UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. FALK PHARMA GMBH Petitioner, vs. ELLODI PHARMACEUTICALS, L.P., Patent Owner	) Case No. IPR2024-01197) U.S. Patent No.) 8,771,729 B2

DEPOSITION OF ALAN PARR, PHARM.D

AUGUST 25, 2025

Reported by: Rosalie A. Kramm, CSR No. 5469, RPR, CRR

APPEARANCES

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I N D E X

EXAMINATION PAGE

By Ms. Agarwal 4

EXHIBITS PREVIOUSLY MARKED THAT WERE REFERRED TO:

Exhibit 1005

Exhibit 1073 - 1083

Exhibit 1085

Exhibit 1091

Exhibit 1092

Exhibit 1093

Exhibit 2007

(No exhibits were marked and attached.)

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AUGUST 25, 2025 MONDAY 9:02 A.M. SAN DIEGO, CALIFORNIA

* * *

THE REPORTER: My name is Rosalie Kramm, California CSR No. 5469.

* * *

ALAN PARR, PHARM.D,

having been first duly sworn, testified as follows:

EXAMINATION

BY MS. AGARWAL:

Q. Hi, Dr. Parr.

A. Good morning.

Q. Nice to see you again.

Just for the record, could you please state your name and address.

A. Yes, my name is Alan Frank Parr, and my address is 23 Glenmore Court, Acworth, Georgia 30101.

Q. Do you understand you're here today for the cross-examination on your reply declaration that you submitted in IPR 2024-01197?

A. Yes, ma'am.

Q. And that is relating to what I'll refer to as the "'729 Patent," correct?

A. Yes, ma'am.

Q. Have you ever been deposed before?

A. Yes.

Q. And have you had any discussions with anyone about the process for this deposition?

A. Just with counsel, explaining what was going to be reviewed, what dates and times, yes.

Q. So I understand you've been deposed before, and we've been through this process before, but I'm just going to explain it briefly here, and we'll get going.

So I'm going to be asking you questions today, and you should answer them to the best of your ability.

And do you understand that you just took an oath with the court reporter to tell the truth here today?

A. Yes, ma'am.

Q. Is there any reason why you cannot completely and truthfully answer my questions today?

A. Not that I'm aware of, no, ma'am.

Q. Do you understand that even if your attorney objects during the deposition, you must still answer the question, unless he instructs you not to do so on the basis of privilege?

A. Yes, ma'am.

Q. And the court reporter cannot record a nod of the head or other body language. So it's important for you to give an audible answer.

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Do you understand that?

A. Yes, ma'am.

Q. If you don't understand the question, please let me know; otherwise, we'll assume that you understood my question; is that fair?

A. Yes, ma'am.

Q. And we'll try to take breaks every hour, but if you need a break, just let me know. I just ask that you don't do so while a question is pending.

Do you understand?

A. Yes, ma'am.

Q. And do you also understand that under the rules, you're not allowed to speak with any of the attorneys here about your testimony or anticipated testimony during breaks?

A. Yes, ma'am.

Q. And you're not in communication right now with anyone via text or chat functions of any sort?

A. No, ma'am. I left my phone in the other room.

Q. Okay. Great.

Have you had any discussions with anyone employed by Dr. Falk about your deposition here today?

A. No, ma'am.

Q. And have you had any discussions with any individuals employed by Dr. Falk about the subject matter

of your declaration?

A. No, ma'am.

Q. Okay. Go ahead and open your binder. We're going to turn to Exhibit 1093. It's the third tab. They're not quite in order.

A. There is nothing behind that tab.

Q. There is nothing behind that tab?

A. There is something in front of it. Do you --

MS. AGARWAL: Do you have the reply declaration here?

MR. LUMAN: Yes, I have it here.

MS. AGARWAL: Could you give it to Dr. Parr?

MR. LUMAN: Yes, I can get a copy for myself.

MS. AGARWAL: Let's go off the record for a second.

(Recess was taken.)

BY MS. AGARWAL:

Q. Back on the record.

So we're at your reply declaration, Exhibit 1093, correct?

A. Yes, ma'am.

Q. And if you turn to the last page, that is your signature, correct?

A. Yes, ma'am, it's my electronic signature.

Q. And it is dated July 10th, 2025, correct?

A. Yes, ma'am.

Q. Did you discuss with Dr. Falk's counsel at any point prior to submitting your reply declaration?

A. Can you ask the question again?

Q. Sure. Prior to submitting your reply declaration on July 10th, 2025, but after -- strike that.

Prior to submitting your reply declaration, how many discussions did you have with Dr. Falk's counsel regarding your reply declaration?

A. I have no idea. I don't recall the exact numbers or number of meetings. I don't know that.

Q. But you did discuss with Dr. Falk's counsel prior to submitting --

A. Yes, ma'am.

Q. -- your reply declaration. Okay.

And if we go to your "List of Materials Considered," that starts on page Romanette i, correct?

A. Yes, ma'am.

Q. Go to page Romanette iii. You cite to a number of exhibits in your reply declaration that you did not cite to in your opening declaration, correct?

A. Yes, ma'am. There are some additional documents I reviewed.

Q. And those would be Exhibits 1073 to 1083, 1085 to 1092, 2007 and Paper 10, correct?

A. Yes, ma'am.
Q. And who first identified these new exhibits?
A. We had discussions and then we -- we did another search, and those were -- that was done by Dr. Falk's counsel.
Q. So Dr. Falk identified these.
A. No, Dr. Falk's counsel.
Q. Sorry. Dr. Falk's counsel identified these new exhibits to you?
A. Based on discussions we had, yes.
Q. Did you identify any of these new exhibits?
A. Not that I'm aware of.
Q. Prior to submitting your reply declaration, did you review any other documents, other than those that are listed here?
A. No, ma'am.
Q. You're not relying on any other documentary evidence to support your reply declaration, correct?
A. No, ma'am, just the documents listed here.
Q. In preparation for today's deposition, who did you meet with?
A. I met with Mr. Luman, Mr. Minnick and -- I forgot Eric's last name, a third Falk counsel member.
Q. And how long did you meet with them for?
A. We met on Thursday and Friday of last week.

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Q. And did you review any documents during your preparation?

A. We talked about my deposition -- my report and associated documents.

Q. Have you done any further investigation of documents or other evidence since July 10th, 2025?

A. No, ma'am.

Q. Have you read Patent Owner's response and its expert declaration that were filed in this matter?

A. If it was one of the documents in this list, I reviewed it. If it's not in this list, I don't recall reviewing it.

Q. So in this list you have the Declaration of Dr. Martyn Christopher Davies. That is Exhibit 2007.

A. Yes, ma'am.

Q. So you reviewed Dr. Davies' expert declaration, correct?

A. Yes, ma'am.

Q. And it says here that you are also relying on the Institution Decision, Paper 10, correct?

A. Yes, ma'am.

Q. So you've reviewed the Institution Decision.

A. I looked at both of those documents, yes, ma'am.

Q. Okay. Let's go to paragraph 23 of your

declaration. Here, about halfway through the paragraph, you state that in your first deposition you testified that, "I haven't done a literature search on {fast dissolving lozenges}, so I wasn't aware if there were any fast-dissolving lozenges in the prior art"; is that correct?

A. Yes, that's what it states.

Q. And at the time you had not done a literature search on fast-dissolving lozenges, correct?

A. I did not. In my mind there was no need to do it, to be able to identify fast-dissolving lozenges, and it identified the use of its synocrint, and all of that made perfectly sense to me as a POSA.

Q. Turn to page, page 13. Starting in paragraph 24 through paragraph 35, which is on page 18, you go through a number of exhibits as examples of what you claim to be fast-dissolving lozenges, correct?

A. I go through documents that listed quick-dissolving lozenges, yes.

Q. Just to be clear, Dr. Falk's counsel identified these examples to you, correct?

A. Yes, they did the literature search, because I don't have access to the appropriate databases.

Q. If we go back to paragraph 23, in this paragraph, you don't define a disintegration time for

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fast-dissolving lozenges, correct?

