

1 UNITED STATES PATENT AND TRADEMARK OFFICE
2 BEFORE THE PATENT TRIAL AND APPEAL BOARD
3

4 DR. FALK PHARMA GMBH,)
5) IPR2025-00052, U.S. Patent No:
6 Petitioner,) 10,632,069
7)
8 v.) IPR2025-00054 U.S. Patent No:
9) 11,246,828
10 ELLODI PHARMACEUTICALS,)
11 L.P.,) IPR2025-00055 U.S. Patent No:
12) 9,486,407
13 Patent Owner.)
14 -----)

15 CORRECTED TRANSCRIPT

16 - - -
17 Wednesday, November 19, 2025
18 - - -

19 Remote Deposition of MARTYN CHRISTOPHER
20 DAVIES, PH.D., beginning at 1:01 p.m. before Nancy J.
21 Martin, a Registered Merit Reporter, Certified
22 Shorthand Reporter. All parties appeared remotely.

23 REPORTED BY NANCY J. MARTIN
24 CSR. NO. 9504, RMR, RPR
25 PAGES 1 - 129

A P P E A R A N C E S :

NATHANAEL LUMAN PH.D., ESQ.

JARED BUNKER, ESQ.

PHILLIP MINNICK, ESQ.

ALEX WAGNER, ESQ.

KNOBBE MARTENS OLSON & BEAR LLP

3579 Valley Centre Drive

Suite 300

San Diego, California 92130

nate.luman@knobbe.com

(949) 760-0404

Counsel for Petitioner

ISHA AGARWAL, ATTORNEY AT LAW

JONATHAN COUSIN, ESQ.

COOLEY LLP

1299 Pennsylvania Avenue NW

Suite 700

Washington, D.C. 20004

iagarwal@cooley.com

Counsel for Patent Owner

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I N D E X

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EXHIBITS PREVIOUSLY MARKED

NUMBER	Description	Page
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NOTTINGHAM, UNITED KINGDOM
NOVEMBER 19, 2025, WEDNESDAY 1:01 P.M.

MARTYN CHRISTOPHER DAVIES, PH.D.,
was sworn/affirmed,
and testified as follows:

REPORTER MARTIN: May I please have
appearances for the record.

MR. LUMAN: Yes.

This is Nate Luman from the law firm of
Knobbe Martens for petitioner. I'm joined by Jared
Bunker and Phillip Minnick, also of Knobbe Martens,
and we may have Alex Wagner join us from Dr. Falk
Pharma from time to time today.

MS. AGARWAL: This is Isha Agarwal from
Cooley, LLP on behalf of patent owner. We also have
Jonathan Cousin, also from Cooley, LLP.

EXAMINATION

BY MR. LUMAN:

Q. Good afternoon, Dr. Davies.
Can you hear me okay?

A. I can. Thank you very much.

Q. Would you please state your full name and

1 home address for the record.

2 A. Yes. My name is Martyn, M-a-r-t-y-n,
3 Christopher Davies, D-a-v-i-e-s. I live at 4 Hall
4 Grounds Drive in Colston Bassett in Nottingham, in the
5 UK.

6 Q. Do you understand that you're under oath
7 today?

8 A. I do.

9 Q. Is there any reason that you would be unable
10 to give truthful and accurate testimony today?

11 A. I don't believe so.

12 Q. I know you've been deposed before. I'll just
13 do some reminders.

14 Today, the court reporter is going to take
15 down my questions and your answers.

16 Would you agree to give verbal responses
17 today?

18 A. I will.

19 Q. I'm going to try to avoid speaking over you,
20 and I would ask that you would try to avoid speaking
21 over me.

22 Is that okay?

23 A. Yes.

24 Q. If you do not understand a question, please
25 let me know. Otherwise, I'll assume you understood my

1 question.

2 Is that fair?

3 A. Yes.

4 Q. Your attorney may object to a question, but
5 you would still need to answer the question unless you
6 are instructed not to answer.

7 Do you understand that?

8 A. I do.

9 Q. I'll probably take a break every hour or so.
10 If you would like to take a break, let me know, and I
11 would ask that you would first answer a pending
12 question before we take a break.

13 Is that okay?

14 A. That's okay.

15 Q. I understand that you have received a box in
16 the mail concerning today's deposition; is that
17 correct?

18 A. That's correct.

19 MR. LUMAN: Would you please open the box.

20 (Pause.)

21 THE WITNESS: Okay. Thank you.

22 BY MR. LUMAN:

23 Q. So in the box there was two binders; is that
24 right?

25 A. That's correct.

1 Q. Okay. The first binder that is labeled
2 "Volume I," do you have that one?

3 A. I do.

4 Q. Okay. Then there's another one labeled
5 "Volume II"; is that right?

6 A. That's correct.

7 Q. So Volume I, that binder contains your
8 declarations. That's Exhibit 2007 from the first IPR
9 and then the other three IPRs. So there's four
10 Exhibit 2007s there.

11 Is that what your binder contains?

12 A. Contains four exhibits, that's right.

13 Q. And then Volume II, that begins with
14 Exhibit 1001, and there's four Exhibit 1001s in.
15 Those are the patents from the proceedings.

16 Then there's Exhibit 1002, and so on there
17 numerical order, eventually with patent owner exhibits
18 starting at Exhibit 2002 and so forth. And so
19 hopefully, we won't need to go into all of those
20 exhibits today, but we have them in the binders in
21 case we need them.

22 A. Okay.

23 MR. LUMAN: All right. So what I'd like to
24 do, I'd like to start in Volume I at your second tab.
25 That's going to be Exhibit 2007 from IPR 2025-00052.

1 Would you turn there with me, please.

2 (Previously marked Exhibit 2007 was made
3 available to the witness.)

4 THE WITNESS: Yes. I've got you. Thank you.

5 BY MR. LUMAN:

6 Q. And we have that on the screen too. I'm
7 going to try and also have us be able to follow along
8 on the screen.

9 So my first question on this declaration is
10 do you recognize this exhibit?

11 A. I do. It's my declaration of the '069
12 patent.

13 Q. Yes. And on the front there's a "Patent
14 No. 10,632,069."

15 Do you see that?

16 A. I do.

17 Q. And when I said, "'069 patent," that's the
18 patent I'm referring to.

19 Is that okay? Is that right?

20 A. Yes. Thank you.

21 Q. So if I refer to that as "the '069 patent"
22 today, would that be okay?

23 A. Yes.

24 Q. Would you please turn with me to the last
25 page of the exhibit.

1 A. Yes.

2 Q. And that's Page 70. There's a signature
3 there.

4 Do you see that?

5 A. I do.

6 Q. Is that your signature?

7 A. It is.

8 Q. Are there any corrections or edits that you
9 would like to make to this declaration?

10 A. I think there's one addition. I think it's
11 in Paragraph 87, which is on Page 36 of my report, and
12 I guess it's the --

13 Q. Go ahead.

14 A. I'll just wait for you to get to Page 36.

15 Q. All right.

16 A. So you think, I think it's six lines down,
17 the sentence ends with "[0060]."

18 Q. Yes.

19 A. I'd like to add an additional one right
20 there, which is [0064].

21 Q. Okay. So the sentence that starts with "In
22 Example 3" and has a citation. Exhibit 1002 should
23 have an additional Paragraph 65 stated there?

24 A. 64. [0064].

25 Q. Okay. So are there any other corrections or

1 edits you would like to make to the declaration at
2 this time?

3 A. No, I don't believe so.

4 MR. LUMAN: Would you turn with me to
5 Paragraph 24 of this declaration? And let me know
6 when you arrive.

7 (Pause.)

8 THE WITNESS: Thank you.

9 BY MR. LUMAN:

10 Q. Do you see above Paragraph 24 there's a
11 header "Materials Considered"?

12 A. Yes.

13 Q. Did you consider any other documents in
14 preparing your declaration on the '069 patent than the
15 materials described in Paragraph 24?

16 A. I don't believe so.

17 Q. About how many hours did you spend drafting
18 this declaration, would you estimate?

19 A. Sorry. I apologize. It should say -- I
20 think it says in the paragraph, I also reviewed the
21 documents that were in the petition for inter partes
22 review and exhibits, including the declaration of
23 Alan F. Parr. So I've reviewed those -- sorry. I
24 just want to be clear on the record.

25 I've reviewed those, as well as I've also

1 considered these documents in addition.

2 Q. Paragraph 24 does say that -- I'm on Page 8.
3 It says that you did review "the Petition for
4 Inter Partes Review (and exhibits, including the
5 Declaration of Alan F. Parr)."

6 Is that what you're referring to?

7 A. That's correct.

8 Q. And so that is included on Paragraph 24.

9 Is there anything that you considered that's
10 not listed in Paragraph 24 in preparing your opinion
11 regarding this declaration?

12 A. I don't believe so.

13 Q. About how many hours did you spend drafting
14 this declaration, would you estimate?

15 A. It was a lot of work because I had a lot of
16 things to review, and I had to think about the issues.
17 So it would be quite a number of hours. I don't know
18 the exact number, but it would be quite a number of
19 hours and days over a period of time and discussions,
20 obviously, with the Cooley legal team.

21 Q. Can you put any sort of ballpark estimate on
22 the amount of hours? Would it be more than 50 hours?

23 A. I wouldn't be surprised if it was more. I
24 don't know, but I wouldn't be surprised, involving the
25 hours. Again, it was a lot of discussion and a lot of

1 reviewing and discussion. Yeah.

2 Q. Could you say if it was more than 100 hours?

3 A. I don't know. It's just a lot of work.

4 MR. LUMAN: Okay. Let's turn to the
5 second -- I guess let's turn to the third tab in your
6 binder, and let me put it up on the screen too.

7 Can you let me know when you get to the third
8 tab in your binder.

9 (Previously marked Exhibit 2007 was made
10 available to the witness.)

11 THE WITNESS: Yes.

12 BY MR. LUMAN:

13 Q. Are you looking at 2007 from IPR 2025-00054?

14 A. I am.

15 Q. Do you recognize this exhibit?

16 A. This is my declaration with regard to the
17 11,246,828 U.S. patent.

18 Q. Thanks. Would it be okay for you if I refer
19 to that patent as "the '828 patent" today?

20 A. Correct. Yes.

21 Q. Would you turn to the last page of
22 Exhibit 2007 regarding the '828 patent.

23 A. Yes.

24 Q. Do you see a signature on the last page?

25 Page 68.

1 A. I do.

2 Q. Is that your signature?

3 A. It is.

4 Q. Are there any corrections or edits that you
5 would like to make to this declaration?

6 A. The same addition of the same paragraph.
7 Paragraph [0064], wherever that is in this. I didn't
8 look at it fully.

9 Q. Okay. If you'd turn to with me to
10 Paragraph 24 of this declaration, which is
11 Exhibit 2007 for the '828 patent.

12 A. Yes.

13 Q. Do you see there's a header above
14 Paragraph 24 labeled "Materials Considered"?

15 A. Yes.

16 Q. Did you consider any other documents in
17 preparing your declaration on the '828 patent other
18 than the materials described in Paragraph 24?

19 A. I don't believe I did other than the same
20 elements in terms of reading the petition, the
21 petition for inter partes review and Dr. Parr's
22 declaration.

23 Q. If you'll turn to Page 8, still within
24 Paragraph 24, the first full sentence on Page 8 says
25 you have "reviewed the Petition for Inter Partes

1 Review (and exhibits, including the declaration of
2 Alan F. Parr)."

3 Is that what you're referring to?

4 A. That's correct.

5 Q. About how many hours did you spend drafting
6 this declaration?

7 A. All three declarations are included in the
8 hours that I was discussing previously. I looked at
9 them together.

10 Q. Okay. So when we had talked about a number
11 of hours for the '069 patent declaration, you were
12 also referring to this declaration as well on the
13 '828 patent?

14 A. Yes. Also in terms of my review of the
15 comments on the next exhibit. I'm sorry.

16 MR. LUMAN: That's a good idea. Let's turn
17 to that one. Please turn to the last tab in your
18 binder of Volume I.

19 And for the record, this is Exhibit 2007 for
20 IPR 2025-00055.

21 (Previously marked Exhibit 2007 was made
22 available to the witness.)

23 BY MR. LUMAN:

24 Q. Dr. Davies, do you recognize this exhibit?

25 A. I do. It is the U.S. Patent No. 9,486,407.

1 Q. Would it be okay with you if I refer to that
2 patent as the '407 patent today?

3 A. Yes.

4 Q. Would you turn to the last page of this
5 exhibit. Page 80.

6 A. Yes.

7 Q. Do you see that signature there (indicating)?

8 A. I do.

9 Q. Is that your signature?

10 A. It is.

11 Q. Are there any corrections or edits that you
12 would like to make to this declaration?

13 A. I don't believe so, other than the one I've
14 already talked about.

15 MR. LUMAN: Would you turn with me to
16 Paragraph 24, please, and let me know when you arrive.

17 (Pause.)

18 THE WITNESS: Yes, I'm here.

19 BY MR. LUMAN:

20 Q. Did you consider any other documents in
21 preparing your opinion regarding the '407 patent other
22 than the materials described in Paragraph 24?

23 A. No, I did not. I don't believe I did.

24 Q. If I've asked you about how many hours you
25 spent preparing this declaration, how would you answer

1 that question?

2 A. Again, I reviewed all three patents in the
3 context of Dr. Parr's comments. So I'd include that
4 in the -- in how many hours of work that I did on
5 these declarations.

6 Q. And you had said that you wouldn't be
7 surprised if it was more than 50 hours. Can you
8 provide any estimate of the number of hours that you
9 spent collectively on the three declarations that we
10 just looked at?

11 A. Again, I don't know. I wouldn't be surprised
12 if it's more than that 50 hours.

13 Q. More than 100 hours?

14 A. I don't know. I'd give you the same answer.
15 I don't know.

16 MR. LUMAN: Okay. Would you turn with me to
17 the first tab in Volume I of your binders.

18 And for the record, this will be Exhibit 2007
19 from IPR 2024-01197.

20 (Previously marked Exhibit 2007 was made
21 available to the witness.)

22 BY MR. LUMAN:

23 Q. Can you let me know when you arrive there.

24 A. Yes, I'm there.

25 Q. And this declaration concerns U.S. Patent

1 No. 8,771,729; is that right?

2 A. Correct.

3 Q. Would it be okay with you if I refer to that
4 patent as the '729 patent today?

5 A. That's fine.

6 Q. Do you recall that we had a deposition in
7 July of this year regarding this declaration on the
8 '729 patent?

9 A. I do.

10 Q. Are you aware that Ellodi canceled all claims
11 from the '729 patent in October of this year?

12 A. I've been advised that they did, yes.

13 Q. Are you aware that the Board entered adverse
14 judgment against Ellodi regarding the '729 patent?

15 A. I don't know about the judgment. I know that
16 they canceled the claims.

17 Q. So you're not aware the Board entered adverse
18 judgment against Ellodi regarding the '729 patent?

19 MS. AGARWAL: Objection. Asked and answered.

20 THE WITNESS: I don't recall being told.

21 (The Reporter requested clarification.)

22 THE WITNESS: I don't recall being told about
23 that. I may have been, but I don't recall. I was
24 focused on the three patents in play today.

25 BY MR. LUMAN:

1 Q. Does Ellodi canceling the '729 patent and the
2 Board entering adverse judgment against Ellodi on the
3 '729 patent change any of your opinions regarding the
4 '069, '828 or '407 patents?

5 MS. AGARWAL: Objection. Form.

6 THE WITNESS: No, not at all. As I said, I
7 don't think I was aware that they canceled the claims.
8 I wasn't aware about that in the preparation of these
9 reports. I just gave my opinions and what I saw from
10 reading Dr. Parr's declaration and reviewing the
11 patents, et cetera.

12 BY MR. LUMAN:

13 Q. And so that was when you wrote these
14 declarations back in April -- I'm sorry. Not April.
15 These ones were from September of this year, and
16 Ellodi canceled the claim in October.

17 Does Ellodi canceling the claims of the '729
18 patent in October of this year change any of your
19 opinions regarding the '069, '828, and '407 patents?

20 A. No. I don't know the reasons why they did,
21 but they didn't -- because they canceled them, as you
22 say in October, it didn't effect my preparation at
23 all. I just give my opinions. In the preparation of
24 the reports that were submitted in September,
25 certainly I don't know why they've canceled those

1 claims, but certainly, it hasn't affected my opinions
2 because they're my opinions.

