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# Transcript of Eric D. Donnenfeld, M.D.

**Date:** February 6, 2025

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

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WORLDWIDE COURT REPORTING & LITIGATION TECHNOLOGY

Transcript of Eric D. Donnenfeld, M.D.  
Conducted on February 6, 2025

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| UNITED STATES PATENT AND TRADEMARK OFFICE<br>-----<br>BEFORE THE PATENT TRIAL AND APPEAL BOARD<br>-----<br>DR. REDDY'S LABORATORIES S.A. and<br>DR. REDDY'S LABORATORIES, INC.,<br>Petitioners,<br>v.<br>EYE THERAPIES, LLC,<br>Patent Owner.<br>-----<br>IPR2024-00563<br>U.S. Patent No. 11,596,600<br>-----<br>(Caption continues below)<br><br>Job No. 569743<br>Pages 1 - 78<br>Reported by: April Reid, RPR, CRR (Stenographer)                                                                             | A P P E A R A N C E S<br><br>ON BEHALF OF THE PETITIONERS:<br><br>CHRISTOPHER J. CASSELLA, ESQ.<br>GOODWIN PROCTER, LLP<br>1900 N Street, NW<br>Washington, DC 20036<br>(202) 346-4000<br><br>ON BEHALF OF THE PATENT OWNER:<br><br>M. DAVID WEINGARTEN, Ph.D., ESQ.<br>FINNEGAN, HENDERSON, FARABOW, GARRETT &<br>DUNNER, LLP<br>271 17th Street, NW<br>Suite 1400<br>Atlanta, GA 30363-6209<br>(404) 653-6400 |   |
| 1<br>2<br>3<br>4<br>5<br>6<br>7<br>8<br>9<br>10<br>11<br>12<br>13<br>14<br>15<br>16<br>17<br>18<br>19<br>20<br>21<br>22                                                                                                                                                                                                                                                                                                                                                                                           | 1<br>2<br>3<br>4<br>5<br>6<br>7<br>8<br>9<br>10<br>11<br>12<br>13<br>14<br>15<br>16<br>17<br>18<br>19<br>20<br>21<br>22                                                                                                                                                                                                                                                                                         | 4 |
| UNITED STATES PATENT AND TRADEMARK OFFICE<br>-----<br>BEFORE THE PATENT TRIAL AND APPEAL BOARD<br>-----<br>DR. REDDY'S LABORATORIES S.A. and<br>DR. REDDY'S LABORATORIES, INC.,<br>Petitioners,<br>v.<br>EYE THERAPIES, LLC<br>Patent Owner.<br>-----<br>IPR2024-0467<br>U.S. Patent No. 11,833,245<br>-----<br>VIDEOTAPED DEPOSITION<br>ERIC D. DONNENFELD, M.D.<br>Thursday, February 6, 2025<br>12:39 p.m. EST<br><br>Videotaped Deposition of ERIC DONNENFELD,<br>M.D. held virtually. All appeared remotely. | A P P E A R A N C E S cont'd<br><br>ALSO PRESENT:<br><br>ALAN ROSS, Videographer<br>TOMAS REYES, Remote Technician                                                                                                                                                                                                                                                                                              |   |

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| <p>1 I N D E X</p> <p>2</p> <p>3 ERIC DONNENFELD, M.D. PAGE</p> <p>4 Examination by Mr. Cassella 7</p> <p>5</p> <p>6</p> <p>7 E X H I B I T S</p> <p>8 DONNENFELD DESCRIPTION PAGE</p> <p>9 Exhibit 1 Declaration of Eric D. 15</p> <p>10 Donnenfeld, M.D. (Preliminary</p> <p>11 Injunction)</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <p>1 David Weingarten, from Finnegan, Henderson,</p> <p>2 Farabow, Garrett &amp; Dunner, on behalf of</p> <p>3 patent owners.</p> <p>4 THE VIDEOGRAPHER: The court reporter</p> <p>5 today is April Reid, representing Planet</p> <p>6 Depos.</p> <p>7 The witness will now be sworn.</p> <p>8 THE COURT REPORTER: Doctor, if I may</p> <p>9 please get you to raise your right hand.</p> <p>10 THE WITNESS: (Complies).</p> <p>11 THEREUPON:</p> <p>12 ERIC DONNENFELD, M.D.</p> <p>13 being first duly sworn or affirmed to</p> <p>14 testify to the truth, the whole truth, and</p> <p>15 nothing but the truth, was examined and</p> <p>16 testified as follows:</p> <p>17 THE COURT REPORTER: Thank you.</p> <p>18 We may begin.</p> <p>19 EXAMINATION</p> <p>20 BY MR. CASSELLA:</p> <p>21 Q. Good afternoon, Dr. Donnenfeld.</p> <p>22 A. <b>Good afternoon.</b></p>                                                                                                             |
| <p>1 P R O C E E D I N G S</p> <p>2 THE VIDEOGRAPHER: Okay. Good</p> <p>3 afternoon.</p> <p>4 We're on the record in the Videotaped</p> <p>5 Deposition of Dr. Eric Donnenfeld in the</p> <p>6 matter of Dr. Reddy's Laboratories S.A.,</p> <p>7 et al., v. Eye Therapies, LLC, before the</p> <p>8 United States Patent Trial and Appeal Board,</p> <p>9 Case No. IPR2024-00563 and IPR2024-00467.</p> <p>10 Today's date is February 6th, 2025. The</p> <p>11 time on the video monitor is 12:39 p.m.</p> <p>12 Eastern.</p> <p>13 The videographer today is Alan Ross,</p> <p>14 representing Planet Depos.</p> <p>15 And this video deposition is taking</p> <p>16 place remotely.</p> <p>17 Would counsel please voice-identify</p> <p>18 themselves and state whom they represent.</p> <p>19 MR. CASSELLA: Good afternoon. This is</p> <p>20 Chris Cassella, from the law firm Goodwin</p> <p>21 Procter, on behalf of the petitioners.</p> <p>22 MR. WEINGARTEN: And good afternoon,</p> | <p>1 Q. Could you please state your full name,</p> <p>2 for the record?</p> <p>3 A. <b>Eric David Donnenfeld.</b></p> <p>4 Q. And what is your home address,</p> <p>5 Dr. Donnenfeld?</p> <p>6 A. <b>5 Verity Lane, Roslyn, New York 11576.</b></p> <p>7 Q. And where are you currently located?</p> <p>8 A. <b>I'm at 711 Stewart Avenue, Suite 160,</b></p> <p>9 <b>Garden City, New York, 11530.</b></p> <p>10 Q. And is anyone in the room with you?</p> <p>11 A. <b>Yes. I'm here with David Weingarten.</b></p> <p>12 Q. Okay. Anyone else?</p> <p>13 A. <b>No.</b></p> <p>14 Q. And do you have any documents in front</p> <p>15 of you?</p> <p>16 A. <b>Yes, I do.</b></p> <p>17 Q. What documents do you have in front of</p> <p>18 you?</p> <p>19 A. <b>I have a binder that contains my</b></p> <p>20 <b>declarations and many of the exhibits that I'll be</b></p> <p>21 <b>referring to from my declaration.</b></p> <p>22 Q. Is there any handwriting or highlighting</p> |

Conducted on February 6, 2025

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| <p>9</p> <p>1 on any of those documents?</p> <p>2 <b>A. No.</b></p> <p>3 Q. And were those documents provided to you</p> <p>4 by counsel?</p> <p>5 <b>A. Yes.</b></p> <p>6 Q. And you're the same Dr. Donnenfeld who</p> <p>7 submitted a declaration in connection with the</p> <p>8 preliminary injunction proceedings in the District</p> <p>9 of New Jersey; correct?</p> <p>10 <b>A. Yes.</b></p> <p>11 Q. And that -- those preliminary injunction</p> <p>12 proceedings involve some of the same patents at</p> <p>13 issue in this IP- -- these IPRs, the '245 patent;</p> <p>14 is that correct?</p> <p>15 <b>A. Yes, it is.</b></p> <p>16 Q. I believe you said you submitted</p> <p>17 declarations in these IPRs also; correct?</p> <p>18 <b>A. Yes.</b></p> <p>19 Q. Okay. We'll review those in a moment.</p> <p>20 Did you do anything to prepare for your</p> <p>21 deposition today?</p> <p>22 MR. WEINGARTEN: And let me just caution</p>                                                                                         | <p>11</p> <p>1 counsel and what documents were or were not</p> <p>2 shown to him is privileged.</p> <p>3 If you put a document in front of him</p> <p>4 and you ask whether he has reviewed a</p> <p>5 document, he can answer that, but he's not</p> <p>6 able to answer what I may or may not have</p> <p>7 shown him.</p> <p>8 MR. CASSELLA: Okay. We'll move on.</p> <p>9 Q. Did you speak with anyone in preparation</p> <p>10 for your deposition today?</p> <p>11 <b>A. David Weingarten.</b></p> <p>12 Q. Did you speak with anyone else?</p> <p>13 <b>A. No.</b></p> <p>14 Q. Let's introduce your IPR declarations.</p> <p>15 MR. CASSELLA: If we could have Tomas</p> <p>16 display the documents. They're -- they're</p> <p>17 both -- begin with EX-2224, Declaration of</p> <p>18 Eric D. Donnenfeld, and one is from a '245</p> <p>19 IPR, and the other is for the '600 IPR. If</p> <p>20 we could just display both of those, maybe</p> <p>21 beginning with the '245 IPR.</p> <p>22 REMOTE TECHNICIAN: Yes. Please stand</p>                                                                                                               |
| <p>10</p> <p>1 you, Dr. Donnenfeld, you can answer that, but</p> <p>2 don't divulge the substance of any</p> <p>3 conversation you had or had -- may have had</p> <p>4 with counsel.</p> <p>5 <b>A. Yes. I reviewed my declarations, and I</b></p> <p>6 <b>reviewed several of the exhibits that -- that are</b></p> <p>7 <b>in my binder.</b></p> <p>8 Q. Which exhibits did you review?</p> <p>9 MR. WEINGARTEN: Objection, calls for</p> <p>10 privileged information.</p> <p>11 I instruct the witness not to answer</p> <p>12 that.</p> <p>13 MR. CASSELLA: That's not privileged.</p> <p>14 The fact that he --</p> <p>15 MR. WEINGARTEN: What he does -- what he</p> <p>16 does to prepare for his deposition -- you can</p> <p>17 ask him whether he reviewed documents, but</p> <p>18 not specifically which ones that he reviewed.</p> <p>19 MR. CASSELLA: You're -- that is</p> <p>20 privileged information, in your opinion?</p> <p>21 MR. WEINGARTEN: Well, it's -- it's --</p> <p>22 the -- the preparation by -- the witness by</p> | <p>12</p> <p>1 by.</p> <p>2 Q. So, Dr. Donnenfeld, I understand that</p> <p>3 you may have hard copies of these documents in</p> <p>4 front of you also, but I'd just like to just have</p> <p>5 them displayed on the screen just so everyone's --</p> <p>6 can be on the same page, and for the benefit of</p> <p>7 the court reporter as well. But feel free to</p> <p>8 refer to the hard copy of your declaration, if</p> <p>9 that's easier. I just think it would be</p> <p>10 beneficial if we also have it displayed on the</p> <p>11 screen, so...</p> <p>12 <b>A. Thank you. Thank you.</b></p> <p>13 Q. Have you seen -- can you see on the</p> <p>14 screen now the -- on the left-hand side, it's</p> <p>15 "Declaration of Eric D. Donnenfeld, M.D.," and</p> <p>16 that is a declaration in connection with U.S.</p> <p>17 Patent No. 11,596,600, and on the right-hand side</p> <p>18 is another declaration of Eric D. Donnenfeld, M.D.</p> <p>19 in connection with U.S. Patent No. 11,833,245?</p> <p>20 <b>A. Yes, I do.</b></p> <p>21 Q. Okay. And take a moment to scroll</p> <p>22 through these or ask the technician to scroll</p> |