A. I do not, because I operate under the FDA's.

The fast-dissolving is something that dissolves in a few -- that disintegrates in a few seconds, within a few seconds or 30 seconds, based on the USP apparatus.

Q. Let's turn to paragraph 24. Here you cite to Exhibit 1075, McEntee, correct?

A. Yes, ma'am.

Q. And you insert a quote from McEntee, the first sentence states. "Fast melt formulations are typically in the form of tablets or lozenges that dissolve or disperse in a patient's mouth within a minute without the need of water or chewing," correct?

A. Yes, ma'am.

Q. And you don't cite to any disintegration or dissolution data for the lozenge from McEntee, correct?

A. No. That's a complete repeat of what was in that patent or that document.

Q. Let's go to Exhibit 1075, which is McEntee. This is the exhibit that you relied on, correct?

A. Yes, ma'am.

Q. And the quote that I just read to you comes from page 3, lines 20 to 28 in that paragraph, the second sentence there, correct?

A. Yes, ma'am.

Q. Okay. And you just stated that this sentence encompasses what is in the document, correct?

MR. LUMAN: Objection. Form; mischaracterizes his testimony.

THE WITNESS: It -- it is a reproduction of what is in this document.

BY MS. AGARWAL:

Q. Could you explain further what you mean by that.

A. Well, if you -- if you look at the sentence in the document, I believe it lines up with what's in -- what I highlighted. I can confirm that just to make sure. But -- to view what I highlighted in paragraph 24 what is written in this reference.

Q. Okay. Let me ask my question a different way.

You don't cite to anything else in Exhibit 1075, correct? You only cite to this quote.

A. Well, that's correct. It's just documented there was a lozenge.

Q. So you don't cite to any of -- you don't cite to any data that might be in Exhibit 1075, correct?

A. No, I -- I just cited that -- that particular sentence that indicated there was -- there does exist a fast-dissolving lozenge.

Q. And you don't cite to any definition in

Exhibit 1075 that would indicate a disintegration time, correct?

A. Again, I -- I operate as any POSA would under the FDA guidance document around what an ODT is.

Q. And staying in Exhibit 1075, this portion that you quoted in your reply declaration, this is the only reference of a lozenge in this reference, correct?

A. I have to go back and re-read it to -- to see if that's the only spot. I don't -- I can't -- I don't memorize it. So I don't know. I'd have to re-read the document to confirm that.

Q. Well, if there were other references of lozenges in this reference, presumably you would put it in your reply declaration, correct?

A. I -- I don't know. This -- this made -- my -- this sentence made the point I was making that there was a fast-dissolving lozenge.

So, again, I can re-read the document and confirm whether that's the only spot, but I don't -- from memory, I can't confirm that.

Q. Let's go to page 20 of Exhibit 1075. Oh, I'm sorry. Page 24.

McEntee discloses -- sorry.

Exhibit 1075 discloses a number of examples starting on page 24, correct?

MR. LUMAN: Objection. Mischaracterizes the document.

BY MS. AGARWAL:

Q. I'm sorry. I think it starts on page 23. It goes to page 40.

A. Yes, it lists 21 examples.

Q. You didn't cite to any of these examples in your reply declaration, correct?

A. I did not.

Q. Okay.

A. Again, the statement was to show that there were fast-dissolving lozenges, and that sentence indicated that.

Q. Let's go back to your reply declaration.

If you want to pop it out of the binder, that might be easier as well. We'll be going back to it a bunch.

MR. LUMAN: I have a stapled one if you want to switch. That way you can --

THE WITNESS: Okay. I'll take this one.

BY MS. AGARWAL:

Q. In paragraphs 25 to 26 of your reply declaration you cite to Exhibit 1076 to Martin, correct?

A. Yes, ma'am.

Q. And you specifically cite to paragraphs 60, 67,

and 64 of Martin, correct?

A. Yes, ma'am.

Q. Let's go to Exhibit 1076. This is the exhibit that you're citing to in paragraphs 25 and 26, correct?

A. Yes, ma'am.

Q. Let's go to paragraph 60, page 22.

This paragraph describes a sublingual tablet wafer, pellet, or lozenge, i.e., a tablet wafer, pellet, or a lozenge, correct?

A. Yeah. The sentence goes on with additional words, but that's what it says, yes, ma'am.

Q. And the last sentence of this paragraph states: "Generally, a sublingual tablet, wafer, pellet or lozenge should dissolve or disintegrate quickly, allowing the analgesic to be rapidly absorbed," correct?

A. Yes, ma'am.

Q. And is paragraph 25 of your reply declaration you cite to that last sentence, correct, that last paragraph of Exhibit 60 of Exhibit 1076.

A. Yes, ma'am.

Q. This paragraph does not give a reference of time for "quickly," correct?

A. Again, a POSA would look at it knowing it is a ODT and -- and would follow the FDA guidance around orally disintegrating tablets or dosage forms.

Q. Let's turn to paragraph 67 in Exhibit 1076. You quote this paragraph, paragraph 67, of Exhibit 1076, in paragraph 25 of your reply declaration, correct?

A. Yes.

Q. The second sentence states that: "In certain embodiments, the orally disintegrating tablets, wafers, pellets, or lozenges of the present invention dissolve completely over a period of about 10 seconds to about 120 seconds, about 10 seconds to about 90 seconds, about 10 seconds to about 60 seconds, about 10 seconds to about 30 seconds, or about 20 seconds to about 60 seconds when placed into human saliva or a solution that mimics human saliva," correct?

A. Yes, ma'am.

Q. And these time frames that are given refer to the orally disintegrating tablets, wafers, pellets, or lozenges, correct?

A. Yes, ma'am.

Q. And this reference does not -- this reference doesn't relate the specific time frames to a particular dosage form, correct?

A. I -- I'm not sure I agree with that. It says, "In certain embodiments, the orally disintegrating tablets, wafers, pellets, or lozenges dissolve," and it gives the timing. So a POSA would look at that and give

those timings that are associated with any of those dosage forms.

Q. Let's go to Exhibit 1005 in your binder.

You rely on Exhibit 1005 in your grounds for obviousness?

A. Yes, ma'am.

Q. Could you please read the title on the first page.

A. "Guidance for Industrial -- "Guidance for Industry - Orally Disintegrating Tablets."

Q. If we go to -- if we go to page 2 of this exhibit --

MR. LUMAN: Is that page 2 on the bottom page number?

MS. AGARWAL: Yes.

MR. LUMAN: Okay.

THE WITNESS: Yes.

BY MS. AGARWAL:

Q. The last paragraph states that -- the last paragraph, second sentence states: "Based on the original product rationale and Agency experience, we recommend that, in addition to the original definition, ODTs be considered solid oral preparations that disintegrate rapidly in the oral cavity, with an in-vitro disintegration time of approximately 30 seconds or less,

when based on the United States Pharmacopeia disintegration test method or alternative."

Do you see that?

A. Yes, ma'am.

Q. So in Exhibit 1076, where the reference provides a range of about 10 to 30 seconds, you would understand that to apply to ODTs, correct?

A. It is a time frame within the ODTs, yes. It doesn't use the -- it doesn't state whether it uses the USP to determine that. It just gives those ranges.

Q. And the time frame from 10 to about 120 seconds, according to the FDA definition, would not be an ODT, correct?

A. Let me -- can I go back to that original document?

Q. Yes. It was Exhibit 1076.

A. 1076.

Q. In paragraph 67.

A. Okay. We have a difference here. In this it talks about releases the analgesic content over those time periods. That defines dissolution.

The US- -- the FDA talks about disintegration. The dosage form has to disintegrate first before it can dissolve.