3 Q. So they haven't affected your opinions as of
4 today; is that right?

5 A. I don't know why if they've canceled the
6 claims, why it would effect my opinions anyway. My
7 opinions are separate. My opinions are the opinion of
8 me trying to understand Dr. Parr's opinions and giving
9 my opinions to the Court so that they can understand
10 what I think about these patents.

11 Q. And how about the Board entering adverse
12 judgment. Does that change any of your opinions
13 regarding the '069, '828, and '407 patents?

14 MS. AGARWAL: Objection. Form.

15 THE WITNESS: Again, I can only give my
16 opinions. All I can really say is this is what I
17 think. So it hasn't affected my judgment at all. I
18 don't know -- I wasn't aware that they had done that,
19 and certainly, even if I was, I am giving my opinions.

20 (A discussion was held off the record.)

21 BY MR. LUMAN:

22 Q. Dr. Davies, would you turn with me to the
23 last tab in Volume I, and this will be -- for the
24 record, this one is Exhibit 2007 from IPR 2025-00055.

25 Can you let me know when you arrive there.

1 A. I'm there.

2 Q. Would you turn with me to Paragraph 47,
3 please.

4 A. Okay.

5 Q. And I'm looking at the first sentence. The
6 first sentence says, "The orally disintegrating solid
7 pharmaceutical composition claimed in the '407 patent
8 solves these problems."

9 Do you see that?

10 A. I do.

11 Q. My question is: What are "these problems"?
12 What problems are you referring to in Paragraph 47?

13 A. Well, the '407 sets out the prior art. If
14 you look in Paragraph 46, it shows prior treatments
15 "included corticosteroids formulations designed for
16 inhalation that are instead applied to the back of the
17 throat, as well as oral administration of systemically
18 active corticosteroids."

19 And it's saying "These treatments pose
20 undesirable side effects, including candidiasis
21 infection --

22 (The Reporter requested clarification.)

23 THE WITNESS: ... "candidiasis,"
24 c-a-n-d-i-d-i-a-s-i-s, "infection and suppression of
25 immune function."

1 BY MR. LUMAN:

2 Q. So the problems referred to in the first
3 sentence of Paragraph 47 include, at least in
4 Paragraph 46, the candidiasis infection and the
5 suppression of the immune function.

6 Is that fair?

7 A. It includes it. But in Paragraph 45 I say
8 that "Topically depositing a therapeutically effective
9 amount of a topically acting Corticosteroid to the
10 upper gastrointestinal tract (for example, esophagus)
11 is challenging, due to the constant flow of saliva and
12 the peristalsis pushing material down toward the
13 stomach."

14 That's another example.

15 Q. Okay. So if I understand, one of the
16 problems that the '407 patent solves is the challenge
17 due to the constant flow of saliva and peristalsis
18 pushing material down that's referenced in
19 Paragraph 45; is that right?

20 A. It is a challenge, isn't it? If you think
21 about it, the location of treating inflammation
22 topically in the esophagus will always be a challenge
23 because it's not a static environment. You've got
24 constant flow of saliva and you've got the peristalsis
25 pushing material down towards the stomach.

1 Q. How does the orally disintegrating
2 composition claimed in the '407 patent solve the
3 challenge of constant flow of saliva and peristalsis?

4 A. Well, it's very surprising that it works,
5 frankly. The patent is teaching you that an ODT can
6 be used for the topical treatment of eosinophilic,
7 that's e-o-s-i-n-o-p-h-i-l-i-c, esophagitis, or EoE
8 for short.

9 You wouldn't expect -- you have my report.
10 You understand my views. You wouldn't expect an ODT
11 to do that. No ODT had been used for topical
12 administration prior to that, specifically for the
13 esophagus. And given the prior art which uses viscous
14 liquid formulations of a defined volume, taken as one
15 bolus dose, you would have been very surprised that an
16 ODT, as claimed, solves most problems.

17 Q. So I understand that you see it as surprising
18 that it solves those problems, but can you explain to
19 me how the ODT claimed in the '407 patent solves the
20 challenge of the flow of saliva and peristalsis?

21 A. Well, it's a harsh environment, essentially,
22 for it to work in. So the ODT, as claimed,
23 disintegrates within 60 seconds, and then it's
24 swallowed such that it provides topical treatment of
25 the EoE.

1 Given that the prior formulations that it
2 demonstrated clinically to work where a viscous
3 solution of a defined volume taken in one bolus, then
4 you would have been surprised that an ODT would be
5 able to do that.

6 And as the patent shows, it does treat that
7 challenging area of the esophagus. For the first time
8 somebody has used an ODT for topical treatment of the
9 esophagus.

10 Q. So the way the claimed ODT solves the
11 challenge of saliva and peristalsis is just by
12 disintegration and then topically treating the
13 esophagus; is that right?

14 A. I refer you to my last answer where the ODT
15 disintegrates within the mouth. So it should, as far
16 as the USP, disintegrate within 30 seconds. It
17 disintegrates and it's swallowed and it's providing a
18 topical treatment for coverage of the EoE, and as the
19 patent shows, it's able to demonstrate it's clinically
20 effective.

21 Q. Okay.

22 A. Despite the fact that it's -- you have this
23 constant flow of saliva and you have peristalsis, it's
24 a difficult -- the transit time is short within the
25 peristalsis, which we'll talk about later. All these

1 factors. It's surprising it works, and that's, I
2 guess, why we have the patent.

3 Q. I'd like to stay in Paragraph 47. If you can
4 turn to the next page with me, Page 19.

5 Let's see. I'm trying to highlight here.
6 There's like a sentence that begins with
7 "Disintegration of the tablet."

8 Do you see that one?

9 A. Yes.

10 Q. It says, "Disintegration of the tablet and
11 dissolution (drug release) occurs near
12 simultaneously."

13 Do you see that part?

14 A. I do.

15 Q. Is there a distinction between disintegration
16 and dissolution for a solid dosage form?

17 A. Yes. I agree with Dr. Parr. We both agree
18 those are different things.

19 Q. And so what is the distinction between
20 disintegration and dissolution that you're referring
21 to?

22 A. I guess I'm talking disintegration of the
23 tablet is the -- it's disintegrating within 60 seconds
24 to form a solution or dispersion that is swallowed.
25 That this solution refers to the solution of the drug,

1 releasing the drug.

2 Q. When I had asked about disintegration, you
3 had said it's disintegration. What's going on with
4 that disintegration? I guess my problem with your
5 answer was I asked what disintegration was, and you
6 said it's disintegration. Can you give any more
7 insight into what's the distinction between
8 disintegration and dissolution?

9 A. Disintegration is the physical disintegration
10 of the tablet. That's what you mentioned when you use
11 the USP disintegration test. You mention the physical
12 disintegration of the tablet. The physical -- sorry.
13 It's physical integrity.

14 Does that help you?

15 Q. Yeah. You're still using the word
16 disintegration a bit much.

17 Is disintegration like the breakdown of the
18 tablet into smaller particles?

19 A. Correct. It breaks down as far as the USP
20 disintegration test is concerned, and it disintegrates
21 into smaller particles, and there's also once it
22 disintegrates, you get dissolution occurring of the
23 drug. Drug release.

24 Q. Is the dissolution of the drug, is that the
25 drug going into the solution -- is that the drug

1 becoming basically a solute within the solution of
2 saliva?

3 MS. AGARWAL: Objection. Form.

4 BY MR. LUMAN:

5 Q. Let me just ask it this way: Can you
6 describe dissolution in any more detail for me?

7 A. Dissolution is the mechanism by which a drug
8 dissolves into a solution and it's released into
9 solution.

10 Q. In Paragraph 47 you said, "Disintegration and
11 dissolution occur near simultaneously."

12 Why did you say, "near simultaneously"
13 instead of "simultaneously"?

14 A. Because you have to have disintegration first
15 before you have dissolution. So water it has to
16 penetrate the tablet, and the tablet has to start
17 disintegrating for the product to start dissolving
18 into the water and the surrounding saliva, should I
19 say.

20 Q. Okay. Still in Paragraph 47 on Page 29,
21 there's a citation to Exhibit 2020.

22 Do you see that one?

23 A. I do.

24 Q. And there's a quote from Page 5708 of
25 Exhibit 2020 that says, "...liquid [esophageal

1 transit time] lasts approximately 1 to 2 seconds."

2 Do you see that?

3 A. Yes.

4 Q. Do you all liquids have the same esophageal
5 transit time of 1 to 2 seconds?

6 A. It would depend, I guess, on many factors of
7 just quoting from the publication, which is looking at
8 esophageal transit times. It would depend.

9 Q. Is one of the things that esophageal transit
10 time depends on the viscosity?

11 A. Yes. So that's a good example. I'm glad you
12 brought that up.

13 Viscosity could potentially slow down the
14 esophageal transit. That's why -- very clearly why in
15 the prior art you used the viscous solution. It was
16 able to coat and adhere to the surface of the --

17 (The Reporter requested clarification.)

18 THE WITNESS: Able to coat and adhere to the
19 surface so that you could -- of the esophagus so you
20 could have topical treatments using the budesonide of
21 EoE. Clearly, that's the key advantage of the viscous
22 solution, isn't it?

23 As you -- I guess, given that you have an
24 ODT, you would not expect for the reasons I've
25 described in detail in my report, an ODT

1 disintegrating within 60 seconds to achieve the same
2 viscous effect because you wouldn't expect that.

3 BY MR. LUMAN:

4 Q. So a viscous solution can have an esophageal
5 transit time longer than 1 to 2 seconds; right?

6 A. It potentially could. One could imagine
7 that, yes, because -- for the reasons I've described.
8 And that's why, you know, in the context of these
9 patents that we've been discussing in the prior art,
10 you could get a -- that's why -- the advantage of the
11 viscous solution, Dohil, et al. That's D-o-h-i-l, I
12 think.

13 It said you needed a defined volume of a
14 particular viscosity to achieve the coverage to
15 achieve the therapeutic effect.

16 Q. How about viscous solutions that coat the
17 esophagus? What's the esophageal transit time for a
18 viscous solution that coats the esophagus?

19 MS. AGARWAL: Objection. Form.

20 THE WITNESS: Well, clearly, if they coat --
21 if the viscous solution, like the Dohil solution,
22 which has a predefined viscosity and volume, and it's
23 taken in one bolus dose and it coats the surface, it
24 would be adhered to the surface, and it's adhered to
25 the surface sufficiently long such that you have the

1 topical treatment of the EoE by budesonide.

2 (The Reporter requested clarification.)

3 THE WITNESS: Budesonide.

4 BY MR. LUMAN:

5 Q. So a viscous solution that coats the
6 esophagus has an esophageal transit time longer than 1
7 to 2 seconds; right?

8 A. Yes, because it's adhering to the surface,
9 whereas then you are almost pre-programming in the
10 viscosity, you make the solution to a defined
11 viscosity. That's what Dohil did. It was a defined
12 volume to achieve the panesophageal coverage that
13 resulted in the effective therapeutic treatment.

14 And in this context of this Paragraph 47, I
15 am pointing out, you know, it's...

16 Q. You did mention Dohil.

17 A. There's a transit time for -- I'm pointing
18 out that there is a transit time for liquid.

19 Q. All right. You had mentioned Dohil. Would
20 you mind turning to Paragraph 84 in your declaration.
21 And I'll just mention, for the record, that we're
22 still in Exhibit 2007 of IPR 2025-00055.

23 A. Paragraph 84? Yeah.

24 Q. All right.

25 In the third sentence it starts, it says,

1 "Dohil also teaches using a viscosity enhancer to
2 increase the viscosity and deliver a viscous form of
3 budesonide entitled that coats the throat."

4 Do you see that?

5 A. I did.

6 Q. What's a "viscosity enhancer"?

7 A. A viscosity enhancer is an excipient that is
8 used in a formulation, such as the liquid compositions
9 of budesonide, to increase the viscosity of the
10 formulation of the liquid.

11 Q. How does a viscosity enhancer work? How
12 does it increase the viscosity of the formulation?

13 A. It depends on the nature of the viscosity
14 enhancer, but it could include some hydrophilic
15 polymers.

16 (The Reporter requested clarification.)

17 THE WITNESS: Hydrophilic, -p-h-i-l-i-c,
18 polymers.

19 There are examples that are given in Dohil to
20 that effect. It also includes some sugars. There are
21 a number of things that can be used to increase the
22 viscosity.

23 BY MR. LUMAN:

24 Q. How do sugars work as a viscosity enhancer?

25 A. They work by increasing the viscosity of the

1 liquid. They do that by their very presence in the
2 sense that there is a lot of sugar. Imagine when you
3 have sugar through a small volume. If you increase
4 that in the sugar, it increases the viscosity, and it
5 does that by reducing the ability of the liquid to
6 flow by its very concentration.

7 Q. After the sentence we just looked at, there's
8 a citation to Dohil and several paragraphs, including
9 Paragraph 13 is one of the paragraphs and
10 Paragraph 37.

11 Do you see that?

12 A. I do.

13 Q. I'd like to take a look at those paragraphs.
14 And to do so, we're going to have to pull out
15 Volume II.

16 So would you please take -- open up the
17 Volume No. II, and turn to Paragraph -- turn to
18 Exhibit 1002, and let me know when you arrive.

19 A. I have it open.

20 MR. LUMAN: I'll put it up on the screen too.

21 (Pause.)

22 MR. LUMAN: And for the record, we are
23 looking at Exhibit 1002, which is a U.S. patent
24 publication with the first named inventor as Dohil.

25 Q. Dr. Davies, would you turn with me to

1 Paragraph [13] of Exhibit 1002.

2 A. Thank you. [13], 1-3?

3 Q. Yes. I'll move the screen there too.

4 Okay. The first sentence of Paragraph [13]
5 says, "Also provided in the present invention," and it
6 mentions there's "a viscosity-increasing excipient,
7 for example, a topical corticosteroid, such as, for
8 example, budesonide."

9 Do you see that?

10 A. I do.

11 Q. And how does budesonide work as a
12 viscosity-increasing excipient?

13 A. I believe what it's saying is -- if you read
14 that sentence, it's saying that the pharmaceutical
15 composition can comprise a corticosteroid and the
16 viscosity-increasing excipient, for example, the
17 topical corticosteroid, such as, for example,
18 budesonide.

19 So I think it's referring to the first part
20 of the patent.

21 MR. LUMAN: Yes, I see that.

22 Let's take a look at Paragraph [37] of Dohil.

23 (Pause.)

24 BY MR. LUMAN:

25 Q. Can you let me know when you arrive there.

1 A. Sure.

2 Q. I'm looking at the sentence that splits the
3 column. It starts with, "For dissolving tablets."

4 Do you see that sentence?

5 A. I do.

6 Q. It says, "For dissolving tablets, appropriate
7 excipients include those that the resulting liquid
8 viscosity of the dissolved tablet, enabling it to
9 reach the esophagus."

10 Do you see that?

11 A. I do.

12 Q. So what are some of the excipients that
13 increase the resulting liquid viscosity of a dissolved
14 tablet?

15 A. So, for example, the one that was cited
16 previously, the hydroxypropyl methycellulose --

17 (The Reporter requested clarification.)

18 THE WITNESS: In Paragraph [37] --

19 Nancy, I don't know if you can see
20 Paragraph [37].

21 (A discussion was held off the record.)

22 THE WITNESS: There are a number of
23 excipients in that list of No. 37 that could increase
24 the viscosity of a dissolving tablet and -- yeah.
25 There are a number that could include the sugars. It

1 could include the polymers present there. It could
2 include the starches. There are a number of
3 excipients that could be used, but they all need
4 sufficient volume for a dissolving tablet, volume of
5 saliva such that they produce one that they can
6 dissolve and generate the viscosity.

7 And Dohil teaches you, you need between 8,
8 12 mils I believe. That's what you would need for the
9 dissolving tablet.

10 BY MR. LUMAN:

11 Q. You had referred to "the polymers." Are
12 those -- are the polymers you're referring to
13 hydroxypropyl methylcellulose?

14 A. That's one of them.

15 Q. What were the other ones you were referring
16 to?

17 A. It could be methylcellulose. It could be
18 sodium carboxymethyl cellulose. It could be
19 polyvinylpyrrolidone. It depends in the way in which
20 these are used within the formulation. These could
21 equally be used as binders within the formulation,
22 binding particles together so that you can make
23 tablets.

