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Transcript of Robert Williams, III, PhD

Date: January 19, 2024

Case: Lumify, In Re:

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WORLDWIDE COURT REPORTING & LITIGATION TECHNOLOGY

Transcript of Robert Williams, III, PhD
Conducted on January 19, 2024

1 (1 to 4)

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	1 UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY IN RE LUMIFY _____))) CASE NO. 21-16766(RK)(RLS) CONSOLIDATED REMOTE VIDEOTAPED DEPOSITION OF ROBERT WILLIAMS III, Ph.D. FRIDAY, JANUARY 19, 2024 LOS ANGELES, CALIFORNIA PAGES 1 - 49 REPORTED BY MARK SCHWEITZER CSR #10514, RPR, CRR	3 A P P E A R A N C E S For the Plaintiff: FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP By: Justin Hasford, Esq. 901 New York Avenue, NW Washington, D.C. 20001 (202) 408-4175 justin.hasford@finnegan.com For the Defendants: GOODWIN PROCTER, LLP By: Denise Go, Esq. The New York Times Building 620 Eighth Avenue New York, New York 10018 dgo@goodwinlaw.com Videographer: Isaac Orihuela Tech: Alan Ross
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	2 Videotaped Deposition of Robert Williams III Ph.D., held remotely: Pursuant to Notice, before Mark Schweitzer, Registered Professional Reporter, Certified Realtime Reporter, and Certified Shorthand Reporter No. 10514, in and for the State of California.	4 I N D E X January 19, 2024 WITNESS: PAGE ROBERT O. WILLIAMS III, Ph.D. EXAMINATION BY MS. GO: 7

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2 (5 to 8)

5 1 EXHIBITS 2 3 EXHIBIT MARKED FOR I.D. 4 435 DECLARATION OF DR. ROBERT O. WILLIAMS 10 III, Ph.D. 5 436 DRUGS@FDA DATABASE DOCUMENT 13 6 238 LABEL FOR OVER-THE-COUNTER NAPHCN A 22 7 244 LABEL FOR OVER-THE-COUNTER VISINE A.C. ITCHY 24 EYE RELIEF 8 245 LABEL FOR VISINE ALLERGY EYE RELIEF 25 MULTI-ACTION 9 248 LABEL FOR OVER-THE-COUNTER CLEAR EYES MAXIMUM 26 REDNESS RELIEF 10 249 LABEL FOR CLEAR EYES MAXIMUM ITCHY EYE RELIEF 28 11 250 LABEL FOR CLEAR EYES TRIPLE RELIEF 29 12 251 LABEL FOR CLEAR EYES COOLING REDNESS RELIEF 31 13 252 LABEL FOR CLEAR EYES COOLING ITCHY EYE RELIEF 32 14 253 LABEL FOR RHOTO COOL MAX 33 15 254 LABEL FOR RHOTO COOL 34 16 17 18 19 20 21 22 23 24 25	7 1 THE REPORTER: Would you please raise your 2 right hand, doctor. 3 4 ROBERT O. WILLIAMS III, Ph.D., SWORN. 5 6 THE REPORTER: Thank you very much. 7 Counsel? 8 9 EXAMINATION 10 BY MS. GO: 11 Q. Good afternoon, Dr. Williams. 12 A. Good afternoon, Ms. Go. 13 Q. So my name is Denise Go, and I'll be the 14 attorney taking your deposition today. 15 A. Okay. 16 Q. And could you please state your full name 17 for the record. 18 A. Yes. My full name is Robert O. Williams 19 III. 20 Q. What is your current address? 21 A. My home address is 2305-A Westlake Drive, 22 Austin, Texas 78746. 23 Q. And have you ever been deposed before, 24 Dr. Williams? 25 A. Yes.
6 1 PROCEEDINGS 2 * * * * * 3 THE VIDEOGRAPHER: We are now on the 4 record. Here begins Media No. 1 to the video 5 deposition of Dr. Robert Williams, Ph.D., in the 6 matter of In Re Lumify. This is in the United States 7 District Court, District of New Jersey. The case 8 number is 21-16766(RK)(RLS). 9 Today's date is January 19, 2024. The time 10 on the video monitor is 1:06 P.M. Eastern Time. 11 The remote videographer today is Isaac 12 Orihuela, representing Planet Depos. All parties of 13 this video deposition are attending remotely. 14 Would counsel please identify themselves 15 and state whom they represent. 16 MS. GO: Denise Go, on behalf of the 17 defendants with Goodwin Procter. 18 MR. HASFORD: Justin Hasford of Finnegan on 19 behalf of plaintiffs. 20 THE VIDEOGRAPHER: Thank you. The court 21 reporter today is Mark Schweitzer, representing 22 Planet Depos. 23 Will the court reporter please swear in the 24 witness. 25 (Discussion held off the record.)	8 1 Q. So I know you've been deposed before, but I 2 would like to go over some ground rules just as a 3 refresher if that's all right. 4 A. Please, yes. 5 Q. Thank you. So you understand that you've 6 been sworn in by the court reporter, correct? 7 A. Yes. 8 Q. And I will be asking you questions, and you 9 have the same obligation to tell the truth as you 10 would in court. 11 Do you understand? 12 A. I understand, yes. 13 Q. And during the course of this deposition, 14 your counsel may make objections, but unless your 15 counsel instructs you not to answer, you have to 16 answer the question to the best of your ability. 17 Do you understand? 18 A. I do, yes. 19 Q. And we have a court reporter, 20 Mr. Schweitzer, who is taking down everything that is 21 said today. So that Mr. Schweitzer may have an 22 accurate record, can we agree that you and I will 23 make an effort to speak slowly and clearly enough so 24 that the court reporter can take down every word? 25 A. I will do my best, yes.