So, in this case, where they're talking about

dissolution, disintegration occurs before these times they have here, and, I believe, would meet what the FDA defines as rapidly disintegrating in approximately 30 seconds.

Again, the FDA says using the USP method. It doesn't state what that method is in this one.

At least I didn't see it, anyway.

Q. The second sentence, however, refers to dissolving completely.

A. Uh-huh.

Q. Correct?

A. Correct.

Q. And that would be what the FDA guidance is discussing, correct?

A. The FDA guidance discusses disintegration, and disintegration has to occur before dissolution. So if these dosage forms are dissolving within that 10 seconds or that 120 seconds, they would have clearly disintegrated before that time period.

Q. So an ODT could dissolve in 120 seconds, according to Exhibit 1076.

A. Yeah, it -- it -- present invention is all completely over a period of 10 seconds to 120 seconds. Right? That's dissolving. It would have disintegrated much sooner than that, because it has to disintegrate

before the drug can dissolve.

Q. And in the first sentence where it states that: "The orally disintegrating tablets, wafers, pellets, or lozenges release their analgesic contents to about 120 seconds," that would have to occur prior to dissolving at 120 seconds?

A. Well, the word -- a POSA would look at the word as content as the drug dissolving. And so the dosage form has to disintegrate first, and then once it disintegrates, then it can start to dissolve the drug.

And so content would be -- a POSA would look at that as meaning dissolved.

Q. So in this context, then, would release and dissolve be synonymous to a POSA?

MR. LUMAN: Objection. Form.

THE WITNESS: It -- this talks about dissolve in the timings that you mentioned previously. So that's the drug being in solution.

For a drug to be in solution -- if it's in a dosage form, a tablet, a wafer, or a lozenge, that dosage form has to first disintegrate to make the drug available to be dissolved.

So if it dissolves within 10 to 120 seconds, it would have had to have disintegrated long before that for the drug to be dissolved.

BY MS. AGARWAL:

Q. Okay. We can move on.

Let's go back to your reply declaration, paragraphs 27 to 28. You cite to a reference called Mezaache. Exhibit 1077, correct?

A. Yes, ma'am.

Q. And in your reply declaration you cite to paragraphs 2, 3, 40, and 10 of Exhibit 1077, correct?

A. Yes, ma'am.

Q. Let's go to Exhibit 1077, to Mezaache, and this is the exhibit you referred to, cite to, in your reply declaration.

A. Yes, ma'am, it appears to be.

Q. Let's go to paragraph 2 of Exhibit 1077. The first sentence of paragraph 2 states: "The invention relates to compressible compositions and dosage forms based thereon, such as tablets and lozenges which, when invested, quickly dissolve in the mouth, but which effectively mask the taste of unpleasant active agent(s) therein," correct?

A. Yes, ma'am.

Q. And you quote that in your declaration in paragraph 27, correct? It spans pages 14 to 15.

A. Yes, ma'am.

Q. This actually relates to taste-masking,

correct?

A. It relates to rapidly-dissolving dosage forms, which includes lozenges that -- and it also relates to taste-masking, yes, ma'am.

Q. Paragraph 2 of Exhibit 1077 does not define "quickly dissolve," correct?

A. Again, it doesn't, but a POSA would be aware that the definition of "quickly dissolve" was defined in the FDA guidance document around ODTs.

Q. And the FDA guidance you're referring to is the one we just looked at, Exhibit 1005, correct?

A. Yes, ma'am.

Q. That FDA guidance doesn't ever refer to lozenges, correct?

A. Can we go back to that document?

Q. Yes.

A. I think it was 1005.

Q. Yes.

A. It refers to a solid dosage form. It doesn't limit itself to tablets, capsules, lozenges. It says a sold dosage form, which disintegrates rapidly in a matter of seconds. So the document doesn't limit us to tablets, capsules, or lozenges.

Q. But this guidance is specifically for orally disintegrated tablets, correct?

A. The -- the title indicates that, but, as you read the document, a POSA would understand a solid oral dosage form can contain tablets, capsules, lozenges. It doesn't limit itself by that definition.

And the only thing the guidance did was it added on to that sentence that the testing should be done with this type of apparatus.

So while the title might say "tablets," ODT is a general term, that, as this statement says, encompasses all dosage forms.

Q. Okay. Let's turn back to Exhibit 1077. And if we go to paragraph 3 of Exhibit 1077, the middle of the paragraph, it states: "One aspect associated with ameliorating the effects of ingesting molecules that are generally unpalatable is to provide the drug in dosage forms, such as tablets and lozenges, which, when ingested, quickly dissolve in the mouth."

Do you see that?

A. Yes, I do.

Q. And you quoted this sentence in your reply declaration, correct, in paragraph 27?

A. Let's see here. 27.

Q. It is the first full quote there.

A. Right. Yes, ma'am.

Q. This paragraph, paragraph 3, does not define

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"quickly dissolve," correct?

A. Again, it does not, but, again, a POSA would be aware of the FDA guidance that we just discussed with the definition of a rapidly-dissolving dosage form.

Q. If we go to the next sentence in paragraph 3 of Exhibit 1077, it defines tablets. It states: "Tablets may be defined as solid dosage pharmaceutical forms containing drug substances with or without suitable fillers."

Do you see that?

A. Yes, ma'am.

Q. Exhibit 1077 does not define lozenges anywhere, correct?

A. I'd have to -- I don't -- didn't put that down to memory. I'd have to read the whole document to determine whether it does. It does identify fast-dissolving lozenges, which was the reason I referenced this document.

Q. Let's go to paragraph 40 of Exhibit 1077.

The last sentence of paragraph 40 states: "Tablets and other dosage forms, e.g., lozenges, made therefrom rapidly dissolve when placed in the mouth, generally less than 30 seconds."

Do you see that?

A. Yes, ma'am.

Q. And you quote this in your reply declaration, correct?

A. Yes, ma'am.

Q. This is the third and last reference to a lozenge in this Exhibit 1077, correct?

A. I would have to go back and re-read the whole document. I didn't count the number of times "lozenge" was used, so I can't say if it is or it isn't.

Q. If there are any other references to a lozenge in Exhibit 1077, you would have put them in your reply declaration, correct?

A. Not necessarily. I -- I think the arguments were substantial where the document has already shown -- talked about rapidly-dissolving lozenges, and I've identified it twice. I'm not so sure if a third or fourth time would have made any difference.

The document clearly shows that -- indicates a rapidly-dissolving lozenge.

Q. And going back to your reply declaration, Exhibit 1093, the only other citation you have to Exhibit 1077 is paragraph 10, correct?

A. Yes, ma'am.

Q. You don't cite to any examples disclosed in Exhibit 1077, correct?

A. I do not.

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Q. Then going to paragraph -- paragraphs 29 and 30 of your reply declaration, you cite to Exhibit 1078, Augsburger, correct?

A. Yes, ma'am.

Q. And in paragraph 29, you cite to paragraph 143 of Augsburger, correct, and paragraph 43?

A. Yes, ma'am. I cite paragraph 43 and 143. I think I also cite 83 to 84.

Q. Yes.

A. And 79 and 85.

Q. Let's turn to Exhibit 1078. This is the reference that you cite to in your reply declaration, correct?

A. Yes, ma'am.

Q. And in your reply declaration, you don't cite to any time frames for lozenges which have a rapid disintegration rate, correct, in paragraphs -- in paragraph 29, your reply declaration?

A. I do not cite any times. It just indicates rapidly disintegration rates, which, again, a POSA would be familiar with what that means according to the FDA guidance.

Q. And going back to Exhibit 1078, paragraph 43, the first sentence states: "The invention still further relates to methods for preparing rapidly-disintegrating

dosage forms comprising active cushioning components of the invention."

Do you see that?

A. Yes, ma'am.

Q. And the end of the second sentence refers to tablets or lozenges which have rapid disintegration rates.

Do you see that?