24 So it depends on the -- if you look at -- it
25 depends on the function within the formulation.

1 Q. Okay. Let's go back to your declaration,
2 Exhibit 2007 for IPR 2025-000055. I'd like to stay --
3 I'd like to go back to Paragraph 47, and we'll be on
4 Page 19.

5 Can you let me know when you arrive there?

6 A. I'm here.

7 Q. And in that paragraph there's a citation to
8 Exhibit 2020.

9 Do you see that?

10 A. I do.

11 Q. And there's some ellipsis in your quote from
12 Page 5708 of Exhibit 2020; right?

13 A. Correct.

14 MR. LUMAN: I'd like to turn to Exhibit 2020.
15 That will be in your Volume II binder. It's kind of
16 near the back. Would you let me know when you arrive
17 at Exhibit 2020.

18 (Pause.)

19 THE WITNESS: Thank you.

20 MR. LUMAN: For the record, Exhibit 2020 is
21 an article with the first author's last name Cordova,
22 C-o-r-d-o-v-a, Fraga, F-r-a-g-a.

23 Q. Dr. Davies, are you familiar with this
24 exhibit?

25 A. I am.

1 Q. Would you turn with me to Page 5708.

2 A. Yes.

3 Q. All right. On the right-hand column, under
4 the "DISCUSSION" header, there is the sentence that
5 you quoted with ellipsis in your report. That
6 sentence, it says, "The ETT reported for solid and
7 semisolid meals is between 4 and 8 seconds, whereas
8 the liquid ETT lasts approximately 1 to 2 seconds in
9 healthy people."

10 Do you see that?

11 A. I do.

12 Q. So the 1- to 2-second transit time here is
13 for healthy people; correct?

14 A. Correct.

15 Q. Your declaration left out the healthy people
16 part of that quote. Why did you leave out the healthy
17 people portion of that sentence in your declaration?

18 A. I'm happy to put it in there. I put it in --
19 I just wanted to show that for liquid esophageal
20 transit time, it lasts approximately 1 to 2 seconds.

21 Q. Now, people suffering from EoE, would you
22 consider them to be healthy people or not?

23 A. Clearly, they have a medical condition.

24 Q. Do you believe that the 1- to 2-second
25 transit time, listed on Page 5708 of Exhibit 2020,

1 applies to people that suffer from EoE?

2 A. Well, what we know is that liquid -- what we
3 know is that liquid, in healthy people, is 1 to
4 2 seconds, and it's much faster than solid or
5 semisolid meals, as in this sentence. So the liquid,
6 albeit in healthy people, has faster esophageal
7 transit time for various, which are solid or
8 semisolid.

9 (The Reporter requested clarification.)

10 THE WITNESS: For solid or semisolid.

11 BY MR. LUMAN:

12 Q. So does the 1- to 2-second esophageal transit
13 time on Page 5708 apply to patients with EoE?

14 A. It is illustrative of the fact that you have
15 a limited time in the esophagus. So when patients
16 have EoE, and you are a formulator thinking about how
17 to provide topically a topical coverage of the
18 surface, you wouldn't know that information, and you'd
19 know that there was -- it may be that, you know, you
20 think then what has been used in the past, and Dohil
21 had used viscous liquid solutions.

22 So in spite of the fact that the liquid would
23 spend little time, potentially, within the esophagus,
24 they demonstrated quite clearly you can have coverage
25 of the disease area of the esophagus to treat EoE

1 irrespective of the fact you have this transit time
2 for liquids.

3 And that's interesting, isn't it?

4 Q. So EoE, that's an esophageal disease, and one
5 of the symptoms of EoE is dysphagia; right?

6 A. It is.

7 Q. Is it likely that the esophageal transit time
8 will differ in patients with EoE than for healthy
9 subjects?

10 A. It depends what's in transit, of course.
11 Clearly, in the case of solid and semisolid, I would
12 agree that it would depend on the makeup of what was
13 being swallowed, but if you're a formulator in a
14 development team trying to think, "how do we treat
15 that condition," knowing that liquids, you're going to
16 have a limited time within the affected esophagus,
17 even for those patients with EoE, that does come
18 into -- you'd be thinking, "Well, we'll use the liquid
19 viscous formulation because that's been shown to work"
20 because that simply has this effect of adhering
21 through the affected surface.

22 In this paragraph I'm highlighting the fact
23 that the claimed ODT actually works, and it deposits
24 within that environment despite the fact it isn't a
25 solution of predefined viscosity, despite the fact it

1 doesn't have the volume of the prior art.

2 Q. Well, let's focus on your citation to an
3 esophageal transit time of 1 to 2 seconds. That's in
4 your report, and you cited it.

5 Is it likely that the esophageal transit time
6 of 1 to 2 seconds applies to patients with EoE?

7 A. Again, it depends on what -- what -- the
8 swallowing. Patients with EoE have problems with
9 swallowing, particularly semisolid meals and solid
10 meals.

11 Q. Okay.

12 A. One would understand that. But in terms of a
13 liquid, you know, frankly 1 to 2 seconds is -- in the
14 healthy patients, even if it was a little longer in
15 the infected patients, there's not an awful lot of
16 time for an ODT to deposit a therapeutically affected
17 amount of a topically active corticosteroid on the
18 esophagus, and the short period of time it actually
19 takes for all that liquid or suspension to transit the
20 esophagus.

21 Q. The patients with EoE that have difficulty
22 swallowing, would that make the esophageal transit
23 time longer or shorter than that seen with healthy
24 people?

25 MS. AGARWAL: Objection. Form.

1 THE WITNESS: Well, it depends on -- I've
2 answered this. It depends on the nature of the -- it
3 depends on the nature of what's being swallowed.

4 BY MR. LUMAN:

5 Q. Okay.

6 A. But as I've said, even if for the liquid
7 formulations where the transit time could be a little
8 longer, a few more seconds, I think a person of skill
9 would find it surprising that an ODT, which is
10 effectively in a solution or suspension as it's
11 entering the esophagus, could provide a
12 therapeutically effective amount of a topically acting
13 corticosteroid on the esophagus what would be
14 effectively a short period of time it takes a
15 suspension to transit the esophagus.

16 MR. LUMAN: Let's go back to your first
17 Volume I binder. We're back to the same declaration
18 we've been looking at. That's Exhibit 2007 for IPR
19 2025-00055. I'd like to turn to Paragraph 90.

20 Would you let me know when you arrive there.

21 (Pause.)

22 THE WITNESS: Yeah.

23 BY MR. LUMAN:

24 Q. The last sentence says, "I am also not aware
25 of any fast or quick dissolving lozenges."

1 Do you see that?

2 A. I agree. I'm not aware of -- in the context
3 of this work or in the context of ODTs, I'm not aware
4 of fast or quick dissolving lozenges. I don't think a
5 person of skill reading the patents would have been
6 aware.

7 A person of skill reading Dohil would be
8 thinking of the lozenge in Dohil is a faster, quick
9 dissolving lozenge for the reasons I've described in
10 my report in these surrounding paragraphs.

11 Q. And so that sentence that you're not aware of
12 any fast or quick dissolving lozenges, that was true
13 when you wrote it, and it's true, in your mind, as you
14 sit here today; correct?

15 A. That's correct because it's a contradiction
16 of terms.

17 Q. Okay.

18 A. Lozenges are named in the context of these
19 patents, and even in the context of Dohil, Dohil
20 requires you to generate the viscous solution using a
21 lozenge which disintegrates over a period of minutes,
22 as I've described, given the flowing of saliva that
23 would be generated has the potential to achieve that
24 volume. So you can get the coverage that Dohil
25 teaches you need with that volume of liquid.

1 You can't do that. You wouldn't think based
2 on Dohil that you could do that with an ODT. One
3 would be thinking of using the viscous solution.

4 Q. Would you turn with me to Paragraph 107 of
5 your declaration. Let me know when you arrived,
6 please.

7 A. Okay.

8 Q. I'm looking at the second sentence, and it
9 says, "A POSA reading Dohil would understand that the
10 first disclosure of situate solving tablets or wafers
11 could refer to solid dosage forms that are dissolved
12 in water."

13 Do you see that?

14 A. I do.

15 Q. I'm interested in the word "could." Is there
16 a reason that you put the word "could" there instead
17 of "would"?

18 A. Well, it's a way to explain the presence
19 because of the reason I described. Dohil teaches in
20 this -- teaches that you need a solution of defined
21 volume viscosity to achieve the panesophageal coverage
22 that allows for the topical treatment of the EoE.

23 I think a person of ordinary skill reading
24 Dohil would see, when they're thinking about
25 dissolving tablets or wafers, would be thinking of a

1 way to do that is to have a defined volume, whether it
2 be 8 to 12 mils, and you dissolve it in water, and
3 dissolving tablets and wafers are meant to be used to
4 dissolve in water, and that could be a way to at least
5 achieving the volume.

6 MS. AGARWAL: Counsel, we've been going for
7 about an hour. Good time for a break?

8 MR. LUMAN: I was going to try and wrap this
9 up. I'm not quite done with this paragraph. How
10 about after this paragraph we take a break?

11 MS. AGARWAL: Sure.

12 BY MR. LUMAN:

13 Q. So, Dr. Davies, maybe I wasn't clear.

14 So the sentence that we were looking at on
15 page -- in Paragraph 107, Page 46, it splits the page,
16 and I guess beforehand, it sites Paragraph 13.
17 Paragraph 13 of Dohil, that's -- let's see how we do
18 this.

19 Your sentence says, "A POSA reading Dohil
20 would understand that the first disclosure dissolving
21 tablets or wafers." The first disclosure is
22 Paragraph 13 in Dohil; right?

23 A. I'd have to go and look back at that if you
24 don't mind.

25 Q. Yeah. I don't think you can see it on the

1 screen. I'm looking at the sentence right above. It
2 says --

3 A. I can see it here. Can I look at the other
4 one? (Indicating)

5 Q. Yes, please.

6 (Pause.)

7 THE WITNESS: Yes.

8 BY MR. LUMAN:

9 Q. Okay. So Paragraph 13 refers to "dissolving
10 tablet or a dissolving wafer."

11 A. Correct.

12 Q. And your declaration said that this could
13 refer to solid dosage forms that are dissolved in
14 water but you didn't say that it would refer to solid
15 dosage forms that dissolve in water.

16 Were you trying to say that Paragraph 13 is
17 ambiguous as to what the dissolving tablet refers to?

18 MS. AGARWAL: Objection. Form.

19 THE WITNESS: Well, I was trying to
20 understand what it was in the context of a person of
21 ordinary skill in the context of Dohil. Dohil tells
22 you what's needed of liquid preparations for the
23 treatment of liquid, long-acting topical
24 corticosteroid preparation is needed.

25 I was trying to understand it in that context

1 and in the context of the whole of Dohil. So in that
2 way, you could, if you wanted, take one of those into
3 a predefined volume of water, 8 to 12 mils. I'm
4 trying to see it from the perspective of the person of
5 ordinary skill could potentially use it that way.

6 BY MR. LUMAN:

7 Q. Could a person of skill in the art also
8 potentially read Dohil's Paragraph 13 dissolving
9 tablet as a tablet that would dissolve in the mouth?

10 A. Well, a person of ordinary skill would
11 understand Dohil says nothing about disintegration
12 time. So we don't know how long that is. It could
13 be -- and I suspect to achieve what Dohil is teaching
14 you, to achieve the required volume and viscosity, a
15 dissolving tablet, like a lozenge, has to be in the
16 mouth for a sufficient time that sufficient volume is
17 being generated such that you could get the coverage
18 as taught by Dohil.

19 Q. So would a person --

20 A. That would take many -- a number of minutes,
21 wouldn't it?

22 Q. So Dohil Paragraph 13 could be referring to a
23 dissolving tablet that dissolves in the mouth.

24 Is that fair?

25 A. Well, in the context of Dohil, a dissolving

1 tablet, in the context of Dohil, would be one which
2 dissolves such that it generates the required amount
3 of liquid, i e., it dissolves in sufficient saliva
4 that you get the 8 to 12 mils as shown by Dohil. And
5 to do that, you could do that by a tablet which
6 dissolves over a number of minutes.

7 Q. And that dissolving would be in the mouth;
8 correct?

9 A. It would over a number of minutes. This is
10 not contemplating ODTs at all. It's silent on ODTs.
11 It doesn't mention. It's also silent on
12 disintegration time.

13 Q. I'm just saying the dissolving tablet could
14 refer to a dissolving tablet that dissolves in the
15 mouth.

16 Is that fair?

17 A. I just answered that question. My previous
18 answer. It could be a tablet which dissolves in the
19 mouth over a period of time, a period of minutes, such
20 that based on the reading of Dohil, you need
21 sufficient volume -- like the lozenge, you need
22 sufficient volume such that you get, as the patent
23 teaches you, the 8 to 12 mils that's required to get
24 the panesophageal coverage. Otherwise, you wouldn't
25 get it.

1 MR. LUMAN: Okay. We can take a break.

2 (A recess was taken from 2:21 p.m.

3 to 2:37 p.m.)

4 MR. LUMAN: Dr. Davies, thanks for answering
5 my questions. Mr. Bunker is going to take over for
6 the remainder of today's deposition.

7 MR. BUNKER: Good afternoon, Dr. Davies.

8 MS. AGARWAL: Just for the record, patent
9 owner objects to having two attorneys question
10 Dr. Davies.

11

12 EXAMINATION

13 BY MR. BUNKER:

14 Q. Dr. Davies, I'm going to spend time on the
15 three declarations that you've been discussing
16 already. These are for the three patents '069, the
17 '828, and the '407 patents.

18 In each of those declarations you have a
19 section titled "OBJECTIVE INDICIA OF NONOBVIOUSNESS";
20 is that correct?

21 A. That's correct.

22 Q. And I'm going to be focused on those
23 sections, and to get you oriented I could point you to
24 those in each of your declarations so you can take a
25 minute to review them.

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1 So for the declaration addressing the
2 '069 patent, that's the -052 IPR that's on Page 67 of
3 your declaration, Exhibit 2007.

4 A. Thank you. I know where it is.

5 (A discussion was held off the record.)

6 MR. BUNKER: For the -055 IPR, this is
7 Exhibit 2007 at Page 77.

8 For the -054 IPR, this is Exhibit 2007 at
9 Page 65.

10 Q. Dr. Davies, are you ready?

11 A. I am. Thank you.

12 Q. Just to start out here, what are objective
13 indicia of nonobviousness?

14 A. So I'll refer you back to the legal standards
15 that I was advised about. Essentially, you could read
16 it in those. Essentially, it's post-filing data can
17 be used as evidence of unexpected results and efficacy
18 for nonobviousness.

19 Q. So in your opinion, there is evidence of
20 unexpected results that support the nonobviousness of
21 the claims in each of these three patents?

22 A. I believe, as I say in Paragraph 141 on
23 Page 68, a person of skill, "A POSA would therefore
24 not have thought an orally dispersing tablet
25 containing budesonide would have been efficacious or

1 well tolerated for the treatment of EoE," and I'm
2 talking specifically about the study performed by
3 petitioner, Dr. Falk.

4 Q. Dr. Davies, can you tell me which declaration
5 you're looking at please.

6 A. I apologize. I'm looking at the '069
7 declaration.

8 Q. Do you understand what I mean by "unexpected
9 results" in the context of patent law to determine
10 whether a claim is nonobvious, Dr. Davies?

11 MS. AGARWAL: Objection. Form.

12 THE WITNESS: Well, as it was explained to
13 me, it could be shown in post-filing data, and in this
14 case, the Dr. Falk study is showing evidence of
15 unexpected results, and the unexpected results of
16 Dr. Falk's. I believe a person of skill would not
17 have thought an orally dispersing tablet containing
18 budesonide would have been efficacious or well
19 tolerated in the treatment of EoE.

