupil size, heart rate, and blood pressure
6 were taken."
7 Do you see that?
8 **A I do.**
9 Q And then, so I want to make sure I
10 understand how this -- how this -- so the next couple
11 of sentences says "measurements of IOP were taken
12 between 7:30 and 9:30 a.m."
13 **A Yes.**
14 Q "And again between 9:30 and 11:30 a.m.,
15 which was two hours after treatment."
16 So am I understanding that those -- IOP was
17 measured prior to administration and then again two
18 hours after administration of the drug?
19 **A Yes.**
20 Q And then it says "Biomicroscopy and a
21 Schirmer tear test were performed."
22 Do you know if that -- if those assessments

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1 were done at the time -- at the measurements occurring
2 before administration or after administration?
3 **A I don't, without looking at the protocol.**
4 Q Okay. And the same is true for "subject
5 comfort" that was assessed?
6 **A I'd have to look at the protocol.**
7 Q Then in the next paragraph, the third
8 paragraph of the "study design" section, it says
9 "Subjects returned for follow-up examinations at weeks
10 1 and 2 and months 1, 2, 3, 6, 9, and 12."
11 Do you see that?
12 **A Yes.**
13 Q Again, it lists the assessments.
14 Says "Efficacy was assessed by evaluating
15 changes from baseline in IOP, visual fields, and
16 cup/disc ratio."
17 Do you see that?
18 **A Yes.**
19 Q And then it lists the ocular safety and a
20 Schirmer tear test and an ophthalmoscopic examination
21 at months 6 and 12.
22 Do you see that?

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1 **A Yes.**
2 Q Do you know -- so the results from these
3 studies report on adverse events as a whole.
4 Am I understanding that correctly?
5 **A Well, they're recorded in all of these**
6 **studies.**
7 Q So in recording them, a patient could have
8 an adverse event at the visit 2 and not have any other
9 adverse events in -- you know, through month 12,
10 correct?
11 MR. DINER: Objection. Calls for
12 speculation.
13 **A I'd have to look how they chose to record**
14 **it for that study.**
15 **BY MS. CIPRIANO:**
16 Q Okay.
17 **A It could be variable.**
18 Q So you don't have any information to say
19 when conjunctival blanching occurred in this study,
20 correct?
21 **A Well, the information is there. I just**
22 **don't have it in this sentence, in this paragraph. It**

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1 **exists somewhere.**
2 Q Okay. But based on the document that
3 you've cited in your declaration, we don't have the
4 information to know when conjunctival blanching was
5 observed in these studies, correct?
6 MR. DINER: Objection, vague. Calls for
7 speculation.
8 **A What do you mean by "when"?**
9 **BY MS. CIPRIANO:**
10 Q At what point in the 12 months that were
11 involved in the study.
12 **A I'd have to look at the study protocol.**
13 Q But you don't cite the study protocol in
14 your declaration, right?
15 **A I'm not sure what you're saying.**
16 Q Did you -- is the study protocol part of
17 the information that you reviewed to prepare your
18 declaration?
19 **A It's the underlying -- it's the basis of**
20 **where all of this information comes from.**
21 Q Did you review it?
22 **A Well, at some point I did, yes, because I**

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1 **helped the study.**
2 Q Okay. I'm trying to get to bottom of your
3 reliance on these studies. And is the study protocol
4 something that you relied on for your opinions in this
5 matter?
6 **A Well, to the extent that I performed these**
7 **studies in the past, I mean, as part of my fund of**
8 **knowledge. And it does contribute, knowing how these**
9 **studies work.**
10 Q So based on your -- the information that
11 you're relying on, when was conjunctival blanch
12 observed in these studies?
13 **A I'd have to go back and look at the**
14 **protocol.**
15 Q Okay. So you're saying you're relying on
16 your memory because you didn't provide it as support
17 for your opinions here, but you don't remember when
18 the conjunctival blanching occurred?
19 **A I'd have to look at the study protocol.**
20 Q You don't remember right now?
21 **A Off the top of my head, no.**
22 Q Okay. I'd like to go back to page -- I

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1 think it's 52 of 286, where -- that's the page that
2 you cite in paragraph 77 of your declaration with
3 respect to the 6.8 percent occurrence of conjunctival
4 blanching with 0.2 percent brimonidine.
5 So in these studies, the control group was
6 administered timolol.
7 Am I interpreting that correctly?
8 **A Yes. That was the comparator.**
9 Q And timolol is another glaucoma medication?
10 **A That's correct.**
11 Q And for conjunctival blanching, where it
12 lists 15 patients were 6.8 percent here in the
13 brimonidine column, in the timolol column, it lists
14 14, with a percentage of 6.3 percent.
15 Do you see that?
16 **A Yes.**
17 Q And then there's a "P" value.
18 Are you familiar with P values?
19 **A Yes.**
20 Q And this P value is 0.838.
21 And that P value essentially tells you that
22 there's not really a difference between the numbers,

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1 correct?
2 **A That's not what a P value -- no.**
3 Q Okay. What does a P value of .838 mean to
4 you?
5 **A So what it means is that's the -- we'll**
6 **say, percentage of the difference that we're seeing**
7 **can be to chance.**
8 Q So when -- you've published articles,
9 correct?
10 **A Yes.**
11 Q In order to say that the numbers are
12 different in your studies, what P value do you
13 normally aim for, for a conclusion that numbers are
14 different?
15 MR. DINER: Objection, vague.
16 **A If the numbers are different, the numbers**
17 **are different.**
18 **BY MS. CIPRIANO:**
19 Q So in order for numbers to be statistically
20 significantly different, does there have to be certain
21 P value associated with them?
22 **A It depends on the study or what the**