A. Yes, ma'am.

Q. What is the time frame that the lozenge, which has a rapid disintegration rate, would dissolve in?

A. Again, a POSA would look at it based on -- it says rapidly-dissolving. So a POSA would look at it in relationship to the FDA guidance.

Q. Go to paragraph 143, page 9. This states: "In another embodiment, the present invention relates to a rapidly disintegrating lozenge."

Do you see that?

A. Yes, ma'am.

Q. What is the time frame that the rapidly disintegrating lozenge dissolves in paragraph 143?

A. Again, a POSA would look at that in relationship to the FDA guidance that we discussed previously.

Q. So Exhibit 1078 doesn't disclose a time frame

for when the lozenge is dissolved, correct?

A. I'd have to re-read the document. I didn't put that down to memory. It may be in there. I don't recall.

Q. If there was a time frame for a lozenge to be dissolved in, you would put it in your reply declaration, though, correct?

A. Possibly. Again, the goal was to identify rapidly-dissolving lozenges, which this document and those references did.

Q. And let's go to paragraph 61 of Exhibit 1078, page 4.

A. I'm -- I'm sorry. Which?

Q. Paragraph 61 of Exhibit 1078.

A. Paragraph 61. Okay. I'm sorry.

Q. There are a lot of numbers.

A. Yeah. Okay.

Q. Paragraph 61 states: "As used herein, the phrase 'fast-disintegrating tablet' encompasses a tablet having a disintegration time on the tongue without the addition of liquid beyond that normally available in the mouth due to salivation of between zero to due to 60 seconds with the most preferred disintegration time of zero to 20 seconds."

Do you see that?

A. Yes, ma'am.

Q. This reference doesn't have a similar definition for a rapidly disintegrating tablet, correct? Or -- sorry, a rapidly disintegrating lozenge.

A. Again, I think the POSA would look at this as -- a fast disintegrating tablet as a general term, and that encompasses anything that is labeled as a fast disintegrating tablet. So that would include tablets, lozenges, capsules; whatever the inventor in this case indicated, that it's a fast-dissolving lozenge.

Q. Going back to your reply declaration, in paragraph 31, you cite to Exhibit 1079 to Tang, correct?

A. In paragraph 31?

Q. Yes.

A. Yes, ma'am, I do.

Q. Let's go Exhibit 1079. This is the reference that you cite to in your reply declaration, correct?

A. Yes, ma'am, it is.

Q. And if we go to column 14 of Exhibit 1079, in your reply declaration you quote from Tang, column 14, lines 9 to 13, correct?

A. Yes.

Q. That states: "In another embodiment, the invention provides 'fast melt' formulation. Such fast melt formulations are typically in the form of a tablet

or lozenge that dissolve or disperse in a patient's mouth in a minute without the need of water or chewing," correct?

A. Yes, ma'am.

Q. If you look at Exhibit 1079, the next sentence after that sentence states: "Such fast melt formulations are described in WO 03/074029."

Do you see that?

A. Yes, ma'am.

Q. This reference, WO 03/074029, is the McEntee reference that you cite to in your reply declaration as Exhibit 1075, correct?

A. Yes, ma'am, it is.

Q. And the portion that you cite to from Tang from Exhibit 1075 -- excuse me -- Exhibit 1079 in your reply declaration is identical to the portion you quote from McEntee in your reply declaration, correct?

A. I'd have to check that.

Q. So we can compare paragraph 24 of your reply declaration, paragraph 21 of your reply declaration, starting with "such fast melt formulations" and "fast melt formulations."

A. Yeah. In paragraph 24, I don't see "such --" I don't see the same thing. I don't see "such fast melt formulations are typically" -- that. I don't see that in

paragraph 24.

Q. So after the word "such," starting in paragraph 31, starting with "fast melt formulations are typically in the form of a tablet or lozenge that dissolve or disperse in a patient's mouth within a minute without the need of water or chewing," that is the same as the first sentence of the quote in paragraph 24, correct?

MR. LUMAN: Mischaracterizes the document.

THE WITNESS: The words are the same, but you could find that statement in any number of documents.

Now, whether it came specifically from that document, I can't say, because it is not verbatim with what's in the McEntee.

So if it was word for word, I would agree with you, but it is not word for word.

So is that verbiage similar to what is in there? The answer is it is. Did it come from there? I can't confirm that.

BY MS. AGARWAL:

Q. You do agree that the sentence in Exhibit 1079 after the portion you quote, "Such fast melt formulations," starting with, "Such fast melt formulations," refers to the McEntee reference, correct.

A. Yeah, that does refer to the McEntee reference, yes.

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Q. And you don't cite to anything else from Exhibit 1079 in your reply declaration, correct?

A. No. That's the only thing I state to -- because, again, I was -- the purpose was to identify the existence of fast-dissolving lozenges, and that paragraph did that.

Q. And you don't cite to any definition of fast melt formulations or dissolution data from Exhibit 1079, correct?

A. I did not. I don't know if the document identified what the definition of rapidly disintegrating was, but it may be in there. I don't recall it by memory.

Q. If it were in the reference, you would have put it in your reply declaration, correct?

A. Not necessarily. Again, I think the statement was -- it was selected to show that a fast-dissolving lozenge does exist, and that document I selected does indicate that.

Q. Okay. And if you turn to column 17 of Exhibit 1079, starting at line 19 and going to column 19, line 44, 45, Exhibit 1079 discloses a number of examples, correct?

A. Yes, ma'am, it shows eight examples.

Q. You don't cite to any of these examples in your

reply declaration, correct?

A. I do not.

Q. Let's go back to your reply declaration.

In paragraph 32, you cite to Exhibit 1080 to Singh, correct?

A. Yes, ma'am.

Q. And you cite to paragraphs 57 and claim 11 in paragraph 32, and in paragraph 33 you cite to paragraph 61 and 83 of Exhibit 1080, correct?

A. Yes, ma'am.

Q. And in paragraph 32, you quote portions of Singh, which refer to quick-dissolving tablets or lozenges, correct?

A. Yes, ma'am.

Q. And you quote, claim 11, which discloses a quick-dissolving lozenge or tablet, correct?

A. Yes, ma'am.

Q. You don't provide any time frame for dissolution for the disintegration rate for the quick-dissolving lozenge.

A. Again, I didn't -- did not, because a POSA would understand what those terms mean based on the FDA guidance.

Q. And let's go to Exhibit 1080, to Singh. This is the reference you cite to in your reply declaration,

correct?

A. Yes, ma'am.

Q. Let's go to paragraph 57.

And the last sentence of paragraph 57 states: "Preferably, the compositions of the present invention are formulated as a tablet or lozenge, in particular quick-dissolving tablets or lozenges, such as those described in U.S. Patent Publication No. 20050226925," correct?

A. Yes, ma'am.

Q. How quickly does the quick-dissolving tablet or lozenge in this paragraph disintegrate?

A. Again, as a POSA reads it, they -- they'd base that disintegration, it says rapidly disintegrating or quick-dissolving, they would follow the FDA guidance as to what that meant.

Q. If we go to claim 11, which is the claim you quoted in your reply declaration, correct?

A. Yes, ma'am.

Q. This discloses a quick-dissolving lozenge or tablet, correct?

A. Yes, ma'am, it does.

Q. How quickly would this quick-dissolving lozenge or tablet dissolve or disintegrate?

A. Again, a POSA would know based on the FDA

guidance. It would go by the FDA guidance of a description of a quick-dissolving or an ODT product.

Q. If we go to claim 12, claim 12 states: "The pharmaceutical composition of claim 1, wherein the composition provides complete dissolution in about 6 minutes or less following administration."

Do you see that?

A. Yes, ma'am.

Q. So would a quick-dissolving lozenge or tablet -- strike that.

Does a quick-dissolving lozenge or tablet always disintegrate within 60 seconds?

A. It depends on -- I would assume it would depend on the method you used. Based on the FDA guidance, they indicate 30 seconds using a USP method. So in -- in --

You've got two questions there: One is disintegration and one is dissolution.