20 So I was asked to look at the study and give
21 my views on the study.

22 BY MR. BUNKER:

23 Q. In your legal standards section, Dr. Davies,
24 you do not reference unexpected results or explain any
25 legal framework for assessing unexpected results under

1 U.S. patent law; correct?

2 MS. AGARWAL: Objection. Form.

3 THE WITNESS: I'd have to go and look at
4 that. I do say, in Paragraph 34, "the extent of any
5 objective indicia of nonobviousness," and then I say,
6 "I understand that the objective indicia which may be
7 considered in such an analysis include commercial
8 success of the patented invention, whether the
9 invention fills a long-felt but unsolved need in the
10 field, the failure of others to arrive at the
11 invention, industry acquiescence and recognition,
12 initial skepticism of others in the field, whether the
13 inventors proceeded in a direction contrary to
14 accepted wisdom of those ordinary skill in the art."

15 And I think I say, "and the taking of
16 licenses under the patent by others, among other
17 factors."

18 BY MR. BUNKER:

19 Q. Can you point me to where you explain the
20 legal standards for assessing whether unexpected
21 reports support the nonobviousness of challenged
22 claims under U.S. law?

23 MS. AGARWAL: Objection. Form.

24 THE WITNESS: Again, I am not a lawyer. I
25 have just been advised that you can use evidence of

1 unexpected results and efficacy, you know, in ensuring
2 that it wasn't obvious, a particular patent wasn't
3 obvious. That's what I've been advised.

4 BY MR. BUNKER:

5 Q. Were you advised of any legal standards for
6 making that assessment, whether unexpected results
7 support the nonobviousness of any challenged claims
8 under U.S. law?

9 A. Again, I understand that my role here is to
10 look at the study and see whether or not -- as I've
11 said, whether or not the results and efficacy as shown
12 by the study would have been obvious or nonobvious,
13 and it's clear that, to me, somebody of ordinary art
14 in the skill, would have not though such an orally
15 dispersing tablet containing budesonide would have
16 been efficacious or well tolerated of the treatment of
17 EoE.

18 So I'm just giving my view based on what I've
19 been asked to do on this study.

20 Q. So you were not provided with the legal
21 standards for assessing whether, under U.S. law,
22 certain results of a test are unexpected to support
23 the nonobviousness of challenged claims under U.S.
24 law?

25 MS. AGARWAL: Objection. Form.

1 THE WITNESS: Again, I've shown you what I've
2 written and what I've been advised, based on what I've
3 written. I've also shown -- I'm describing to you
4 that my role here was to look at that study, and does
5 the data support the patents in a sense that, you
6 know, they're showing post-filing that it's successful
7 in treatment of EoE as an oral dispersing formulation
8 tablet containing budesonide.

9 I was asked is that clearly shown here, and I
10 believe it is. I'm told that if you find such
11 information, that allows a legal team to provide, show
12 evidence of unexpected results and efficacy for
13 nonobviousness. That's what I was told and that's
14 what I did.

15 BY MR. BUNKER:

16 Q. Are you aware that under U.S. patent law when
17 unexpected results are used as evidence of
18 nonobviousness, those results must be shown to be
19 unexpected compared to the closest prior art?

20 A. Well, I guess what I'm showing is this is
21 unexpected based on the patent, which I guess would be
22 the closest prior art because it's after the patent,
23 and it is.

24 Q. My question was a little bit different.

25 My question was: Are you aware that under

1 U.S. patent law, when unexpected results are used as
2 evidence of nonobviousness, those results must be
3 shown to be unexpected compared to the closest prior
4 art?

5 Are you aware of that?

6 A. Well, I was aware, but if you're talking
7 about I was told that I would be making the comparison
8 against the patents, and the patents are effectively
9 the closest prior art because they're also ODTs. This
10 is also an ODT containing budesonide, and it's shown
11 that it's efficacious and well tolerated for the
12 treatment of EoE just like the prior art in terms of
13 those patents.

14 Q. My question was a little bit different,
15 Dr. Davies.

16 My question was: Are you aware that under
17 U.S. patent law, when unexpected results are used as
18 evidence of nonobviousness, those results must be
19 shown to be unexpected compared to the closest prior
20 art.

21 Are you aware of that?

22 A. Well, if you think the closest prior art
23 isn't the closest prior art of the patents because
24 they're already published.

25 Q. I'm happy to ask that question, but I need

1 you to answer my question first, and then we can
2 answer that question.

3 A. I was told that I was aware that we were
4 comparing it to the patents, which I was told was
5 effectively the prior art. If that answers your
6 question, you know, I'm relying on the legal team to
7 guide me in terms of the legal standards.

8 Q. In your understanding, the patents, meaning
9 the '407 patent, the '069 patent, and the '828 patent,
10 are the closest prior art?

11 MS. AGARWAL: Objection. Form.

12 THE WITNESS: Because they're the ones that
13 have been considered nonobvious for obviousness.
14 They're the ones -- and I'm showing that Dr. Falk
15 having an ODT, and they did this study. Without going
16 through all that, it showed that it was successful.
17 And so in that sense, I'm saying it's clearly, you
18 know, not obvious.

19 BY MR. BUNKER:

20 Q. My question was a little bit different,
21 Dr. Davies.

22 My question is: Is it your position that the
23 patents, the '407, the '069, and the '828 patents are
24 the closest prior art?

25 A. Those are the ones I've been asked to compare

1 to, and in that sense, you know, they are the closest
2 because they're the ones that go after the -- show
3 that an ODT could be used for the topical treatment of
4 EoE using an orally-dispersing tablet with a
5 particular disintegration time.

6 Q. What do you think is the closest prior art to
7 the claims that are challenged in these three patents,
8 the '407 patent, the '069 patent, and the '828 patent?

9 What do you think is the closest prior art?

10 A. Well, I guess the ones that I've reviewed
11 that Dr. Parr has claimed is the closest prior art,
12 which is Dohil, Growther, and there may be more.

13 (The Reporter requested clarification.)

14 THE WITNESS: G-r-o-w-t-h-e-r.

15 And the others that Dr. Parr claims.

16 BY MR. BUNKER:

17 Q. Just to get oriented here, so for the
18 '407 patent, it's your understanding that the claims
19 in the '407 patent are directed to pharmaceutical
20 compositions comprising less than or equal to
21 20 milligrams of a topical corticosteriod that
22 disintegrate within 60 seconds according to the USP
23 test; is that right?

24 A. Which one are you in now. Are you in '407,
25 or are you in '069?

1 Q. '407.

2 A. Thank you. I'd have to look at the patents,
3 which are in my folder, I think.

4 Q. Or you can look in the big binder.

5 (Exhibit Share logistics discussed.)

6 BY MR. BUNKER:

7 Q. If you look starting down on Line 50.

8 A. It's also on Page 20, I guess, of my '407
9 report.

10 Q. And so just to orient you, Dr. Davies, you
11 agree that these claims are directed to
12 "pharmaceutical compositions that comprise less than
13 or equal to 20 milligrams of a topical corticosteriod
14 that disintegrate within 60 seconds according to the
15 USP test, among other requirements?

16 A. Correct.

17 Q. Okay. Now let's turn to the '069 patent.
18 This will be Exhibit 1001.

19 A. I apologize. This also calls Claim 35, which
20 talks about it -- in the '407, which talks about an
21 orally disintegrating solid pharmaceutical
22 composition.

23 Q. Yeah. Correct.

24 A. Okay. I just wanted to be clear.

25 So which one do you want to go to now?

1 Q. Look at the '069 patent, again, Exhibit 1001,
2 '069 patent.

3 And if we look at the claims in the '069
4 patent, if we start with Claim 1, for example, these
5 claims are directed to -- this says Column 18, again,
6 starting at about Line 47. These claims are directed
7 to orally disbursing tablets comprising 0.5 milligrams
8 to 5 milligrams of budesonide that disintegrate within
9 60 seconds in simulated saliva using the USP test,
10 among other requirements; is that correct, Dr. Davies?

11 A. Well, it is the whole -- you're giving a very
12 brief overview, but if you read the whole thing,
13 it's -- yeah.

14 You've given me a very cut-down version of
15 it, but it is an orally dispersing tablet, yeah.

16 Q. And in the '828 patent, those claims in the
17 '828 patent, again, they're directed to orally
18 dispersing tablets of budesonide?

19 A. Correct. Again, in the Falk claim, yeah.

20 Q. In your opinion, is a lozenge with budesonide
21 more similar to the claims of these patents than a
22 liquid solution of budesonide?

23 A. Neither. Neither are similar. It's not a
24 matter of one. It's not similar of one or the other.
25 Neither are.

1 Q. In your -- please continue.

2 A. Sorry. How can one be more -- one is a
3 liquid form and one, a lozenge, certainly doesn't
4 meet -- so liquid form doesn't meet an orally
5 dispersing tablet. A lozenge is also distinct from an
6 orally dispersing tablet, and a lozenge doesn't --
7 will not meet -- disintegrates within 60 seconds and
8 simulates saliva using the USP test.

9 So they're both equally not apply to the
10 claims, or covered by the claims.

11 Q. My question was a little different.

12 My question is not whether they're covered by
13 the claims, but is one more similar to the claims than
14 the other?

15 MS. AGARWAL: Objection. Asked and answered.

16 THE WITNESS: I think they're both not
17 similar. So I wouldn't judge them. I haven't been
18 asked to think about that, but I wouldn't judge either
19 of them to be more similar or less similar because
20 they both don't meet the claims.

21 BY MR. BUNKER:

22 Q. Are there any similarities between a liquid
23 formulation of budesonide and the challenged claims?

24 A. Well, the liquid formulation, as in Dohil,
25 has a defined viscosity, has a defined volume, and it

1 is therapeutically effective in that sense. It is
2 clearly different, and it's not covered by the orally
3 dispersing tablet.

4 Q. Does a lozenge with budesonide have any
5 similarities to the challenged claims of these three
6 patents?

7 A. It depends on how you define any similarities
8 for the reasons I've said. Somebody of ordinary skill
9 looking at a lozenge would not think they're an orally
10 dispersing tablet. So they're not similar at all.

11 Q. Do you agree that an ODT and a lozenge are
12 both solid formulations?

13 A. They are both solid formulations, but that's
14 as far as it goes.

15 Q. Do you agree that --

16 A. You know, you can have solid formulations
17 which only release the drug in the stomach -- in the
18 small intestine. You can have solid formulations
19 that -- all kinds of different formulations, but it's
20 irrelevant.

21 (A discussion was held off the record.)

22 BY MR. BUNKER:

23 Q. Dr. Davies, can we agree that a lozenge of
24 budesonide and an ODT of budesonide both disintegrate
25 in the mouth?

1 A. I agree they both disintegrate from the
2 mouth. The lozenge, in the context of Dohil will
3 disin- -- and in the context of using a lozenge will
4 disintegrate slowly over many minutes.

5 Q. Can we agree that a lozenge of budesonide and
6 an ODT of budesonide are both administered orally to
7 a patient?

8 A. I agree that both are administered orally to
9 a patient, for different reasons, of course.

10 Q. Okay. Switching to the liquid solution, can
11 we agree that an ODT of budesonide disintegrates in
12 the mouth while a liquid solution of budesonide does
13 not?

14 A. I agree. The liquid solution as shown by
15 Dohil is predefined viscosity and volume, and is taken
16 in a single bolus, yeah.

17 Q. And in any of your declarations do you
18 discuss any results of tests that were conducted with
19 patients using any lozenge with budesonide?

20 A. I discuss the use of the term lozenge in the
21 context of Dohil, and lozenge, which is said, contains
22 budesonide. Dohil has no exemplary formulations other
23 than liquid formulations. So they don't test the
24 lozenge clinically.

25 So in that context you can't -- all we know

1 is that, frankly, they don't test any solid dosage
2 form. They only test liquid ones. So in that
3 context, somebody skilled, reading Dohil, looking at
4 the logic will think, how do I mimic a liquid
5 formulation? I mimic it by using a lozenge which
6 releases gradually, dissolves gradually so it
7 generates sufficient volume, but there's nothing in
8 Dohil which shows you any example, exemplary example
9 of a lozenge or any other solid protocol or any
10 clinical data.

11 Q. So we can agree that in your declaration,
12 your three declarations, you do not discuss the
13 results of any tests before the patent, or even after
14 the patent, that were conducted in humans using any
15 lozenge with budesonide; correct?

16 A. I do not for the reasons I described in my
17 last answer.

18 Q. Okay.

19 A. There were none, and Dr. Parr could not point
20 to any in the literature.

21 MR. BUNKER: Let's look at a statement in
22 your declarations.

23 For the record, we'll point to the same
24 statement in each of the declarations, and let's start
25 with the declaration for the '069 patent. So this is

1 Exhibit 2007 for the '069 patent or the -052 IPR.

2 This will be Paragraph 139.

3 THE WITNESS: Yes.

4 BY MR. BUNKER:

5 Q. Paragraph 139, about the middle there's a
6 sentence that says, "A POSA would understand."

7 Do you see that?

8 A. I do.

9 Q. Okay. And you use this term "POSA" in your
10 declarations. That refers to person of ordinary skill
11 in the art; correct?

12 A. Correct.

13 Q. And you're okay if I use the abbreviation,
14 POSA, for our deposition today?

15 A. Yes. That's fine.

16 Q. Here in this sentence you say, "A POSA would
17 understand that Dohil teaches that 8-12 milliliters of
18 a viscous liquid formulation provides pan-esophageal
19 coating that topically delivers an effective dose of
20 budesonide to the esophagus to treat EoE."

21 Did I read that correctly?

22 A. You did.

23 Q. Okay. And if it we turn to your declaration,
24 Exhibit 2007 for the '828 patent, which is the -054
25 IPR, and we turn to Paragraph 137 in that exhibit,

1 about five lines down we see that same sentence;
2 correct?

3 A. Correct.

4 Q. And if we go to your declaration for the
5 other patent, the '407 patent, which is the -055 IPR
6 and we turn to Paragraph 162, which is on Page 77, we
7 see a portion of that same sentence. This is
8 Paragraph 162, about five lines down.

9 It says, "Dohil teaches that 8 to
10 12 milliliters of a viscous liquid formulation
11 provides pan-esophageal coating and delivers an
12 effective dose of budesonide to the esophagus to treat
13 EoE."

14 Did I read that correctly?

15 A. Yes.

16 Q. Okay. Now, is it your position that a person
17 of ordinary skill in -- that a person of ordinary
18 skill reading Dohil would understand that a viscous
19 formulation of budesonide that is less than
20 8 milliliters would be ineffective?

21 A. No.

22 Q. You'd agree --

23 A. Sorry. My point is that Dohil teaches that 8
24 to 12 mils of a viscous liquid formulation provides
25 panesophageal coating and delivers an effective dose

1 of budesonide for the esophagus to treat EoE.

2 And I'm making a point in the last part of
3 the sentence that the claimed ODT could not produce 8
4 to 12 mils.

5 Q. You agree that Dohil teaches that liquid
6 formulations of budesonide as small as 5 milliliters
7 can be effective?

8 A. Yes. That was the example, the first example
9 or second example that they did. They then
10 subsequently did the larger study, and they say
11 clearly -- if you want to go to Dohil, I can show you
12 where they say it.

13 If you go to Dohil Page 8, Paragraph 67,
14 [0067], it says, talking of the viscous budesonide
15 solution, "It may have advantages over other therapies
16 in that it is palatable, its volume (8 to 12 mil)
17 provides pan-esophageal mucosal coverage and it
18 requires only once daily administration."

19 MR. BUNKER: And, for the record, Dohil is
20 Exhibit 1002.

21 Q. Correct?

22 A. That's correct.

23 Q. All right. So let's stay with Exhibit 1002,
24 and if we can look at Page 3, Paragraph [0031].

25 And that Paragraph [0031] spreads between two

1 columns. Do you see that, Dr. Davies?

2 A. That's correct.

3 Q. And looking at the second column, there's no
4 line numbers, but maybe about 10 lines down or so it
5 says, "In an illustrative embodiment," and it goes
6 down from there.

7 Do you see that?

8 A. I do.

9 Q. "In an illustrative embodiment, the dosage is
10 provided in a sufficient volume to allow the
11 composition to reach the esophagus in an effective
12 amount. In general, in a liquid dose, the dosage may
13 be provided in, for example, 5 to 50 milliliters, or
14 for example, 5 to 40 milliliters or, for example 5 to
15 30 milliliters," and it goes on from there; correct?

16 A. Right.

17 Q. All right. So we can agree that Dohil
18 teaches that liquid formulations of budesonide as
19 small as 5 milliliters can be effective at treating
20 EoE?