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9 1 Q. Great. And we agree that if I'm asking a 2 question, you'll do your best to let me finish before 3 you respond? 4 A. I will do my best at that, yes. 5 Q. And I will also do the same while you are 6 answering a question. 7 A. Yes. 8 Q. And do you agree to make verbal "yes" or 9 "no" responses rather than nonverbal responses? 10 A. Yes, I do. 11 Q. And we'll also take breaks from time to 12 time, and I encourage you to please let me know if 13 you need a break. But I ask that before we take a 14 break, if I'm in the middle of a question, that you 15 finish responding to the question. 16 Is that okay? 17 A. Yes, that's fine. I understand. 18 Q. And I ask that you listen carefully to my 19 questions, and please ask for clarification if you 20 need any. 21 A. I will on both counts. 22 Q. Is there any reason that would prevent you 23 from giving complete and truthful answers today? 24 A. There's not. 25 Q. And just to make sure, you have a clear	11 1 can see Dr. Williams's signature. I believe that is 2 on Page 23 of the document. 3 Dr. Williams, is that your signature? 4 A. It is, yes. 5 Q. And that is dated January 17th, 2024. 6 A. Yes, that's right. 7 Q. And is this the complete statement of 8 opinions you plan to offer at trial? 9 MR. HASFORD: Object to the form of the 10 question. 11 Q. BY MS. GO: Does the declaration in front 12 of you contain a complete statement of all the 13 opinions you plan to offer at the hearing? 14 MR. HASFORD: Same objection. 15 Q. BY MS. GO: You may answer. 16 A. It does contain my opinions that I set out, 17 assuming there's nothing else that I'm asked to opine 18 upon. 19 Q. Is there anything about this declaration 20 that you feel that you need to change? 21 MR. HASFORD: Objection. Assumes facts not 22 in evidence. 23 THE WITNESS: No. 24 Q. BY MS. GO: And did you draft this 25 declaration?
10 1 desk and there's nothing on your desk since we're in 2 a remote deposition? 3 A. Yes. The only thing I have is I did print 4 out a clean copy of my declaration and a clean copy 5 of the '245 patent, and a few of the other references 6 that I cite to in my declaration. They are all clean 7 copies, but I wanted a hard copy as opposed to on the 8 screen. 9 Q. Okay. 10 A. That's the only thing, besides office 11 paraphernalia, that's the only thing I have document 12 wise. 13 Q. Okay. Thank you. So we will begin with 14 Exhibit 435, which is the declaration of Dr. Robert 15 O. Williams in support of plaintiff's motion for a 16 preliminary injunction. 17 (Exhibit 435 for identification.) 18 Q. BY MS. GO: Dr. Williams, does this exhibit 19 look familiar to you? 20 A. Yes, it does. 21 Q. And what is it? 22 A. Well, it's the first page of my declaration 23 in support of plaintiff's motion for a preliminary 24 injunction. 25 Q. And let's scroll to the very end where we	12 1 A. Yes, I did. 2 Q. Was anyone else involved? 3 A. Well, I mean, it's my opinion counsel was 4 involved with some of the actual typing and 5 formatting and things like that. But it's my 6 opinions that are contained within the declaration. 7 Q. I don't want to get into any privileged 8 information, but could you please identify the 9 counsel who assisted you. 10 A. It was Mr. Zhang and Mr. Hasford. 11 Q. And how much time did you spend writing 12 this declaration? 13 A. Oh, I don't know. 14 Q. What documents did you review to draft this 15 declaration? 16 A. To draft the declaration, I reviewed the 17 documents that I've cited within the declaration 18 itself. 19 Q. And did you rely on anything else that 20 isn't cited in the declaration? 21 A. I have not, no. 22 Q. And have you reviewed any new materials 23 since drafting your declaration? 24 A. I have not, no. 25 Q. Okay. And I understand that there was a

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13 1 previous IPR that challenged the '742 patent that 2 was -- that is related to the patent at issue here. 3 Are you familiar with that? 4 MR. HASFORD: Object to the form of the 5 question. 6 Q. BY MS. GO: You may answer. 7 A. Actually, I don't think I am. To the '245 8 patent, it doesn't sound familiar to me. 9 Q. The patent at issue in the different case 10 was the '742 patent. Are you familiar with that? 11 MR. HASFORD: Object to form. 12 THE WITNESS: Sorry. If it's the '742 13 patent, yes, I recall that IPR for the '742 patent. 14 Q. BY MS. GO: And do you recall that you 15 submitted a declaration on behalf of one of the 16 parties in that IPR? 17 A. Yes, I do. 18 Q. Great. And you are the same Robert 19 Williams? 20 A. I am, yes. 21 Q. So if we could please pull up what is now 22 going to be Exhibit 436, the Drugs@FDA database 23 document. 24 (Exhibit 436 for identification.) 25 Q. BY MS. GO: Dr. Williams, just to be clear,	15 1 THE WITNESS: I'm actually not sure if the 2 Drugs@FDA gives a reason. I don't know, sitting here 3 today. 4 Q. Okay. I'm going to represent that this is 5 a printout of the Drugs@FDA database, which includes 6 information on Alphagan .2 percent. And please take 7 a moment to scroll through the exhibit if you'd like. 8 A. Okay. So just to make sure, this 9 Exhibit 436, it's only a single page. There's two 10 pages, but Page 2, at least that I'm seeing, is 11 blank. 12 Q. Yes, that's correct, Dr. Williams. Thank 13 you. 14 A. Thank you. 15 Q. So doesn't this printout of the Drugs@FDA 16 database state that Alphagan .2 percent was not 17 discontinued or withdrawn for safety or effectiveness 18 reasons? 19 A. That's what it says under the strength 20 column. 21 Q. And do you have any personal knowledge on 22 why that may not be true? 23 MR. HASFORD: Objection to the form of the 24 question. 25 THE WITNESS: No, I assume that that
14 1 do you want control of the screen when you're looking 2 through the documents? 3 A. Well, at some point, yes. It just depends 4 what I need to do based on your question. 5 Q. Okay. Could we please give Dr. Williams 6 control of the screen so he may scroll through the 7 document. 8 THE TECH: You should have control, sir. 9 If you click anywhere on the screen, you should be 10 able to take control. 11 THE WITNESS: I'm just making sure I can do 12 it. Thank you. 13 Q. BY MS. GO: Great. Dr. Williams, are you 14 familiar with the Drugs@FDA database? 15 A. I am, yes. 16 Q. Information on FDA approved products can be 17 found on this database, correct? 18 A. That's my understanding, yes. 19 Q. And this would include information on 20 whether an FDA-approved product was discontinued, 21 correct? 22 A. I believe it does, yes. 23 Q. Including any reasons why that product was 24 discontinued? 25 MR. HASFORD: Object to the form.	16 1 statement from -- that's explained in Drugs@FDA is a 2 true statement. 3 Q. BY MS. GO: Thank you. We can put that 4 aside. 5 Dr. Williams, you provided some opinions in 6 your declaration regarding preservatives, correct? 7 A. I did, yes. 8 Q. And generally why do drug products use 9 preservatives? 10 A. So generally drug products use 11 preservatives in order to prevent microbial 12 contamination of the product just in general. 13 Q. Why do eye drops use preservatives 14 specifically? 15 A. Eye drops, the aqueous-based eye drops, 16 they can use preservatives, can use preservatives. 17 Not all of them do. They can use preservatives in 18 order to, again, inhibit microbial growth in the 19 aqueous formulation. 20 Q. Could we please go back to, I believe, 21 Exhibit 435, which is Dr. Williams's declaration. 22 And may we please go to Page 18. 23 And, Dr. Williams, could you please read 24 Paragraph 54. 25 A. Read it out loud?