Disintegration has to occur. Dissolution has to occur second.

So which one would you like me to respond to?

Q. So does -- would you understand a quick-dissolving lozenge, based on the FDA guidance, to always disintegrate within 60 seconds?

A. Their recommendation is -- if I recall, I'd have to go back and look. Let me check and make sure of

the approximately 30 seconds? Let's see. That was 1005, right? Its definition says "in a matter of seconds." It doesn't define number of seconds. For example, and it also says, for example, that talks about 30 seconds in there.

So I guess if you could repeat your question, I could try to answer it.

Q. Would you always expect a quick-dissolving lozenge to dissolve within 60 seconds?

A. Based on the FDA guidance, it talks about disintegration. It doesn't mention "dissolve." So it could easily disintegrate much sooner than 60 seconds, but it could take 60 seconds for it to dissolve.

Q. So you would understand a quick-dissolving lozenge or tablet to disintegrate within 60 seconds according to the US -- or according to the FDA guidance.

A. It -- it talks about disintegration in the guidance, and it says "seconds," dissolves within seconds. It doesn't define exactly the number of seconds, but it would have to disintegrate before it dissolves.

And -- and in 11 it talks about "quick-dissolving," and you've referenced six minutes, it talks about dissolving, but that disintegration could have occurred much sooner than that 6-minute time point.

Q. The FDA guidance does give a time frame, correct? It adds on 30 seconds, or less, as part of the disintegration rate for orally disintegrating tablet, correct?

A. What it does say is: "We surveyed applications of products submitted to Agency. Completed review in the laboratory show that although disintegrations did range from a few seconds to longer than a minute, the majority of these disintegrate within 30 seconds or less."

So that's based on data that they've observed.

Q. And the last paragraph on numbered page 2, in Exhibit 1005, states that: "The FDA recommended that in addition to the original definition, ODTs be considered solid oral preparations that disintegrate rapidly in the oral cavities with an in vitro disintegration time of approximately 30 seconds or less," correct?

A. Correct. But, again, it says "approximately 30 seconds." So we've got some leeway there based on the size of the tablet, the type of disintegration formulation that was used. I think that's recommended -- that's mentioned in -- if you go to page 3, in, like, the third paragraph, it talks about additional parameters for consideration.

MS. AGARWAL: We have been going for about an hour. Do you can want to take a break?

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THE WITNESS: Sure.

(Recess was taken.)

BY MS. AGARWAL:

Q. Let's go to your reply declaration, Exhibit 1093, and go to paragraph 34.

A. Okay.

Q. And in the paragraph 34, you cite to Exhibit 1081, to Barman, correct?

A. Yes, ma'am.

Q. And you quote portions of Barman, paragraph 44, and claims 31 and 33 in Exhibit 1081, correct?

A. Yes, ma'am.

Q. And in quoting your first quote of Barman, of Exhibit 1081, you quote, "A fast-dissolving dosage form such as a tablet, troche, or lozenge," correct?

A. Yes, ma'am.

Q. And for claims 31 and 33, these claims refer to a method for preventing oral mucositis comprising the administration of fast-dissolving lozenge or troche dissolved in the mouth, correct?

A. Yes.

Q. You don't provide any time frame for dissolution or disintegration for the fast-dissolving lozenge in your reply declaration, correct?

A. I do not. Again, a POSA would follow the FDA

suggestion or guidance as to determining what that is.

Q. Let's go to Exhibit 1081, to Barman. This is the reference that you cite to in your reply declaration, correct?

A. Yes, ma'am.

Q. If we go to paragraph 44, it states: "A fast-dissolving dosage form, such as a tablet, troche, or lozenge or dry film, is preferable for delivery of the beta Glucan containing prophylactic or therapeutic in the oral space," correct?

A. Correct.

Q. It's your opinion that a POSA would read the fast-dissolving dosage form, such as a tablet, troche, or lozenge, to be according to the FDA guidance, correct?

A. Again, if it wanted to be a fast-dissolving dosage form, yes, ma'am.

Q. And does Exhibit 1081 disclose a time frame for fast-dissolving anywhere?

A. I'd have to re-read it, but I didn't -- I don't recall right offhand whether it does or doesn't.

Q. If it did, you would include that in your reply declaration, correct?

A. Again, maybe not. I -- I wouldn't think so, because, again, the goal was to identify fast-dissolving lozenges, and paragraph 44 indicates a fast-dissolving

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lozenge, and a POSA would know based on FDA guidance what that means.

Q. And if you -- and you don't cite to any examples of -- in Exhibit 1081, correct?

A. I don't see where it indicates any examples.

Q. Exhibit 1081 doesn't have any examples of a fast-dissolving lozenge, correct?

A. I don't -- I don't see anything in there. It just references -- it indicates that the patent covers a fast-dissolving lozenge.

Q. Let's go back to your reply declaration. In paragraph 35 you cite to Exhibit 1082 to Than; is that correct?

A. Yes, ma'am.

Q. And you cite to page 2 of Than which states that: "Compounding pharmacies can prepare unique routes of administration, such as a quick-dissolving lozenge, a lollipop, or a transdermal patch," correct?

A. Yes, ma'am.

Q. In your reply declaration, you don't provide any time frame for dissolution or disintegration for the quick-dissolving lozenge disclosed in Than, correct?

A. Again, based on FDA guidance, that term is defined.

Q. And if we go to Exhibit 1082, to Than, this is

the reference that you cite to in your reply declaration, correct?

A. Yes, ma'am.

Q. Go to page 2, about a little more than halfway down the page, where it states: "Prepare unique routes of administration such as quick-dissolving lozenge, lollipop, or transdermal patch." That's what you quote in your reply declaration, correct?

A. Yes, ma'am.

Q. And it's your opinion that the quick-dissolving lozenge disclosed here would dissolve or disintegrate according to the FDA guidance, correct?

A. A POSA would -- would read that as quick-dissolving and put that with the FDA guidance, yes, ma'am.

Q. Let's go back to your reply declaration, Exhibit 1093, and let's go to paragraph 52. Here in paragraph 52 you point to examples of solid ODT formulations that have the same drug dosage amount as the corresponding liquid formulation, correct?

A. Yes, ma'am.

Q. And then you list out four examples, correct?

A. Yes, ma'am.

Q. Those are Claritin, Zofran, Clarinex, and Pepcid, correct?

A. Yes, ma'am.

Q. The first example you point to is Claritin ODT and liquid syrup, which are both dosed at 10 milligrams, correct?

A. Yes, ma'am.

Q. Claritin or loratadine, I believe it's pronounced --

A. Uh-huh.

Q. -- is absorbed systemically to provide therapeutic effect, correct?

A. Yes, ma'am, it is.

Q. And that would be both the ODT and the liquid syrup, correct?

A. Yes, ma'am.

Q. And the ODT and liquid syrup are both administered orally, correct?

A. Yes, ma'am.

Q. And based on your knowledge, neither the ODT nor the liquid syrup has a modified release profile, correct?

A. I'd have to re-read the insert, but none of these would indicate that they -- at least these two products have a modified release, no, ma'am.

Q. So both the ODT and liquid syrup for Claritin are administered in the same route and have the same

release profile, correct?

A. They are administered the same route. I'd have to go back and look at the package inserts to see if they're bioequivalent or not. That, I don't know.

Q. Let's go to Exhibit 1089, which is the Claritin insert, correct?

A. Yes, ma'am.

Q. Okay. I apologize. It is very tiny.

On page 1, if you go to the third bolded section header, it says, "Pharmacokinetics Absorption."

Do you see that?

A. Yes, ma'am.

Q. The package insert here states, the second sentence, it starts with: "Based on a cross-study." I don't know if you can read that.