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| <p>13</p> <p>1 through them -- through them, if you need, but do<br/>2 you recognize these documents, Dr. Donnenfeld?<br/>3 <b>A. Yes, I do.</b><br/>4 Q. And are these the declarations that you<br/>5 submitted in connection with the IPRs involving<br/>6 the '245 and '600 patents?<br/>7 <b>A. Yes, they are.</b><br/>8 MR. CASSELLA: If we could go to -- for<br/>9 the '245 declaration, if we could go to<br/>10 page 37 of that PDF.<br/>11 Q. And, Dr. Donnenfeld, is that your<br/>12 signature on page 37 of the PDF, which appears to<br/>13 be page 34 of the declaration itself?<br/>14 <b>A. Yes, it is.</b><br/>15 Q. Okay. And you signed this declaration<br/>16 on November 18th, 2024?<br/>17 <b>A. Yes.</b><br/>18 Q. Sitting here today, do you have any<br/>19 corrections to make to this '245 declaration?<br/>20 <b>A. No, I do not.</b><br/>21 Q. Okay. For the '600 declaration on the<br/>22 other side of the screen --</p>                               | <p>15</p> <p>1 Tomas please display -- it's the document<br/>2 that begins "Declaration of Eric D.<br/>3 Donnenfeld, M.D." and then, in parens,<br/>4 "Preliminary Injunction." If we could just<br/>5 have that displayed really quickly.<br/>6 This has not been premarked as an<br/>7 exhibit in the IPR, I don't believe, so we<br/>8 can just mark this as Donnenfeld Exhibit 1.<br/>9 (Donnenfeld Exhibit 1 was marked for<br/>10 identification and is attached to the<br/>11 transcript.)<br/>12 REMOTE TECHNICIAN: I'm sorry. Counsel,<br/>13 what was the -- what was the -- the title<br/>14 again?<br/>15 MR. CASSELLA: It's just Declaration of<br/>16 Eric D. Donnenfeld, M.D. and "Preliminary<br/>17 Injunction" in parenthesis.<br/>18 REMOTE TECHNICIAN: I actually don't see<br/>19 that one, Counsel.<br/>20 MR. CASSELLA: It says -- on my screen,<br/>21 it says "uploaded."<br/>22 REMOTE TECHNICIAN: Let me double-check</p> |
| <p>14</p> <p>1 MR. CASSELLA: If we could go to page 36<br/>2 of the PDF. A little too far. Yeah.<br/>3 Q. So page 36 of the PDF, which appears to<br/>4 be page 33 of the declaration itself, is that your<br/>5 signature on this page, Dr. Donnenfeld?<br/>6 <b>A. Yes, it is.</b><br/>7 Q. And did you sign this document on<br/>8 November 30th, 2024?<br/>9 <b>A. Yes, I did.</b><br/>10 Q. And sitting here today, do you have any<br/>11 corrections to make to this '600 declaration?<br/>12 <b>A. No, I do not.</b><br/>13 Q. And did you draft these declarations?<br/>14 <b>A. I drafted them with the help of counsel.</b><br/>15 Q. Did you speak to anyone other than<br/>16 counsel in preparing these declarations?<br/>17 <b>A. No, I did not.</b><br/>18 Q. And you have not spoken with any patent<br/>19 owners or experts in these IPRs in connection with<br/>20 these declarations?<br/>21 <b>A. No, I have not.</b><br/>22 MR. CASSELLA: And if we could have</p> | <p>16</p> <p>1 to see if it -- if it was something that was<br/>2 an upload issue.<br/>3 I see. Give me one second.<br/>4 Your document should be on screen,<br/>5 Counsel.<br/>6 MR. CASSELLA: Great. Thank you so<br/>7 much.<br/>8 Q. Dr. Donnenfeld, can you see what's been<br/>9 marked as Donnenfeld Exhibit 1 on the screen?<br/>10 <b>A. Yes, I do see it.</b><br/>11 Q. And this document is titled,<br/>12 "Declaration of Eric D. Donnenfeld, M.D., in<br/>13 Support of Plaintiffs' Motion for a Preliminary<br/>14 Injunction."<br/>15 Do you see that?<br/>16 <b>A. I do.</b><br/>17 Q. And please take as much time as you<br/>18 need, but does this document appear to be the<br/>19 declaration that you submitted in connection with<br/>20 the preliminary injunction proceedings that we<br/>21 discussed earlier?<br/>22 MR. WEINGARTEN: Doctor, I advise you to</p>                                                          |

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| <p>17</p> <p>1 look through the document before answering.</p> <p>2 THE WITNESS: Yes.</p> <p>3 MR. WEINGARTEN: I'm unable to do that</p> <p>4 on my side, so I ask you to do that.</p> <p>5 THE WITNESS: Yes. Do I have a copy of</p> <p>6 this in my -- no? Can --</p> <p>7 <b>A. Where is this document from?</b></p> <p>8 Q. This is a copy -- an electronic copy of</p> <p>9 the declaration that you submitted in the</p> <p>10 preliminary injunction proceedings, I believe.</p> <p>11 I'm just asking you to confirm that, if</p> <p>12 you can.</p> <p>13 You can -- you can get control of the</p> <p>14 screen, if you'd like to scroll through it.</p> <p>15 <b>A. Is this from a year ago?</b></p> <p>16 Q. Yeah.</p> <p>17 MR. CASSELLA: Can we -- maybe we can go</p> <p>18 to the signature page on page 20 of the PDF,</p> <p>19 page 18 of the declaration.</p> <p>20 <b>A. Yes. Okay. Yeah. Yes, I am aware of</b></p> <p>21 <b>this document, and that is my signature.</b></p> <p>22 Q. Okay. Thank you.</p> | <p>19</p> <p>1 it. Great.</p> <p>2 Q. Okay. Do you see paragraph 27 displayed</p> <p>3 on the screen, Dr. Donnenfeld?</p> <p>4 <b>A. Yes, I do.</b></p> <p>5 Q. All right. Do you see the last sentence</p> <p>6 in this paragraph, you state, "I was also informed</p> <p>7 that the term 'an ocular drop' in Claim 1, due to</p> <p>8 the presence of the 'consisting of' transitional</p> <p>9 phrase, should be understood to mean 'a single</p> <p>10 ocular drop'?"</p> <p>11 Do you see that?</p> <p>12 <b>A. Yes, I do.</b></p> <p>13 Q. So you say you were informed of this;</p> <p>14 correct?</p> <p>15 <b>A. Yes.</b></p> <p>16 Q. And were you informed by counsel?</p> <p>17 <b>A. Yes, I was.</b></p> <p>18 MR. WEINGARTEN: You can answer that</p> <p>19 "yes" or "no."</p> <p>20 <b>A. Yes.</b></p> <p>21 Q. Okay. So my question is: Do you have</p> <p>22 any independent opinion as to whether the phrase</p>                                                                                      |
| <p>18</p> <p>1 MR. CASSELLA: We can take that down for</p> <p>2 now, Tomas.</p> <p>3 And if we could display the '245</p> <p>4 declaration again. Only -- we only need the</p> <p>5 '245 declaration for now.</p> <p>6 REMOTE TECHNICIAN: No problem. Please</p> <p>7 stand by.</p> <p>8 MR. CASSELLA: Okay. If we could go</p> <p>9 to --</p> <p>10 Q. So, Dr. Donnenfeld, we have displayed on</p> <p>11 the screen here -- this is the document we just</p> <p>12 saw earlier. It's Exhibit 2224 in the '245 patent</p> <p>13 IPR.</p> <p>14 MR. CASSELLA: If we could go to</p> <p>15 paragraph 27, please.</p> <p>16 Q. And, again, feel free to refer to the</p> <p>17 hard copy you have in front of you, if that's</p> <p>18 easier.</p> <p>19 MR. CASSELLA: But I'd like to have it</p> <p>20 also displayed on the screen for the court</p> <p>21 reporter's benefit. And if we could make</p> <p>22 that text bigger, just so everyone can read</p>                                                                    | <p>20</p> <p>1 "an ocular drop" should be construed to mean a</p> <p>2 single drop?</p> <p>3 MR. WEINGARTEN: Objection, calls for a</p> <p>4 legal opinion.</p> <p>5 <b>A. Well, I have no legal background to make</b></p> <p>6 <b>that statement. I was advised by counsel.</b></p> <p>7 Q. Okay. So your opinion is based on what</p> <p>8 counsel informed you about the meaning of the</p> <p>9 phrase; is that correct?</p> <p>10 <b>A. Yes.</b></p> <p>11 Q. Do you have any understanding as to</p> <p>12 whether any claims of the '245 or '600 patents</p> <p>13 that do not include the phrase "consisting of"</p> <p>14 should be construed to mean a single ocular drop?</p> <p>15 MR. WEINGARTEN: Objection, calls for</p> <p>16 legal opinion.</p> <p>17 <b>A. I have no expertise in this area. I</b></p> <p>18 <b>have been advised by counsel.</b></p> <p>19 Q. Okay.</p> <p>20 MR. CASSELLA: If we could go to</p> <p>21 paragraph 21, please.</p> <p>22 Q. So please take a moment to just read</p> |