17 1 Q. Oh, read it to yourself. 2 A. Thank you. 3 Q. Thank you. 4 A. Okay. I've read it. 5 Q. So the first sentence of Paragraph 54 6 states: "Given BAK's recognized potential to cause 7 toxicity to the eye even at low concentrations, 8 market demands were push to go eliminate such harmful 9 preservatives and either replace BAK with better 10 tolerated preservatives or develop preservative-free 11 formulations." Is that correct? 12 A. That's my opinion, yes. 13 Q. And what is your basis for this? 14 A. My basis is my experience formulating 15 aqueous-based liquids, particularly for ophthalmic 16 solutions. And yeah, it's from my experience. 17 Q. Is it your opinion that since 2008 to 18 today, market demands pushed to eliminate 19 preservatives in eye drops? 20 MR. HASFORD: Object to the extent it 21 mischaracterizes the witness's testimony. 22 THE WITNESS: I mean, in my opinion, it was 23 even before 2008. In the literature formulation that 24 I'm familiar with regarding ophthalmic 25 solutions's and other aqueous products, but	19 1 THE WITNESS: I think it did. I think it 2 exists even today. 3 Q. BY MS. GO: And you'd expect that market 4 pressure to reduce the BAK, correct? 5 A. Well, I would expect that a formulation 6 scientist that is going to -- that tasks with 7 formulating an ophthalmic solution that's going to be 8 used for like an eye drop, that they -- that would be 9 a concern of theirs to, you know, to consider when 10 they are choosing the particular preservative. I do 11 think that is true today. And it was true in 2008. 12 Q. Did you see a reduction in the use of BAK 13 in 2008? 14 MR. HASFORD: Object to the form of the 15 question. 16 THE WITNESS: I think that it, you know, 17 the ultimate use of it depends on the particular 18 formulation scientist that's task was developing a 19 particular product. You know, I'm not -- I just 20 haven't looked into trends since -- since then to 21 see, you know, overall, is, you know, what's used. 22 But I know in the literature that there has 23 been, you know, a discussion in papers where the use 24 of more toxic to the ocular surface preservatives 25 has, you know, there's been, you know, discussion in
18 1 particularly ophthalmic solutions, that there was 2 concerns raised in the literature about 3 surfactants -- sorry, not surfactants, but 4 preservatives that affect the ocular surface. And 5 so there was concerns even before 2008. 6 Q. BY MS. GO: So to clarify, is it your 7 opinion that before 2008 to today in 2024, market 8 demands pushed to eliminate preservatives in eye 9 drops? 10 A. Well, I think that's -- I mean, it's -- 11 before 2008 is a very long period of time. So I 12 think, you know, the formulation literature that I'm 13 familiar with basically, you know, back early 2000's, 14 late 1990's, there was literature questioning, you 15 know, based on animal studies about ocular toxicity 16 on the surface of the eye that I'm familiar with. 17 So in my opinion, there has, you know, been 18 a -- a concern from -- at least from the formulators' 19 viewpoint about using preservatives that, you know, 20 damage the surface of the -- or the ocular surface. 21 Excuse me. 22 Q. Specifically, however, in just 2008, did 23 that market pressure to eliminate preservatives 24 exist? 25 MR. HASFORD: Object to the form.	20 1 the literature in these papers about going to less 2 toxic preservatives or preservative-free. That's 3 what I talked about in this section in my 4 declaration. 5 Q. BY MS. GO: So you haven't studied the 6 trends since 2008 to today on a reduction in BAK in 7 eye drops, have you? 8 MR. HASFORD: Object to the extent it 9 mischaracterizes the witness's testimony. 10 THE WITNESS: Sitting here now, I'm not 11 aware, because I haven't looked into it, as to, you 12 know, how many eye products that BAK has been used 13 in. I'm not aware of that. But I do know there is 14 literature references that report on ocular toxicity, 15 cytotoxicity of using BAK. And there is discussion 16 in literature. I pointed one, Agarol, from 2001 that 17 demonstrates the concern of using BAK. So I know 18 it's a concern for formulation scientists. 19 Q. BY MS. GO: But people haven't stopped 20 using BAK; is that correct? 21 A. I think BAK is still used in some products, 22 but I'm aware of products that it's still used in. 23 Q. So drug formulators still use BAK in eye 24 drops today, correct? 25 MR. HASFORD: Object to the form.