A. A little bit.

Q. Okay. It states: "Based on a cross-study comparison of single doses of loratadine syrup and tablets given to healthy adult volunteers, the plasma concentration profile of decarboethoxy-loratadine for the two formulations is comparable."

Do you see that?

A. Yes.

Q. This type of cross-study establishes that the syrup form and the tablet form have comparable plasma

concentrations in subjects, correct?

A. It does. This says "comparable." It doesn't say "bioequivalent," but it says "comparable," yes.

Q. That would mean the bioavailability of the drug is comparable or similar, correct?

A. Yeah, I don't know what their definition of "comparable" is, but it says, "comparable."

Q. Does the FDA define "bioequivalent"?

A. They do.

Q. And they define it as "comparable," correct?

A. That, I don't know. Bioequivalence has very defined parameters. I don't know whether "comparable" -- I don't believe the FDA has a definition around "comparable."

Bioequivalence is very clear. They have very clear criteria.

Q. When switching from one dosage form to another, for example, from an ODT to a liquid, or vice versa, you would need to ensure that the -- there was bioequivalence, correct?

MR. LUMAN: Objection. Form; incomplete hypothetical.

THE WITNESS: When we go from one formulation to the next, we would do PK studies, and typically we would do a pharmacokinetic study, which would be

bioequivalence that shows based on bioequivalent -- bioavailability parameters they are equivalent to the FDA, yes, ma'am.

BY MS. AGARWAL:

Q. Let's go back to your reply declaration. The second example you give is for Zofran, correct?

A. Yes, ma'am.

Q. And the Zofran ODT and the oral solution are both dosed at either 4 milligrams or 8 milligrams, correct?

A. Yes, ma'am.

Q. And you also state that the oral solution and the ODT are bioequivalent, correct?

A. Yes, ma'am.

Q. Zofran or -- I believe it's pronounced ondansetron --

A. Very good.

Q. -- are systemically acting, correct?

A. They are.

Q. That would be in both ODT and the oral solution, they're both systemically acting.

A. Correct. I would like to clarify one point.

Again, it goes back to disintegration. Whether a drug acts systemically or locally, it's based on the drug. It's a far bigger challenge to get a drug absorbed

orally than it is to get it to work topically.

In both cases, topical or oral, it has to interact with the GI tract.

And in the case of systemic, it has to get through the GI tract and then to the systemic. In the case of topical, it just has to interact with the topical.

So the fact that you can -- ODTs and oral solutions are equivalent systemically means there is going to be equivalent topically, as well, because topical interaction is the first step in getting the drug absorbed to get to the membrane.

Q. That wouldn't apply to drugs that are not systemically available, though, correct?

A. I'm not sure I understand the question. Could you rephrase it?

Q. So you described that systemically-acting drugs, there is the interaction with the GI tract. It needs to be absorbed.

A. Uh-huh.

Q. The topically-acting drugs, it's only the site of action that matters, correct?

A. That's actually not true. In the case of desonide, not only does it interact topically, but it does get in the systemic, but it's cleared by the liver

before it gets to the systemic.

So the topical could be local, or it could be systemic. It's just that it's cleared before it gets to the bloodstream.

But irrespective, topical or systemic, there is always an interaction with the GI tract, topically or systemically, for that -- for any drug.

Q. When you talk about the absorption of the budesonide systemically, that's not referring to any therapeutic effect, correct, because therapeutic effect of budesonide is topical?

A. That's correct. The -- there is a topical effect with the interaction with the system. The drug does get absorbed, but it's metabolized by the liver before it gets to generating any systemic activity.

Q. What percentage of budesonide is absorbed?

A. You know, I -- I think it's around 10 percent. I think that was the number that Dr. Davies mentioned in his reply, but I'm -- it's in -- it's low enough to where it doesn't generate any systemic effect.

Q. I believe we were talking about Zofran in your example, paragraph 52 of your reply declaration.

So based on the discussions that we just had, and your statement here that the ODT in oral solutions of Zofran are bioequivalent, that would mean that both the

ODT and the oral solution have similar rates of absorption into the bloodstream, correct?

A. Yes, ma'am.

Q. Okay.

A. Whether you give it as an ODT or an oral solution, you're going to get the same blood levels.

Q. And that's important -- the absorption is important for therapeutic effect for a drug like Zofran, correct?

A. For that drug, yes, ma'am.

Q. The third example, you cite to is Clarinex or desloratadine, correct?

A. Yes, ma'am.

Q. And the Clarinex ODT and liquid syrup are both dosed at 5 milligrams, correct?

A. Yes, ma'am.

Q. And desloratadine is systemically acting, correct?

A. Yes, ma'am.

Q. Let's go to Exhibit 1091. This is the exhibit you cite to for your Clarinex example, correct?

A. Sorry. I phased out. My apologies.

Q. Okay. If you turn to page 2, there is a heading that states, "Pharmacokinetic Absorption," correct?

A. Yes, ma'am.

Q. And this section goes from page 2 to page 3, correct?

A. Yes, ma'am.

Q. And at the top of page 3, the first paragraph states: "The pharmacokinetic profile of Clarinex syrup was evaluated in a three-way crossover study in 30 adult volunteers. A single dose of 5 mls of Clarinex syrup containing 5 milligrams of desloratadine was bioequivalent to a single dose of 5 milligrams Clarinex tablet."

Do you see that?

A. Yes, ma'am.

Q. Are so this type of study establishes that the syrup form and the tablet form have bioequivalence, correct?

A. Yes. It means that an ODT that disintegrates or dissolves in the mouth in a small volume is equivalent to the bioavailability of, in this case, an oral syrup. Yes, ma'am.

Q. Corticosteroids, such as budesonide, have very low bioavailability, correct?

A. I don't know that. I know budesonide and that there are corticosteroids like Prednisone, Prednisolone, they're systemically active, but I don't know what

percent of bioavailability.

Q. A topical corticosteroid, such as budesonide, has low to no bioavailability, correct?

A. No, that's not true. It -- it acts locally. It gets to the liver, and it's rapidly metabolized to its inactive form. So it depends on how you define "absorbed."

The FDA defines "absorbed" as to what gets in the systemic circulation, whether it is active or metabolized.

So in the case of budesonide, I'm assuming that it's metabolized to an inactive. You may still measure that, and that's how you use to calculate their overall bioavailability.

Q. The '729 Patent claims topical corticosteroids with no systemic activity, correct?

A. Correct. Right. But, again, as I said previously, budesonide doesn't have activity, because it's rapidly metabolized in the liver. So its active component gets to the systemic circulation in very, very small amounts.

Q. So for the '729 Patent, in topical corticosteroids, a measure of bioavailability is not appropriate or relevant to determine the therapeutic effect of that corticosteroid, correct?

MR. LUMAN: Mischaracterizes the document; incomplete hypothetical.

THE WITNESS: The -- if you're asking in those studies, would you do -- measure blood levels. Is that what you are asking?

BY MS. AGARWAL:

Q. I'm asking whether a measure of bioavailability is relevant to determine the therapeutic effect of a topical corticosteroid.

A. The FDA expects you, even for topical, any topical, to measure blood levels to determine what percentage gets there systemically, so that PK analysis is done.

In the case of budesonide, it works locally. It's rapidly metabolized in the liver, but it's still going to generate some PKs.

So the FDA requires the company to understand that drug and that process.

Does that answer your question?

Q. But that's not relevant to therapeutic effect of budesonide, correct?

A. It -- the therapeutic effect is topically, but you still have to measure that in clinical studies to ensure that your formulation hasn't changed where you get a higher bioavailability than in a different formulation.

But the efficacy isn't determined -- isn't determined by PK. It's determined by clinical studies.

Q. The fourth example that you give in paragraph 52 is Pepcid or famotidine, correct?

A. Famotidine, yes, ma'am.

Q. I got three out of four.

A. You are doing very well for a non-pharmacist. You're doing excellent.

Q. The Pepcid ODT and oral suspension are both dosed at 40 milligrams, correct?

A. Correct.

Q. And the ODT and the oral suspension are bioequivalent, correct?

A. Correct. So this example, along with the other three, show that -- or two of the three that have bioequivalence -- that you can take an ODT and get an equivalent exposure as you do a solution or suspension.

