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Transcript of Stephen G. Davies, DPhil

Date: October 28, 2022

Case: Slayback Pharma LLC -v- Eye Therapies LLC (PTAB)

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October 28, 2022

1 (1 to 4)

1	3
1 UNITED STATES PATENT AND TRADEMARK OFFICE	1 C O N T E N T S
2 -----	2 EXAMINATION OF PROFESSOR STEPHEN G. DAVIES PAGE
3 BEFORE THE PATENT TRIAL AND APPEAL BOARD	3 By Mr. Cassella 5
4 -----	4 By Ms. O'Connell 93
5 SLAYBACK PHARMA LLC,	5 E X H I B I T S
6 Petitioner,	6 (All Exhibits were previously marked.)
7 v.	7 SLAYBACK EXHIBITS PAGE
8 EYE THERAPIES, LLC,	8 Exhibit 1001 U.S. Patent 8,293,742 62
9 Patent Owner.	9 Exhibit 1002 Sher Declaration 14
10 -----	10 Exhibit 1003 Laskar Declaration 14
11 Case IPR2022-00142	11 Exhibit 1004 U.S. Patent 6,294,553 54
12 U.S. Patent No. 8,293,742	12 Exhibit 1006 Norden reference 58
13 -----	13 Exhibit 1007 U.S. Patent 6,242,442 63
14 Deposition of PROFESSOR STEPHEN G. DAVIES	14 Exhibit 1009 Federal Register reference 65
15 Washington, DC	15 1988, 21 CFR Parts 349/369
16 Friday, October 28, 2022	16 Exhibit 1016 Griffith reference 69
17 9:08 a.m.	17 Exhibit 1031 Alphagan® NDA 41
18	18 Exhibit 2020 Noecker Declaration 46
19	19 Exhibit 2022 Davies Declaration 11
20 Job No.: 468946	20
21 Pages: 1 - 100	21
22 Reported By: Dawn M. Hart, RPR/RMR/CRR	22
2	4
1 Pursuant to Notice, before Dawn M. Hart,	1 P R O C E E D I N G S
2 RPR/RMR/CRR.	2 THE VIDEOGRAPHER: Here begins Media No.
3 A P P E A R A N C E S	3 1 in the videotaped deposition of Dr. Stephen G.
4 ON BEHALF OF THE PETITIONER:	4 Davies, in the matter of Slayback Pharma, LLC, v.
5 CHRISTOPHER J. CASSELLA, ESQUIRE	5 Eye Therapies, LLC, in the United States Patent
6 GOODWIN PROCTER LLP	6 and Trademark Office before the Patent Trial and
7 1900 N Street, Northwest	7 Appeal Board, Case No. IPR2022-00142.
8 Washington, DC 20036	8 Today's date is October 28th, 2022. The
9 (202) 346-4000	9 time on the video monitor is 9:08 a.m. The
10 ON BEHALF OF THE PATENT OWNER AND THE	10 videographer today is Peyton Abrams, representing
11 WITNESS:	11 Planet Depos. This video deposition is taking
12 CAITLIN E. O'CONNELL, ESQUIRE	12 place at Finnegan, Henderson, Farabow, Garrett &
13 BRYAN C. DINER, ESQUIRE	13 Dunner, LLC.
14 FINNEGAN, HENDERSON, FARABOW,	14 Would counsel please voice identify
15 GARRETT & DUNNER, LLP	15 themselves and state whom they represent.
16 901 New York Avenue, Northwest	16 MR. CASSELLA: Good morning. This is
17 Washington, DC 20001	17 Chris Cassella of the law firm Goodwin Procter, on
18 (202) 408-4000	18 behalf of the Petitioner.
19 ALSO PRESENT:	19 MS. O'CONNELL: Good morning. This is
20 Kristi McIntyre, Esquire, Bausch & Lomb	20 Caitlin O'Connell. I'm from Finnegan, on behalf
21 Peyton Abrams, Videographer	21 of the Patent Owner and witness. And with me is
22 Diamante Parrish, Notary Public	22 my colleague Bryan Diner, also of Finnegan, and