21 1 THE WITNESS: I mean, it is still used 2 today in eye drop formulations, and it is a choice 3 formulators have. But based on my experience and 4 based on many articles in the literature, there is 5 concerns with BAK. 6 So a skilled person would have to consider 7 that, and they would consider that when they are 8 formulating with a preservative in an ophthalmic 9 aqueous drop. 10 Q. Do you know whether BAK is used eye redness 11 relievers in the market today? 12 A. Actually, I don't know, sitting here right 13 now. I would have to look. 14 Q. And are you aware of anything saying this 15 formulator cannot use BAK in eye drops that would 16 leave redness? 17 MR. HASFORD: Object to the form of the 18 question. 19 THE WITNESS: I'm not aware of a reference 20 that specifically says don't use it. I'm aware of 21 many references that give data on its effects in 22 vitro and in vivo when applied to either an in vitro 23 system or an animal eye. 24 So there is caution for sure in the 25 literature, but I'm not aware of a document that	23 1 A. My understanding, it is, but I'll add that 2 it also cautions to stop use and ask your doctor if 3 redness or irritation of the eyes gets worse. 4 Q. We can set that aside. 5 Dr. Williams, please scroll the exhibit. 6 A. Okay. 7 Q. And on Page 3, which is where you are, it 8 seems like this is an over-the-counter Visine 9 Original, correct? 10 A. That's what it appears to be, yes. 11 Q. And under use, it states for relief of 12 redness of the eye due to minor irritations, correct? 13 MR. HASFORD: Object to the extent it 14 mischaracterizes the text. 15 THE WITNESS: So under use, it says for 16 relief of redness of the eye due to minor eye 17 irritations. 18 Q. BY MS. GO: And benzalkonium chloride is 19 listed under inactive ingredients, correct? 20 A. Under inactive ingredients, benzalkonium 21 chloride is mentioned. And again, I'll point out 22 that it also has a similar caution here. Stop use 23 and ask your doctor if redness or irritation of the 24 eye lasts or condition worsens or lasts more than 25 72 hours.
22 1 specifically says do not use BAK in an ophthalmic 2 product. 3 Q. BY MS. GO: Okay. Could we please go to 4 Exhibit 238. And, Dr. Williams, please take your 5 time to scroll through this exhibit. 6 (Exhibit 238 for identification.) 7 A. Okay. 8 Q. Okay. This is a label for over-the-counter 9 Naphcon A, correct? 10 A. That's what it appears to be, yes. 11 Q. And under uses, it lists for temporary 12 relief of redness. And is there a way to increase 13 the -- to zoom into the document? 14 A. It's okay for me, actually. 15 Q. Great. 16 A. Yeah. 17 Q. So under uses, it lists for temporary 18 relief of redness, correct? 19 A. It does, yes. 20 Q. And benzalkonium chloride is listed under 21 inactive ingredients, correct? 22 A. Benzalkonium chloride is one of the 23 inactive ingredients. 24 Q. And do you know whether this is still being 25 sold in the U.S.?	24 1 Q. On Page 4, which is the next page, at the 2 very bottom, I believe, or maybe Page 5, it states 3 that the marketing start date of Visine Original 4 Redness Relief is October 1, 2009, correct? 5 A. It does, yes. 6 Q. And is this drug still being sold in the 7 United States? 8 A. As far as I'm aware, it is, yes. 9 Q. Thank you. Please set that aside. And 10 let's go to Exhibit 244. 11 (Exhibit 244 for identification.) 12 (Discussion held off the record.) 13 Q. BY MS. GO: Dr. Williams, please take a 14 moment to scroll through Exhibit 244. 15 A. Okay. 16 Q. This is a label for over-the-counter 17 Visine A.C. Itchy Eye Relief, correct? 18 A. It appears to be, yes. 19 Q. And on Page 4, a listed use is for 20 temporary relief of discomfort and redness of the eye 21 due to minor eye irritations, correct? 22 A. I can't really tell what page I'm on. 23 Q. Oh, you're on Page 2. 24 A. 2. Okay. 3, 4. Okay. So use for 25 Visine A.C. Itchy Eye Relief for temporary relief of