21 A. It is shown in the example, I think Example 1
22 and 2, that you could use 5 mil, but it also teaches
23 that you could -- you should use 8 to 12 mils. But we
24 can agree that there's 5 mils, though.

25 Q. And staying in Exhibit 1002, Dohil, if you

1 can turn to Paragraph [065], and this spreads on
2 between two pages. We can actually go to Page 8.

3 Roughly seven or eight lines down it says,
4 "Most of the patients responded to 1 milligram daily."

5 Did I read that correctly?

6 A. You did.

7 Q. Okay. So can we agree that Dohil teaches
8 that viscous oral solutions containing as little as 1
9 milligram of budesonide, can be effective at treating
10 EoE?

11 A. I don't agree with your characterization. I
12 think it's saying most of the patients responded to 1
13 milligram daily. So they're responding to
14 1 milligram.

15 Q. In your view, does that indicate that a
16 liquid formulation of budesonide containing
17 1 milligram can be effective at treating EoE?

18 A. Yes. And it's shown in the example that we
19 saw from the -- yes. It's shown, I guess, in the
20 example that we discussed -- that I discussed when we
21 were looking at the -- yeah.

22 Q. I'd like to go back to your declarations. If
23 we can start with your declaration, Exhibit 2007 for
24 the '069 patent. This is the -052 IPR. And if we can
25 turn to Paragraph 139 on Page 67.

1 A. Yeah.

2 Q. The last two sentences -- well, there's a
3 sentence at the bottom of Page 67. It says, "Further,
4 a POSA would have known that oral budesonide
5 administration causes candidiasis," and then it goes
6 on, "and the longer budesonide was held in the mouth,
7 the greater the chance of candidiasis developing."

8 Did I read that correctly?

9 A. You did.

10 Q. Now, for that sentence you have no citation;
11 correct?

12 A. It's the -- well, you could cite the patent.
13 The patent talks, in the first column, about the
14 previous formulations, which were held in the mouth
15 and they have a greater chance of candidiasis
16 developing. That was one of the side effects.

17 Q. Other than the '069 patent, do you have any
18 documentary support for your statement here that a
19 POSA would have known that oral budesonide
20 administration causes candidiasis, and the longer
21 budesonide was held in the mouth, the greater the
22 chance of candidiasis developing?

23 A. Well, the '069 patent is pretty powerful
24 evidence. We also -- also refer to clinical trials
25 where, you know, there were clearly other issues from

1 a safety perspective, but they were looking at
2 candidiasis development and they were looking for the
3 incidence of candidiasis with the tablet formulations.

4 Why were they doing that? Because they would
5 be concerned, because they knew, as the '069 patent
6 would show you, the previous formulations would show
7 that candidiasis could develop by the very fact that
8 the budesonide was in the mouth.

9 Q. Which clinical trials are you referring to,
10 Dr. Davies?

11 A. These are the ones that compared the clinical
12 trials of the budesonide ODT with the liquid solution.
13 I cite to them in my report.

14 Q. If you could find that for me, so we can have
15 a clear record, that would be great.

16 MS. AGARWAL: I believe that's Exhibit 2006.

17 THE WITNESS: That's correct.

18 BY MR. BUNKER:

19 Q. And exhibit 2006 is dated what? 2015,
20 Dr. Davies?

21 A. Right. Yep.

22 Q. Okay. This was not available before the
23 filing date of the '069 patent; is that correct?

24 A. Correct. But it's just illustrative of the
25 fact that people knew that even with new formulations

1 being tested, that they would need to test for
2 candidiasis because they knew that previous budesonide
3 formulations, as described in the '069 patent and in
4 all these patents, illustrates the problem.

5 Q. Going back to your declaration, besides the
6 '069 patent and beside Exhibit 2006, the 2015
7 publication, do you have any documentary support for
8 your statement that a POSA would have known that an
9 oral budesonide administration causes candidiasis, and
10 the longer budesonide was held in the mouth, the
11 greater the chance of candidiasis developing?

12 A. Other than those two documents, I'd have to
13 think about it, but they're pretty important. Before
14 the patent it was known, and after the patent it was
15 known.

16 And so it's an issue with the treatment with
17 budesonide orally, but you have to be concerned about
18 candidiasis. And that's what the patent teaches you
19 in the introduction.

20 Q. Going back to your declaration in that same
21 paragraph, Paragraph 139, after that sentence you
22 say -- again, this is Exhibit 2007 for the -052 IPR,
23 "A POSA would thus further deferred from developing
24 any dosage form that would be held in the mouth and
25 increased the time budesonide resided in the mouth for

1 the risk of increased prevalence on candidiasis."

2 Did I read that correctly?

3 A. You did.

4 Q. Okay. And, again, for that sentence, you
5 have no citation for support; correct?

6 A. Again, it could be the patent. It could be
7 clinical trial publication where, you know, the
8 knowledge that if you're using oral budesonide, you
9 have this problem. But, you know, the person of skill
10 wouldn't be thinking of an ODT at all. They'd be
11 thinking about using a viscous solution, which you're
12 taking one bolus, and it would not be held in the
13 mouth like an ODT.

14 So if a person of skill -- the only reason
15 Dr. Parr comes up with the ODT because of these
16 patents, which is --

17 (Indiscernible crosstalk.)

18 THE WITNESS: -- a hindsight argument anyway.

19 BY MR. BUNKER:

20 Q. Sorry. I didn't mean to cut you off.

21 A. Sorry. I'm just highlighting that a person
22 of skill would have known the problems you can have
23 with candidiasis in the mouth because budesonide
24 suppresses the immune function in the mouth and allows
25 the candidiasis to grow and causes a candidiasis

1 problem, then a person of skill would be thinking, you
2 know, I want to use the liquid formulation because
3 that's what's been shown to work.

4 Q. Dr. Davies, in your view, what documentary
5 evidence supports your statement that "A POSA would
6 thus been further deterred from developing any dosage
7 form that would be held in the mouth and increased the
8 time budesonide resided in the mouth for the risk of
9 increased prevalence on candidiasis"?

10 MS. AGARWAL: Objection. Asked and answered.

11 THE WITNESS: I've answered that. So I've
12 explained that, you know, as the patent teaches you,
13 there's a problem with dealing with oral budesonide,
14 and Dohil also mentioned it.

15 So the problem -- you know, now they're
16 coming up to, you know, if a person of ordinary skill
17 was thinking about developing a budesonide formulation
18 for treatment of EoE, they'd be thinking of an oral
19 viscous solution or some modification of a liquid oral
20 solution, which you take in a bolus and it is not held
21 in the mouth.

22 And I'm just citing in this paragraph, where
23 I've talked about the fact that a viscous liquid works
24 and that Dohil has shown that it does work, and a
25 person of ordinary skill wouldn't have looked for an

1 ODT which has to be held in the mouth. Why would they
2 do that? They could look at a viscous solution
3 because that's shown to be effective.

4 BY MR. BUNKER:

5 Q. So in your view, the patent, the '069 patent
6 and Dohil support your statement that "A POSA would
7 thus been further deterred from developing any dosage
8 form that would be held in the mouth and increased the
9 time budesonide resided in the mouth for the risk of
10 increased prevalence on candidiasis"?

11 A. I think a person of skill would have, when
12 faced with the question to develop a formulation for
13 budesonide treatment of EoE, would have looked at
14 Dohil and used Dohil, the viscous solution.

15 I do not believe, based on, you know, the
16 knowledge that was known and that's cited in the
17 patent, also cited in Dohil, knowledge that was known
18 that budesonide could cause problems with candidiasis
19 in the mouth, I do not believe a person would even
20 think about developing an ODT because Dohil worked, no
21 inference that it didn't work, and why would you
22 develop an alternate formulation, particularly one
23 which has to be held in the mouth.

24 That's my view. Because it would have been
25 knowledge, common knowledge that budesonide orally can

1 cause candidiasis. And that's why the patent talks
2 about it in its introduction.

3 Q. Tell me where in Dohil it says that holding
4 budesonide in the mouth increases the risk of
5 candidiasis.

6 A. I'd have to go and look at it, but certainly,
7 it would be known in the literature, the '069 patent.
8 Dr. Parr doesn't ever challenge the fact that the
9 prior formulations, when sprayed into the mouth, cause
10 candidiasis, as cited in the patent.

11 Q. You reviewed Dohil for -- you reviewed Dohil
12 as you were preparing these declarations; correct,
13 Dr. Davies? You spent a fair amount of time reviewing
14 Dohil?

15 A. I did.

16 Q. Please take a look at Dohil, and tell me
17 where it says that holding budesonide in the mouth
18 increases the risk of candidiasis.

19 THE WITNESS: I'd have to look at it.

20 MR. BUNKER: Take your time.

21 (Pause.)

22 THE WITNESS: I can't find it at the moment,
23 but I believe they did look at candidiasis in the
24 biopsies. But I can't find it at the moment. They
25 did look at the prevalence. I believe they did.

1 BY MR. BUNKER:

2 Q. You can't find it?

3 A. I can't. But that doesn't mean that a person
4 of ordinary skill would know that if you put
5 budesonide into the mouth, like the '069 teaches you,
6 that you could have problems with candidiasis.

7 Q. Besides the patent itself, the '069 patent
8 itself, do you have any documentary support for that
9 position, that a person of skill in the critical date,
10 2009, would know that putting budesonide in the mouth
11 for 60 seconds would cause candidiasis?

12 A. I think a person of skill would know, based
13 on the patent, also based on the substantive work. As
14 such, you can have problems associated with the
15 budesonide residing in the mouth. A person of skill
16 would know that, and I think that would deter a person
17 of skill from -- it would deter a person of skill from
18 actually using such a formulation, an ODT formulation.

19 Q. So you can't point to anything dated before
20 the patent to support that position; correct?

21 A. Well, the patent teaches you that, and that's
22 based on prior art. That's based on the prior
23 experience. So, of course, you'd take that into
24 account. You're just not speaking that the patent
25 teaches that the previous formulations, which were

1 placed in the mouth, one of the problems associated
2 with that is candidiasis. It is --

3 Q. The question was a little bit different,
4 Dr. Davies.

5 My question was: So you can't point to
6 anything dated before the patent that supports your
7 position that a person of ordinary skill in 2009 would
8 think or know that putting budesonide in the mouth for
9 60 seconds would cause candidiasis?

10 A. That's a different question. You can
11 certainly look, if somebody of ordinary skill, as the
12 patent teaches you in the introduction, that when you
13 place budesonide in the mouth, they would be aware
14 that you can have candidiasis, and if you wanted
15 further evidence, you could find that.

16 You could find it before, and you can find it
17 afterward, because, frankly, still after the patents,
18 they were still looking at that issue because they
19 were aware, even they were aware at the time of the
20 patent and they were aware in the subsequent studies,
21 and even Dr. Falk, in their studies, they were aware
22 of the problem, and they studied it to make sure that
23 the formulations didn't cause candidiasis. And they
24 were surprised that they didn't.

25 Q. Dr. Davies, you said you could find it

1 before, but do you have any citation or any document
2 dated before that does support it.

3 Did you find one? Do you cite one?

4 A. I don't need to cite it because it's there
5 and it's not been contested by anyone in this case in
6 the patent. Nobody has contested that such
7 formulations, when you place them in the mouth, can
8 cause candidiasis. That's why, in clinical trials,
9 they test for it. If they felt it wasn't an issue,
10 they wouldn't have tested for it.

11 Q. Dr. Davies, Dohil -- talking about Dohil
12 Exhibit 2007, you agree that a POSA would understand
13 that Dohil is describing a lozenge with budesonide
14 that remains in the patient's mouth for two to three
15 minutes?

16 A. I believe a person of skill would be thinking
17 that a lozenge, if you were going to use a lozenge, it
18 would stay in the mouth for at least two or three
19 minutes.

20 Q. And we can agree that two to three minutes is
21 obviously longer than 60 seconds?

22 A. Correct.

23 Q. Does Dohil say that a lozenge would increase
24 the risk of a patient developing candidiasis?

25 A. Dohil is silent on lozenge and its use other

1 than a single statement. Dohil doesn't show any
2 clinical data. And somebody of ordinary skill
3 knowing, you know, it would be surprising to them that
4 the only way they're using a lozenge is that they have
5 to keep it in the mouth for that period of time.

6 And a person of ordinary skill would be
7 thinking, "Well, wouldn't that have an impact on
8 candidiasis because they have to keep it in." That's
9 what a person of ordinary skill. But the lozenge is
10 described in one sentence or two in the Dohil.

11 Q. So we can agree Dohil does not say that the
12 lozenge would increase the risk of a patient
13 developing candidiasis?

14 MS. AGARWAL: Objection. Form.

15 THE WITNESS: Dohil does not discuss the use
16 of the lozenge. The clinical data that it uses and
17 the only exemplary examples are the liquid
18 formulations. It does not describe in any detail the
19 lozenge and its clinical use.

20 BY MR. BUNKER:

21 Q. Does Dohil say that the lozenge poses an
22 increased risk of any side effect compared to a liquid
23 formulation?

24 A. Dohil barely mentions the lozenge, as I've
25 described in my previous answers. Somebody of

1 ordinary skill, when reviewing this, would think that
2 the only way you achieve the volume and potentially
3 even the viscosity struggle, the only way you could
4 try to match the liquid formulation is to keep it in
5 the mouth for a longer period of time. That would
6 concern a person of ordinary skill.

7 Q. Dr. Davies, my question is a little bit
8 different.

9 Does Dohil say that the lozenge poses an
10 increased risk of any side effect?

11 A. Dohil is largely silent on the clinical use
12 of the lozenge. It doesn't talk about it at all.
13 Dohil only discusses the lozenge primarily in two
14 sentences, and even then it -- you know, it doesn't
15 give you any exemplary examples. It doesn't show you
16 the clinical data. It doesn't discuss it at all,
17 whereas it does discuss in detail the liquid
18 formulation.

19 Q. In your declaration, you expressed the view
20 that if a POSA would formulate budesonide as a solid
21 composition, the POSA would formulate it as a lozenge
22 that required several minutes to dissolve rather than
23 an ODT; correct?

24 A. Correct. Could you point to where I say
25 that, please.

1 Q. Sure. So why don't we start in the
2 declaration Exhibit 2007 for the '069 patent. This is
3 the -052 IPR. We can go to Paragraph 103.

4 A. Yep.

5 (Pause.)

6 BY MR. BUNKER:

7 Q. And we can go there, but you say the same
8 thing in each of the other two declarations; correct?

9 A. I believe that's the case.

10 MR. BUNKER: All right. Let go to your
11 declaration for the '407 patent. This is the -055 IPR
12 Exhibit 2007, '407 patent, -055 IPR, and if we can
13 turn to Page 77.

14 So just to get oriented, I'm going to ask you
15 some questions about Paragraphs 162 and 164. If you
16 want to review those briefly, and let me know when
17 you're ready.

18 (The witness reviewed materials.)

19 THE WITNESS: Yes.

20 BY MR. BUNKER:

21 Q. In these paragraphs, you talk about some
22 formulations or some embodiments that you contend show
23 unexpected safety and efficacy; is that correct?

24 A. Right.

25 Q. I want to make sure I have all the examples

1 that you are pointing to.

2 In my reading, I see an example of a -- well,
3 I see a formulation of 1.5 milligrams of fluticasone.

4 Q. Did I pronounce that correctly?

5 A. You did.

6 Q. I see a formulation of 3 milligrams
7 fluticasone?

8 A. That's correct.

9 Q. And in Paragraph 164 I see an example of a
10 tablet with 1 milligram budesonide; is that correct?

11 A. Sorry. Where?

12 Q. In Paragraph 164 on Page 78 --

13 A. Okay.

14 Q. -- you refer to a formulation that contains
15 1 milligram of budesonide.

16 A. Yes. That's from the Dr. Falk study.
17 Correct.

18 Q. So for this declaration, you're pointing to
19 three examples, the 1.5 milligram fluticasone,
20 3 milligrams fluticasone, and the 1 milligram
21 budesonide; correct?

22 THE WITNESS: Just let me check on it.

23 MR. BUNKER: Sure.

24 (The witness reviewed materials.)

25 THE WITNESS: So those are the three

1 formulations, that's correct. 1.5, 3 milligram
2 fluticasone, and there's a formulation which is 1 mil
3 of budesonide -- 1 milligram of budesonide in a
4 tablet, and they also test 2 milligram of budesonide
5 in a viscous solution.