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5	<p>1 Kristi McIntyre from Bausch.</p> <p>2 THE VIDEOGRAPHER: The Court Reporter</p> <p>3 today is Dawn Hart, representing Planet Depos.</p> <p>4 Would the Notary please swear in the witness.</p> <p>5 PROFESSOR STEPHEN GRAHAM DAVIES</p> <p>6 being first duly sworn or affirmed to</p> <p>7 testify to the truth, the whole truth, and nothing</p> <p>8 but the truth, was examined and testified as</p> <p>9 follows:</p> <p>10 EXAMINATION BY COUNSEL FOR THE PETITIONER</p> <p>11 BY MR. CASSELLA:</p> <p>12 Q Good morning, Dr. Davies.</p> <p>13 A Good morning.</p> <p>14 Q As you just heard, my name is</p> <p>15 Chris Cassella. I represent the Petitioner in</p> <p>16 this case and I'll be taking your deposition</p> <p>17 today.</p> <p>18 Could you please state and spell your</p> <p>19 full name for the record?</p> <p>20 A Stephen Graham Davies. S-T-E-P-H-E-N,</p> <p>21 G-R-A-H-A-M, D-A-V-I-E-S.</p> <p>22 Q Dr. Davies, you're here to testify as an</p>	7	<p>1 deposition, your counsel may make objections, but</p> <p>2 do you understand that unless you're instructed</p> <p>3 specifically not to answer, you must answer my</p> <p>4 questions to the best of your ability despite the</p> <p>5 objection?</p> <p>6 A Yes.</p> <p>7 Q As you can see, we have a Court Reporter</p> <p>8 transcribing everything that's being said today.</p> <p>9 This means that you and I both must make an effort</p> <p>10 to speak slowly and clearly so that the Court</p> <p>11 Reporter can transcribe every word. Do you</p> <p>12 understand?</p> <p>13 A I understand.</p> <p>14 Q We also need to be sure to give verbal</p> <p>15 answers to make sure we have a clear written</p> <p>16 record, so no head nods or hand gestures. Do you</p> <p>17 understand?</p> <p>18 A Yes.</p> <p>19 Q Okay. I'll try to take a five- to</p> <p>20 10-minute break once every hour or so, maybe a</p> <p>21 little less than an hour, and we can take a longer</p> <p>22 break for lunch if we get that far into the day.</p>
6	<p>1 expert witness on behalf of the Patent Owner,</p> <p>2 Eye Therapies, LLC, in this matter, correct?</p> <p>3 A That's correct.</p> <p>4 Q And are you the same Dr. Davies who</p> <p>5 submitted the Declaration of Stephen G. Davies,</p> <p>6 DPhil, in support of Patent Owner's response in</p> <p>7 this matter?</p> <p>8 A I am, yes.</p> <p>9 Q Dr. Davies, have you been deposed</p> <p>10 before?</p> <p>11 A I have, yes.</p> <p>12 Q About how many times?</p> <p>13 A I've lost count. More than a dozen.</p> <p>14 Q So you're probably pretty familiar with</p> <p>15 the way these depositions work, but nonetheless,</p> <p>16 I'd like to go over some ground rules for your</p> <p>17 deposition today just so we're on the same page.</p> <p>18 You understand that I'll be asking you</p> <p>19 questions and your answers will be under oath as</p> <p>20 if you're testifying in court?</p> <p>21 A I understand that.</p> <p>22 Q Now, during the course of the</p>	8	<p>1 If you need any additional breaks, please just let</p> <p>2 me know. The only thing that I ask is if there's</p> <p>3 a question pending, please answer that pending</p> <p>4 question before we break. Is that fair?</p> <p>5 A Okay.</p> <p>6 Q Please listen carefully to my questions</p> <p>7 and let me know if you don't understand my</p> <p>8 questions. If you answer my question, then I'll</p> <p>9 assume that you understood the question; is that</p> <p>10 fair?</p> <p>11 A That's fine.</p> <p>12 Q And do you understand that you are not</p> <p>13 permitted to discuss the substance of your</p> <p>14 testimony with your counsel at any time today?</p> <p>15 A Yes.</p> <p>16 Q Is there any reason that you cannot</p> <p>17 testify truthfully and completely today?</p> <p>18 A No.</p> <p>19 Q Dr. Davies, did you do anything to</p> <p>20 prepare for your deposition today?</p> <p>21 A Well, I read my report, which I brought</p> <p>22 with me, and I met with counsel yesterday.</p>