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25 1 discomfort and redness of the eye due to minor eye 2 irritations. 3 Q. And benzalkonium chloride is listed as an 4 inactive ingredient, correct? 5 A. Yes, it is. And I'll also point out that 6 this label mentions or warns to stop use and ask a 7 doctor if redness or irritation of the eye lasts or 8 the condition worsens or lasts more than 72 hours. 9 Q. If you could please scroll to the last 10 page. The marketing start date is listed as May 6, 11 2019; is that correct? 12 A. It is, yes. 13 Q. And is Visine A.C. Itchy Eye Relief still 14 being sold in the United States? 15 A. As far as I'm aware, it is, yes. 16 Q. Thank you. Please set that aside, and 17 let's go to Exhibit 245. 18 (Exhibit 245 for identification.) 19 Q. BY MS. GO: And, Dr. Williams, again, 20 please take your time to go through the exhibit. 21 A. Okay. 22 Q. Dr. Williams, is this a label for Visine 23 Allergy Eye Relief Multi-Action? 24 A. It appears to be, yes. 25 Q. And on this page, under use, it states	27 1 A. Okay. 2 Q. Dr. Williams, this is a label for 3 over-the-counter Clear Eyes Maximum Redness Relief; 4 correct? 5 A. It appears to be, yes. 6 Q. Let's go up to Page 2, since the image on 7 this page, Page 4, is a little blurry. Under use on 8 this page, it states that the listed use -- one of 9 the listed uses is for the relief of redness of the 10 eye due to minor eye irritations, correct? 11 A. It does, yes. 12 Q. And on Page 5, if we could scroll down to 13 the last page, benzalkonium chloride is listed as an 14 inactive ingredient, correct? 15 A. It is, yes. And I would just point out 16 above on Page 3, I think this is Page 3. I'm 17 actually not quite sure. But the page that's showing 18 now, if you could tell me what page it's on. Oh, 19 Page 3. 20 Q. Yes. 21 A. Thank you. There's a warning that says 22 stop using and ask your doctor if you experience 23 continued redness of the eye, the condition worsens, 24 or symptoms last for more than 72 hours. 25 Q. If we go back to the last page, Page 5.
26 1 temporarily relieves itchy red eyes due to pollen, 2 rag weed, grass, animal hair, and dander, correct? 3 A. It does, yes. 4 Q. And benzalkonium chloride is listed as an 5 inactive ingredient, correct? 6 A. Benzalkonium chloride is listed as one of 7 the active ingredients. And I'll point out again to 8 stop use and ask a doctor if redness or irritation of 9 the eye lasts, conditions worsen last or more than 10 72 hours. 11 Q. And on the last page, if we could please 12 scroll down. The marketing start date is May 6, 13 2019; is that correct? 14 A. It looks like there's two products. A 15 different -- what the carton holds. And the number 16 one product listed is May 16, 2019, marketing start 17 date. 18 Q. And this product is still being sold in the 19 U.S., correct? 20 A. As far as I'm aware, yes. 21 Q. You can set that aside, and let's go to 22 Exhibit 248. 23 (Exhibit 248 for identification.) 24 Q. BY MS. GO: And, Dr. Williams, please take 25 your time to scroll through Exhibit 248.	28 1 A. Okay. 2 Q. The marketing start date is listed as 3 September 1, 2010; is that correct? 4 A. Yes, it is. 5 Q. And do you know whether this product is 6 still being sold in the U.S.? 7 A. My understanding is it is. 8 Q. We can set that aside. And let's go to 9 Exhibit 249. 10 (Exhibit 249 for identification.) 11 Q. BY MS. GO: Dr. Williams, please take your 12 time to scroll through this document. 13 A. Okay. 14 Q. On Page 5, which is the second to last 15 page -- 16 A. Okay. 17 Q. -- one of the listed uses is relieves 18 redness of the eye due to minor eye irritations; is 19 that correct? 20 A. That's what it says, yes. 21 Q. And benzalkonium chloride is listed as an 22 inactive ingredient on the same page, correct? 23 A. Benzalkonium chloride is listed as an 24 inactive ingredient, and again, I'll point out the 25 warning to stop use and ask a doctor if -- if the

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29 1 patient experiences continued redness or irritation 2 of the eye, condition worsens, symptoms last more 3 than 72 hours. 4 Q. And on the same page, if you scroll down, 5 and continue scrolling to the sixth page. 6 A. Oh, okay. 7 Q. You see that there are two marking start 8 dates -- correct? -- March 13, 2011, and September 4, 9 2018? 10 A. I do, yes. 11 Q. And is Clear Eyes Maximum Itchy Relief 12 still being sold in the United States? 13 A. This one I actually don't know if it is or 14 not. 15 Q. Okay. Please set that aside. 16 Could we please go to Exhibit 250. 17 (Exhibit 250 for identification.) 18 THE WITNESS: I don't know what I'm 19 supposed to -- 20 Q. BY MS. GO: Is Exhibit 250 up on the 21 screen? 22 THE TECH: My apologies. I thought it was. 23 Let me try again. 24 MS. GO: Thank you, Alan. 25 Q. Dr. Williams, do you see Exhibit 250?	31 1 A. I -- I don't know for sure on this product. 2 Q. Please set that aside. 3 And if we could please pull up Exhibit 251. 4 (Exhibit 251 for identification.) 5 Q. BY MS. GO: Dr. Williams, please take your 6 time to scroll through Exhibit 251. 7 A. Okay. 8 Q. So let's go back up to Page 2. And one of 9 the uses listed here is for the relief of redness of 10 the eye due to minor eye irritations; isn't that 11 correct? 12 A. That's -- that's what the document says, 13 yes. 14 Q. And if we scroll down to about Pages 4 and 15 5. 16 A. Let's see. Okay. 17 Q. Benzalkonium chloride is listed as an 18 inactive ingredient, correct? 19 A. Benzalkonium chloride is listed as one of 20 the inactive ingredients, and again, I'll note that 21 in the cautions to patients, it says stop -- on 22 Page 3, it says stop use. Ask a doctor if you 23 experience continued redness or irritation of the 24 eye. 25 Q. And the marketing start date listed on the
30 1 A. I do, yes. 2 Q. Great. Please take a moment to scroll 3 through Exhibit 250. 4 A. Okay. 5 Q. So on the second page of this exhibit, 6 you'll see that under use, one of the uses is 7 relieves redness of the eye due to minor eye 8 irritations; is that correct? 9 A. That's what it says, yes. 10 Q. And on Pages -- on Page 5 of this document. 11 A. 5. Okay. Okay. 12 Q. Benzalkonium chloride is listed as one of 13 the inactive ingredients, correct? 14 A. Benzalkonium chloride is one of the active 15 ingredients. And again, I point out the warning 16 that's up on Page 3, where it says stop use and ask a 17 doctor if you experience continued redness or 18 irritation of the eye, condition worsens, or symptoms 19 last more than 72 hours. 20 Q. And on that last page that we were just on, 21 the marketing start date is listed as March 15, 2011, 22 correct? 23 A. It is, yes. 24 Q. And do you know whether this product is 25 still being sold in the U.S.?	32 1 very last page of the document is February 15, 2011; 2 is that correct? 3 A. That is correct. 4 Q. And do you know if this product is still 5 being sold in the United States? 6 A. I -- I don't know about this -- this line 7 of products. I'm not sure if it is or not. I'm just 8 not aware of it, sitting here today. 9 Q. Okay. You can please set that aside, and 10 we can go to Exhibit 252. 11 (Exhibit 252 for identification.) 12 Q. BY MS. GO: Again, Dr. Williams, please 13 scroll through this exhibit and let me know when 14 you're done. 15 A. Okay. 16 Q. And if you scroll to Page 4, one of the 17 uses for Clear Eyes Cooling Comfort is that it 18 relieves redness of the eye due to minor eye 19 irritations; is that correct? 20 A. That's what the document says. 21 Q. And for the record, for clarification, 22 Exhibit 252 is a label for Clear Eyes Cooling 23 Comfort, correct? 24 A. Yes, it is. 25 Q. And on the same page, under inactive