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| <p>1 paragraph 21 and familiarize yourself with it. I<br/>2 won't read the whole thing into the record. And<br/>3 just let me know when you've had a chance to read<br/>4 it.</p> <p>5 <b>A. I have read it.</b></p> <p>6 Q. Okay. And this -- in this paragraph 21,<br/>7 you say that Examples 1, 4, and 5, and Figures<br/>8 5A-C, all use a single drop of brimonidine;<br/>9 correct?</p> <p>10 <b>A. Of low-dose brimonidine, yes.</b></p> <p>11 Q. Thank you.</p> <p>12 MR. CASSELLA: So let's put the '245<br/>13 patent up. It's Exhibit 1001. And then, in<br/>14 parenthesis, "'245 patent," Tomas.</p> <p>15 REMOTE TECHNICIAN: Sounds good. Give<br/>16 me one second here.</p> <p>17 And the document should be on screen,<br/>18 Counsel.</p> <p>19 MR. CASSELLA: Could we make the text<br/>20 just a little bit bigger? Just zoom in a<br/>21 little bit.</p> <p>22 Q. Okay. Dr. Donnenfeld, do you see</p>                      | <p>1 patent. And can you see Example -- Example 1<br/>2 displayed here in column 20, Dr. Donnenfeld?</p> <p>3 <b>A. Yes.</b></p> <p>4 Q. Now, please feel free to take a moment<br/>5 to re-read Example 1.</p> <p>6 My question to you is: Does Example 1<br/>7 ever explicitly state that one drop is<br/>8 administered?</p> <p>9 <b>A. It does not say that one drop was used</b><br/>10 <b>in this session -- in this section, but it's</b><br/>11 <b>implied that one drop was used.</b></p> <p>12 Q. Okay. I understand that you believe it<br/>13 is implied that it -- that one drop was used, but<br/>14 the example does not explicitly state that one<br/>15 drop was used; correct?</p> <p>16 <b>A. Correct.</b></p> <p>17 Q. Now, in this example, the brimonidine<br/>18 concentrations are administered repeatedly over<br/>19 the course of several hours; correct?</p> <p>20 MR. WEINGARTEN: Objection to form.</p> <p>21 Q. Sorry. Let me -- let me rephrase that.<br/>22 So in Example 1, brimonidine is</p> |
| <p>1 Exhibit 1001 displayed on the screen?</p> <p>2 <b>A. Yes, I do.</b></p> <p>3 Q. And do you recognize this document?</p> <p>4 <b>A. Yes, I do.</b></p> <p>5 Q. And this is the '245 patent, which is<br/>6 the subject of one of the IPRs; correct?</p> <p>7 <b>A. Yes.</b></p> <p>8 Q. Okay. I want to look at Example 1,<br/>9 which begins in column 20 of the patent.</p> <p>10 MR. CASSELLA: If we could scroll down<br/>11 to column 20, Example 1. It's going to be<br/>12 much further down. Yeah, towards -- towards<br/>13 the end. Yeah. Sorry. It's -- it's,<br/>14 like -- maybe go to page 22 of the PDF.<br/>15 Somewhere around there. There we are. See<br/>16 the right-hand side, column 20. We got it<br/>17 now.</p> <p>18 And if we could scroll down to under<br/>19 Examples, Example 1.</p> <p>20 And maybe make that text just a little<br/>21 bit bigger.</p> <p>22 Q. Okay. So we're in column 20 of the '245</p> | <p>1 administered at different concentrations over the<br/>2 course of several hours; correct?</p> <p>3 MR. WEINGARTEN: Objection to form,<br/>4 mischaracterizes the evidence.</p> <p>5 <b>A. I'm sorry. Could you repeat the</b><br/>6 <b>question, please.</b></p> <p>7 Q. Yeah.</p> <p>8 So in -- well, let me just read the<br/>9 realtime back.</p> <p>10 In Example 1, brimonidine is<br/>11 administered at different concentrations over the<br/>12 course of several hours; correct?</p> <p>13 MR. WEINGARTEN: Objection to form,<br/>14 mischaracterizes the evidence.</p> <p>15 <b>A. Yes.</b></p> <p>16 Q. And these different concentrations were<br/>17 administered to a patient; correct?</p> <p>18 <b>A. Yes.</b></p> <p>19 Q. And so that's just a single patient in<br/>20 this Example 1; correct?</p> <p>21 <b>A. Yes.</b></p> <p>22 Q. Now, it says that Fig. B shows the</p>                                                                                                                             |

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| <p>25</p> <p>1 patient's left eye three hours after treatment<br/>2 with 0.01 percent brimonidine.<br/>3 Do you see that?<br/>4 <b>A. Fig. 4B?</b><br/>5 Q. Yeah.<br/>6 Just, in column 20, maybe line 49 or so,<br/>7 the -- the text of the -- of Example 1 says that<br/>8 Fig. B shows the patient's left eye three hours<br/>9 after treatment with 0.01 percent brimonidine; is<br/>10 that right?<br/>11 <b>A. I'm reading Fig. 4B.</b><br/>12 Q. Yeah. I -- I think I'm reading the same<br/>13 thing. Are you --<br/>14 <b>A. Okay. So, yeah, Fig. 4B and Fig. B are</b><br/>15 <b>the same?</b><br/>16 Q. Sorry. I couldn't hear the question.<br/>17 <b>A. You mentioned "Fig. B." I only see a</b><br/>18 <b>Fig. 4B being referenced here.</b><br/>19 Q. Oh. Sorry. Yes. I -- I meant to say<br/>20 "Fig. 4B." If I did not say "4B," I apologize.<br/>21 <b>A. Okay. That helps.</b><br/>22 Q. Okay. So in Example 1, Example 1 states</p> | <p>27</p> <p>1 mischaracterizes the document, outside the<br/>2 scope.<br/>3 <b>A. Yes.</b><br/>4 Q. And so would that be yet another<br/>5 administration of brimonidine in this example?<br/>6 MR. WEINGARTEN: Objection, outside the<br/>7 scope.<br/>8 <b>A. Yes.</b><br/>9 Q. Okay. And then the example goes on and<br/>10 says that Fig. 4E shows the effect of treatment<br/>11 with 0.033 percent brimonidine in the left eye of<br/>12 the patient four hours after the effects shown in<br/>13 Fig. 4D; correct?<br/>14 <b>A. Yes.</b><br/>15 Q. And so would you agree, Dr. Donnenfeld,<br/>16 that there were at least three administrations of<br/>17 brimonidine to this patient?<br/>18 MR. WEINGARTEN: Objection, outside the<br/>19 scope.<br/>20 <b>A. Yes.</b><br/>21 Q. Now, if we could go to the next column.<br/>22 It's on the next page, on the left-hand side,</p>                                                                |
| <p>26</p> <p>1 that in Fig. 4B, there's shown the patient's left<br/>2 eye three hours after treatment with 0.1 -- excuse<br/>3 me, 0.01 percent brimonidine; correct?<br/>4 <b>A. Yes.</b><br/>5 Q. Okay. And then it says in Fig. 4C, that<br/>6 shows the patient's left eye four hours after<br/>7 baseline where the eye was treated with<br/>8 0.02 percent brimonidine; correct?<br/>9 <b>A. Yes.</b><br/>10 Q. Okay. So is that an additional<br/>11 administration of brimonidine, then?<br/>12 MR. WEINGARTEN: Objection, outside the<br/>13 scope.<br/>14 <b>A. Yes, it does.</b><br/>15 Q. Okay. And then in Fig. 4D, it says<br/>16 that -- strike that.<br/>17 So the text of Example 1 says that<br/>18 Fig. 4D shows the patient's left eye after a<br/>19 further four hours, where the left eye has again<br/>20 been treated with 0.02 percent brimonidine;<br/>21 correct?<br/>22 MR. WEINGARTEN: Objection,</p>                     | <p>28</p> <p>1 column 21.<br/>2 So this is -- so this is sort of the end<br/>3 of the text of Example 1 at the very top of column<br/>4 21. Do you see that, Dr. Donnenfeld?<br/>5 <b>A. Yes.</b><br/>6 Q. And so that text reads that<br/>7 "compositions of the present invention may be used<br/>8 every three to four hours with low incidence of<br/>9 hyperemia."<br/>10 Correct?<br/>11 <b>A. Yes.</b><br/>12 Q. For the moment, let's assume that the<br/>13 administration of brimonidine in this example was<br/>14 administration of a single drop. Okay?<br/>15 <b>A. Yes.</b><br/>16 Q. So in your opinion, Dr. Donnenfeld,<br/>17 would the administration of a single drop of<br/>18 brimonidine every three to four hours be a method<br/>19 of administering multiple drops of brimonidine?<br/>20 MR. WEINGARTEN: Objection, outside the<br/>21 scope, incomplete hypothetical.<br/>22 <b>A. No. I would say that this is a single</b></p> |

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| <p>29</p> <p>1 dose delivered every three to four hours and --</p> <p>2 and not multiple drops. It's multiple drops in a</p> <p>3 day, but it's a single drop at a time.</p> <p>4 Q. So would it be fair to say that</p> <p>5 Example 1 discloses -- assuming that Example 1</p> <p>6 does disclose administration of a single drop,</p> <p>7 would it be fair to say that Example 1 then</p> <p>8 discloses a method of administering a single drop,</p> <p>9 and that single-drop method is repeated every</p> <p>10 three to four hours?</p> <p>11 MR. WEINGARTEN: Same objection. And</p> <p>12 objection for asked and answered.</p> <p>13 A. Yes.</p> <p>14 Q. Okay.</p> <p>15 MR. CASSELLA: If we could go to -- a</p> <p>16 little further down in column 21, there's an</p> <p>17 Example 4.</p> <p>18 Q. Do you see where Example 4 begins in --</p> <p>19 at the bottom of column 21 and continues on to the</p> <p>20 next column at the top of column 22?</p> <p>21 Do you see that, Dr. Donnenfeld?</p> <p>22 A. Yes, I do.</p>                                   | <p>31</p> <p>1 MR. WEINGARTEN: Objection,</p> <p>2 mischaracterizes the witness's testimony.</p> <p>3 A. I'm saying that "each" implies one drop.</p> <p>4 "All" would imply more than one drop.</p> <p>5 Q. So, in your opinion, an administration</p> <p>6 cannot include more than a single drop; is that</p> <p>7 correct?</p> <p>8 MR. WEINGARTEN: Same ob- -- same</p> <p>9 objection.</p> <p>10 A. Yes.</p> <p>11 Q. You see a little further down in that</p> <p>12 same paragraph, it states that "the patients were</p> <p>13 calculated to have 68.71 percent reduction in</p> <p>14 redness score after administration of a single</p> <p>15 dose of brimonidine at 0.018 percent"?</p> <p>16 A. Yes.</p> <p>17 Q. Now, this says the patients were</p> <p>18 administered a dose; correct?</p> <p>19 A. Yes.</p> <p>20 Q. That does not say a single drop;</p> <p>21 correct?</p> <p>22 MR. WEINGARTEN: Objection,</p> |
| <p>30</p> <p>1 Q. And Example 4 states that 18 patients</p> <p>2 were treated with a composition of the present</p> <p>3 invention; i.e., brimonidine at 0.018 percent.</p> <p>4 Do you see that?</p> <p>5 A. Yes.</p> <p>6 Q. Now, Example 4 also does not explicitly</p> <p>7 disclose the number of drops that were</p> <p>8 administered in this example; correct?</p> <p>9 And please feel free to take time to</p> <p>10 review the rest of the example on the other side</p> <p>11 of the column.</p> <p>12 MR. WEINGARTEN: Let me just object to</p> <p>13 that as mischaracterizing the example.</p> <p>14 A. In Example 4, it states, "The patients</p> <p>15 were assigned 'cumulative red scores' prior to</p> <p>16 each administration," each administration means</p> <p>17 one drop, "and then 10 minutes after each dose."</p> <p>18 So that -- I would say that this states</p> <p>19 that one drop was applied.</p> <p>20 Q. And that's based on your opinion that a</p> <p>21 single administration must mean a single drop; is</p> <p>22 that correct?</p> | <p>32</p> <p>1 argumentative.</p> <p>2 A. A single dose and a single -- single</p> <p>3 drop are synonymous, in my estimation.</p> <p>4 Q. Okay.</p> <p>5 MR. CASSELLA: Can we go to -- back to</p> <p>6 the declaration for a moment, please. The --</p> <p>7 Dr. Donnenfeld's declaration in the '245 IPR.</p> <p>8 Sorry.</p> <p>9 REMOTE TECHNICIAN: And the doc- --</p> <p>10 excuse me. The document is on screen.</p> <p>11 MR. CASSELLA: Thank you.</p> <p>12 And if we could go to page 18 of the</p> <p>13 declaration. Right. Yep. And at the bottom</p> <p>14 of page 18.</p> <p>15 Q. Dr. Donnenfeld, do you see footnote 3 on</p> <p>16 page 18 of your declaration?</p> <p>17 A. Yes.</p> <p>18 Q. And there, you wrote that "Norden used a</p> <p>19 dose of approximately 0.4 percent (0.2 percent</p> <p>20 administered twice within a 10-minute period)."</p> <p>21 Do you see that?</p> <p>22 A. Yes.</p>      |