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<p style="text-align: right;">9</p> <p>1 Q Who did you meet with yesterday?</p> <p>2 A Caitlin O'Connell, Bryan Diner, and</p> <p>3 Kristi McIntyre.</p> <p>4 Q And for about how long did you meet with</p> <p>5 them?</p> <p>6 A We discussed my report for about four</p> <p>7 hours, probably, five hours.</p> <p>8 Q And did you review any other documents</p> <p>9 to prepare for your deposition today?</p> <p>10 A I looked at the ones attached to my</p> <p>11 report, or the, in the Appendix C, the things that</p> <p>12 I had done, looked at. I looked at a few other</p> <p>13 things as well.</p> <p>14 Q Do you recall specifically which</p> <p>15 documents those would have been?</p> <p>16 A Not specifically, no.</p> <p>17 Q Did you review any of the Petitioner's</p> <p>18 expert Declarations?</p> <p>19 A I looked – I read, again, Dr. Laskar's</p> <p>20 report, Dr. Sher's report.</p> <p>21 Q Okay. Other than the attorneys you just</p> <p>22 mentioned, did you discuss your anticipated</p>	<p style="text-align: right;">11</p> <p>1 document that's been stamped Eye Therapies Exhibit</p> <p>2 2022 in the bottom right-hand corner. Do you see</p> <p>3 that?</p> <p>4 A I see that, yes.</p> <p>5 Q Do you recognize this document?</p> <p>6 A Yes, it's my signed Declaration.</p> <p>7 Q Thank you.</p> <p>8 And could you please turn to page 24 of</p> <p>9 73, or I'm sorry, page 24 of your Declaration.</p> <p>10 A Okay.</p> <p>11 Q Which is page 26 of 73 of the entire</p> <p>12 document.</p> <p>13 Are you there?</p> <p>14 A I'm there, yes.</p> <p>15 Q Okay. Is that your signature on the</p> <p>16 bottom of page 24 of Exhibit 2022?</p> <p>17 A It is, yes.</p> <p>18 Q And you reviewed this Declaration before</p> <p>19 signing it, correct?</p> <p>20 A I did, yes.</p> <p>21 Q And by applying your signature to this</p> <p>22 Declaration, you were signaling that the contents</p>
<p style="text-align: right;">10</p> <p>1 testimony with anyone else?</p> <p>2 A No.</p> <p>3 Q So no one at Eye Therapies, LLC?</p> <p>4 A I don't think I know anybody at</p> <p>5 Eye Therapies, LLC.</p> <p>6 Q Anyone at any Bausch & Lomb entity?</p> <p>7 A Well, only Kristi McIntyre.</p> <p>8 Q Okay. Did you speak with any of the</p> <p>9 Patent Owner's other experts?</p> <p>10 A No.</p> <p>11 Q Dr. Davies, I believe you testified</p> <p>12 earlier that you submitted a Declaration in this</p> <p>13 matter; is that right?</p> <p>14 A I did, yes.</p> <p>15 Q Okay. I'm going to hand you a copy of</p> <p>16 your Declaration.</p> <p>17 MR. CASSELLA: And I have four copies,</p> <p>18 so I don't --</p> <p>19 MR. DINER: We can share.</p> <p>20 (A discussion was held off the record.)</p> <p>21 BY MR. CASSELLA:</p> <p>22 Q And, Dr. Davies, I just handed you a</p>	<p style="text-align: right;">12</p> <p>1 of the Declaration were true and correct to the</p> <p>2 best of your knowledge; is that right?</p> <p>3 A That's correct.</p> <p>4 Q How did you prepare this Declaration?</p> <p>5 A By reading Dr. Laskar's report and</p> <p>6 responding to the chemistry aspects therein.</p> <p>7 Q Did you write the first draft of this</p> <p>8 report?</p> <p>9 A I certainly wrote the first draft of my</p> <p>10 experience and qualifications, et cetera. Some of</p> <p>11 the, any of the legal parts were supplied by the,</p> <p>12 by counsel, and then all of the science part comes</p> <p>13 from me in, while I'm explaining to counsel what</p> <p>14 my opinions were.</p> <p>15 Q And just for clarity, if I refer to</p> <p>16 "report" and/or "Declaration," will you understand</p> <p>17 that those are the same thing?</p> <p>18 A I understand that.</p> <p>19 Q Okay. So out of an abundance of</p> <p>20 caution.</p> <p>21 Sitting here today, are you aware of any</p> <p>22 inaccuracies in this Declaration?</p>