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33 1 ingredients, benzalkonium chloride is listed as an 2 inactive ingredient, correct? 3 A. For this product, benzalkonium chloride is 4 listed as one of the inactive ingredients, and again, 5 I note in the warnings to patients, it says stop use 6 and ask a doctor if you experience continued redness 7 or irritation of the eye. 8 Q. And on the last page, the marketing start 9 date for this drug is February 15, 2011, correct? 10 A. That's what it says, yes. 11 Q. And do you know whether this product is 12 still being sold in the U.S.? 13 A. I -- I don't know, sitting here today. 14 Q. Okay. We can set that aside and go to 15 Exhibit 253. 16 (Exhibit 253 for identification.) 17 Q. BY MS. GO: And take your time to scroll 18 through this exhibit, Dr. Williams. 19 A. Okay. 20 Q. And if you go to Page 2, under uses, one of 21 the uses listed here is relieves redness of the eye 22 due to minor eye irritations; is that correct? 23 A. That's what the document says, yes. 24 Q. And this is a label for Rhoto Cool Max, 25 yes?	35 1 Q. And this is a label for over-the-counter 2 Rhoto Cool, correct? 3 A. So this says it's Rhoto Cooling Eye Drops. 4 Q. And if you scroll to Page 2, under uses, it 5 states relieves redness of the eye due to minor eye 6 irritations; is that correct? 7 A. That's what the document says, yes. 8 Q. And if you go to Page 3, benzalkonium 9 chloride is listed as an inactive ingredient; is that 10 correct? 11 A. Benzalkonium chloride is listed as one of 12 the inactive ingredients on this page, and again, I'd 13 just point out for the consumer patient, the warning 14 is stop use. Ask a doctor if there's -- redness or 15 irritation of the eye lasts. 16 Q. And if you scroll to the very last page, 17 under marketing date, that date is August 21, 2001, 18 correct? 19 A. It is. That's what's stated on this page. 20 Q. Please set that aside. 21 MR. HASFORD: Denise, it looks like we've 22 been going about an hour. Do you think this would be 23 a good time for a break? 24 MS. GO: Yes. I do have one question, if 25 that's all right.
34 1 A. It is, yes. 2 Q. And if we look on Page 3, benzalkonium 3 chloride is listed under inactive ingredients, 4 correct? 5 A. Benzalkonium chloride is one of the 6 inactive ingredients listed on this page, yes. And I 7 note again, it's similar for all these products, but 8 there's a warning to the consumer to stop use, ask a 9 doctor if redness or irritation of the eye lasts. 10 Q. And on the very last page, the marketing 11 start date for this product is May 5, 2014; is that 12 correct? 13 A. Yes, it is. 14 Q. And do you know whether this product is 15 still being sold in the United States? 16 A. I actually don't. I mean, this label was 17 revised February 2023, but I don't know if it's still 18 sold today. I just don't know that, sitting here 19 today. 20 Q. Okay. Thank you. Please set that aside, 21 and let's go to Exhibit 254. 22 (Exhibit 254 for identification.) 23 Q. BY MS. GO: And again, Dr. Williams, please 24 take your time to scroll through Exhibit 254. 25 A. Okay.	36 1 MR. HASFORD: Sure. 2 MS. GO: Thank you. 3 Q. And, Dr. Williams, do you know if Rhoto 4 Cool is still being sold in the United States, the 5 previous drug we looked at? 6 A. I don't know, sitting here today. I don't 7 know. I see where the label was modified, I think, 8 February 2023, but I don't know, sitting here today. 9 MS. GO: Thank you. 10 THE WITNESS: You're welcome. 11 MS. GO: We can go off the record for a 12 break. How long would you like? 13 THE VIDEOGRAPHER: Would you like to have 14 that discussion off the record? 15 MS. GO: Yes. 16 THE VIDEOGRAPHER: One second. We are 17 going off the record at 11:02 A.M. Pacific. 18 (Recess taken.) 19 THE VIDEOGRAPHER: We are back on the 20 record at 11:13 A.M. 21 MS. GO: Welcome back, Dr. Williams. 22 THE WITNESS: Thank you. 23 Q. BY MS. GO: And did you discuss any matters 24 related to this deposition with your counsel during 25 the break?