77

1 **question -- what we're trying to answer is.**
2 Q In your view, is there any statistical
3 significance to the difference between 6.8 percent
4 conjunctival blanching in the brimonidine group versus
5 6.3 percent conjunctival blanching in the timolol
6 group?
7 **A Well, there's a numerical difference.**
8 Q That's not my question though.
9 **A What was the question?**
10 Q Is there any statistical significance to
11 the difference between those numbers in this study?
12 **A There's always a difference. It depends**
13 **where you want to draw the line.**
14 Q What do you mean by that?
15 **A What difference you find acceptable to be**
16 **to chance.**
17 Q Would you accept an 83 percent chance that
18 this is due to -- chance significant?
19 MR. DINER: Objection, vague.
20 **A I don't understand your question.**
21 **BY MS. CIPRIANO:**
22 Q Okay. Here there's an 83 percent chance

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1 that the difference between 6.8 percent and
2 6.3 percent is due to chance, correct?
3 **A Yes.**
4 Q Okay. So you said you were involved with
5 the studies related to 0.2 percent brimonidine.
6 **A Yes.**
7 Q How were adverse events recorded in these
8 studies?
9 **A There was a form you fill out.**
10 Q Is it -- are the options laid out in the
11 study protocol and you check boxes, or is it an open
12 narrative?
13 **A It depends on the study.**
14 Q Okay. In this study, do you recall how it
15 was done?
16 **A I don't recall exactly how it was, no.**
17 Q I'd like to turn to the last part of
18 paragraph 77, when you talk about Alphagan P.
19 So if we look at -- look at Exhibit 2014.
20 I'm going to hand you a document that's been marked
21 Exhibit 2014 in the IPR.
22 You cite to Exhibit 2014 for the fact that

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1 blanching is not mentioned at all in the label, right?
2 **A Yes.**
3 Q Do you know if eye redness was measured in
4 any of the clinical trials that are reported in this
5 label?
6 **A I don't recall off the top of my head, but**
7 **I'm sure there's certainly some notation made, yes.**
8 Q And by "some notation," you're talking
9 about the same sort of notation that you were talking
10 about in the Alphagan?
11 **A On the form we have to fill out about the**
12 **patients' exams.**
13 Q Okay. But you don't have any information
14 if a redness scale was used, right?
15 **A I'd have to look at the protocol.**
16 Q Okay. We can put that away.
17 **A (Witness complies.)**
18 Q Switching gears a little bit.
19 In your declaration, you talk a bit about
20 Figures 2 and 6 in the '74 [sic] patent.
21 Do you recall that?
22 **A The '742 patent?**

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1 Q I think that's right.
2 Yes. Yes.
3 **A Yes.**
4 Q Okay.
5 MS. CIPRIANO: So for ease of reference,
6 I'm going to mark a document as Exhibit 1046.
7 (Exhibit 1046 was received and marked for
8 identification, as of this date.)
9 BY MS. CIPRIANO:
10 Q Just so we're on the same page, I thought
11 it would be easier to look at this side by side. And
12 if you could just take a moment to confirm that on the
13 left-hand side of this document, we've placed the
14 color figure -- or, the color version of Figure 2 of
15 the '742 patent.
16 And I can -- you can confirm that these
17 come from -- they come from the color version of the
18 '742 patent, which was produced as Exhibit 2161.
19 And I can give that to you if you want.
20 **A Could I have a copy of that?**
21 Q Yes, absolutely.
22 So just so we're on the same page, the

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1 document that I've marked as 1046, on the left-hand
2 page, has a copy of Figure 2 of the '742 patent as it
3 appears in Exhibits 2061.
4 Do you see that?
5 **A Yes.**
6 Q And then on the right-hand side of
7 Exhibit 1046, I've reproduced Figure 6 of the '742
8 patent as it appears in Exhibit 2161, correct?
9 **A Yes.**
10 Q So it doesn't matter to me which you refer
11 to, whether you want to look at them side by side or
12 look at them in the patent or look at them in your
13 declaration -- there's several copies here -- but I'd
14 like to talk a little bit about these Figures.
15 **A Okay.**
16 Q Let's start with Figure 2.
17 And to make sure that we're understanding
18 the figures -- we're on the same page as we understand
19 the figures, so on the X axis there are concentrations
20 of brimonidine, correct?
21 **A Yes.**
22 Q And there aren't any units on the Y axis,

82

1 right?
2 MR. DINER: Objection. Mischaracterizes
3 the document.
4 **A There's no units. There's a -- I mean,**
5 **it's understood that, as you go up, the magnitude**
6 **increases.**
7 **BY MS. CIPRIANO:**
8 Q Okay. It goes from zero to four plusses on
9 effect?
10 **A Correct.**
11 Q And in this figure, the thick black line is
12 what is identified in the key of Figure 2 as
13 vasoconstriction, right?
14 **A Yes.**
15 Q And near the bottom of that -- of the
16 figure, there are a thinner black line, a dotted black
17 line, and a thin gray line that are labeled in the key
18 as "IOP reduction, endo cell pump inhibition," and
19 "rebound hyperemia," right?
20 **A Yes.**
21 Q And then the thicker gray line that goes up
22 into the yellow box and then comes back down -- that's

83

1 what's labeled as "net vasoconstriction benefit,"
2 correct?
3 **A Yes.**
4 Q So the net vasoconstriction benefit
5 represents the vasoconstriction effect in the black
6 line -- thick black line, minus the rebound hyperemia,
7 correct?
8 MR. DINER: Objection to the extent it
9 mischaracterizes the patent.
10 **A I'm not sure it's minus. It's talking**
11 **about the desired endpoint, which is vasoconstriction**
12 **versus a bad thing.**
13 **BY MS. CIPRIANO:**
14 Q Okay. So then when it says "net
15 vasoconstriction benefit," it takes into account the
16 bad thing that you're talking about, right?
17 **A Yes.**
18 Q And that bad thing, for the purposes of
19 this '742 patent, is rebound hyperemia, right?
20 **A Yes.**
21 Q So do you agree that this figure is not --
22 the net vasoconstriction benefit is not actually