6 BY MR. BUNKER:

7 Q. Okay. But as far as the ones you contend
8 show unexpected safety and efficacy, it's
9 1.5 milligram fluticasone, 3 milligrams fluticasone,
10 and 1 milligram budesonide; correct?

11 A. Those are the doses that are described in
12 Paragraphs 162 and 163 and 164. And then I go on in
13 165 to talk about the safety in terms of candidiasis.

14 Q. I'm trying to make sure I capture all the
15 examples that you say show unexpected safety and
16 efficacy. Are there others besides those three that I
17 listed, 1.5 milligram fluticasone, 3 milligram
18 fluticasone, 1 milligram budesonide?

19 Did I miss any in your declaration?

20 A. I'd have to look, but I don't believe so.
21 These are part of two very large clinical trials.

22 Q. Okay. All right. Now --

23 THE WITNESS: Could we take a break if
24 you're --

25 MR. BUNKER: Of course. That's fine.

1 THE WITNESS: We've been going an hour and 20
2 minutes.

3 MR. BUNKER: Absolutely. Let's go off for
4 10 minutes.

5 THE WITNESS: That would be great.

6 (A recess was taken from 3:40 p.m.
7 to 3:51 p.m.)

8 BY MR. BUNKER:

9 Q. All right. We're going to start back up.

10 So to get reoriented, Dr. Davies, we've been
11 discussing your declaration, Exhibit 2007 for the
12 '407 patent. That's the -055 IPR; correct?

13 A. Correct.

14 Q. And in Paragraphs 162 through 164 we were
15 discussing the example formulations that you point to
16 as showing unexpected safety and efficacy; is that
17 right?

18 A. I show that they're therapeutically effective
19 and well tolerated. Is that correct? Yeah.

20 Q. And those three examples are 1.5 milligrams
21 fluticasone, 3 milligrams fluticasone, and 1 milligram
22 budesonide. Did I get that correct?

23 A. Those aren't the doses. Those are the
24 tablets that are used, the ODTs that are used. Those
25 aren't the doses, as you know. But those tablets are

1 multiples of them that are used.

2 Q. Do you know whether any of these tablets
3 satisfy all the limitations of the claims that are
4 challenged in the '407 patent?

5 A. In the '407 patent?

6 Q. Yes.

7 A. Well, they certainly satisfied the claim
8 related to the use for the topical. Yes. They
9 certainly satisfy a topical delivery of budesonide and
10 demonstrating its therapeutic effect.

11 Is that what you're asking.

12 Q. No.

13 Do you understand there are 42 -- there are
14 42 claims in the '407 patent?

15 A. As far as the '407, I believe it's the method
16 of treating the inflammatory condition with a
17 pharmaceutical composition comprising less than or
18 equal to 20 milligram of a topically administered
19 corticosteroid under this excipient. That's all met
20 by those two. There has been no significant systemic
21 cortico --

22 (The Reporter requested clarification.)

23 THE WITNESS: I apologize.

24 The composition has no significant systemic
25 glucocorticoid or mineral or corticoid activity after

1 oral administration. And they're both ODTs, and
2 certainly, as my understanding from Dr. Falk and
3 reading that document, the disintegration of
4 swallowing occurs within -- they have to swallow
5 within 90 seconds to 120 seconds. So that would more
6 than likely pass the disintegration test.

7 BY MR. BUNKER:

8 Q. Let me stop you there, Dr. Davies.

9 How do you know that any of these tablets
10 would disintegrate within 60 seconds when tested using
11 USP 701 disintegration test?

12 A. Well, I haven't seen it, but my understanding
13 is I've been told that 162, those tablets did pass the
14 disintegration test.

15 Q. Who told you that? Who told you that,
16 Dr. Davies?

17 A. The legal team, the lawyers. But I haven't
18 seen the data. And with Dr. Falk, I guess when you
19 look at that, the way in which they work, the tablet
20 held at the top of the palate of the mouth, by the
21 tongue, and the people are told within 90 seconds to
22 swallow this. I think it's 90 to 120 seconds.

23 It looks like that would pass -- those kind
24 of formulations would pass, would be rapidly
25 disintegrating in that sense of an ODT.

1 Q. It doesn't say, "rapidly disintegrating,"
2 does it, Dr. Davies?

3 A. Well --

4 Q. What does the claim say?

5 THE WITNESS: I'll go back to it.

6 (The witness reviewed materials.)

7 THE WITNESS: It would disintegrate within
8 60 seconds. I believe it would disintegrate within
9 60 seconds.

10 BY MR. BUNKER:

11 Q. When tested using USP 701 disintegration
12 test; correct?

13 A. Yes.

14 Q. What is "USP 701 disintegration test"?

15 A. It's a USP, United States Pharmacopeia
16 disintegration test.

17 Q. Have you seen any data for any of these three
18 examples, 1.5 milligrams fluticasone, 3 milligrams
19 fluticasone, 1 milligram budesonide, any case data
20 conducted using USP 701 disintegration test?

21 A. I have not seen that data, but I'm advised
22 that certain terms of the Ellodi Pharmaceutical's
23 formulations, that provides that has been done.

24 Q. I don't quite understand.

25 Is it your position that the 1.5 milligram

1 fluticasone and the 3 milligram fluticasone examples
2 that you point to disintegrate within 60 seconds when
3 tested using USP 701 disintegration test?

4 Is that your position?

5 A. I've been advised that they do. I have not
6 seen the data, but I'm advised that they do.

7 Q. And you're advised that by Cooley, the
8 lawyers at Cooley?

9 A. Correct.

10 Q. Were you advised by the lawyers at Cooley
11 that the 1 milligram budesonide example that you point
12 to disintegrates within 60 seconds using USP 701
13 disintegration test?

14 A. No, I was not.

15 Q. Do you have any data from any USP 701
16 disintegration test conducted using the 1 milligram
17 budesonide tablet that you refer to in this
18 declaration to show that it dissolves within 60
19 seconds of that test?

20 A. You mean disintegrate?

21 Q. My apologies. Disintegrate, yes.

22 A. I do not have the data, but I looked at the
23 actual study, and the patients are asked to swallow
24 within 120 seconds. That is an effervescent tablet
25 and, therefore, based on that premise, I believe that

1 would have disintegrated in the mouth within
2 60 seconds.

3 Q. And when you say you "looked at the study,"
4 are you talking about Exhibit 2006?

5 A. Correct.

6 Q. All right. Tell me, where in Exhibit 2006
7 does it say that the tablet disintegrates within
8 60 seconds when tested using USP 701 disintegration
9 test?

10 A. It does not say that, as I've highlighted,
11 but what it does say is that -- excuse me.

12 On Page 2 it's talking about the patients
13 receiving the tablet, placing on the tip of the tongue
14 and pressed gently against the hard palate, and it
15 completely disintegrated by contact with saliva.
16 (Unintelligible), as described, would be swallowed 5
17 to 10 swallows within 90 to 120 seconds.

18 So that's what I've -- in reading that, I
19 think that's clearly, to me, disintegrated within
20 60 seconds.

21 Q. How is that putting in your mouth and
22 swallowing after 90 seconds to 120 seconds mean that
23 it would disintegrate within 60 seconds according to
24 the United States Pharmacopeia test 701 disintegration
25 test?

1 A. Because -- well, this isn't the Pharmacopeia
2 test I've cited in the publication, but a person of
3 ordinary skill leading this, knowing that it's an
4 effervescent tablet would understand that it is
5 disintegrating rapidly, and the patients are being
6 asked to swallow within 90 to 120 seconds. Multiple
7 swallows.

8 That says, to me, and I think it would say to
9 a person of ordinary skill, that that is something
10 that is disintegrating within 60 seconds.

11 Q. Then why would they need to waste 90 seconds?

12 A. Because I guess they were asked to -- within
13 90 to 120 seconds, they talk about, because they ask
14 for it to disintegrate and potentially dissolve the
15 drug. So the drugs are in the solution, and then they
16 swallow.

17 Q. Where in your declaration do you explain that
18 any of these examples, 1.5 fluticasone, 3 milligrams
19 fluticasone, or 1 milligram budesonide meet that
20 requirement of a claim, disintegrate within 60 seconds
21 using USP 701 disintegration test?

22 A. I don't specifically mention that. What I do
23 mention is that I believe these show these are ODTs
24 that are demonstrating after the filing of the patent,
25 that they achieve the effective treatment of EoE. In

1 contrast with the other prior art, which Dohil also
2 demonstrates it. So they're shown to be equivalent in
3 some respects.

4 Q. Going back to the '407 patent, Dr. Davies,
5 the '407 patent, Claim 2 has a requirement that the
6 composition disintegrate within 30 seconds when tested
7 using USP 701 disintegration test; correct?

8 THE WITNESS: I'll have a look at that.

9 (The witness reviewed materials.)

10 THE WITNESS: That's correct.

11 BY MR. BUNKER:

12 Q. In your declaration, you do not explain
13 anywhere that any of those examples, the 1.5 milligram
14 fluticasone, 3 milligram fluticasone, or 1 milligram
15 budesonide examples disintegrate within 30 seconds
16 when tested using USP 701 disintegration test;
17 correct?

18 A. I think I've answered that question.

19 Q. Dr. Davies, you have not answered that
20 question.

21 A. I think I've answered that question. I've
22 told you that I am advised by the parties that the 1.5
23 and 3 milligram fluticasone passed the disintegration
24 test. I haven't seen the data. I've told you that.
25 And my basis for the -- for Dr. Falk is based on the

1 data which we've just discussed in the publication.

2 Q. So you were told by Cooley's attorneys that
3 the 1.5 milligram fluticasone and 3 milligram
4 fluticasone disintegrated within 30 seconds when
5 tested using USP 701 disintegration test?

6 A. I don't believe I was -- it was within
7 60 seconds, I believe. Yeah. Which is in Claim 1 of
8 the '407.

9 Q. My question was about the 30 seconds in
10 Claim 2, Dr. Davies.

11 Were you informed by counsel for Cooley that
12 the 1.5 milligram fluticasone and 3 milligram
13 fluticasone disintegrated within 30 seconds when
14 tested using the USB 701 disintegration test?

15 A. Sorry. I think I've got my head around this
16 wrong. I apologize.

17 I was told by Cooley that it's the -- it's 60
18 seconds, not the 30 seconds. I was not told about the
19 30 seconds. And I think, actually, I was told it's
20 the 1 milligram budesonide, which was Dr. Falk
21 studied, not Ellodi. I apologize for that.

22 Q. Okay. So I want to make sure I'm
23 understanding.

24 So you were told by Cooley's attorneys that
25 the 1 milligram budesonide ODT disintegrates within in

1 60 seconds when tested using USP 701 disintegration
2 test?

3 A. Yes. I believe that's the case. Yeah.

4 Q. Were you told by Cooley's counsel that the
5 1.5 milligram fluticasone or the 3 milligram
6 fluticasone ODTs that you describe in your declaration
7 disintegrate within 60 seconds using USP 701
8 disintegration test?

9 A. I don't believe so, no.

10 Q. Have you seen any data using any of those
11 three examples, 1.5 milligram fluticasone, 3 milligram
12 fluticasone, 1 milligram budesonide, that they
13 disintegrate within 60 seconds when tested using USP
14 701 disintegration test?

15 A. I have answered this question. I have not
16 seen that data, but I've been advised about the data
17 by Cooley.

18 Q. And to clarify, when you say you've been
19 advised by Cooley, you're referring to only the
20 1 milligram budesonide example; correct?

21 A. I believe that's the case, yes.

22 Q. Now, in the claims of the '407 patent,
23 Dr. Davies, if we go back there, and if we look at
24 Claim 6.

25 Let me know when you're ready.

1 A. Yeah.

2 Q. It says, "The method of claim 5, wherein the
3 drug particles have an average particle size of less
4 than about 400 micrometers."

5 Do you see that?

6 A. I do.

7 Q. In your declaration, you do not explain
8 anywhere that any of those three examples,
9 1.5 milligram fluticasone ODT, 3 milligram fluticasone
10 ODT, or 1 milligram budesonide ODT have drug particles
11 with an average particle size of less than about
12 400 micrometers; correct?

13 MS. AGARWAL: Objection. Form.

14 THE WITNESS: I was not asked to look at that
15 by Cooley, no. I've not addressed that.

16 BY MR. BUNKER:

17 Q. If we go down to Claim 9, for example, in the
18 '407 patent, it says, "The method of claim 5, wherein
19 in the ODT further comprises" MCC, and it goes on from
20 there; correct?

21 A. You're talking, to be accurate,
22 microcrystalline cellulose, which is MCC, that's
23 correct.

24 Q. And in your declaration you did not explain
25 anywhere that those three examples, any of them

1 include MCC; correct?

2 MS. AGARWAL: Objection. Form.

3 THE WITNESS: I do not because I was not
4 asked to. I was asked what I've shown in these two
5 reports, which demonstrates that ODTs, these two
6 examples demonstrate that they can be used for
7 treatment of EoE. But I didn't look -- I wasn't asked
8 to look at Claim 9.

9 BY MR. BUNKER:

10 Q. And in your declaration you don't explain how
11 those three examples satisfy all the requirements of
12 the claims in the '407 patent; correct?

13 A. Of all the claims? Is that what you're
14 saying?

15 Q. Yes.

16 A. I've not been asked to look at all those
17 claims, but clearly, in terms of Claim 1, I believe
18 that it satisfies. But I wasn't asked to look at
19 these other claims that you've highlighted.

20 Q. And where in your declaration do you explain
21 that those examples satisfy Claims 1 of the
22 '407 patent?

23 A. Well, there is -- to me, there is a
24 correlation between what is in the clinical trials run
25 by the patent owner and the clinical trials run by

1 Dr. Falk with what's described in Claim 1.

2 I'm just being asked is there an example of
3 an ODT which published after the filing date which
4 demonstrates that an ODT can be used to treat EoE, and
5 I believe those two examples in this case demonstrate
6 that.

7 Q. I didn't ask if there was a correlation
8 between the clinical trials, Dr. Davies. I've asked
9 you where in your declaration do you explain that any
10 of those examples satisfy all the requirements of
11 Claim 1 of the '407 patent?

12 A. I do not say that they require -- I wasn't
13 asked to do that. I wasn't asked to do that. I'm
14 just simply pointing out post-filing date that there
15 is -- there are ODTs out there which match the
16 objectives of the Claim, 1, and they, I believe,
17 demonstrate post-filing date, the unexpected results.
18 That's what I've talked about in these two pages.

19 MR. BUNKER: Let's turn to your declaration
20 for the '069 patent. This is Exhibit 2007 of the '069
21 patent. This is the -052 IPR, and we can turn to
22 Page 67.

23 And I'm going to be asking questions about
24 Paragraphs 139 and 140. Dr. Davies, if you want to
25 read that to get oriented, and let me know when you're

1 ready.

2 (The witness reviewed materials.)

3 THE WITNESS: Thank you.

4 BY MR. BUNKER:

5 Q. And in these paragraphs, you describe a
6 1 milligram budesonide ODT that shows unexpected
7 efficacy and safety; is that correct?

8 A. That's correct.

9 Q. And in these paragraphs, that's the only
10 example that you are pointing to of an ODT that shows
11 unexpected efficacy and safety; correct?

12 A. Well, the '069 refers specifically to
13 budesonide. So I'm referring to the budesonide
14 formulation and, you know, the petitioner's study, and
15 that demonstrates very effectively, to my mind, that,
16 you know, it's surprising that it worked, and it shows
17 post-filing date that I think a person of ordinary
18 skill would not have thought that such an orally
19 dispersing type containing budesonide would have been
20 efficacious or well tolerated for the EoE.

21 It's demonstrating post-filing date, but in
22 fact, there's an example of one that is.

23 Q. This tablet, this ODT, the 1 milligram
24 budesonide, in your declaration you do not explain how
25 the 1 milligram budesonide ODT satisfies all the

1 limitations of Claim 1 of the '069 patent; correct?

2 A. Well, I'm simply showing -- what I've been
3 asked to do is simply showing is this -- I believe
4 that it does. I've been advised, as you know, that
5 the -- in terms of the disintegration, it does. And,
6 look, I believe it does match those claims, but I'm
7 simply providing evidence of unexpected results in
8 efficacy in response to the nonobviousness, and that's
9 what I've done.