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| <p>33</p> <p>1 Q. So you characterized Dr. Norden as</p> <p>2 administering a single dose, which consisted of</p> <p>3 two administrations of 0.2 percent; correct?</p> <p>4 MR. WEINGARTEN: Objection,</p> <p>5 mischaracterizes the declaration and</p> <p>6 ambiguous.</p> <p>7 <b>A. Yeah. I state that Norden used a dose</b></p> <p>8 <b>of approximately 0.4 percent, which I define by</b></p> <p>9 <b>saying that there were two drops that were</b></p> <p>10 <b>admitted. So I'm being specific that there were</b></p> <p>11 <b>two drops applied to this dose. If I did not</b></p> <p>12 <b>write that there were two drops, then I would have</b></p> <p>13 <b>said that that was one dose.</b></p> <p>14 Q. Okay.</p> <p>15 MR. CASSELLA: If we could go back to</p> <p>16 the '245 patent, please, Exhibit 1001.</p> <p>17 REMOTE TECHNICIAN: And the document is</p> <p>18 on screen, Counsel.</p> <p>19 MR. CASSELLA: Thank you.</p> <p>20 If we could go to the next page,</p> <p>21 Example 5. And if we could make that text</p> <p>22 bigger, please.</p> | <p>35</p> <p>1 sorry. Column 20. I apologize.</p> <p>2 Q. So in column 20, there's a description</p> <p>3 of Figs. 5A to 5C.</p> <p>4 Do you see that, Dr. Donnenfeld?</p> <p>5 <b>A. Yes.</b></p> <p>6 Q. Now, it says that Fig. 5B shows the left</p> <p>7 eye of a patient after treatment with a</p> <p>8 composition of the present invention comprising</p> <p>9 brimonidine at 0.015 percent; correct?</p> <p>10 MR. WEINGARTEN: Objection,</p> <p>11 mischaracterizes the document.</p> <p>12 <b>A. Yes.</b></p> <p>13 Q. Now, that does not explicitly specify</p> <p>14 the number of drops; correct?</p> <p>15 <b>A. It states at the conclusion of the</b></p> <p>16 <b>paragraph that "an additional drop of the</b></p> <p>17 <b>composition of the present invention," which is</b></p> <p>18 <b>one drop.</b></p> <p>19 Q. Correct.</p> <p>20 But that's in Fig. 5C; right?</p> <p>21 <b>A. Yes.</b></p> <p>22 Q. So my question was about Fig. 5B.</p>                                    |
| <p>34</p> <p>1 Q. So, Dr. Donnenfeld, we have, displayed</p> <p>2 on the screen here, Example 5 of the '245 patent.</p> <p>3 Do you see that?</p> <p>4 <b>A. Yes, I do.</b></p> <p>5 Q. And Example 5 says that patients were</p> <p>6 treated with extreme low dose (ELD) brimonidine at</p> <p>7 0.015 percent; correct?</p> <p>8 <b>A. Yes.</b></p> <p>9 Q. And then it says that "treatment was</p> <p>10 through drops twice a day for three to</p> <p>11 five weeks."</p> <p>12 Correct?</p> <p>13 <b>A. Yes.</b></p> <p>14 Q. So Example 5 states that multiple drops</p> <p>15 were administered twice a day; correct?</p> <p>16 MR. WEINGARTEN: Objection,</p> <p>17 mischaracterizes the document.</p> <p>18 <b>A. Yes.</b></p> <p>19 MR. CASSELLA: Now, if we could go to</p> <p>20 Figs. 5A to 5C. Oh, I'm sorry. Just a</p> <p>21 moment. If we could stay here. And in</p> <p>22 column -- I think it's column 22. Oh. I'm</p>                                                                                                                                     | <p>36</p> <p>1 <b>A. I'm sorry.</b></p> <p>2 Q. Does Fig. 5B specify the -- explicitly</p> <p>3 specify the number of drops?</p> <p>4 <b>A. It states that they receive the</b></p> <p>5 <b>brimonidine at 0.015 percent. If it was more than</b></p> <p>6 <b>one drop, there would have been a cumulative</b></p> <p>7 <b>dosage that would have increased the percentage.</b></p> <p>8 <b>So that -- this, I believe, states one drop is</b></p> <p>9 <b>being applied here. Although, you are correct, it</b></p> <p>10 <b>does not say one drop specifically.</b></p> <p>11 Q. Dr. Donnenfeld, you're a practicing</p> <p>12 ophthalmologist; correct?</p> <p>13 <b>A. Yes.</b></p> <p>14 Q. And you've prescribed eye drops before?</p> <p>15 <b>A. Yes.</b></p> <p>16 Q. Are you familiar with the abbreviation</p> <p>17 GTT?</p> <p>18 <b>A. Yes.</b></p> <p>19 Q. What does GTT mean?</p> <p>20 <b>A. Drop.</b></p> <p>21 Q. And that's "drop" in the singular form?</p> <p>22 <b>A. Yes.</b></p> |

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| <p>37</p> <p>1 Q. And are you familiar with the</p> <p>2 abbreviation GTTS?</p> <p>3 <b>A. Just to be clear, GTTS, yes.</b></p> <p>4 Q. And what does GTTS mean?</p> <p>5 <b>A. Drops.</b></p> <p>6 Q. And that would be "drops," plural;</p> <p>7 correct?</p> <p>8 <b>A. Yes.</b></p> <p>9 Q. Okay.</p> <p>10 MR. CASSELLA: If we could scroll up,</p> <p>11 please, to Figs. 5A to 5C, the actual</p> <p>12 figures, which are towards the beginning of</p> <p>13 this document. Probably around page 4 or so.</p> <p>14 Further down. A couple more pages. Figs. 5A</p> <p>15 to 5C. There we go. Okay.</p> <p>16 Q. Dr. Donnenfeld, do you see displayed on</p> <p>17 the screen Figs. 5A, 5B, and 5C of the '245</p> <p>18 patent?</p> <p>19 <b>A. Yes.</b></p> <p>20 MR. CASSELLA: If we could zoom in a</p> <p>21 little bit on Fig. 5B.</p> <p>22 Q. Dr. Donnenfeld, do you see above both</p>                                                                                                               | <p>39</p> <p>1 TID means?</p> <p>2 <b>A. Three times a day.</b></p> <p>3 Q. So would you agree, Dr. Donnenfeld, that</p> <p>4 the annotations in Fig. 5B means two drops, three</p> <p>5 times a day?</p> <p>6 MR. WEINGARTEN: Objection to form.</p> <p>7 <b>A. It means drops were given three times a</b></p> <p>8 <b>day.</b></p> <p>9 <b>It doesn't specifically say that one</b></p> <p>10 <b>drop was given three times a day. It says that</b></p> <p>11 <b>cumulatively, drops were given three times a day.</b></p> <p>12 <b>That's why it's plural.</b></p> <p>13 Q. Dr. Donnenfeld, in your opinion, is the</p> <p>14 administration of two drops, three times a day</p> <p>15 part of a multiple-drop method of administration?</p> <p>16 MR. WEINGARTEN: Objection, incomplete</p> <p>17 hypothetical.</p> <p>18 <b>A. It's conventional in studies to often</b></p> <p>19 <b>give two drops to make certain that one drop got</b></p> <p>20 <b>in. But when you're giving the drops at the same</b></p> <p>21 <b>time, the tear film only holds a fraction of one</b></p> <p>22 <b>drop, so, essentially, only one drop is getting</b></p> |
| <p>38</p> <p>1 the left and right eyes in this photo, Fig. 5B is</p> <p>2 annotated with the text -- I believe that's</p> <p>3 romanette 2, or ii, lower case "ii gtts tid"?</p> <p>4 Do you see that?</p> <p>5 <b>A. Yes.</b></p> <p>6 Q. So let's break this down for just a</p> <p>7 moment.</p> <p>8 What does "ii gtts" mean?</p> <p>9 <b>A. I'm not sure what the "ii" means. GTTS</b></p> <p>10 <b>means drops.</b></p> <p>11 Q. You have no opinion as to whether the ii</p> <p>12 would stand for the number 2?</p> <p>13 MR. WEINGARTEN: Objection, asked and</p> <p>14 answered.</p> <p>15 <b>A. When written as two, it's a straight</b></p> <p>16 <b>line with two dots coming down. This is not the</b></p> <p>17 <b>conventional way that doctors write two drops.</b></p> <p>18 Q. But you would agree that GTTS means</p> <p>19 drops, plural; correct?</p> <p>20 <b>A. Yes.</b></p> <p>21 Q. Okay. And then the other part of that</p> <p>22 annotation that I just read, TID, do you know what</p> | <p>40</p> <p>1 into the eye.</p> <p>2 <b>And when you're giving more than one</b></p> <p>3 <b>drop at the same time, you're essentially only</b></p> <p>4 <b>applying the volume of less than one drop. When</b></p> <p>5 <b>drops are spread apart chronologically, then you</b></p> <p>6 <b>get a cumulative effect of drops being given more</b></p> <p>7 <b>than one at a time.</b></p> <p>8 <b>Giving two drops at the same time is</b></p> <p>9 <b>essentially the same as giving one drop, just to</b></p> <p>10 <b>make certain that one of the -- that one of the</b></p> <p>11 <b>drops got in. There's no additional efficacy of</b></p> <p>12 <b>using two drops at the same time.</b></p> <p>13 MR. CASSELLA: If we could scroll just a</p> <p>14 little bit further down to Fig. 5C.</p> <p>15 Q. And do you see, Dr. Donnenfeld, above</p> <p>16 the left and right eyes in Fig. 5C there's, again,</p> <p>17 the abbreviation "ii gtts"?</p> <p>18 <b>A. Yes.</b></p> <p>19 Q. And, again, you agree that GTTS refers</p> <p>20 to drops, plural; correct?</p> <p>21 <b>A. Yes.</b></p> <p>22 MR. CASSELLA: If we could go back to</p>    |