84

1 plotted as a direct comparison of two other of the
2 lines on the figure, right?
3 MR. DINER: Objection, vague.
4 **A I don't understand the question.**
5 **BY MS. CIPRIANO:**
6 Q So this could have been plotted as -- the
7 net vasoconstriction benefit could be plotted as the
8 vasoconstriction curve minus the values in the
9 rebound-hyperemia curve, right?
10 MR. DINER: Objection. No foundation.
11 Calls for speculation.
12 **A I'm not sure you're talking about values.**
13 **BY MS. CIPRIANO:**
14 Q Okay. Well, I mean, on a graph, we usually
15 are talking about values, right?
16 MR. DINER: Objection, vague.
17 **A Depends what the graph is.**
18 **BY MS. CIPRIANO:**
19 Q Okay. So this Figure 2 doesn't report
20 specific values, right?
21 **A Specific numbers?**
22 MR. DINER: Objection, vague.

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1 **A It think it does report relative values.**
2 **BY MS. CIPRIANO:**
3 Q Okay. But you'd agree that the net
4 vasoconstriction benefit is not directly a comparison
5 of the vasoconstriction value in relation to the
6 rebound-hyperemia value, right?
7 MR. DINER: Objection, vague to the extent
8 it mischaracterizes testimony.
9 **A I don't understand exactly what you're**
10 **saying.**
11 **BY MS. CIPRIANO:**
12 Q Okay. So the net vasoconstriction
13 benefit -- let me step back.
14 If there was zero hyperemia, the net
15 vasoconstriction benefit would mirror or mimic the
16 vasoconstriction curve, correct?
17 **A So if rebound hyperemia never occurred, the**
18 **net would be the same.**
19 Q But in this case, it doesn't, because this
20 is reporting on some rebound hyperemia.
21 Here, the net vasoconstriction benefit
22 decreases, so it -- let me step back.

86

1 The net vasoconstriction benefit peaks at
2 around 0.3 percent brimonidine, correct?
3 **A It's less than that, .02.**
4 Q So if we could take a look at page 45 of
5 your declaration, paragraph 94.
6 **A (Witness complies.)**
7 Q You in the first -- second full sentence on
8 page 45, you said "Relatedly, Figure 2 teaches that
9 brimonidine's maximum vasoconstriction effect after
10 netting out its tendency to cause rebound hyperemia is
11 at 0.03 percent, as seen from the apex of the thick
12 gray arrow."
13 Do you see that?
14 **A I see that.**
15 Q So are you changing your mind that the apex
16 of the thick gray arrow is at .03 percent?
17 **A I'll stand by what's in my report.**
18 Q Okay. So going back to Figure 2, we see
19 that the net vasoconstriction benefit increases --
20 comes to an apex at .03 percent and then drops off
21 after at higher concentrations above .3 percent,
22 correct?

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1 **A Yes.**
2 Q And the change in the net vasoconstriction
3 benefit curve is more significant than the change in
4 the rebound-hyperemia curve, correct?
5 MR. DINER: Objection, vague.
6 **A Ask me that question again. I'm sorry.**
7 **Didn't quite follow.**
8 **BY MS. CIPRIANO:**
9 Q So the net -- let's step back.
10 The rebound-hyperemia curve here, right?
11 MR. DINER: Are we talking about Figure 2
12 or Figure 6?
13 MS. CIPRIANO: Figure 2.
14 BY MS. CIPRIANO:
15 Q The rebound-hyperemia curve that's the
16 thinner gray line gradually increases to about, I
17 guess, just higher than .05, and then has a steeper
18 slope after at concentrations above, we'll say, .05.
19 Do you see that?
20 **A I'm sorry. Say it one more time.**
21 Q Sure. I'm just trying to understand the
22 rebound-hyperemia line.

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1 So the rebound-hyperemia line, I see that
2 it gradually increases up to about a little above
3 .05 percent. There's one slope, if you will, of the
4 curve up until a little higher than .05 percent?
5 **A Okay.**
6 Q And then it changes in slope. It becomes
7 steeper, increases more quickly, higher than
8 .05 percent.
9 Do you see that?
10 **A Okay.**
11 Q Do you agree with that?
12 **A Yes.**
13 Q Okay. And what I'm trying to just confirm
14 is that the net vasoconstriction benefit curve starts
15 to decrease at .03, but the net -- but the rebound
16 hyperemia doesn't really start to increase in Figure 2
17 until after .05 percent, right?
18 MR. DINER: Objection to the extent it
19 mischaracterizes the graph.
20 **A Well, it's increasing throughout. Starts**
21 **very low, and it just -- it's a positive slope**
22 **throughout the whole graph.**

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1 **BY MS. CIPRIANO:**
2 Q Okay. Now, Figures 2 and Figure 6 don't
3 represent actual data from a clinical study, right?
4 MR. DINER: Objection, vague.
5 **A They're not necessarily in association with**
6 **the clinical study.**
7 **BY MS. CIPRIANO:**
8 Q Okay. These are more akin to illustrations
9 of what the data represents?
10 MR. DINER: Objection no foundation. Calls
11 for speculation.
12 **A Yeah. These are from the patent.**
13 **BY MS. CIPRIANO:**
14 Q Do you know where this data came from?
15 **A I saw it in the patent.**
16 Q Do you know where the patentee got this
17 information?
18 **A I don't know.**
19 Q And there's no -- there are no error bars
20 associated with Figure 2 and Figures 6, correct?
21 **A There are no error bars.**
22 Q Do you know if there are -- there's any