In this case, it's a suspension, not a solution.

So -- so, again, it shows a POSA, that going from a solution or a suspension to an ODT, you don't have to change the dose, and you're going to get similar bioavailability systemically, which means you're going to get similar exposure topically, because you have to give the same exposure topically to the GI tract to get the

same exposure systemically.

Q. Where in the GI tract are these systemic drugs absorbed according to the example?

A. I couldn't even begin to tell you.

An absorption can occur in the stomach. It can occur in the early small intestine. It can occur in the late small intestine. I've developed drugs that had high absorption in the colon. So I'd have to sit down and evaluate each drug to figure out where they're absorbed at. And it could be all the way across those areas.

Q. And none of those are in the upper GI tract, correct?

A. I have no idea. The -- the famotidine is used to treat ulcers. So that could be ulcers in the stomach and the esophagus, because you have reflux. So at least famotidine could be to treat ulcers in the lower esophagus, early small -- which is the early small intestine, early GI tract, or the stomach.

Q. But the famotidine is a systemically-acting drug, correct?

A. It is. But it may have a topical component. I don't -- I know what the drug is used for. I don't know if it's just systemic or if it's topical as well.

But you asked, these don't work in the upper GI tract, and the answer is Pepcid does, because it could be

the stomach or the esophagus where the ulcers are at.

Q. Your reply declaration doesn't cite to any examples that show a topically-acting corticosteroid in liquid form that can use the same dose as a topically-acting drug in an ODT, correct?

A. I'm sorry. Rephrase that again.

Q. You don't cite to anything in your reply declaration that shows a topically-acting corticosteroid in a liquid form that has the same dose as a topically-acting corticosteroid in an ODT, correct?

MR. LUMAN: Objection. Mischaracterizes the document.

THE WITNESS: I don't show specific examples, but, again, a POSA would realize topically is very easy to do, because I don't have to get the drug absorbed. So if I can get the same level of drug with an ODT, as I do with the syrup or a solution, which these four examples show, I can do it with a systemic, if I can do it with a systemic, a POSA would know you can do it topically, because it has to interact topically before it can go systemically.

So by proving it's a systemic activity, a priority would prove that it's working topically or -- or it interacts topically for that topical drug to do what it needs to do.

So that was the purpose of these examples, is to show -- in particular, topical, I don't need a higher dose. Systemically, I don't need a higher dose. So, topically, I shouldn't need a higher dose, either, a POSA would know that, for the same indication.

Now, if you changed medical indications, then that might change.

But for the same indication, you shouldn't need that if it's an ODT versus a solution or a suspension.

MS. AGARWAL: Let's take a five-minute break before we go on to the next topic.

MR. LUMAN: Sure.

(Recess was taken.)

BY MS. AGARWAL:

Q. Let's turn to paragraph 75 of your reply declaration, and in this paragraph you refer to the '865 Patent, correct?

A. Yes, ma'am.

Q. That is Exhibit 1085.

A. Yes, ma'am.

Q. Let's go to Exhibit 1085. This is the patent you are referring to in your reply declaration, correct?

A. Yes, ma'am.

Q. Look at the first sentence of the abstract. It states: "A taste-masked microcapsule composition for

administration of the drug is provided," correct?

A. Yes, ma'am.

Q. If we go to column 4 of the '865 Patent, line 12, 12 or 13, it starts: "The term 'drug'" in quotation marks.

A. Yes, ma'am.

Q. Do you see that?

A. Yes, ma'am.

Q. And so this paragraph defines the term "drug," correct?

A. It says, "Any therapeutic, or otherwise, active agents," yes.

Q. And it goes on to state: "Drugs useful in conjunction with the present invention include antibiotics, antiviral agents," et cetera, and it lists a bunch of drugs, correct?

A. Yes, ma'am.

Q. Corticosteroids are not listed in this list of useful drugs, correct?

A. I'd have to quickly peruse it.

Q. Okay.

A. What I will say is it -- in general, it indicates antiinflammatory agents, I think on line -- it must be 19. Corticosteroids are antiinflammatory agents. So corticosteroids would fall in that general category,

as you list general categories.

Now, I'll have to look and see it if mentions corticosteroids specifically.

I don't -- I don't see anything in there that lists necessarily specific drugs. He just lists class of drugs, and, again, the corticosteroids fall in the area of antiinflammatory agents.

Q. And if you go further down in the paragraph, around line 28, it states: "Generally, the drugs used in conjunction with the present methodology are those which are bitter, or otherwise unpleasant tasting, and thus in need of taste-masking."

Do you see that?

A. Yes, ma'am.

Q. And if we go to claim 1 of the '865 Patent, claim 1 claims a taste-masked microcapsule composition, correct?

A. Yes.

Q. And it is a microcapsule composition of a water-soluble drug, correct?

A. Yes.

Q. And claim 2 claims the taste-masked microcapsule composition, correct?

A. Yes, ma'am.

Q. And claim 3 claims the taste-masked

microcapsule composition of a water-soluble drug, correct?

A. Yes, ma'am.

Q. And budesonide is not a water-soluble drug, correct?

A. In its low dose, it may very well be. I don't know exactly.

Q. Are corticosteroids generally water-soluble?

A. It depends on their -- each compound could be different, and it would depend on their dose. So I can't -- and I don't know if we're -- I don't exactly know for any of the compounds. So some of them could be highly water-soluble -- some could be water-soluble; some could not.

Q. And one last claim I want to point you to, claim 4 claims the taste masks microcapsule composition, correct?

A. Yes, ma'am.

Q. Claims 1, 2, 3, and 4 are directed to taste-masking, correct?

A. They are, but I think if you -- again, look at my report. The reason I looked at that is while it's taste-masked, it also says it releases a drug rapidly once it passes the mouth. So it shows, if I recall correctly, rather the taste-mask loss is virtually

immediately, and shortly thereafter.

So, again, it is to show that this taste-mask could be used in an ODT.

I'm not denying that this talks about taste-masking, but it -- it talks about taste-masking, but it also says that it allows the virtual immediate release shortly after it passes through the mouth.

Q. So I believe you're referring to paragraph 76 of your reply declaration.

A. Yes, ma'am.

Q. And you cite to a few places in the '865 Patent in that paragraph, correct?

A. Yes, ma'am.

Q. And the first quote that you cite to is what you're referring to as the virtually immediate release of the drug, correct?

A. Yes, ma'am.

Q. You don't define what "immediate release" means in your reply declaration, correct?

A. I do not indicate that. Again, it's -- I think as you talk about, it does say shortly after -- virtually immediately and shortly after passage to the mouth. So it's -- when you say "virtually immediately," it means very, very short; very, very quick, a POSA would interpret that as.

What the time would be? To me "virtually immediately" is seconds, and I think a POSA would look at "virtually immediately" as seconds.

Q. If we go back to Exhibit 1085, which is the '865 Patent, and look at that quote in column 2, line 65 to column 3, line 3, and the end of that sentence in column 3 states: "Achieving virtually immediate release of the drug," correct?

A. Correct.

Q. The '865 Patent -- or does the '865 Patent define "immediate release"?

A. I'd have to read it. I don't remember it at that level of detail.

Again, as a POSA reads, virtually immediate release would mean a very, very short period of time.

Q. Does the FDA have a definition for immediate release?

A. They have a rapid releasing -- they do define different things, and I believe rapid -- very rapid releasing is -- is 80 percent at 15 minutes. So anything faster than that is considered very rapid release. I believe that's the correct number. I might be not quite right. And so that -- and so that could entertain anywhere from immediate to within -- you know, 80 percent within a minute or less to up to 15 minutes. And the FDA

considers those equivalent to a solution.