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| <p>41</p> <p>1 Dr. Donnenfeld's declaration in the '245 IPR,<br/>2 paragraph 34.<br/>3 REMOTE TECHNICIAN: And the document is<br/>4 on screen and should be on paragraph 34.<br/>5 MR. CASSELLA: Great.<br/>6 Q. Dr. Donnenfeld, do you see paragraph 34<br/>7 of your declaration in the '245 IPR displayed on<br/>8 the screen?<br/>9 <b>A. Yes, I do.</b><br/>10 Q. Okay. And in that paragraph, you state,<br/>11 "And as I have been informed, it is also<br/>12 consistent with the law, which, for pharmaceutical<br/>13 inventions, considers the obviousness inquiry from<br/>14 the perspective of a skilled person confronted<br/>15 with the same problems as the inventor, including<br/>16 demands in the relevant market and design<br/>17 community, in developing a commercially viable<br/>18 pharmaceutical therapy, in this case, a<br/>19 commercially viable eye redness reliever."<br/>20 Do you see that?<br/>21 <b>A. Yes, I do.</b><br/>22 Q. So would it be fair to say,</p>        | <p>43</p> <p>1 change gears. I could keep going for now, if<br/>2 you'd like, or we can take a short break. Up<br/>3 to you, Dr. Donnenfeld.<br/>4 THE WITNESS: I'm fine.<br/>5 MR. CASSELLA: Keep going?<br/>6 THE WITNESS: I'm ready. Yeah. That's<br/>7 fine with me, Chris.<br/>8 MR. CASSELLA: Okay. We'll keep going.<br/>9 THE WITNESS: Okay.<br/>10 Q. If we could go to paragraph 44 of your<br/>11 declaration.<br/>12 MR. CASSELLA: And -- I'm sorry. Could<br/>13 we scroll up to the -- to the beginning of<br/>14 this subsection of the declaration. Keep<br/>15 going up just a little bit. There.<br/>16 Q. Do you see, Dr. Donnenfeld, in your<br/>17 declaration of the '245 IPR, you have this section<br/>18 titled: Clinical Studies Contain Uniform<br/>19 Protocols for Reporting Adverse Events?<br/>20 Do you see that?<br/>21 <b>A. Yes.</b><br/>22 Q. Okay. And then in paragraph 44 -- if we</p>                                       |
| <p>42</p> <p>1 Dr. Donnenfeld, that your opinions in this case<br/>2 are based on the assumption that the POSA would<br/>3 have needed to develop a "commercially viable<br/>4 redness reliever"?<br/>5 MR. WEINGARTEN: Objection to the form,<br/>6 mischaracterizes the reference. And asks for<br/>7 a legal conclusion.<br/>8 <b>A. Can you repeat the question, please?</b><br/>9 Q. Sure.<br/>10 So would it be fair to say,<br/>11 Dr. Donnenfeld, that your opinions in this case<br/>12 are based on the assumption that the POSA would<br/>13 have needed to develop a "commercially viable<br/>14 redness reliever"?<br/>15 MR. WEINGARTEN: Objection,<br/>16 mischaracterizes the declaration.<br/>17 <b>A. My opinion here is that -- I have been</b><br/>18 <b>informed by counsel that this is a legal opinion,</b><br/>19 <b>and I've stated what I've been told by counsel.</b><br/>20 Q. Okay.<br/>21 MR. CASSELLA: We haven't been going<br/>22 quite an hour, but I'm about to sort of</p> | <p>44</p> <p>1 could scroll down.<br/>2 You state in paragraph 44, "As Alphagan<br/>3 NDA documents confirm, the Alphagan study protocol<br/>4 for identifying and reporting adverse events,<br/>5 including conjunctival blanching (whitening),<br/>6 looked at changes from baseline using a grading<br/>7 scale."<br/>8 Do you see that?<br/>9 <b>A. Yes.</b><br/>10 Q. Now, Dr. Donnenfeld, you still have not<br/>11 seen the actual study protocol from any Alphagan<br/>12 clinical study; correct?<br/>13 <b>A. Correct.</b><br/>14 Q. And so, obviously, you have not cited or<br/>15 produced any protocol from a Alphagan clinical<br/>16 study in your declaration; correct?<br/>17 <b>A. Correct.</b><br/>18 Q. And so you have not seen any actual<br/>19 grading scale that may have been used in any<br/>20 Alphagan clinical study; correct?<br/>21 MR. WEINGARTEN: Objection, form.<br/>22 <b>A. I've seen the adverse events, and I have</b></p> |

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| <p>45</p> <p>1 <b>seen that they have been graded on a scale. So I</b></p> <p>2 <b>have seen that.</b></p> <p>3 Q. But you've never actually seen the</p> <p>4 grading scale; correct?</p> <p>5 <b>A. Well, I've seen how they are graded.</b></p> <p>6 Q. Have you seen the actual grading scale</p> <p>7 that was used in connection with any Alphagan</p> <p>8 clinical study?</p> <p>9 MR. WEINGARTEN: Objection to form.</p> <p>10 <b>A. I have seen the adverse events. I</b></p> <p>11 <b>haven't seen the protocols that were used, but I</b></p> <p>12 <b>have seen the results of the study that demarcates</b></p> <p>13 <b>that there was a grading scale that was used.</b></p> <p>14 Q. All right. So I -- I understand your</p> <p>15 opinion that you believe there was a grading scale</p> <p>16 that was used in connection with the Alphagan</p> <p>17 clinical studies.</p> <p>18 My question is: You haven't actually</p> <p>19 seen that grading scale to the extent that it</p> <p>20 exists; correct?</p> <p>21 <b>A. Correct.</b></p> <p>22 Q. And so you do not know, then, what</p> | <p>47</p> <p>1 believes there's a grading scale, and I'm</p> <p>2 asking whether he's actually seen it.</p> <p>3 <b>A. I have seen the grading scale that is in</b></p> <p>4 <b>the results section, which in an FDA document has</b></p> <p>5 <b>to be the same that was used in the study document</b></p> <p>6 <b>itself.</b></p> <p>7 Q. Okay. Which grading scale are you</p> <p>8 referring to?</p> <p>9 <b>A. I'll have to find that. Excuse me.</b></p> <p>10 MR. WEINGARTEN: Counsel, since this</p> <p>11 isn't a memory test, do you want to point him</p> <p>12 to the -- the document in sight?</p> <p>13 <b>A. I -- yeah. I apologize. But I do</b></p> <p>14 <b>recall that the blanching was graded as trace,</b></p> <p>15 <b>mild, moderate, and severe.</b></p> <p>16 <b>I'm just looking for the specific</b></p> <p>17 <b>reference page that I cannot find right now.</b></p> <p>18 Q. Maybe we can shortcut this.</p> <p>19 <b>A. Okay. That would be helpful.</b></p> <p>20 Q. Would the grading scale have been</p> <p>21 included in the study -- the Alphagan clinical</p> <p>22 study protocols?</p> |
| <p>46</p> <p>1 severity grades for blanching would have been used</p> <p>2 in any such grading scale; correct?</p> <p>3 MR. WEINGARTEN: Objection,</p> <p>4 mischaracterizes the evidence.</p> <p>5 <b>A. I know the results, and they are graded</b></p> <p>6 <b>based on a scale of four different levels of</b></p> <p>7 <b>blanching, and that result confirms that there was</b></p> <p>8 <b>a scale that was used.</b></p> <p>9 Q. Right.</p> <p>10 I -- I understand that. But my question</p> <p>11 is whether you have any personal knowledge of what</p> <p>12 that grading scale actually said.</p> <p>13 MR. WEINGARTEN: Objection.</p> <p>14 You changed the question, Counsel.</p> <p>15 You're now asking about his personal</p> <p>16 knowledge, not based on the evidence he's</p> <p>17 presented. I just want to make sure we're</p> <p>18 fair on the question.</p> <p>19 MR. CASSELLA: Okay. I've been asking</p> <p>20 him what he has seen and whether he has any</p> <p>21 personal -- I think that is the same</p> <p>22 question. I'm asking him about -- he</p>                     | <p>48</p> <p>1 <b>A. I did not see the Alphagan protocol. I</b></p> <p>2 <b>just saw the results.</b></p> <p>3 Q. Okay. So, again, just to confirm, you</p> <p>4 have not actually --</p> <p>5 MR. WEINGARTEN: Let him ask his</p> <p>6 questions. You can stop looking. He's</p> <p>7 asking a question.</p> <p>8 THE WITNESS: All right.</p> <p>9 Okay. I'm sorry.</p> <p>10 Q. So just to confirm, you have not</p> <p>11 actually seen the actual grading scale used in any</p> <p>12 Alphagan clinical study protocol; correct?</p> <p>13 MR. WEINGARTEN: Objection,</p> <p>14 mischaracterizes the evidence.</p> <p>15 <b>A. I have not seen the grading scale in the</b></p> <p>16 <b>preoperative protocol.</b></p> <p>17 Q. And so it would be fair to say, then,</p> <p>18 Dr. Donnenfeld, that you don't know whether the</p> <p>19 term "blanching" had a definition specified in</p> <p>20 the -- any Alphagan clinical study protocol;</p> <p>21 correct?</p> <p>22 <b>A. I know that blanching was defined at</b></p>                                                                                             |

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| <p>49</p> <p>1 four different levels, of trace, mild, moderate,<br/>2 and severe.<br/>3 Q. That wasn't my question.<br/>4 My question was: Do you know whether<br/>5 "blanching" had a specific definition listed in<br/>6 any of the Alphagan clinical study protocols?<br/>7 A. I'm not aware of that.<br/>8 Q. And do you have any knowledge as to<br/>9 whether the Alphagan clinical study protocols<br/>10 would have been publicly available in 2008?<br/>11 A. I have no direct knowledge, but they --<br/>12 they should have been available, yes.<br/>13 Q. But you have no direct knowledge of<br/>14 that; correct?<br/>15 MR. WEINGARTEN: Objection, asked and<br/>16 answered.<br/>17 A. All studies for the FDA are available<br/>18 for review.<br/>19 I have no direct knowledge of this one,<br/>20 though.<br/>21 MR. CASSELLA: If we could go, please,<br/>22 to Exhibit 1067.</p> | <p>51</p> <p>1 And 1067 is on screen.<br/>2 Q. All right. Dr. Donnenfeld, do you<br/>3 recognize Exhibit 1067?<br/>4 A. Yes, I do.<br/>5 Q. And this is a compilation of Alphagan<br/>6 and Alphagan P labels; is that correct?<br/>7 And please feel free to take as much<br/>8 time as you need to scroll through. You can take<br/>9 control of the screen, or if you have a hard copy,<br/>10 you can review that.<br/>11 A. Yes.<br/>12 Q. Okay. So let's look at the first --<br/>13 first section, roughly the first third of this<br/>14 document, which relates to Alphagan 0.5 percent.<br/>15 That's the first page of this document.<br/>16 Do you see that?<br/>17 A. Yes.<br/>18 Q. And if we could go to the second page<br/>19 under Clinical Studies.<br/>20 Do you see, Dr. Donnenfeld, sort of in<br/>21 the middle of the page, it says, "In two<br/>22 controlled, multi-center studies, Alphagan</p> |
| <p>50</p> <p>1 REMOTE TECHNICIAN: 1067 or 1068?<br/>2 MR. CASSELLA: It should be 1067.<br/>3 Is that not in there?<br/>4 REMOTE TECHNICIAN: No.<br/>5 Here, let me double-check.<br/>6 MR. CASSELLA: Here. I can -- I'll<br/>7 reupload that one then, if I could.<br/>8 REMOTE TECHNICIAN: Sure.<br/>9 Yeah. I do not see 1067 on my end.<br/>10 MR. CASSELLA: Okay. I'm reuploading<br/>11 it. My apologies.<br/>12 REMOTE TECHNICIAN: No problem.<br/>13 MR. CASSELLA: And Dr. Donnenfeld, just,<br/>14 you know, let me know whenever you'd like to<br/>15 take a break. We can keep going or -- yeah,<br/>16 whatever you prefer. So just let me know.<br/>17 THE WITNESS: Thank you.<br/>18 MR. CASSELLA: Okay. The 1067 should<br/>19 have been uploaded now.<br/>20 REMOTE TECHNICIAN: Okay. Let me<br/>21 double-check. And I do see that. Give me<br/>22 one moment to download.</p>         | <p>52</p> <p>1 0.5 percent ophthalmic solution was significantly<br/>2 more effective in decreasing the incidence of<br/>3 post-operative IOP elevations than was the vehicle<br/>4 at one, two, and three hours post-Argon laser<br/>5 trabeculoplasty"?<br/>6 Do you see that?<br/>7 A. Yes.<br/>8 Q. So would it be fair to say,<br/>9 Dr. Donnenfeld, that this -- these two clinical<br/>10 studies -- the duration of these two clinical<br/>11 studies was approximately two to three hours?<br/>12 MR. WEINGARTEN: Objection, lack of<br/>13 foundation.<br/>14 A. Yes.<br/>15 Q. And if we could go to the next -- I'm<br/>16 sorry, maybe two pages down under Adverse<br/>17 Reactions.<br/>18 And do you see that displayed on the<br/>19 screen?<br/>20 A. Yes.<br/>21 Q. So in this Exhibit 1067 for Alphagan<br/>22 0.5 percent, it lists transient conjunctival</p>                                        |