10 Q. So we can agree that the '069 patent,
11 Exhibit 1001, the '069 patent, Claim 1 requires that
12 the ODT disintegrate within 60 seconds in simulated
13 saliva when tested using USP 701 disintegration test;
14 correct?

15 A. That's correct.

16 Q. And your basis for saying that the
17 1 milligram budesonide ODT that you describe in your
18 declaration as being unexpectedly safe and
19 efficacious, your basis for saying that it satisfies
20 that limitation is because Cooley's counsel told you
21 it did; correct?

22 A. I'm advised by Cooley's counsel that it did,
23 but I'm demonstrating this is an ODT of budesonide,
24 which is post-filing date, which has demonstrated that
25 it's efficacious and safe, and that, in itself, would

1 be unexpected result. That's what I'm trying to
2 explain.

3 Q. Nowhere in your declaration do you
4 demonstrate that that 1 milligram budesonide ODT
5 disintegrates within 60 seconds using USP 701;
6 correct?

7 A. That's correct. It's not cited within my
8 report, but as I indicated to you, I've been advised
9 it does. But that doesn't take away from the fact
10 that the petitioner's study showed that they could use
11 an ODT which was safe and efficacious after the filing
12 date.

13 MR. BUNKER: In the '069 patent,
14 Exhibit 1001, if you could turn to Claim 6.

15 (Pause.)

16 THE WITNESS: Yes.

17 BY MR. BUNKER:

18 Q. Claim 6 says, "The orally disbursing tablet
19 of claim 5, wherein the excipient is mannitol";
20 correct?

21 A. That's correct.

22 Q. In your declaration, you do not explain or
23 demonstrate that the 1 milligram budesonide ODT
24 includes mannitol; correct?

25 A. That's the wrong exhibit, by the way. I was

1 not asked to do that --

2 Q. And you don't know -- you don't know whether
3 it did or not?

4 A. I was not asked to do that. I do not know.
5 But what I do know is that petitioner's ODT was safe
6 and efficacious in the treatment of EoE. That was
7 after the filing date.

8 A person of skill would be -- as I've said,
9 would not have thought an orally disintegrating tablet
10 containing budesonide would have been efficacious or
11 well tolerated in the treatment of EoE. I'm simply
12 pointing that out.

13 Q. And looking at the '069 patent, Claim 7,
14 says, "The ODT of claim 5, wherein the excipient is
15 sucralose"; correct?

16 A. That's correct.

17 Q. And in your declaration, you do not explain
18 or demonstrate that the 1 milligram budesonide ODT
19 included sucralose; correct?

20 A. That's correct. I was not asked to do that.

21 Q. All right. And you don't know if it did;
22 correct?

23 A. I was not asked to do that.

24 Q. I didn't ask you if you were asked to do it
25 or not.

1 I asked you if you knew that it did have
2 sucralose. I had asked you to confirm that you don't
3 know whether it had sucralose.

4 A. I do not know.

5 Q. Okay. And this '069 patent, again, Claim 8
6 refers to "magnesium stearate"; correct?

7 A. That's correct.

8 Q. And in your declaration, you do not explain
9 or demonstrate that the 1 milligram budesonide ODT
10 included magnesium stearate; correct?

11 A. That's correct. I haven't been asked to give
12 comments of that. I've just been asked to release, as
13 I've described, an ODT as in Claim 1. You know, ODT
14 as in Claim 1, I believe, the Petitioner's study using
15 an ODT for the reasons I've described, which is safe
16 and efficacious, and it's been demonstrated that
17 post-filing date, and I think a person of ordinary
18 skill would have found that surprising and unexpected.

19 MR. BUNKER: Let's turn to your declaration.
20 This is Exhibit 2007 for the '828 patent or -054 IPR,
21 and I'm going to be asking you about Paragraphs 137
22 through 139, if you'd like to read that to get
23 oriented.

24 THE WITNESS: Thank you.

25 MR. BUNKER: Just let me know when you're

1 ready.

2 (The witness reviewed materials.)

3 THE WITNESS: Thank you. I've read it.

4 BY MR. BUNKER:

5 Q. Okay. And then the patent, again, is the
6 '828 patent, which is Exhibit 1001.

7 Looking at your declaration, you describe a
8 1 milligram budesonide ODT that, in your view, shows
9 unexpected safety and efficacy; correct?

10 A. That's correct.

11 Q. Do you point to any other example
12 formulations that show unexpected -- that you're
13 relying on for unexpected results of safety and
14 efficacy?

15 A. I do not because the -- this particular claim
16 requires budesonide. I'm focused on the budesonide
17 formulation that the petitioner, Dr. Falk, published.

18 Q. And in your declaration, you do not explain
19 or demonstrate that that 1 milligram budesonide ODT
20 satisfies all the requirements of Claim 1 of the
21 '828 patent; correct?

22 A. Again, I was just asked -- I did not do that.
23 I was just asked to look at the ODT, and I believe
24 it's an ODT that meets the -- certainly meets the ODT,
25 which is rapidly disintegrating, and as I've

1 demonstrated, a person of skill would be deterred from
2 developing any -- a person of skill would have
3 understood that it's safe and efficacious, and that
4 would have been surprising.

5 Q. Dr. Davies, in all due respect, my question
6 was not whether a person of skill would be surprised.
7 My question was in your declaration, you do not
8 explain or demonstrate that the 1 milligram budesonide
9 ODT satisfied all the requirements of Claim 1 of the
10 '828 patent; correct?

11 A. I was not asked to do that. I was asked to
12 demonstrate that the -- Dr. Falk's study demonstrates
13 that an ODT can be used for the efficacious treatment
14 and is well tolerated, and I point to the fact that
15 that is surprising, and it would be an unexpected
16 result.

17 Q. Again, Dr. Davies, with all due respect, I
18 didn't ask you what you were asked to do. I asked you
19 in your declaration -- in your declaration, you do not
20 demonstrate or explain that the 1 milligram budesonide
21 ODT satisfies all the requirements of Claim 1 of the
22 '828 patent; correct?

23 A. That's correct. I've said that's correct. I
24 was not asked to do that. I was asked simply to
25 comment is this unexpected results, and I talked about

1 the fact that it's unexpected results for an ODT.

2 Q. And in your declaration you do not explain or
3 demonstrate that the 1 milligram budesonide ODT
4 satisfies the requirements of any of the claims in the
5 '828 patent; correct?

6 MS. AGARWAL: Objection. Form.

7 THE WITNESS: It depends on what you mean by
8 that, any other claims. Clearly, I've been asked -- I
9 was asked specifically to look at whether these were
10 unexpected results for an ODT, and I believe they are.

11 BY MR. BUNKER:

12 Q. You don't understand what I mean by "any
13 other claims"?

14 MS. AGARWAL: Objection. Form.

15 THE WITNESS: You mean Claims 2 through 16;
16 is that correct?

17 BY MR. BUNKER:

18 Q. Correct.

19 A. Yes.

20 Q. You agree that in your declaration, you do
21 not explain or demonstrate that the 1 milligram
22 budesonide ODT satisfies the requirements of any of
23 Claims 2 through 16 in the '828 patent?

24 A. I agree it's not in my report because I was
25 not asked to do that. I was asked simply to say is

1 this unexpected results in efficacy in the response to
2 nonobviousness.

3 BY MR. BUNKER:

4 Q. Dr. Davies, in your opinion a person of skill
5 would not have expected an ODT with budesonide that
6 disintegrates in 60 seconds to be efficacious because
7 that POA would recognize that the formulation would
8 generate only about 1 to 2 milliliters of saliva; is
9 that correct?

10 A. It's one of the reasons. You wouldn't
11 expect -- given the fact -- it's one of the reasons
12 because the -- you know, you'd be thinking of the
13 preformed, prior art in Dohil, that the viscosity was
14 determined, a volume was determined, and you took it
15 in a single bolus, that you wouldn't think an ODT
16 which breaks up within 60 seconds, disintegrates
17 within 60 seconds, I believe a person of skill would
18 not think that that would provide effective treatment
19 and safety.

20 Q. You agree that a POA in 2009 would
21 understand that more than one ODT could be
22 administered to a patient in a day; correct?

23 MS. AGARWAL: Objection. Form.

24 THE WITNESS: It depends what you mean by
25 that. If you mean an ODT can be given for systemic

1 administration, yes, absolutely. To my knowledge, and
2 I think to Dr. Parr's knowledge, nobody had used an
3 ODT for topical treatment of the esophagus.

4 BY MR. BUNKER:

5 Q. In your view, a person of ordinary skill
6 would not understand that a patient can be given
7 multiple ODTs in a single day to treat EoE?

8 MS. AGARWAL: Object to form.

9 THE WITNESS: Sorry.

10 I think a person of ordinary skill would not
11 even contemplate that. They would not even
12 contemplate use in ODT for treatment of EoE because
13 there is already out there the viscous formulation or
14 defined volume that you could use or it be shown to
15 demonstrate that you could treat EoE, and it was
16 effective and safe.

17 But, again, I wouldn't even think somebody
18 would do that. You know, if you're thinking of a
19 systemic, you know, yes, of course, you can have
20 multiple tethers. But a person of skill wouldn't even
21 be in that position to think, "I can give multiple
22 doses" because they wouldn't have the expectation of
23 success.

24 BY MR. BUNKER:

25 Q. For the systemic use, you agree that a

1 person of skill in 2009 would recognize that a patient
2 could be administered four ODTs in one day; correct?

3 A. For systemic use, I guess it could be
4 delivered a number of doses in a particular day, yeah,
5 for systemic use. But nobody has ever done that.
6 Nobody that's ever used an ODT has a topical method
7 for EoE.

8 MR. BUNKER: Dr. Davies, why don't we take
9 another break, if that's okay.

10 THE WITNESS: Sure.

11 MR. BUNKER: 10 minutes.

12 (A recess was taken from 4:31 p.m.
13 to 4:41 p.m.)

14 BY MR. BUNKER:

15 Q. Dr. Davies, I wanted to change topics a
16 little bit and just kind of ask you what you did to
17 prepare for deposition today.

18 So to prepare for the deposition today, did
19 you meet with any attorneys?

20 A. I had a Zoom call with the attorneys from --
21 (The Reporter asked for clarification.)

22 THE WITNESS: I apologize.

23 I had a Zoom call with the attorneys from
24 Cooley yesterday, I believe. I also -- as you're
25 probably aware, we had to switch the dates. I also

1 did a Zoom call with them the day -- I think on the
2 Monday before the Tuesday.

3 BY MR. BUNKER:

4 Q. And could you identify all the people who
5 participated in those Zoom calls?

6 A. They're on the call today. Isha and
7 Jonathan.

8 Q. And besides Isha and Jonathan, did you speak
9 with anybody to prepare for your deposition today?

10 A. No, I did not.

11 Q. And to prepare for your deposition today, did
12 you speak with anybody at Ellodi Pharmaceuticals?

13 A. No.

14 Q. During those Zoom calls, did you review
15 documents to prepare for your deposition?

16 MS. AGARWAL: I'll just caution the witness
17 not to reveal any privileged information.

18 THE WITNESS: I reviewed the documents that
19 are in my report, that I cited in my report. Nothing
20 else.

21 BY MR. BUNKER:

22 Q. All right. During your work on these three
23 IPRs, these three declarations, did you provide any
24 documents to the attorneys? And that's just a "yes"
25 or a "no" question.

1 A. Yes, I'm sure I did.

2 Q. Do you recall what documents you provided to
3 the attorneys?

4 A. I guess I provided the ones related to
5 transit in the esophagus. I think I did that one. I
6 can't recall. I'd have to go through them all, but I
7 can't recall all of the ones I did.

8 Q. Did you provide any documents to the
9 attorneys that are not referenced in your report?

10 A. No.

11 Q. Can you approximate the amount of time you
12 spent preparing for your deposition today?

13 A. I guess -- I don't know. I did it over a
14 number of days, reviewing the documents, reading and
15 reading as much as I can. I don't know.

16 Q. And for the -- for this deposition today, are
17 you located in your home?

18 A. I am.

19 Q. And while we were asking questions and
20 discussing, was there anybody else in the room with
21 you?

22 A. No. The house is empty apart from my dog.

23 Q. Besides that box of documents that you
24 received, do you have any other documents with you at
25 the desk or table or wherever you're sitting?

1 A. No.

2 Q. And during the deposition, other than what's
3 been shown on the Zoom, did you pull up any electronic
4 copies of any documents?

5 A. No.

6 Q. And have you had any E-mail or messaging or
7 communication platforms open on your devices?

8 A. No.

9 Q. Your last deposition related to these related
10 proceedings was back in July; is that right?

11 A. That's correct.

12 Q. Between that deposition and today, have you
13 been deposed in any other U.S. proceedings or
14 lawsuits?

15 A. No.

16 MR. BUNKER: Dr. Davies, I don't have any
17 more questions for you at this time. I appreciate the
18 time. Your attorneys might have some questions, but
19 I'm -- I don't have any more right now. Thank you.

20

21 EXAMINATION

22 BY MS. AGARWAL:

23 Q. Martyn, I just have a few questions for you.

24 Do you remember petitioner's counsel asking
25 you about viscosity-enhancing agents?

1 A. I do.

2 Q. And you testified generally that there are
3 some excipients that are viscosity enhancing.

4 Do you remember that?

5 A. I do, yeah.

6 Q. What are those -- what types of excipients
7 would be viscosity enhancing?

8 MR. BUNKER: Objection to form.

9 THE WITNESS: It's been a long afternoon. So
10 I guess you could -- the patent teaches you you can
11 use different kinds of materials that could be used
12 for viscosity-enhancing agents. You can use high
13 molecular polymers which will --

14 (The Reporter requested clarification.)

15 THE WITNESS: High molecular polymers, such
16 as HPMC and there are -- you can use a range of
17 things.

18 So in Dohil they used specifically high
19 concentrations of sugars. When you use high
20 concentrations of sugars, it increases the viscosity,
21 makes the solution flow slower, and effectively, you
22 can -- that's one way of doing it, or you can use
23 polymers, which will -- by the way, which when they
24 dissolve, they tie together, and they will inhibit the
25 flow. And that's a common way of increasing the

1 viscosity.

2 And so the -- so, for example, in a solution
3 you predissolve those polymer or you predissolve the
4 sugars, and those would be used as an example. Those
5 are examples of increasing the viscosity.

6 BY MS. AGARWAL:

7 Q. And you just mentioned Dohil. Let's go to
8 Dohil. That's Exhibit 1002. I'm going to direct you
9 to Paragraph [46].

10 At the top of [46] it says, "EXAMPLE 1."

11 Do you see that?

12 A. Yeah, I'm not seeing that. Sorry. Which
13 exhibit is Dohil? Sorry.

14 Q. 1002.

15 A. Thank you.

16 Q. Just generally, can you explain what this
17 example is describing?

18 A. Okay. So in Example 1, it's describing the
19 treatment of the patient, six-year-old male. They use
20 a particular formulation, and if you go down, sort of
21 relatively the bottom of Column -- the left-hand
22 column on Page 5, an "oral budesonide suspension,"
23 which is Pulmicort, and that is "mixed with about 10
24 packets of sucralose," or Splenda, "a non-absorbed
25 sugar in order to increase the fluid viscosity to be

1 swallowed twice a day." That's the example that's
2 being used there.

3 If you look at this Column 5, you can see
4 that they actually mention viscosity. So they're
5 almost preprogramming the viscosity into a formulation
6 because they're dissolving it up, ensuring it's fully
7 dissolved, and then measuring the viscosity, and they
8 tell you you can add different levels to achieve
9 different viscosities. They tell you ways in which to
10 measure viscosity as well.

11 Q. You mentioned that the budesonide suspension
12 that's given to the patient in Example 1 is 10 packets
13 of the sucralose, Splenda.

14 A. Right.

15 Q. How many grams of the sucralose is that?

16 A. That's 10 grams of sucralose, yes.

17 Q. And if we turn the page --

18 A. According to the preparation, it's about 7 or
19 8 mils. Yeah.

20 Q. If we go to the next page, in Paragraph [53],
21 it starts with "Treatment". This is describing the
22 treatment given to patients in Example 3; correct?