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1 information about a standard deviation or variable in
2 this data associated with Figures 2 and Figure 6?
3 **A I haven't seen any of that.**
4 Q And you agree that Figure 2 and Figure 6
5 represent -- let me start that again.
6 You agree that Figures 2 and Figure 6 are
7 different, correct?
8 MR. DINER: Objection to the extent it
9 mischaracterizes his testimony.
10 **A I don't know what you mean by "different."**
11 **They're obviously similar. And I think I kind of go**
12 **back and forth when I interpret them together.**
13 **BY MS. CIPRIANO:**
14 Q Okay. So in para 95, you said that "in,
15 effectively, an expanded version of Figure 2," and I'm
16 trying to understand that statement.
17 Figure 6 is not a reproduction of a section
18 of Figure 2, right?
19 MR. DINER: Objection to the extent it
20 mischaracterizes testimony.
21 **A What do you mean by "reproduction"?**
22

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1 BY MS. CIPRIANO:
2 Q You agree that the rebound-hyperemia curve
3 in Figure 6 is different than the rebound-hyperemia
4 curve in Figure 2?
5 **A No. I don't know to what -- I don't**
6 **understand what you're saying.**
7 Q It has a different shape?
8 **A They're fairly similar.**
9 Q So in Figure 2, the rebound-hyperemia curve
10 is always lower than the endo-cell pump inhibition
11 curve, correct?
12 **A In which graph?**
13 Q Figure 2?
14 **A Figure 2. I think the rebound is -- it**
15 **appears that the rebound-hyperemia curve is always**
16 **below the endothelial cell pump inhibition curve.**
17 Q In Figure 2?
18 **A Yes.**
19 Q And in Figure 6, that's not the case,
20 correct? -- well, let's step back. Let me ask a
21 different question first.
22 You agree that -- or, your interpretation

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1 of Figure 6 is that the curves have the same, or
2 follow the same key as in the legend of Figure 2; is
3 that correct?
4 **A Yeah. The way I interpret these is**
5 **together. I tend to use them as a package.**
6 Q Okay. So the dotted line in Figure 6 is
7 also a line representing endothelial cell pump
8 inhibition?
9 **A I believe so.**
10 Q So in Figure 6, the rebound-hyperemia curve
11 is not always below the endo-cell pump inhibition
12 curve, right?
13 **A In Figure 6?**
14 Q In Figure 6.
15 **A No. It's not always below there.**
16 Q Okay. So then you'd agree that
17 rebound-hyperemia curve in Figures 2 and Figure 6 are
18 different?
19 MR. DINER: Objection. Mischaracterizes
20 prior testimony. And the document speaks for itself.
21 **A I would use -- I mean, I use these**
22 **together. I kind of use them as a package.**

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1 **BY MS. CIPRIANO:**
2 Q I understand how you use them. I'm just
3 trying to establish that you would agree that the data
4 represented in the figures is different?
5 MR. DINER: Objection, vague. Asked and
6 answered. To the extent it mischaracterizes
7 testimony, objection to form.
8 **A I just used them interchangeably. I go**
9 **back and forth.**
10 **BY MS. CIPRIANO:**
11 Q Okay. Have you seen any clinical data
12 comparing 0.025 percent and 0.03 percent brimonidine?
13 **A What do you mean, "clinical data"?**
14 Q Any clinical studies comparing those two
15 percentages of brimonidine.
16 **A No.**
17 Q Okay. We can put that away.
18 **A (Witness complies.)**
19 Q I'd like to turn now to what we referred to
20 in this case as the '553 patent.
21 I'm going to hand you a document that's
22 been marked Exhibit 1004.

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1 Do you recognize this as the '553 patent
2 that's discussed in the papers in this proceeding?
3 **A Yes.**
4 Q And a focal point of this discussion, your
5 declaration and the other papers in this proceeding,
6 is example 1 of the '553 patent.
7 Do you recall that?
8 MR. DINER: Objection. Mischaracterizes
9 the declaration.
10 **A It's one of the things talked about.**
11 **BY MS. CIPRIANO:**
12 Q Example 1 discusses administration of
13 brimonidine following radial keratotome surgery,
14 correct?
15 **A Yes.**
16 Q And radial keratotomy surgery is a
17 procedure where the surgeon uses a blade and makes
18 incisions in the cornea, correct?
19 **A Yes.**
20 Q And is it performed while the patient is
21 awake?
22 **A Typically.**

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1 Q In your -- have you ever performed radial
2 keratotomy?
3 **A Yes.**
4 Q Now, is the eye held still during the
5 procedure?
6 **A What do you mean, "held still"?**
7 Q Is there any device that's used to prevent
8 the patient from moving their eye?
9 **A To prevent the patient from moving their**
10 **eye?**
11 Q Yes.
12 **A To prevent them from moving their eye, no.**
13 Q So the patient can look around during the
14 procedure?
15 **A Yes.**
16 Q One of the things that's talked about in
17 the '553 patent is ocular inflammation.
18 Do you recall that?
19 **A Can you point me specifically?**
20 Q Sure. Let's look at example 1 in the third
21 paragraph.
22 **A (Witness complies.)**