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| <p>1 blanching in 50 percent of patients; correct?</p> <p>2 <b>A. Yes.</b></p> <p>3 Q. And that would have been 50 percent of</p> <p>4 patients in this multi-hour or potentially</p> <p>5 single-day clinical study; is that right?</p> <p>6 <b>A. Yes.</b></p> <p>7 Q. Now, if we could go to the next drug on</p> <p>8 page 6 of 16. This is Alphagan 0.2 percent.</p> <p>9 Do you see that, Dr. Donnenfeld?</p> <p>10 <b>A. Yes.</b></p> <p>11 Q. And if we could go to the next page</p> <p>12 under Clinical Evaluations. In the second</p> <p>13 paragraph under Clinical Evaluations, do you see</p> <p>14 where it says, "In comparative clinical studies</p> <p>15 with timolol 0.5 percent lasting up to one year,</p> <p>16 the IOP lowering effect of Alphagan was</p> <p>17 approximately 4 to 6 millimeters of" I believe</p> <p>18 that's "mercury Hg compared with approximately</p> <p>19 6 millimeters Hg for timolol"?</p> <p>20 Do you see that?</p> <p>21 <b>A. Yes.</b></p> <p>22 Q. And so would it be fair to say,</p>                           | <p>1 "Events occurring in approximately 3 to 9 percent</p> <p>2 of the subjects, in descending order, included" --</p> <p>3 I'm not going to read all of them, but do you see</p> <p>4 "conjunctival blanching" listed in the last line</p> <p>5 there?</p> <p>6 <b>A. Yes, I do.</b></p> <p>7 MR. WEINGARTEN: Counsel, can we hold</p> <p>8 for one second? My -- my Zoom closed down,</p> <p>9 and it's trying to reconnect.</p> <p>10 MR. CASSELLA: Okay. Yeah. We can --</p> <p>11 you want to take a break or...</p> <p>12 THE WITNESS: Yeah. Why don't we take a</p> <p>13 break now. That sounds fine.</p> <p>14 THE VIDEOGRAPHER: Okay. Off the record</p> <p>15 at 13:51.</p> <p>16 (Recess in proceedings.)</p> <p>17 THE VIDEOGRAPHER: Back on record 14:04.</p> <p>18 BY MR. CASSELLA:</p> <p>19 Q. Welcome back, Dr. Donnenfeld.</p> <p>20 <b>A. Thank you.</b></p> <p>21 Q. So if we could please put Exhibit 1067</p> <p>22 back on the screen. And we were on page 9 of 16</p>                                            |
| <p>1 Dr. Donnenfeld, that these comparative clinical</p> <p>2 studies referenced here in Exhibit 1067 for</p> <p>3 Alphagan 0.2 percent lasted up to one year?</p> <p>4 MR. WEINGARTEN: Objection to form.</p> <p>5 <b>A. Correct.</b></p> <p>6 Q. Okay.</p> <p>7 MR. CASSELLA: And if we could go two</p> <p>8 pages down under Adverse Reactions for</p> <p>9 Alphagan 0.2 percent. A little bit further.</p> <p>10 There it -- there it is. Oh. There we go.</p> <p>11 Q. Do you see the Adverse Reactions section</p> <p>12 for the Alphagan 0.2 percent displayed on the</p> <p>13 screen here?</p> <p>14 <b>A. Yes.</b></p> <p>15 Q. Now, in this Adverse Events -- or</p> <p>16 Adverse Reactions section, it says, "Adverse</p> <p>17 events occurring in approximately 10 to 30 percent</p> <p>18 of the subjects, in descending order of incidence,</p> <p>19 included oral dryness, ocular hyperemia" -- I</p> <p>20 won't read the rest of them, but there's a list of</p> <p>21 adverse events there.</p> <p>22 And then in the next paragraph, it says,</p> | <p>1 looking at the Adverse Reactions section.</p> <p>2 And -- so, Dr. Donnenfeld, before the</p> <p>3 break, we were discussing this Alphagan</p> <p>4 0.2 percent label, and the Adverse Reactions</p> <p>5 section of that label.</p> <p>6 Do you see that here on the screen?</p> <p>7 <b>A. Yes.</b></p> <p>8 Q. And I believe we established earlier</p> <p>9 that the -- the clinical studies of Alphagan</p> <p>10 0.2 percent listed in this label lasted up to one</p> <p>11 year; is that correct?</p> <p>12 MR. WEINGARTEN: Objection to form,</p> <p>13 mischaracterizes the evidence.</p> <p>14 <b>A. Yes.</b></p> <p>15 Q. And I apologize if I read this to you</p> <p>16 earlier, but in the second paragraph of the</p> <p>17 Adverse Reactions section, it says, "Events</p> <p>18 occurring in approximately 3 to 9 percent of the</p> <p>19 subjects, in descending order included" -- and one</p> <p>20 of the adverse reactions listed there is</p> <p>21 "conjunctival blanching."</p> <p>22 Do you see that?</p> |

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| <p>1 <b>A. Yes.</b></p> <p>2 Q. The -- the Adverse Reactions section</p> <p>3 here lists a percentage range for the adverse</p> <p>4 reactions; correct?</p> <p>5 <b>A. Yes.</b></p> <p>6 Q. But this section of Exhibit 1067 doesn't</p> <p>7 explicitly say what precise percentage of patients</p> <p>8 experienced conjunctival blanching; correct?</p> <p>9 <b>A. It says 3 to 9 percent.</b></p> <p>10 Q. And this Adverse Reaction -- Reactions</p> <p>11 section does not specify what severity grade any</p> <p>12 individual patient may have experienced in -- in</p> <p>13 terms of their conjunctival blanching; correct?</p> <p>14 <b>A. Correct.</b></p> <p>15 Q. And this Adverse Reactions section does</p> <p>16 not specify when in the study the conjunctival</p> <p>17 blanching may have occurred; right?</p> <p>18 <b>A. Yes.</b></p> <p>19 Q. And this Adverse Reactions section does</p> <p>20 not specify how frequently conjunctival blanching</p> <p>21 may have occurred for any individual patient;</p> <p>22 correct?</p> | <p>1 state that "A POSA would have understood that the</p> <p>2 reduction in bleeding complications, including</p> <p>3 both subconjunctival hemorrhage and micro-vessel</p> <p>4 hemorrhage (Norden's hyperemia), observed by</p> <p>5 Norden in the brimonidine group was due to</p> <p>6 brimonidine's narrowing of the blood vessels in</p> <p>7 the eye before surgery..."</p> <p>8 Do you see that?</p> <p>9 <b>A. Yes.</b></p> <p>10 Q. Now, you would agree, Dr. Donnenfeld,</p> <p>11 that in 2008, the POSA would have understood that</p> <p>12 redness relievers generally work by narrowing</p> <p>13 blood vessels in the front of the eye; correct?</p> <p>14 MR. WEINGARTEN: Objection to form.</p> <p>15 <b>A. Yes.</b></p> <p>16 Q. Okay. At the end of paragraph 55, you</p> <p>17 state that the dose in Norden was about</p> <p>18 0.4 percent (0.2 percent times 2).</p> <p>19 Do you see that?</p> <p>20 <b>A. Yes.</b></p> <p>21 Q. And is it your opinion, then,</p> <p>22 Dr. Donnenfeld, that the administration of two</p>                                                                                                                                                                                                  |
| <p>1 <b>A. Correct.</b></p> <p>2 Q. Okay.</p> <p>3 MR. CASSELLA: If we could go back to</p> <p>4 Dr. Donnenfeld's '245 declaration, please.</p> <p>5 REMOTE TECHNICIAN: And the document is</p> <p>6 on screen.</p> <p>7 MR. CASSELLA: If we could scroll down</p> <p>8 to paragraph 55, please.</p> <p>9 Q. And do you see paragraph 55 displayed on</p> <p>10 the screen, Dr. Donnenfeld?</p> <p>11 <b>A. Yes.</b></p> <p>12 Q. Okay. Just take a moment to familiarize</p> <p>13 yourself with this paragraph.</p> <p>14 MR. WEINGARTEN: And, Doctor, feel free</p> <p>15 to look at the earlier paragraphs to get a</p> <p>16 sense of where you are in your declaration.</p> <p>17 And you have your hard copy if it's more</p> <p>18 convenient.</p> <p>19 Q. And just let me know when you're ready</p> <p>20 to keep going.</p> <p>21 <b>A. Yes.</b></p> <p>22 Q. So in the middle of paragraph 55, you</p>                                                                                                                                      | <p>1 drops of 0.2 percent brimodidine -- brimonidine is</p> <p>2 equivalent to the administration of a single drop</p> <p>3 of 0.4 percent brimonidine?</p> <p>4 MR. WEINGARTEN: Objection. Objection,</p> <p>5 mischaracterizes his statement and incomplete</p> <p>6 hypothetical.</p> <p>7 <b>A. No, I do not.</b></p> <p>8 Q. Can you explain what you mean when you</p> <p>9 say the dose of brimonidine was about 4 --</p> <p>10 0.4 percent, 0.2 percent times two?</p> <p>11 <b>A. Well, it is defined that the patient got</b></p> <p>12 <b>two drops of 0.2 percent, which is 0.2 percent</b></p> <p>13 <b>twice, and we're reading it as 0.4 percent, but</b></p> <p>14 <b>that is not the same as one drop of 0.4 percent.</b></p> <p>15 Q. Could you explain what you mean, why it</p> <p>16 is not the same as one drop of 0.4 percent?</p> <p>17 <b>A. Because 0.4 percent is twice the</b></p> <p>18 <b>concentration in one dose rather than twice the</b></p> <p>19 <b>dose in one concentration. The dose here is --</b></p> <p>20 <b>the -- the cumulative amount is the same, but it's</b></p> <p>21 <b>given in a larger volume of drops rather than one</b></p> <p>22 <b>drop being applied with a higher concentration.</b></p> |