23 A. Correct.

24 Q. And can you just describe what the treatment
25 regiment given here is?

1 A. Yeah, patients received 1.5 to 2 milligrams
2 daily and were instructed not to ingest any solids or
3 liquids. The viscous budesonide was made by mixing
4 0.5 milligram Pulmicort with 5 grams -- that's 5
5 packets of sucralose -- to create a volume of 8 to
6 12 mils, and they took that volume.

7 Q. So would either 5 or 10 grams of Splenda
8 change the viscosity of the suspension that's
9 disclosed in these examples in Dohil?

10 A. Absolutely. It would make them more viscous,
11 and because you're predissolving it, they've got all
12 the time to dissolve it and leave in the solution so
13 they can create the viscosity. Yeah.

14 Q. Let's turn to the '407 patent. This is
15 Exhibit 1001 for the -055 IPR.

16 A. Yep.

17 Q. And I'm going to direct you to Column 17,
18 starting on Lines 38 or 39, for Example 1.

19 Let me know when you're there.

20 A. Yes.

21 Q. Does Example 1 in the '407 patent contain --
22 strike that.

23 Does the ODT in Example 1 of the '407 patent
24 contain 5 grams of sucralose?

25 MR. LUMAN: Objection to form.

1 THE WITNESS: Does the ODT contain 5 grams of
2 sucralose. It does not, I don't think. No.

3 BY MS. AGARWAL:

4 Q. Does it disclose 10 grams of sucralose?

5 MR. LUMAN: Objection to form.

6 THE WITNESS: No, it does not.

7 BY MS. AGARWAL:

8 Q. In your opinion, would the ODT in Example 1
9 in the '407 patent have similar viscosity as the
10 Example 1 or 3 in Dohil?

11 MR. LUMAN: Outside the scope of cross.

12 THE WITNESS: In my view, it would not. In
13 my view, the ODT, you would be thinking it's going to
14 dissolve in a limited amount of saliva, and that
15 amount of saliva, as I've said in my report, is highly
16 bearable depending on the time of day, what the
17 patient's had to drink, where in the disease state,
18 all kinds of things.

19 So when it dissolves, it's not going to
20 produce the same viscosity as the previous example in
21 Dohil. In fact, you would not know what the viscosity
22 is because there's nothing in there really -- there's
23 nothing -- how would you know because it's measured in
24 the viscous solution in Dohil, but in this case, it's
25 difficult to see how you would produce an equivalent

1 viscosity based on the formulation.

2 BY MS. AGARWAL:

3 Q. Changing gears a little bit, do you remember
4 petitioner's counsel asking you about whether the
5 1.5 milligram tablet and 3 milligram tablets of
6 fluticasone that you opine on in your report
7 disintegrate within 60 seconds according to the USP
8 701 disintegration test?

9 A. Yes, I do. Yeah.

10 Q. If we stay in the '407 patent, which is
11 Exhibit 1001 of the -055 IPR, and, again, in
12 Example 1, starting in Column 17, Line 38, what
13 corticosteroid is disclosed in this example?

14 A. Fluticasone propionate.

15 Q. And the example goes from Column 17 on to
16 Column 18 to about Line 23.

17 Do you see that?

18 A. I do.

19 Q. And does Example 1 refer to the USP 701
20 disintegration test?

21 A. It does.

22 Q. And how quickly does the tablet containing
23 fluticasone disintegrate according to Example 1?

24 A. It disintegrated in about 60 seconds or less.

25 Q. Shifting gears again, do you recall

1 petitioner's counsel asking you about the unexpected
2 results of the claimed ODTs?

3 A. I do.

4 Q. Let's go to Exhibit 1002, to Dohil.

5 In general, what formulations are exemplified
6 in Dohil?

7 A. The only formulations that are exemplified in
8 Dohil are viscous solutions.

9 Q. And are those viscous solutions efficacious?

10 A. Yes. Dohil demonstrates that they are
11 efficacious, as I've cited in my reports.

12 Q. And the patents in these IPRs, the '069,
13 '828, and '407 patents claim an ODT; correct?

14 A. Correct.

15 Q. Are those claimed ODTs efficacious?

16 A. Yes.

17 Q. Is that surprising?

18 A. Yes, it's very surprising because a person of
19 ordinary skill, reading Dohil, would not even consider
20 an ODT because an ODT has to disintegrate and dissolve
21 in the mouth in a limited volume, and then contrast to
22 Dohil, which uses a viscous solution where the
23 viscosity is premade, the amount is premade, and it's
24 taken in a single bolus as opposed to multiple
25 swallowings in the case of an ODT.

1 Yeah, it would be surprising. Somebody of
2 skill would not expect an ODT to work as well as a
3 viscous solution of budesonide.

4 Q. And shifting gears one last time, if you
5 could go to Exhibit 2007 for the -052 IPR, and let's
6 go to Paragraph 139.

7 A. 2007; right?

8 Q. Yes. 2007. That's your declaration for the
9 '069 patent.

10 A. Okay. Yes.

11 Q. Do you --

12 MS. AGARWAL: Let me know when you're there.

13 (Pause.)

14 THE WITNESS: Yes.

15 BY MS. AGARWAL:

16 Q. Do you recall petitioner's counsel asking you
17 questions about a sentence that expands -- let me
18 start over.

19 Do you recall petitioner's counsel asking you
20 questions about the sentence that spans Pages 67 to
21 68, starting with, "Further, a POSA would have known
22 that oral budesonide administration causes
23 candidiasis"?

24 A. Yes.

25 Q. And do you recall counsel asked you questions

1 about whether you cite to anything for this position?

2 A. Yes.

3 Q. And you mentioned that -- or you testified
4 that Dohil would support your position here, or the
5 statement here?

6 MR. BUNKER: Objection to form.

7 THE WITNESS: I believe I did.

8 BY MS. AGARWAL:

9 Q. And counsel asked to you find where in Dohil
10 it discusses candidiasis; right?

11 MR. BUNKER: Objection to form.

12 (A discussion was held off the record.)

13 THE WITNESS: Yes.

14 BY MS. AGARWAL:

15 Q. If you go to Dohil, Exhibit 1002, to
16 Paragraph [57]. What is this paragraph discussing?

17 A. Paragraph [57]?

18 Q. Yes.

19 A. It's -- it's talking about the results. It's
20 one of those sections talking about the results, and
21 it's talking about initially cortico levels, and then
22 it's talking about gained weight. It's talking about
23 the safety aspects of the formulation.

24 Then it says, "No adverse effects
25 attributable to OVB were noted except for one child

1 with low IgG which developed esophageal candida."

2 So what that last sentence demonstrates is
3 primarily talking about safety. In Dohil, they were
4 interested in whether or not esophageal candidiasis
5 was present, and they found that in only for one child
6 with lower IgG they developed esophageal candida.

7 So they were looking for, what I said, person
8 of ordinary skill would follow the patent, and after
9 the patents were filed, particularly that you'd need
10 to look at candidiasis when dealing with oral
11 formulations of budesonide.

12 MS. AGARWAL: Thank you. I have no further
13 questions.

14 MR. BUNKER: Dr. Davies, I have a few
15 follow-up questions for you.

16
17 FURTHER EXAMINATION

18 BY MR. BUNKER:

19 Q. So staying in this Paragraph [57] in Dohil,
20 which is Exhibit 1002 that you were looking at,
21 Paragraph [57] references "candida"; is that right?

22 A. Yes.

23 Q. And this is discussing a patient who had
24 taken liquid formulation of budesonide; is that right?

25 A. That's correct.

1 Q. This does not say that holding budesonide in
2 the mouth is increasing the risk of candidiasis;
3 right?

4 A. It doesn't say those words, but the reason
5 they're doing this is because they know that
6 budesonide, when taken orally, can have an impact on
7 the immune system orally, and you can have candidiasis
8 prevalent, and that's why they're measuring it. If
9 they didn't think there would be any problem, they
10 wouldn't measure it, but because the prior art teaches
11 them, and people would know this, they have to measure
12 it because that's one of the clinical implications
13 that they need to tell the public, you know, that they
14 also refer to low incidence of candidiasis.

15 Q. Does that say that holding budesonide in the
16 mouth presents an unacceptable, unacceptable risk of
17 developing candidiasis?

18 MS. AGARWAL: Objection. Form.

19 THE WITNESS: Again, what it does say -- and
20 I think I've answered you multiple times on this, is
21 that even with a liquid formulation that you take with
22 a single bolus, it will touch the side of the mouth.
23 They want to look to see whether they get candidiasis.

24 Because -- the reason they do that is because
25 they've known previous attempts at treatment using

1 budesonide with different formulations have caused a
2 problem with candidiasis, and it's because of the
3 problem of candidiasis, because there has been
4 residual budesonide in the mouth.

5 Therefore, that's the reason why they're
6 doing this. If they felt there would be, you know --
7 I hope that answers your question.

8 BY MR. BUNKER:

9 Q. Let's turn to your declaration for the
10 '407 patent. So this is Exhibit 2007 for the
11 '407 patent, and the -- this is the -055 IPR, and
12 we're going to look at Paragraph 162.

13 If you can let me know when you're ready.

14 A. 162. Thank you.

15 Q. Here in the second sentence you reference the
16 1.5 milligram fluticasone formulation and the
17 3 milligram fluticasone formulation; correct?

18 A. I do.

19 Q. And you refer to Exhibit 2002; right?

20 A. Correct.

21 Q. All right. So if you could please open up to
22 Exhibit 2002 in the binder.

23 A. Okay.

24 Q. What is Exhibit 2002 that you're citing to?

25 A. It is a publication talking about

1 "Fluticasone Propionate Orally Disintegrating" --

2 (The Reporter requested clarification.)

3 THE WITNESS: It's "Fluticasone Propionate
4 Orally Disintegrating Tablet for Eosinophilic
5 Esophagitis," and it's a "Randomized Controlled
6 Trial."

7 BY MR. BUNKER:

8 Q. And does Exhibit 2002 refer to the
9 '407 patent at all?

10 A. I don't think it does refer to the
11 '407 patent, but it's a formulation of fluticasone
12 propionate.

13 Q. In this Exhibit 2002, does it refer to any
14 Ellodi patent?

15 A. This is a clinical paper. So they're
16 clinically using the Ellodi formulations to assess
17 them. So in clinical papers they typically don't
18 refer to the patents and the like.

19 Q. Do you have any evidence to show that the
20 tablets used that are discussed in this clinical paper
21 match exactly the examples in the '407 patent?

22 A. Clearly, this paper, there's the clinical
23 trials in the background which relate to the -- to
24 this background data. But clearly, this is an Ellodi
25 formulation. It's an orally disintegrating tablet,

1 and Ellodi orally disintegrating tablet for
2 fluticasone propionate will have a rapidly
3 disintegrating formulation.

4 Q. Do you know how many formulations of
5 fluticasone ODTs that Ellodi has?

6 A. Again, why would they test a fluticasone
7 disintegrated tablet which didn't meet the 60-second
8 mark if they knew from the patent that, indeed, that
9 showed efficacious. Why would they do that? It
10 doesn't make any sense.

11 Q. So you don't have any evidence to show that
12 the tablets that were reported in this clinical report
13 match any examples in the '407 patent; correct?

14 A. Well, the only evidence I have is the fact
15 that it's an Ellodi ODT, and the Ellodi ODTs, as cited
16 in the patent and they would need to be protected by
17 the patent, have disintegration with less than
18 60 seconds.

19 I don't know if that helps you.

20 MR. BUNKER: Thank you, Dr. Davies. I have
21 no further questions.

22 MS. AGARWAL: I have no further questions.

23 REPORTER MARTIN: Are we concluded?

24 MR. LUMAN: We are.

25 REPORTER MARTIN: Thank you. We're off the

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record.

(Witness excused.)

(Deposition concluded at 5:16 P.M.)

C E R T I F I C A T E

I do hereby certify that the aforesaid testimony was taken before me, pursuant to notice, at the time and place indicated; that said deponent was by me duly sworn to tell the truth, the whole truth, and nothing but the truth; that the testimony of said deponent was correctly recorded in machine shorthand by me and thereafter transcribed under my supervision with computer-aided transcription; that the deposition is a true and correct record of the testimony given by the witness; and that I am neither of counsel nor kin to any party in said action, nor interested in the outcome thereof.



Nancy J. Martin, RMR, CSR

Dated: November 25, 2025

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

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ACKNOWLEDGMENT OF DEPONENT

I, MARTYN C. DAVIES, PH.D., do hereby certify
that I have read the foregoing pages, _____ to
_____, and that the same is a correct transcription
of the answers given by me to the questions therein
propounded, except for the corrections or changes in
form or substance, if any, noted in the attached
Errata Sheet.

DATE

SIGNATURE

Subscribed and sworn to before me this _____ day
of _____, 20__.

My commission expires: _____.

Notary Public

1 ISHA AGARWAL

2 iagarwal@cooley.com

3 November 25, 2025

4 RE: Dr. Falk Pharma GMBH v. Ellodi Pharmaceuticals, LP

5 11/19/2025, Martyn Christopher Davies , Ph.D., (#7751937).

6 The above-referenced transcript has been

7 completed by Veritext Legal Solutions and

8 review of the transcript is being handled as follows:

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10 to schedule a time to review the original transcript at
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21 ___ Waiving the CA Code of Civil Procedure per Stipulation of
22 Counsel - Original transcript to be released for signature
23 as determined at the deposition.

24 ___ Signature Waived - Reading & Signature was waived at the
25 time of the deposition.

Page 127

1 ___ Federal R&S Requested (FRCP 30(e)(1)(B)) - Locked .PDF
2 Transcript - The witness should review the transcript and
3 make any necessary corrections on the errata pages included
4 below, notating the page and line number of the corrections.
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7 appearing counsel within the period of time determined at
8 the deposition or provided by the Federal Rules.
9 ___ Federal R&S Not Requested - Reading & Signature was not
10 requested before the completion of the deposition.

1 Dr. Falk Pharma GMBH v. Ellodi Pharmaceuticals, LP
2 Martyn Christopher Davies , Ph.D. (#7751937)
3 E R R A T A S H E E T
4 PAGE_____ LINE_____ CHANGE_____
5 _____
6 REASON_____
7 PAGE_____ LINE_____ CHANGE_____
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24 (Martyn Christopher Davies , Ph.D.) Date
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California Code of Civil Procedure

Article 5. Transcript or Recording

Section 2025.520

(a) If the deposition testimony is stenographically recorded, the deposition officer shall send written notice to the deponent and to all parties attending the deposition when the Original transcript of the testimony for each session of the deposition is available for reading, correcting, and signing, unless the deponent and the attending parties agree on the record that the reading, correcting, and signing of the transcript of the testimony will be waived or that the reading, correcting, and signing of a transcript of the testimony will take place after the entire deposition has been concluded or at some other specific time.

(b) For 30 days following each notice under subdivision (a), unless the attending parties and the deponent agree on the record or otherwise in writing to a longer or shorter time period, the deponent may change the form or the substance of the answer to a question, and may either approve the transcript of the deposition by signing it, or

refuse to approve the transcript by not signing it.

(c) Alternatively, within this same period, the deponent may change the form or the substance of the answer to any question and may approve or refuse to approve the transcript by means of a letter to the deposition officer signed by the deponent which is mailed by certified or registered mail with return receipt requested. A copy of that letter shall be sent by first-class mail to all parties attending the deposition.

(d) For good cause shown, the court may shorten the 30-day period for making changes, approving, or refusing to approve the transcript.

(e) The deposition officer shall indicate on the original of the transcript, if the deponent has not already done so at the office of the deposition officer, any action taken by the deponent and indicate on the original of the transcript, the deponent's approval of, or failure or refusal to approve, the transcript. The deposition officer shall also notify in writing the parties attending the deposition of any changes which the deponent timely made in person.

(f) If the deponent fails or refuses to approve the transcript within the allotted period, the

deposition shall be given the same effect as though it had been approved, subject to any changes timely made by the deponent.

(g) Notwithstanding subdivision (f), on a seasonable motion to suppress the deposition, accompanied by a meet and confer declaration under Section 2016.040, the court may determine that the reasons given for the failure or refusal to approve the transcript require rejection of the deposition in whole or in part.

(h) The court shall impose a monetary sanction under Chapter 7 (commencing with Section 2023.010) against any party, person, or attorney who unsuccessfully makes or opposes a motion to suppress a deposition under this section, unless the court finds that the one subject to the sanction acted with substantial justification or that other circumstances make the imposition of the sanction unjust.

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