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1 Q The second sentence in that third paragraph
2 under example 1 is "Symptoms of ocular inflammation
3 (burning/stinging, tearing, et cetera) are also
4 recorded."
5 Do you see that?
6 **A So I see those words here.**
7 Q Okay. You agree that redness could be one
8 sign of ocular inflammation, correct?
9 MR. DINER: Objection, vague.
10 **A What kind of redness?**
11 **BY MS. CIPRIANO:**
12 Q Redness in the eye.
13 MR. DINER: Objection, vague.
14 **A You have to give me more information on the**
15 **clinical scenario.**
16 **BY MS. CIPRIANO:**
17 Q So you don't agree that redness is a sign
18 of inflammation generally?
19 **A It would have to be -- it depends on the**
20 **clinical scenario.**
21 Q So in paragraph 146 of your declaration,
22 you state: "It has long been known that inflammation,

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1 including ocular inflammation, produces five cardinal
2 symptoms, including swelling, pain, redness, heat, and
3 loss of function."
4 Do you see that?
5 **A Yes.**
6 Q Do you agree with that statement?
7 **A That's a general statement for medicine.**
8 Q Okay. So in paragraph 49 of your
9 declaration, you refer to a clinical study near the
10 bottom of the page.
11 Do you see that?
12 **A I'm sorry. Where are you?**
13 MR. DINER: Paragraph 49?
14 MS. CIPRIANO: Paragraph 149.
15 THE WITNESS: 149?
16 MS. CIPRIANO: I'm sorry if I misspoke.
17 BY MS. CIPRIANO:
18 Q Are you there?
19 **A I'm there. 149, yes.**
20 Q So you talk about a redness scale,
21 including a redness scale from this clinical study,
22 including a zero, related to no eye redness, right?

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1 **A Yes.**
2 Q Do you know if anyone in that study
3 actually was rated a zero on the redness scale?
4 **A Which study are you talking about?**
5 Q The study that's reported in -- that you're
6 referring to in paragraph 149.
7 Do you want to take a look at it?
8 **A (Witness reviews document.)**
9 **Yes.**
10 Q We'll look at Exhibit 2166.
11 Do you recognize this as the clinical study
12 report that you cite in paragraph 149 of your
13 declaration?
14 **A It appears to be.**
15 Q Okay. And you cite to page 16 that sets
16 forth the redness scale -- 16 of the document which is
17 marked as page 30 of the study report.
18 Do you see the scale that's in the middle
19 of the page?
20 **A Table 5?**
21 Q Yeah.
22 Do you know if any of the patients in this

99

1 study were ever recorded as having a zero on the
2 conjunctival redness descriptor scale?
3 **A I need to look.**
4 (Witness reviews document.)
5 I'm sorry. What was the question?
6 Q So my question was if you knew if any of
7 the patients in this study were ever recorded as
8 having a zero on the redness scale that's reported on
9 page 16 of the document.
10 **A Well, I think at entry they had to probably**
11 **be zero.**
12 Q That's your assumption?
13 **A Yeah, for inclusion criteria.**
14 Q And what about the inclusion criteria makes
15 you think --
16 **A Well, the exclusion criteria says that if**
17 **they have -- where does it say -- "of clinically**
18 **active conjunctivitis with greater than one redness in**
19 **any vessel bed."**
20 **So some of them must have.**
21 Q Do you -- do you know what the average eye
22 redness score would be for healthy eyes, based on this

100

1 scale?
2 MR. DINER: Objection, vague. Incomplete
3 hypothetical.
4 **A It would depend on the population.**
5 **BY MS. CIPRIANO:**
6 Q This study report does not report on a
7 baseline eye redness score in this study population,
8 right?
9 MR. DINER: Objection, vague. Asked and
10 answered.
11 **A I'm not sure what you're saying. I'm sure**
12 **it was recorded somewhere.**
13 **BY MS. CIPRIANO:**
14 Q Is it reported in this clinical study
15 report?
16 **A No, but you can also see on table 13 that**
17 **the mean is 0.48 or 0.61. So these are means,**
18 **less-than. So sometimes people have zeros.**
19 Q In table 4 -- I'm sorry, what?
20 **A Table 13, when the mean is less than 1,**
21 **that implies that somebody had to be a zero to make it**
22 **less than 1.**

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1 Q I'm not seeing where you -- table 13?
2 **A Yeah. So when you see these scores, so it**
3 **says "mean."**
4 Q Understood.
5 **A You know, if the mean is less than 1, that**
6 **means somebody is zero -- or, some people's.**
7 Q And what does "ciliary redness" mean?
8 **A It's redness around the limbus, which is**
9 **where the white part meets the colored part.**
10 Q And is that different than hyperemia?
11 MR. DINER: Objection, vague.
12 **A Depends on the clinical scenario.**
13 **BY MS. CIPRIANO:**
14 Q Could it be?
15 **A It depends how you define it.**
16 Q So tables 9 through 12 report on
17 conjunctival redness.
18 Do you see that?
19 **A Yes, yes.**
20 Q And then, separately, it studies -- it
21 reports on ciliary redness.
22 **A Yes.**

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1 Q So which of -- let me strike that.
2 Would you interpret conjunctival redness to
3 equate to hyperemia?
4 **A It could be.**
5 Q What else could it be?
6 **A It could be a lot of different things. It**
7 **could be blood.**
8 Q What do you mean "could be blood"?
9 **A It depends. You're just talking about the**
10 **term "conjunctival redness" in a vacuum?**
11 Q No. Conjunctival redness as it's reported
12 in tables 9 through 12 of this clinical study.
13 **A So this is a study looking at hyperemia.**
14 **So that's what they're measuring.**
15 Q Okay. So the study report makes -- calls
16 out the difference between conjunctival redness and
17 ciliary redness.
18 Do you agree?
19 **A They're -- they're blood vessels on that**
20 **surface.**
21 Q But they're measured differently here?
22 MR. DINER: Objection. Mischaracterizes

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1 testimony.
2 **A They're anatomically -- they're just --**
3 **they're surface blood vessels in different locations.**
4 **BY MS. CIPRIANO:**
5 Q Okay. Is ciliary redness considered
6 hyperemia?
7 **A Depends on the context.**
8 Q In the context of this study.
9 **A Ciliary redness is typically the ciliary**
10 **blood vessels engorging.**
11 Q And is it considered the hyperemia that was
12 studied in this clinical study report?
13 **A Well, it's something that they recorded in**
14 **this study.**
15 Q Did they only record ciliary redness at
16 visit 6?
17 Well, let me ask a more direct question.
18 So if you look at page 26 of the exhibit,
19 there's a section titled "Ciliary Redness."
20 **A Yes.**
21 Q So ciliary redness was measured at more
22 than just visit 6, right?