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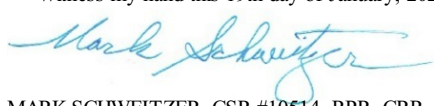
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37 1 A. I did not, no. 2 Q. Thank you. So based on all the drug labels 3 that we went through, do you agree that 4 pharmaceutical formulates would still use BAK with 5 redness relievers after 2008? 6 MR. HASFORD: Objection to the extent it 7 mischaracterizes the documents. 8 THE WITNESS: Well, I mean, the labels have 9 shown that BAK was used in those products after 2008, 10 but I still maintain my opinion that a skilled person 11 would -- a skilled formulation scientist, you know, 12 would understand the literature and the toxicity 13 issues that have been discussed in the literature and 14 the studies done, and that it would not be one that 15 they would consider first. There would be other ones 16 or preservative-free that they would consider. 17 Q. BY MS. GO: But those labels show that 18 pharmaceuticals still used BAK in 2008 and beyond, 19 correct? 20 MR. HASFORD: Objection. Argumentative. 21 THE WITNESS: Well, those labels show BAK 22 was used in those particular products, and I did 23 point out also that there's a warning on the label 24 that those products, you know, if there was 25 irritation or redness, further redness, that they	39 1 Q. BY MS. GO: Of course. Are you aware of 2 any drug labels that are specific to redness 3 relievers showing that they don't use BAK? 4 MR. HASFORD: Object to form. 5 THE WITNESS: I'm not, sitting here today. 6 Q. BY MS. GO: Do you recall providing 7 opinions in your declaration on whether a person of 8 skill in the art would be motivated to use a pH below 9 physiological pH? 10 A. I did discuss that in my declaration in 11 response to Dr. Lascar. 12 Q. Do you know of any specific prior art that 13 states that an eye drop should not be formulated at a 14 pH of 6.5? 15 MR. HASFORD: Do you object to the form? 16 THE WITNESS: Object to the form, correct. 17 I mean, I'm aware in the literature, the goal is to 18 formulate ophthalmic products, generally, and 19 physiological pH, and I'm aware, from being told by a 20 clinician, that, you know, the further a product like 21 an ophthalmic liquid deviates from a physiological 22 pH, like 7.4, that it causes burning, stinging, 23 irritation, and that that, in fact, can, as I 24 explained in my report, cause the, you know, tear 25 product and basically washing out of the drug after
38 1 should stop use and consult a physician. So... 2 Q. BY MS. GO: So you just stated that you did 3 point out the route, the exercise that there were 4 warnings on the labels that we went through that 5 states stop use and ask a doctor if there is further 6 eye redness; is that right? 7 MR. HASFORD: Object to form. 8 THE WITNESS: Well, the warning on the 9 label says further eye redness or irritation from the 10 product containing whatever the active is and the BAK 11 that you pointed out. 12 Q. Are you aware of whether Lumify has the 13 same warning? 14 A. I'd have to look at the label. 15 Q. And do you know whether redness relievers 16 that don't use BAK have the same warning? 17 A. Well, I don't know for sure. If they are 18 monographed, I think the monograph rules on what has 19 to be on the label. 20 Q. And are you aware of any labels for redness 21 relievers that don't use BAK? 22 MR. HASFORD: Object to the form of the 23 question. 24 THE WITNESS: Could you say the question 25 one more time, Ms. Go? Thank you.	40 1 its application. 2 So that -- that's what I'm aware of, you 3 know, a physician telling me that's the problem with 4 a more acidic pH of an ophthalmic solution being 5 applied onto the ocular surface. 6 Q. But you are not aware of anything specific 7 in the prior art that states an eye drop should not 8 be formulated at a pH of 6.5 in particular; is that 9 correct? 10 MR. HASFORD: Object to the extent it 11 mischaracterizes the witness's testimony. 12 THE WITNESS: Well, as I said, in the 13 literature I'm familiar with in my experience, the 14 goal is to formulate an aqueous solution at a 15 physiological pH, you know, neutral, 7.4. And I 16 understand from a clinician, when I asked, as part of 17 this team that would be developing a product, when I 18 asked what are the consequences so that I know from a 19 formulations standpoint what to target, as I 20 explained in my report, that the clinician tells me 21 more acidic pH yields more discomfort in the eye, 22 burning, irritation, which, again, can cause 23 wash-out. And that's -- that's what I know as a 24 formulator, and that's the guidance I take. 25 Q. BY MS. GO: Is there anything specific to a

41 1 pH of 6.5? 2 MR. HASFORD: Object to the form of the 3 question. 4 THE WITNESS: Specific in what regards? 5 Q. BY MS. GO: Is there anything in the 6 literature that is specific toward teaching away from 7 a pH of 6.5 in particular? 8 MR. HASFORD: Object to the form of the 9 question. I'll object to the extent it calls for a 10 legal conclusion. 11 THE WITNESS: So I'm not sure about 12 "teaching away." But as I just said, I mean, I -- as 13 I explained in my report, I -- I ask a clinician as 14 part of the team about attributes of the product I'm 15 developing so that I understand from a formulations 16 standpoint what -- that gives a skilled person, a 17 formulations scientist, direction on developing in 18 this case ophthalmic solution as drops. And that 19 clinician is telling me that for ophthalmic solution 20 drops, that if you're -- the more acidic you are, 21 away from the neutral physiological pH 7.4, the more 22 burning, stinging, irritation that solution causes, 23 which is from a formulations standpoint is 24 detrimental for keeping the solution, you know, as 25 long as possible on the -- on the surface of the eye.	43 1 therapeutic or effective from my understanding. 2 Q. BY MS. GO: But did the clinician mention 3 anything specifically about the pH of 6.5? 4 MR. HASFORD: Same objection. 5 THE WITNESS: I think the clinician was 6 giving -- well, let me just read what I put. 7 I'm looking at my -- I'm not familiar with 8 the exhibit number, but it's my declaration. 9 MS. GO: I believe that's Exhibit 435. 10 THE WITNESS: Thank you. 11 MS. GO: Thank you. 12 THE WITNESS: So in my Paragraph 43 of my 13 declaration, I state I understand from Dr. Noecker 14 that he'll explain, based on his experience when 15 the pH of a formulation is further away from the 16 physiological pH, the likelihood of eye irritation 17 increases, and I understand that Dr. Noecker will 18 explain that administration of an eye drop with an 19 acidic pH, i.e., below pH 7, will often cause burning 20 and stinging or redness. 21 And so therefore, in my opinion, 22 understanding that guidance from a clinician, a POSA 23 formulation scientist, a POSA would not be motivated 24 to formulate that at an acidic pH. 25 Q. Do you whether Dr. Noecker specifically
42 1 So I take that direction. And then I also 2 pointed out, to answer your question, about the 3 knowledge from Alphagan and Alphagan P and a 4 formulation person understanding the difference in pH 5 between the early Alphagan product to the Alphagan P 6 products that change a pH from, you know, more acidic 7 to more basic. With a 1 percent Alphagan P, the pH 8 goes up to 8.0. And so a skilled person would 9 understand that. 10 And the consequences with regards to 11 providing an un-ionized species that better permeate 12 to the site to relieve the redness. 13 Q. BY MS. GO: You mentioned a clinician in 14 your answer, correct? 15 A. I did, yes. 16 Q. Has that clinician ever stated you cannot 17 formulate an eye drop at a pH of 6.5? 18 MR. HASFORD: Object to the extent it 19 mischaracterizes the witness's testimony. 20 THE WITNESS: Well, as I say in my report, 21 the clinician has told me as a POSA, that the more 22 acidic you are, that results from -- that clinicians 23 experience results in a product that burns, stings, 24 and causes eye irritation, again, which is 25 detrimental to that product being able to be	44 1 states that an eye drop should not be formulated at a 2 pH of 6.5? 3 MR. HASFORD: Object to the form. 4 THE WITNESS: I don't recall specifically. 5 I'd have to look through his report. 6 Q. BY MS. GO: Okay. Other than looking 7 through Dr. Noecker's report, are you aware of any 8 literature that specifically states that an eye drop 9 should not be formulated as a pH of 6.5? 10 MR. HASFORD: Object to the form. 11 THE WITNESS: Well, I mean, from my 12 experience, there's literature that says that pH -- 13 you know, you have to -- pH is one of the 14 considerations for formulating an ophthalmic 15 solution, and it's known in the art formulation 16 science that the more acidic you are or a formulation 17 solution is for the eye, the more irritating. So 18 that's known in the literature. 19 Q. BY MS. GO: And I understand that it's not 20 your opinion that an acidic pH is not ideal, but can 21 you point to anything that says that an eye drop 22 should not be formulated as 6.5? 23 MR. HASFORD: Object to the form, and 24 object to the extent it mischaracterizes the 25 witness's testimony.