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<p style="text-align: right;">13</p> <p>1 A I don't believe so.</p> <p>2 Q Could you please turn to Appendix C of</p> <p>3 your Declaration. I believe it begins on page 70</p> <p>4 of 73.</p> <p>5 A (Complying.)</p> <p>6 Q Are you there?</p> <p>7 A Do you mean 70 or 71?</p> <p>8 Q 71 I guess is the actual substance of</p> <p>9 Appendix C.</p> <p>10 A I'm there, yes.</p> <p>11 Q Okay. And what is Appendix C?</p> <p>12 A This is the list of materials I</p> <p>13 considered when preparing my report.</p> <p>14 Q Did you review all of the documents</p> <p>15 listed here in preparing your Declaration?</p> <p>16 A I believe so.</p> <p>17 Q And does this list contain all of the</p> <p>18 documents you reviewed in preparing your</p> <p>19 Declaration?</p> <p>20 A I believe so.</p> <p>21 Q Did you consider any documents that are</p> <p>22 not listed here that you reviewed in preparing</p>	<p style="text-align: right;">15</p> <p>1 your, next to the entry for Declaration of</p> <p>2 Dr. Sher and Dr. Laskar, at the end of that, those</p> <p>3 entries you say "and the materials cited therein."</p> <p>4 A Okay.</p> <p>5 Q Do you see that?</p> <p>6 A I see that.</p> <p>7 Q And what do you mean when you say you</p> <p>8 considered the materials cited therein?</p> <p>9 A Well, I considered -- I didn't read all</p> <p>10 of them, all of the references therein, but I</p> <p>11 looked at the ones that were relevant to the</p> <p>12 chemistry, that I thought were relevant to the</p> <p>13 chemistry discussion in those reports.</p> <p>14 Q And do you recall which of those</p> <p>15 materials were relevant to the chemistry as you</p> <p>16 put it?</p> <p>17 A I think it was essentially Griffith.</p> <p>18 Q Is Griffith the only reference cited in</p> <p>19 either Sher or Laskar that you reviewed?</p> <p>20 A I don't recall. I'd have to look</p> <p>21 through my report and see what I cite.</p> <p>22 Q So when you reviewed the Declarations of</p>
<p style="text-align: right;">14</p> <p>1 your Declaration?</p> <p>2 A I don't believe there are any.</p> <p>3 Q Who provided the materials listed in</p> <p>4 Appendix C that you considered?</p> <p>5 A Well, counsel provided the patent and</p> <p>6 the expert Declaration of Dr. Sher and Dr. Laskar.</p> <p>7 Griffith's was listed in Dr. Laskar's report so I</p> <p>8 don't remember if I downloaded that or not, or</p> <p>9 they gave it to me. The file wrapper counsel gave</p> <p>10 me. And I believe I produced the Mendoza</p> <p>11 document.</p> <p>12 Q And you mentioned Exhibits 1002 and</p> <p>13 1003, which were the Declaration of Dr. Sher as</p> <p>14 Exhibit 1002 and the Declaration of Dr. Laskar</p> <p>15 which is Exhibit 1003. Did you review those</p> <p>16 Declarations in their entirety?</p> <p>17 A I believe so, yes.</p> <p>18 Q And for each of those Declarations,</p> <p>19 you've considered the materials cited therein; is</p> <p>20 that right?</p> <p>21 A Can you repeat that question?</p> <p>22 Q Sure. In your Exhibit C, and under</p>	<p style="text-align: right;">16</p> <p>1 Dr. Sher and Dr. Laskar, if either of them had</p> <p>2 cited a reference, you did not then go to that</p> <p>3 reference and review that reference separately,</p> <p>4 outside of what was cited in the body of those</p> <p>5 Declarations?</p> <p>6 A Well, I certainly did Griffith.</p> <p>7 Q Okay. Any others that you can recall?</p> <p>8 A I don't recall.</p> <p>9 Q I believe earlier you testified that you</p> <p>10 had not spoken with any of Patent Owner's other</p> <p>11 experts in preparation for this deposition.</p> <p>12 Did you speak with any other Patent</p> <p>13 Owner's experts in preparation for your</p> <p>14 Declaration?</p> <p>15 A No.</p> <p>16 Q Did you speak with anyone other than</p> <p>17 your attorneys in preparing your Declaration?</p> <p>18 A No, I don't believe so.</p> <p>19 Q So no one at Eye Therapies or Bausch &</p> <p>20 Lomb, other than perhaps counsel, in-house counsel</p> <p>21 at Bausch & Lomb?</p> <p>22 A Other than counsel at Bausch & Lomb, I</p>

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