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1 **A I need to look at the protocol.**
2 Q I mean, it says there were no statistically
3 significant differences in ciliary redness scores
4 among the treatment groups at visits 3B, 4B, or 5B.
5 Do you see that?
6 **A Yes.**
7 Q So at least they were measured at visits
8 3B, 4B, 5B, and visit 6.
9 **A Okay.**
10 Q Is that logical?
11 **A That's logical.**
12 Q Could someone be considered to have
13 hyperemia and have no ciliary redness?
14 MR. DINER: Objection, vague. Incomplete
15 hypothetical.
16 **A I don't understand that question.**
17 **BY MS. CIPRIANO:**
18 Q Okay.
19 So we've been talking about adverse events
20 related to various products today, and we've been
21 referring to it as -- generally as "hyperemia."
22 And I -- is that hyperemia limited to

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1 what's classified as "conjunctival redness" in this
2 study report?
3 MR. DINER: Objection, vague.
4 **A So you're specifically talking about just**
5 **this study. Is that what this question is about?**
6 MS. CIPRIANO: Let me ask a better question
7 then.
8 BY MS. CIPRIANO:
9 Q Hyperemia, in general, when we're talking
10 about hyperemia of the eye -- it can occur -- strike
11 that. Let me start over.
12 So what I'm trying to understand is, there
13 are -- if someone only had ciliary redness, would that
14 still classify as hyperemia?
15 MR. DINER: Objection, vague.
16 **A Depends on the clinical criteria, what**
17 **you're defining it as.**
18 **BY MS. CIPRIANO:**
19 Q So in the Alphagan clinical studies when it
20 talks about adverse event of hyperemia, what does that
21 mean to you?
22 **A It depends -- it depends on the specific**

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1 **clinical studies, how, number 1, the data was**
2 **solicited, and in the context that you're using it in.**
3 Q I'd like to look at a different study.
4 I'm going to hand you what's been marked as
5 Exhibit 1006.
6 Do you recognize this as the document
7 that's referred to in the papers as "Norden"?
8 **A Yes.**
9 Q In your declaration, you talk a little bit
10 about the construction of ocular condition as it's
11 used in the claims of the '742 patent; is that
12 correct?
13 **A Yes.**
14 Q You do not dispute that LASIK would
15 constitute -- a patient that had LASIK would
16 constitute as a patient having an ocular condition
17 within the scope of the claims of the '742 patent,
18 correct?
19 MR. DINER: Objection to the extent it
20 calls for a legal conclusion.
21 **A LASIK is a procedure.**
22

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1 BY MS. CIPRIANO:
2 Q I'm not sure I understand your answer. Let
3 me ask another question.
4 We can move on.
5 So the Norden paper states in the -- I
6 guess, in the second paragraph, if you want to take a
7 look in the right-hand column.
8 It states that the study was designed to
9 "objectively assess the effect of brimonidine
10 administration before LASIK on subconjunctival
11 hemorrhage, hyperemia, and micropannus bleeding."
12 Do you see that?
13 MR. DINER: I don't.
14 MS. CIPRIANO: The last paragraph before
15 "Patients and Methods."
16 THE WITNESS: Okay.
17 BY MS. CIPRIANO:
18 Q "This prospective, double-masked trial."
19 Do you see that?
20 **A Yes.**
21 Q I just want to make sure I understand your
22 declaration a bit.

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1 So in paragraph 169, this is in the section
2 you're talking about Norden 2002, you state a
3 conclusion that -- end of the sentence, it states "a
4 conclusion that, in fact, was contemporaneously
5 questioned by ophthalmologists."
6 **A Where are you reading from?**
7 Q The last section of paragraph 169.
8 **A Okay.**
9 Q You don't cite anything in this paragraph,
10 but you're referring to the Euretman and Munos
11 articles that you cite later; is that correct?
12 **A Yes. But also in the community, that's one**
13 **place, but also, just, I questioned it.**
14 Q Okay. But the only -- so I guess if you
15 look at paragraph 175, it's where the two articles are
16 there, the only documents you point to as the
17 contemporaneous reports of other surgeons are
18 Exhibit 2175 by Munos and Exhibit 2186, by Euretman?
19 **A Yes.**
20 Q Looking at the Norden article a bit, you
21 discuss this in section of your declaration starting
22 at paragraph 166, if you want to take a look.

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1 But I understand that you essentially make
2 three criticism of the Norden data.
3 Does that sound familiar?
4 MR. DINER: Objection, vague.
5 **A Could you elaborate?**
6 **BY MS. CIPRIANO:**
7 Q Sure. Let's -- we can walk through them.
8 **A Okay.**
9 Q So you have paragraph 170.
10 You state "First, Norden 2002 measured
11 redness only once, five minutes after the LASIK
12 surgery."
13 Do you see that?
14 **A Yes.**
15 Q So in your view -- and this is -- I'm just
16 trying to understand this critique.
17 In your view, in order to inform a person
18 of ordinary skill about the ability of brimonidine to
19 reduce redness, redness needs to be measured at least
20 twice, correct?
21 MR. DINER: Objection to the extent it
22 mischaracterizes the document.