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12 (45 to 48)

45 1 THE WITNESS: And sorry. Would you mind, 2 Ms. Go, repeating the question? I didn't hear the 3 first part. 4 MS. GO: Of course. 5 THE WITNESS: Thank you. 6 Q. BY MS. GO: So I understand that it's your 7 opinion that an acidic pH is not ideal, but can you 8 point to anything in the literature that states that 9 an eye drop should not be formulated at a pH of 6.5? 10 MR. HASFORD: Object to the form. 11 THE WITNESS: I didn't look specifically 12 for that. So sitting here right now, I -- I don't -- 13 I'm not aware of something -- I would have to look 14 because I just didn't -- I didn't spend time trying 15 to answer that specific question. 16 Q. BY MS. GO: Okay. Thank you. And you 17 mentioned earlier the change in pH between Alphagan 18 and Alphagan P products; is that correct? 19 A. Yes, I did. 20 Q. And do you have any personal knowledge on 21 what caused that change in pH? 22 A. I don't have personal knowledge. I 23 answered -- I analyzed it as a POSA with -- based on 24 what's in the literature and knowledge from the 25 clinician about the target for the brimonidine to	47 1 the deposition of Robert Williams. We are going off 2 the record at 11:29 -- 11:30 A.M. Pacific. 3 (Proceedings concluded at 11:30 A.M.) 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25
46 1 act. 2 THE REPORTER: I'm sorry. For the? 3 THE WITNESS: Brimonidine. It's the active 4 drug in the Lumify product. And so where that drug 5 needed to be delivered. And I also pointed out that 6 your expert, Dr. Dana (phonetic), also says that to 7 the episclera and sclera regions. And so that's why 8 the increase in pH to the Alphagan P level, at least 9 from understanding of providing for nonionized 10 species, which are more permeable through the 11 membrane, that that made sense from a therapeutic 12 activity standpoint. But I don't have direct 13 knowledge as to why the pH was changed. 14 MS. GO: Okay. I think that's all my 15 questions for now. Thank you, Dr. Williams. 16 MR. HASFORD: Nothing from us at this time. 17 And likewise, thank you, Dr. Williams. And 18 Dr. Williams will reserve reading and signing. I 19 don't think I heard anything that necessitates 20 designating the transcript confidential, but we'll 21 review it for that as well. 22 THE VIDEOGRAPHER: Okay to conclude? 23 MS. GO: Yes. Thank you. I appreciate 24 your time, Dr. Williams. 25 THE VIDEOGRAPHER: This marks the end of	48 1 STATE OF CALIFORNIA.)) 2 COUNTY OF LOS ANGELES) 3 4 I, Mark Schweitzer, Certified 5 Shorthand Reporter No. 10514, do hereby 6 Certify: 7 That prior to being examined, the witness 8 named in the foregoing deposition was by me duly 9 sworn to testify the truth, the whole truth, and 10 nothing but the truth; 11 That said deposition was taken down by me 12 in shorthand and thereafter reduced to print by 13 means of computer-aided transcription; and the same 14 is a true, correct, and complete transcript of said 15 proceedings. 16 I further certify that I am not interested in 17 the outcome of the action. 18 Witness my hand this 19th day of January, 2024. 19 20  21 22 MARK SCHWEITZER, CSR #10514, RPR, CRR 23 Certified Shorthand Reporter 24 In and for the State of California 25

Transcript of Robert Williams, III, PhD
Conducted on January 19, 2024

13 (49 to 52)

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1 DECLARATION UNDER PENALTY OF PERJURY

2
3 I, Robert Williams III, Ph.D, do hereby
4 certify under penalty of perjury that I have read the
5 foregoing transcript of my deposition taken Friday,
6 January 19, 2024; that I have made such corrections
7 as appear noted on the Deposition Errata Page
8 attached hereto and signed by me; that my testimony
9 as contained herein, as corrected, is true and
10 correct.

11
12 Dated this _____ day of _____, 2024,
13 at _____.

14
15
16 _____
17 ROBERT WILLIAMS III, Ph.D
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