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| <p>1 Q. I see.</p> <p>2 So the -- the difference, in your</p> <p>3 opinion, is just the -- the number of drops --</p> <p>4 the -- that the -- the cumulative concentration is</p> <p>5 the same; is that correct?</p> <p>6 <b>A. The cumulative amount of brimonidine was</b></p> <p>7 <b>the same and if -- in your hypothetical. But the</b></p> <p>8 <b>amount -- but that would have a different effect</b></p> <p>9 <b>on the eye.</b></p> <p>10 Q. What would have a different effect on</p> <p>11 the eye?</p> <p>12 <b>A. Giving two drops of 0.2 percent is not</b></p> <p>13 <b>the same as one drop of 0.4 percent. Although,</b></p> <p>14 <b>the cumulative amount of brimonidine would be the</b></p> <p>15 <b>same in both examples.</b></p> <p>16 Q. So I'm a little bit confused. Are you</p> <p>17 saying that that would or would not have a</p> <p>18 different effect on the eye?</p> <p>19 <b>A. It would most likely have a different</b></p> <p>20 <b>effect.</b></p> <p>21 Q. And can you explain why that is, in your</p> <p>22 opinion?</p>                                                                                                                                                                                                                                                                            | <p>1 of a single drop would lead to a trough?</p> <p>2 <b>A. I do not.</b></p> <p>3 MR. WEINGARTEN: Objection, incomplete</p> <p>4 hypothetical.</p> <p>5 <b>A. No. I -- I do not know that.</b></p> <p>6 <b>And it varies from patient to patient.</b></p> <p>7 Q. So in Norden, the two drops were</p> <p>8 administered 10 minutes apart; correct?</p> <p>9 <b>A. Yes.</b></p> <p>10 Q. And you state -- again, I apologize for</p> <p>11 re-reading this, you state that the dose of</p> <p>12 brimonidine was about 0.4 percent (0.2 percent</p> <p>13 times two); correct?</p> <p>14 <b>A. Yes.</b></p> <p>15 Q. So that's just a -- simple arithmetic,</p> <p>16 adding 0.2 percent plus 0.2 percent equals</p> <p>17 0.4 percent; correct?</p> <p>18 <b>A. Yes.</b></p> <p>19 Q. So would your opinion change if Norden</p> <p>20 had administered the second drop of brimonidine</p> <p>21 one week later?</p> <p>22 <b>A. One week later?</b></p>                                                                                                   |
| <p>1 <b>A. The higher concentration achieves a</b></p> <p>2 <b>higher peak acutely, which will have a different</b></p> <p>3 <b>effect than using two drops of a lower</b></p> <p>4 <b>concentration. So the peak is going to be higher,</b></p> <p>5 <b>the amount of medication, at 0.4 percent, while</b></p> <p>6 <b>the plateau will be longer on two drops of</b></p> <p>7 <b>0.2 percent. So the peaks and the plateaus will</b></p> <p>8 <b>be different, which will most likely have a</b></p> <p>9 <b>different effect on the eye.</b></p> <p>10 Q. And how, if at all, does the amount of</p> <p>11 time in between administration of the two drops</p> <p>12 affect the peak or the plateau?</p> <p>13 <b>A. Well, when there's one drop given,</b></p> <p>14 <b>the -- the peak concentration is right when the</b></p> <p>15 <b>drop is applied. When two drops are given at</b></p> <p>16 <b>different times, there's a longer plateau, but the</b></p> <p>17 <b>peak is not as high. And the duration of time</b></p> <p>18 <b>between the drops determines how flat the plateau</b></p> <p>19 <b>is and whether there is a period of time when the</b></p> <p>20 <b>plateau becomes more of a trough.</b></p> <p>21 Q. And for brimonidine specifically, do you</p> <p>22 know what period of time in between administration</p> | <p>1 Q. One week later.</p> <p>2 <b>A. Yes.</b></p> <p>3 Q. How so?</p> <p>4 <b>A. The second drop would now have -- would</b></p> <p>5 <b>have no effect on the efficacy of the first drop.</b></p> <p>6 Q. And why not?</p> <p>7 <b>A. Because the half-life of brimonidine is</b></p> <p>8 <b>4 to 6 hours, and the second drop would not impact</b></p> <p>9 <b>the drop that had been given previously.</b></p> <p>10 Q. What if the second drop had been</p> <p>11 administered four to six hours after the first</p> <p>12 drop?</p> <p>13 <b>A. I don't know the pharmacokinetic dose</b></p> <p>14 <b>curve of how much brimonidine would be available</b></p> <p>15 <b>from the first drop, so I can't give a reasonable</b></p> <p>16 <b>answer as to whether there would be an effect or</b></p> <p>17 <b>not.</b></p> <p>18 Q. Would your answer be the same if the</p> <p>19 second drop were administered one hour after the</p> <p>20 first drop?</p> <p>21 MR. WEINGARTEN: Objection to form.</p> <p>22 I'm not sure which answer you're</p> |

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| <p>1 referring to, Counsel.</p> <p>2 Q. So we're -- we're just talking about the</p> <p>3 end of paragraph 55 in your declaration. We've</p> <p>4 established that the -- that Norden administers a</p> <p>5 single drop twice, 10 minutes apart; correct?</p> <p>6 Are you with -- are you with me there?</p> <p>7 <b>A. Yes.</b></p> <p>8 Q. Okay. And then you say that that dose,</p> <p>9 then, is about 0.4 percent; correct?</p> <p>10 <b>A. Yes.</b></p> <p>11 Q. So what I'm asking is: Would the dose</p> <p>12 be -- still be about 0.4 percent if those two</p> <p>13 drops were administered one hour apart instead of</p> <p>14 10 minutes apart?</p> <p>15 <b>A. Well, the total dose would still be</b></p> <p>16 <b>0.4 percent, but the effect on the eye would be</b></p> <p>17 <b>unknown at one hour apart as the tear film turns</b></p> <p>18 <b>over. So the Alphagan given in the first drop</b></p> <p>19 <b>would probably not be in the tear film when the</b></p> <p>20 <b>second drop was delivered 10 minutes later.</b></p> <p>21 <b>So it's impossible to say what the</b></p> <p>22 <b>effect would be an hour apart, but it would be</b></p>          | <p>65</p> <p>1 <b>the tear film if they're delivered five minutes</b></p> <p>2 <b>apart than ten minutes apart. But the plateau of</b></p> <p>3 <b>medication in the tear film would be longer if</b></p> <p>4 <b>they were delivered ten minutes apart.</b></p> <p>5 Q. Dr. Donnenfeld, in your opinion, does</p> <p>6 Norden disclose a multiple-drop method of</p> <p>7 administering brimonidine?</p> <p>8 <b>A. Yes.</b></p> <p>9 Q. And if Norden had administered the two</p> <p>10 drops, say, one week apart, would Norden, in your</p> <p>11 opinion, still be performing a method -- a</p> <p>12 multiple-drop method of administering brimonidine?</p> <p>13 <b>A. It would still be multiple drops, but</b></p> <p>14 <b>there'd be no rationale for doing that.</b></p> <p>15 Q. And if Norden had administered the two</p> <p>16 drops of brimonidine six hours apart from one</p> <p>17 another, in your opinion, would that still be a</p> <p>18 multiple-drop method of administering brimonidine?</p> <p>19 <b>A. Yes.</b></p> <p>20 Q. Do you know, Dr. Donnenfeld, whether</p> <p>21 there is a linear relationship between the number</p> <p>22 of drops of brimon- -- brimonidine administered</p> |
| <p>66</p> <p>1 <b>more likely to have an additional effect then it</b></p> <p>2 <b>would be at four hours.</b></p> <p>3 Q. So I -- I just want to understand your</p> <p>4 answer.</p> <p>5 I believe you mentioned the tear film</p> <p>6 turning over; is that correct?</p> <p>7 <b>A. Yes.</b></p> <p>8 Q. Can you just explain what you mean by</p> <p>9 that?</p> <p>10 <b>A. New tears are produced by the lacrimal</b></p> <p>11 <b>gland. So that drops that are applied into the</b></p> <p>12 <b>tear film are diluted and halved every</b></p> <p>13 <b>five minutes. So that a medication applied to the</b></p> <p>14 <b>tear film will be diluted by the patient producing</b></p> <p>15 <b>more tears. So that the longer you go between</b></p> <p>16 <b>drops, the more likely it is that there's no drops</b></p> <p>17 <b>left in the tear film from the previous drop.</b></p> <p>18 Q. In your opinion, Dr. Donnenfeld, would</p> <p>19 the dose in Norden still be about 0.4 percent if</p> <p>20 the two drops were administered only five minutes</p> <p>21 apart instead of ten minutes apart?</p> <p>22 <b>A. There would be a higher concentration in</b></p> | <p>68</p> <p>1 and the cumulative concentration that results?</p> <p>2 MR. WEINGARTEN: Objection, incomplete</p> <p>3 hypothetical.</p> <p>4 <b>A. I do not know the dose-response curve</b></p> <p>5 <b>over time, no.</b></p> <p>6 <b>I do know that the half-life is four to</b></p> <p>7 <b>six hours, however.</b></p> <p>8 Q. So, for example, if three drops of</p> <p>9 0.2 percent brimonidine were administered all</p> <p>10 10 minutes apart from each other, do you have any</p> <p>11 opinion as to whether that would be equivalent to</p> <p>12 administering a single drop of 0.6 percent</p> <p>13 brimonidine?</p> <p>14 <b>A. It would be different.</b></p> <p>15 Q. Now, Dr. Donnenfeld, you have</p> <p>16 administered eye drops yourself to patients;</p> <p>17 correct?</p> <p>18 <b>A. Yes.</b></p> <p>19 Q. And eye drops are typically dispensed</p> <p>20 via an eye dropper; is that correct?</p> <p>21 <b>A. Yes.</b></p> <p>22 Q. Is that the correct term in your field,</p>                                                                                                                                                                                                            |

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|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>69</p> <p>1 a dropper? I want to make sure we're speaking the</p> <p>2 same language.</p> <p>3 <b>A. More likely, I would say they're</b></p> <p>4 <b>delivered from a -- a bottle of eye drops.</b></p> <p>5 Q. Okay. And can different bottles of eye</p> <p>6 drops dispense different volumes of eye drops?</p> <p>7 MR. WEINGARTEN: Objection, incomplete</p> <p>8 hypothetical.</p> <p>9 <b>A. They can, but most do not.</b></p> <p>10 Q. And would eye drops of different volumes</p> <p>11 contain different amounts of active ingredient?</p> <p>12 MR. WEINGARTEN: Objection, outside the</p> <p>13 scope, incomplete hypothetical. Objection to</p> <p>14 form.</p> <p>15 <b>A. Yes.</b></p> <p>16 Q. Is a "drop" a standard volume in your</p> <p>17 field?</p> <p>18 <b>A. Sorry. Repeat that one more time.</b></p> <p>19 Q. Is a "drop" a standard volume in your</p> <p>20 field?</p> <p>21 <b>A. I'm not aware of that term.</b></p> <p>22 Q. Drop, as in eye drop.</p> | <p>71</p> <p>1 <b>it would be different than what I just stated.</b></p> <p>2 MR. CASSELLA: Could we pull up</p> <p>3 Exhibit 2050, please.</p> <p>4 REMOTE TECHNICIAN: Yes. Please stand</p> <p>5 by.</p> <p>6 MR. WEINGARTEN: Which exhibit?</p> <p>7 MR. CASSELLA: 2050. 2050.</p> <p>8 Let's see when it comes on the screen,</p> <p>9 and then you can see what it is.</p> <p>10 MR. WEINGARTEN: Okay.</p> <p>11 REMOTE TECHNICIAN: And the document is</p> <p>12 on the screen.</p> <p>13 MR. CASSELLA: And if you could just --</p> <p>14 maybe just scroll through the first couple of</p> <p>15 pages so Dr. Donnenfeld can familiarize</p> <p>16 himself with the document.</p> <p>17 Q. And Dr. Donnenfeld, have you ever seen</p> <p>18 this document?</p> <p>19 <b>A. I'm not certain.</b></p> <p>20 Q. So I will represent to you that patent</p> <p>21 owner has cited this document in connection with</p> <p>22 these IPRs.</p> |
| <p>70</p> <p>1 <b>A. Expander?</b></p> <p>2 Q. Drop, as in eye drop.</p> <p>3 MR. WEINGARTEN: I think he misun- --</p> <p>4 misheard your question. It didn't come</p> <p>5 through well. Can you restate it?</p> <p>6 MR. CASSELLA: Yeah.</p> <p>7 Q. So I'm -- I'm asking about eye drops.</p> <p>8 Can you guys hear me okay?</p> <p>9 <b>A. Yes.</b></p> <p>10 Q. Okay. So I'm -- I'm asking about eye</p> <p>11 drops, and my question is: Is an eye drop a</p> <p>12 standard volume?</p> <p>13 <b>A. Yes. There are roughly about 20 to 25</b></p> <p>14 <b>drops per milliliter.</b></p> <p>15 Q. So there's a range in that standard</p> <p>16 volume?</p> <p>17 <b>A. Yes.</b></p> <p>18 Q. And you don't know, Dr. Donnenfeld, what</p> <p>19 volume of eye drops were used in Norden or Gil;</p> <p>20 correct?</p> <p>21 <b>A. I don't. But I would assume it was a</b></p> <p>22 <b>standard eye drop; that there would be no reason</b></p>                                   | <p>72</p> <p>1 And this is a copy of the Lumify label.</p> <p>2 And you're familiar with Lumify; correct?</p> <p>3 <b>A. Yes.</b></p> <p>4 Q. And you've seen the label before;</p> <p>5 correct?</p> <p>6 MR. WEINGARTEN: Objection, lack of</p> <p>7 foundation.</p> <p>8 <b>A. Yes.</b></p> <p>9 Q. Let's go to page 2 of this Exhibit 2050.</p> <p>10 And let's zoom in on the label.</p> <p>11 And, Dr. Donnenfeld, do you see on the</p> <p>12 Lumify label in Exhibit 2050, under Active</p> <p>13 Ingredient, it lists "brimonidine tartrate</p> <p>14 0.025 percent"?</p> <p>15 <b>A. Yes.</b></p> <p>16 Q. Is that text big enough? Can you read</p> <p>17 that, or no?</p> <p>18 <b>A. I can.</b></p> <p>19 Q. Okay. And then under the Directions</p> <p>20 section of the label or the package, you see the</p> <p>21 Directions section towards the bottom there?</p> <p>22 <b>A. Yes.</b></p>                                     |