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1 **A The biggest problem with that is there's no**
2 **baseline.**
3 **BY MS. CIPRIANO:**
4 Q Okay.
5 **A So how do you know -- how do you measure**
6 **where you're going if you don't know where you came**
7 **from?**
8 Q Without a baseline measurement, you're
9 unable to understand the impact on redness?
10 MR. DINER: Objection, vague.
11 **A The problem with the study is everybody had**
12 **hyperemia, almost. 95 percent of people had**
13 **hyperemia. So everybody has hyperemia. So how do you**
14 **measure anything?**
15 **BY MS. CIPRIANO:**
16 Q I think that falls into your second -- your
17 second critique, but I'd like to focus on your first
18 critique, talking about the measurements.
19 And I just want to confirm that your
20 position is that in order to understand the impact on
21 redness, you need to have a baseline measurement and
22 then some test measurement at the minimum, right?

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1 MR. DINER: Objection. Mischaracterizes
2 the testimony.
3 **A What I'm -- what I'm saying is that,**
4 **because everyone had hyperemia, maybe everybody got**
5 **worse. Maybe nobody had hyperemia at the beginning of**
6 **the study. He didn't -- he didn't measure it. This**
7 **is a bad study.**
8 **BY MS. CIPRIANO:**
9 Q Okay. But it's a bad study because -- one
10 of the reasons it's a bad study is that he didn't
11 measure twice?
12 MR. DINER: Mischaracterizes his testimony.
13 **A He didn't establish a baseline.**
14 **BY MS. CIPRIANO:**
15 Q Okay. And then -- so turning to the second
16 point in paragraph 172, you say "Second, Norden 2002
17 failed to establish proper exclusion criteria."
18 Do you see that?
19 **A Yes.**
20 Q And so, in your view, in order to provide
21 information about the ability of brimonidine to reduce
22 redness the study has to exclude patients taking other

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1 medication that could impact eye redness, right?
2 MR. DINER: Objection, vague.
3 **A The biggest problem with this study is the**
4 **sloppiness of it. He didn't account for it. You can**
5 **do a study on anything if you account for it. The**
6 **problem is, we don't know. It's just he was winging**
7 **it. And there's all these other confounding factors**
8 **that could really skew the results. He didn't take --**
9 **he didn't take into account other variables.**
10 **BY MS. CIPRIANO:**
11 Q So in order to draw a conclusion about eye
12 redness, the study has to be limited to looking at eye
13 redness?
14 MR. DINER: Objection, vague. Incomplete
15 hypothetical.
16 **A It always depends what you're trying to**
17 **measure. And this is -- this study didn't -- it**
18 **didn't set up success for accurate measurement. It**
19 **didn't get a baseline; it didn't define what the**
20 **patients could look like coming in. Maybe they all**
21 **had horrible red eyes to start with. Who knows? --**
22 **those that treated and the untreated people. Who**

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1 **knows? He didn't randomize for individuals. We don't**
2 **like to make comparisons inside an individual because**
3 **eyes are different from one person to another. It's**
4 **flawed at every single level.**
5 **BY MS. CIPRIANO:**
6 Q The third critique, starting on
7 paragraph 174 of your declaration, you state "Third,
8 the study protocol Norden 2002 had too many variables
9 to make any meaningful assessment."
10 And then you go on and you talk about the
11 hyperemia scale that Norden used, correct?
12 **A Yes.**
13 Q So in your view, in order to draw
14 conclusions about whether brimonidine could reduce
15 redness, you'd need more information about the scale
16 that was being used in the study correct?
17 MR. DINER: Objection. Mischaracterizes
18 the document.
19 **A No. I'm saying it was a crummy study, and**
20 **we can't draw any conclusions from how he reported the**
21 **data.**
22

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1 BY MS. CIPRIANO:
2 Q Right.
3 I'm just trying to understand what makes a
4 crummy study.
5 **A So when he's looking at the scale, he's**
6 **saying some eyes had blood; some had hyperemia. I**
7 **mean, how do you tell the difference? If a big blob**
8 **of blood is overwhelming the blood vessels, how do you**
9 **make any assessment of hyperemia? If there's a blob**
10 **of blood over it, how can you say anything?**
11 Q So you'd want more information about the
12 scale that he used and how he assessed redness?
13 MR. DINER: Objection. Mischaracterizes.
14 **A I'd like the study to be designed**
15 **appropriately.**
16 **BY MS. CIPRIANO:**
17 Q Which would include some more information
18 about a subjective scale that was used to assess the
19 redness?
20 MR. DINER: Objection, vague.
21 Mischaracterizes testimony.
22 **A Sure, that -- but that's -- honestly,**

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1 **that's the least of our problems. But yes, that would**
2 **be nice.**
3 **BY MS. CIPRIANO:**
4 Q We can put Norden away.
5 If we could turn to paragraph 138 of your
6 declaration, and that's on page 65.
7 **A Yes.**
8 Q Now, this paragraph is talking a little bit
9 about the pH of an ocular formulation, right?
10 **A Yes.**
11 Q And you're not providing an opinion on the
12 motivation of a person of ordinary skill to target a
13 specific pH, correct?
14 MR. DINER: Objection. Mischaracterizes
15 the paragraph.
16 **A Well, the eye is very sensitive to pH, and**
17 **we'd like to work at a physiologic pH if we can.**
18 **BY MS. CIPRIANO:**
19 Q Again, you're not providing -- there's a
20 bunch of statements in this paragraph that refer to
21 what Dr. Williams will explain?
22 **A Yes. And I will defer to him, yes.**