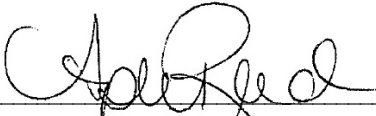
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| <p>73</p> <p>1 MR. WEINGARTEN: Counsel, I am going to<br/>2 lodge an objection for all your questions on<br/>3 this document because you haven't laid a<br/>4 foundation.<br/>5 Dr. Donnenfeld said he has no<br/>6 recollection of seeing this document, and so<br/>7 you're asking him questions based on a<br/>8 document he's not familiar with.<br/>9 MR. CASSELLA: It's a copy of a Lumify<br/>10 label, which he's said he's seen before. But<br/>11 it...<br/>12 MR. WEINGARTEN: You asked him if he saw<br/>13 this document, and he said he does not<br/>14 recall. And you have not laid a foundation<br/>15 for him seeing this document. And this is<br/>16 what you're asking questions on. So the<br/>17 objection stands.<br/>18 MR. CASSELLA: It's -- it's a copy of a<br/>19 Lumify label.<br/>20 You want me to hold up a package to the<br/>21 camera?<br/>22 MR. WEINGARTEN: I'm just telling you</p>                                | <p>75</p> <p>1 own effect as it's beyond the half-life of the<br/>2 medication that's been applied. So while it is<br/>3 multiple drops in a day, I don't think there would<br/>4 be a cumulative effect by using the drops every<br/>5 six to eight hours.<br/>6 MR. CASSELLA: Okay. Thank you,<br/>7 Dr. Donnenfeld. I have no further questions.<br/>8 MR. WEINGARTEN: Okay. So we'll go off<br/>9 the record for about 15 minutes, and I will<br/>10 come back and decide if I'm going to do a<br/>11 redirect or -- or not.<br/>12 So if we can go off the record.<br/>13 THE VIDEOGRAPHER: Okay. Off record<br/>14 14:31.<br/>15 (Recess in proceedings.)<br/>16 THE VIDEOGRAPHER: Back on record 14:52.<br/>17 MR. WEINGARTEN: Patent owner has no<br/>18 questions for Dr. Donnenfeld and would like<br/>19 to thank the witness for his time.<br/>20 MR. CASSELLA: Thank you,<br/>21 Dr. Donnenfeld.<br/>22 THE WITNESS: Thanks.</p> |
| <p>74</p> <p>1 that this document, he has said he has not --<br/>2 he doesn't recall seeing this.<br/>3 You can continue asking your questions.<br/>4 I'm just laying the objection on the record.<br/>5 MR. CASSELLA: Okay.<br/>6 Q. You see the Directions section,<br/>7 Dr. Donnenfeld?<br/>8 A. Yes. Yes, I do.<br/>9 Q. And the directions on the Lumify label<br/>10 state, "Instill 1 drop in the affected eyes every<br/>11 6-8 hours."<br/>12 Do you see that?<br/>13 A. Yes.<br/>14 Q. So if I follow the directions on the<br/>15 Lumify label, and I instill one drop of Lumify in<br/>16 my eye every six to eight hours, am I performing a<br/>17 multiple-drop method of administering brimonidine?<br/>18 MR. WEINGARTEN: Objection, calls for a<br/>19 legal conclusion, outside the scope. And<br/>20 lack of foundation.<br/>21 A. This would be multiple drops given a<br/>22 day, but each drop would have it -- it -- have its</p> | <p>76</p> <p>1 MR. CASSELLA: Nice to see you again.<br/>2 Thank you for your expertise. I think this<br/>3 is probably the last time --<br/>4 Oh, we can go off the record. Sorry.<br/>5 THE VIDEOGRAPHER: Okay. This concludes<br/>6 the Videotaped Deposition of Dr. Eric<br/>7 Donnenfeld. Off record at 14:52.<br/>8<br/>9<br/>10<br/>11 AND FURTHER THIS DEPONENT SAITH NOT.<br/>12 SIGNATURE RIGHTS RESERVED.<br/>13 (Videotaped Deposition concluded at 2:52 p.m.)<br/>14<br/>15<br/>16 * * * * *<br/>17<br/>18<br/>19<br/>20<br/>21<br/>22</p>                                                                                                                                                                                                                                                                                                                                                                                        |

Transcript of Eric D. Donnenfeld, M.D.  
Conducted on February 6, 2025

20 (77 to 80)

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| <p>77</p> <p>1 CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC</p> <p>2 I, April Reid, Registered Professional</p> <p>3 Reporter, Certified Realtime Reporter and Notary</p> <p>4 Public within and for the State of North Carolina</p> <p>5 do hereby certify:</p> <p>6 That ERIC D. DONNENFELD, M.D., the</p> <p>7 witness whose deposition is hereinbefore set</p> <p>8 forth, was duly sworn by me before the</p> <p>9 commencement of such deposition and that such</p> <p>10 deposition was taken before me and is a true</p> <p>11 record of the testimony given by such witness.</p> <p>12 I further certify that the adverse</p> <p>13 party, EYE THERAPIES, LLC, was represented by</p> <p>14 counsel at the deposition.</p> <p>15 I further certify that the deposition of</p> <p>16 ERIC D. DONNENFELD, M.D. occurred remotely via</p> <p>17 Zoom on THURSDAY, FEBRUARY 6, 2025, from 12:39</p> <p>18 p.m. Eastern Standard Time to 2:52 p.m. Eastern</p> <p>19 Standard Time.</p> <p>20 I further certify that I am not related</p> <p>21 to any of the parties to this action by blood or</p> <p>22 marriage, I am not employed by or an attorney to</p> |  |
| <p>78</p> <p>1 any of the parties to this action, and that I am</p> <p>2 in no way interested, financially or otherwise, in</p> <p>3 the outcome of this matter.</p> <p>4 IN THE WITNESS WHEREOF, I have hereunto set my</p> <p>5 hand this 18th day of February, 2025.</p> <p>6 My commission expires: March 4, 2025.</p> <p>7</p> <p>8 </p> <p>9</p> <p>10 APRIL REID, NOTARY PUBLIC IN AND FOR THE</p> <p>11 STATE OF NORTH CAROLINA, MECKLENBURG COUNTY.</p> <p>12 Notary Registration No. 20012210079</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |  |

| A                                                                                                                             |                                                                                                                                                                 |                                                                                                                                                                                                             |                                                                                                                                                                                                                          |
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| <b>abbreviation</b>                                                                                                           | 63:20, 64:11,<br>64:19, 65:13,<br>66:20, 67:9,<br>67:15, 67:22,<br>68:9, 68:16                                                                                  | 26:2, 26:6,<br>26:18, 27:12,<br>30:17, 31:14,<br>35:7, 64:11,<br>64:19                                                                                                                                      | 18:20, 19:6,<br>30:6, 41:11                                                                                                                                                                                              |
| 36:16, 37:2,<br>40:17                                                                                                         | <b>administering</b>                                                                                                                                            | <b>afternoon</b>                                                                                                                                                                                            | <b>although</b>                                                                                                                                                                                                          |
| <b>able</b>                                                                                                                   | 28:19, 29:8,<br>33:2, 67:7,<br>67:12, 67:18,<br>68:12, 74:17                                                                                                    | 6:3, 6:19,<br>6:22, 7:21, 7:22                                                                                                                                                                              | 36:9, 61:13                                                                                                                                                                                                              |
| 11:6                                                                                                                          | <b>administers</b>                                                                                                                                              | <b>again</b>                                                                                                                                                                                                | <b>ambiguous</b>                                                                                                                                                                                                         |
| <b>about</b>                                                                                                                  | 65:4                                                                                                                                                            | 15:14, 18:4,<br>18:16, 26:19,<br>40:16, 40:19,<br>48:3, 63:10,<br>76:1                                                                                                                                      | 33:6                                                                                                                                                                                                                     |
| 20:8, 35:22,<br>42:22, 46:15,<br>46:22, 59:17,<br>60:9, 63:12,<br>65:2, 65:9,<br>65:12, 66:19,<br>70:7, 70:10,<br>70:13, 75:9 | <b>administration</b>                                                                                                                                           | <b>ago</b>                                                                                                                                                                                                  | <b>amount</b>                                                                                                                                                                                                            |
| <b>above</b>                                                                                                                  | 26:11, 27:5,<br>28:13, 28:14,<br>28:17, 29:6,<br>30:16, 30:21,<br>31:5, 31:14,<br>39:14, 39:15,<br>59:22, 60:2,<br>62:11, 62:22                                 | 17:15                                                                                                                                                                                                       | 60:20, 61:6,<br>61:8, 61:14,<br>62:5, 62:10                                                                                                                                                                              |
| 37:22, 40:15                                                                                                                  | <b>administrations</b>                                                                                                                                          | <b>agree</b>                                                                                                                                                                                                | <b>amounts</b>                                                                                                                                                                                                           |
| <b>achieves</b>                                                                                                               | 27:16, 33:3                                                                                                                                                     | 27:15, 38:18,<br>39:3, 40:19,<br>59:10                                                                                                                                                                      | 69:11                                                                                                                                                                                                                    |
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