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1 Q Near the bottom of the page in
2 paragraph 138, you state "In my experience,
3 administration of a topical eye drop with an acidic pH
4 leads to burning and stinging, tear production, or
5 redness."
6 Do you see that?
7 **A Yes.**
8 Q What was the pH of the eye drops where you
9 observed burning, stinging, tearing, and redness?
10 **A Probably the lowest pH, like, 4.6. But I**
11 **mean, I personally put many of these medications in my**
12 **eye, and when it's -- the pH is less than 7, they tend**
13 **to sting more.**
14 Q So less than 7.
15 Would -- in your experience, would an
16 eye drop at pH 6.9 cause burning and stinging?
17 MR. DINER: Objection, vague. Incomplete
18 hypothetical.
19 **A It would depend on the eye drop.**
20 **BY MS. CIPRIANO:**
21 Q And what would it depend on?
22 **A Active ingredients, the other incipients,**

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1 **the other things in the formulation. PH is one**
2 **factor.**
3 Q So in your experience, would an eye drop at
4 pH, for example, 6.9 cause burning and stinging due to
5 the pH?
6 MR. DINER: Objection. Incomplete
7 hypothetical. Asked and answered.
8 **A It could. It would depend on the exact**
9 **clinical scenario.**
10 **BY MS. CIPRIANO:**
11 Q Are you aware of any study comparing the
12 effects of 0.025 percent brimonidine with 0.2 percent
13 brimonidine?
14 MR. DINER: Objection, vague.
15 **A For treatment of?**
16 **BY MS. CIPRIANO:**
17 Q Anything.
18 **A Not off the top of my head.**
19 Q So are you aware of any clinical study
20 comparing the effects of 0.025 percent brimonidine
21 with 0.3 percent brimonidine?
22 **A For treatment for?**

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1 Q Anything.
2 **A Not off the top of my head.**
3 MS. CIPRIANO: Let's take a quick break.
4 THE VIDEOGRAPHER: We're now going off the
5 record. The time is 12:43.
6 (Recess.)
7 THE VIDEOGRAPHER: We're now back on the
8 time is 12:52.
9 MS. CIPRIANO: Doctor, I really appreciate
10 your time. I don't have any further questions at this
11 time.
12 EXAMINATION
13 BY MR. DINER:
14 Q Dr. Noecker, I'd like to refer you to
15 paragraph 38 of your declaration.
16 **A (Witness complies.)**
17 Q Do you recall this morning that counsel was
18 asking you questions with regard to paragraph 38 and
19 the figures of the eye, asking you questions about the
20 sclera?
21 **A Yes.**
22 Q Do you recall talking about the conjunctiva

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1 having blood vessels that were dilated can make the
2 eye appear red?
3 **A Yes.**
4 Q Does the episclera -- strike that.
5 Do you have an opinion of whether the
6 episclera has blood vessels that, when dilated, can
7 make the eye appear red?
8 **A Yes. They have some blood vessels that can**
9 **dilate and make the eye look red.**
10 Q I'd like you to -- can you take a look at
11 paragraph 38?
12 **A Yes.**
13 Q Can you read that paragraph into the
14 record, please?
15 MS. CIPRIANO: Objection to form.
16 BY MR. DINER:
17 Q Can you read paragraph 38 into the record,
18 please?
19 **A "Each of the conjunctiva, episclera, and**
20 **sclera have blood vessels. The conjunctiva and**
21 **episclera have blood vessels known as 'superficial and**
22 **deep conjunctival capillary and episcleral plexuses.'**

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1 **Dilation of these blood vessels make them more**
2 **visible, triggering eye redness. The surface of the**
3 **sclera, deep into the episclera, also contains blood**
4 **vessels. When dilated, these blood vessels at the**
5 **sclera interface with the episclera, which can make**
6 **the eye appear red."**
7 Q And as you sit here today, do you maintain
8 the same opinion as you just read from paragraph 38 of
9 your declaration?
10 **A Yes.**
11 MR. DINER: No further questions.
12 MS. CIPRIANO: I have no further questions.
13 THE VIDEOGRAPHER: This concludes today's
14 deposition. The time is 12:54. We're now off the
15 record.
16 MS. CIPRIANO: Five business days.
17 MR. DINER: Five business days.
18 MS. CIPRIANO: Rough draft.
19 MR. DINER: Rough draft.
20
21 (Time noted: 12:54 p.m.)
22

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1 CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC
2 I, Angela (Angie) Shaw-Crockett, Certified
3 Reporter and Notary Public within and for the States
4 of New York, New Jersey and Connecticut, do hereby
5 certify: That Dr. Robert Noecker, the witness whose
6 deposition is hereinbefore set forth, was duly sworn
7 by me before the commencement of such deposition and
8 that such deposition was taken before me and is a true
9 record of the testimony given by such witness.
10 I further certify that the adverse party,
11 Eye Therapies, was represented by counsel at the
12 deposition.
13 I further certify that the deposition of,
14 Dr. Robert Noecker, occurred at the offices of
15 Residence Inn Norwalk, 45 South Main Street, Norwalk,
16 Connecticut 06845, on Sunday, November 13, 2022,
17 commencing at 9:25 a.m. to 12:54 p.m.
18 I further certify the inspection, reading
19 and signing of said deposition was not discussed on
20 the record. I further certify that I am not related
21 to any of the parties to this action by blood or
22 marriage, I am not employed by or an attorney to any

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1 of the parties to this action, and that I am in no way
2 interested, financially or otherwise, in the outcome
3 of this matter.
4 IN WITNESS WHEREOF, I have hereunto set my
5 Hand this 18th day of November, 2022.
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8 _____
9 NOTARY PUBLIC IN AND FOR THE
10 CONNECTICUT
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