Q. If we turn to column 8 of the '865 Patent, line 47, all the way to the end, it starts: "In," going to the next line, "quantitative terms."

Do you see that?

A. Yes, ma'am.

Q. It states: "In quantitative terms, the targeted release microcapsules desirably provide dissolution of at least 75 percent of the drug within 45 minutes when tested according to the United States pharmacopeia dissolution activity."

Do you see that?

A. Yes, ma'am.

Q. Does this provide any guidance as to what "immediate release" means in the '865 Patent?

A. It -- it doesn't, because it says, at least or at -- at least about 75 and 45 minutes.

I could have 75 percent released in one minute, and it still meets 75 and 45 minutes.

So unless you have a full profile, it can be anything along that.

When I develop a product, I try to get as wide a dissolution spec as I can so I don't fail batches. So even if my drug is a very rapidly, and it dissolves within 5 minutes, I'm shooting for a spec at 75 percent

in 45 minutes. Actually, I shoot for 80 percent, because that's -- that's what the FDA's target is in 45 minutes. That way, you never have to worry about any batches failing. So that's a target.

That doesn't indicate what the actual release rate is. I mean a POSA sees "virtually immediately," or whatever -- yeah, "virtually immediately," they would think it as much faster than 75 percent at 45 minutes.

Q. Let's move on to the second quote that you have in your reply declaration. The last sentence quoting from the abstract states: "These high-coating levels give rise to effective taste-masking, while nevertheless targeted release of the drug."

A. I'm sorry. Can you -- which paragraph are we on?

Q. The second full one.

A. "The composition comprises"?

Q. Yes. The last sentence of that.

A. Uh-huh.

Q. "These high-coating levels give rise to effective taste-masking, while nevertheless allowing targeted release of drugs so that the drug is released shortly after passage through the mouth."

Do you see that?

A. Yes, ma'am.

Q. And that's what you were referring to as the drug being released shortly after passage through the mouth.

A. Yes, that's what the cap said. It goes along with the virtually immediately releasing the drug.

Q. Does the '865 Patent define how long after the drug passes through the mouth the drug would be released?

A. It doesn't give a time, but it says, "virtually immediately." So, again, a POSA would look at it going, that's -- "virtually immediately" is within seconds.

Q. Let's go back to Exhibit 1085, the '865 Patent. If you turn to column 9, we go to lines 23, 25, it states: "An ideal taste-masking microcapsule would allow no dissolution of the drug at all in one minute."

Do you see that?

A. Yes, I do.

Q. So the '865 Patent teaches that the drug is not released at all in one minute, correct?

A. It says, An ideal taste-masking microcapsule would not -- would allow no dissolution of the drug in one minute.

And then it says, "Thus, the preferred microcapsule should allow dissolution of considerably less than 75 percent of the drug in one minute."

So they've already -- they right there -- it

said "the preferred microcapsule should allow dissolution of considerably less than 75 percent of the drug in one minute." So they have already set a limit of 75 percent.

Then they go down to 50 percent, 25, and 5.

So they've already acknowledged that -- that there are targets that it could release within one minute.

Q. If you keep going after less than 5 percent, it says, "Less than 1 percent are still more preferred," correct?

A. Correct. It does. So, obviously, the lower the better, but it still says the preferred is less than 75, and it just keeps working its way down.

So as a POSA reads that, okay, we could have -- as long as you have less than 75 percent a minute, it meets one of the embodiments of this patent.

Q. And you agree that this reference is directed towards taste-masking of bitter drugs, correct?

A. One facet of this is taste-masking, but it also continuously stresses that while there it effectively taste-masks, it allows the drug to work, to be released virtually immediately, and then -- and that section implies that it can be used in ODTs.

So does it have a taste-masking component? Absolutely. But it also stresses the value of the patent

around virtual immediate release of the drug.

Q. Releasing the drug in the mouth would defeat the purpose of the taste-masking that's disclosed in the '865 Patent, correct?

A. Right. But it says it virtually releases shortly after passage through the mouth. So it's not saying -- this patent doesn't say releasing it. It says it rapidly releases or it virtually immediately releases it after it leaves the mouth.

So the time between when it leaves the mouth and it gets into the stomach, it could release in the esophagus.

Q. If we go to column 6 of the '865 Patent, starting at line 56, it states that: "Another preferred class of drugs are water-soluble H2-antagonists, more preferably H2-antagonists selected from the group consisting of ranitidine; famotidine," et cetera. Correct?

A. Yes, ma'am.

Q. Then it gives the example of ranitidine.

A. Ranitidine, yes, ma'am.

Q. And ranitidine is a systemically-acting drug, correct?

A. Yes, ma'am, it is, to the best of my knowledge. Yes, it is.

Q. So the taste-masking of ranitidine, specifically, would ensure that the drug is taste-masked in the mouth, but would not affect bioavailability, correct?

A. That would be an intent, yes. That would be taste-masked well enough to mask it, but it would release the drug virtually immediately, which means early in the small -- early in the GI tract, so it was available to be absorbed throughout the whole GI tract.

So the patent is really designed, in my mind, as a POSA would look at, as two things: Taste-masking, but still being able to -- to achieve a virtual release of a drug to allow its best chance for being absorbed; or to work actively, locally within the GI tract.

Q. How long would a drug like ranitidine last in the stomach or the GI tract while it's being absorbed?

MR. LUMAN: Incomplete hypothetical.

THE WITNESS: What do you mean? Can you repeat the question again?

BY MS. AGARWAL:

Q. Yes. How -- for how long would a drug like ranitidine last in the stomach or the GI tract while it's being absorbed?

MR. LUMAN: Incomplete hypothetical.

THE WITNESS: What do you mean by "last"?

BY MS. AGARWAL:

Q. How long would it take for it to be completely absorbed?

MR. LUMAN: Same objection.

THE WITNESS: To the best of my knowledge, ranitidine is not completely absorbed. It has low bioavailability. I don't recall us doing -- I worked on the drug, so I don't -- but I don't recall us doing regional absorption studies. So I don't know exactly where it is absorbed at. So I can't answer that question, sorry.

BY MS. AGARWAL:

Q. How long does it take for a tablet or something that you swallow to go from the mouth to the stomach?

A. It -- it depends on the size of the tablet. It could be anywhere from -- I'm estimating now -- probably 4 or 5 seconds up to hours. It all depends on the size of the dosage form. It depends on the surface coating of the tablet or capsule. Is it tacky? If they're large, and they're tacky, they can hang up in a sphincter that connects the esophagus to the stomach, and the patient never knows that. So it could be anywhere from, like I said, four to five seconds to hours.

Q. An orally disintegrating tablet, an ODT, how long would it take for an ODT to transverse from the

mouth to the stomach?

A. I haven't measured those times, but based on the way they work, I would expect them to be more in the matter of seconds to minutes, because it is a small volume, as I indicated in my report.

Usually, when you get about 1.1 mls, which is what's in the literature, 1 to 2 mls, you'll swallow, and so it's -- but it's going to be a small volume of a few mls that's going to take its time to work down the esophagus, or it takes much longer for an ODT than it would for a standard immediate-release tablet that you swallow with large amounts of water.

Q. Let's go back to your reply declaration.

In paragraph 77, you cite to the '865 Patent's disclosure of a porous structure, correct?

A. Yeah, what I -- what I recite from it is it talks about the polymeric walls and the microcapsule and the form by coacervation and that they typically have pores, yes, they do, in 77.

Q. And go back to the '865 Patent, Exhibit 1085, to where you cite to that porous structure. It is column 9, and starting at line 31 of column 9, it states: "Although the present invention is not limited by any theory of operation, it is believed that the polymeric walls of the microcapsules, particularly those formed by

coacervation, typically have pores," correct?

A. Yes, ma'am.

Q. And if you go down further to line 41, it states that: "Another mechanism of release is believed to occur --" sorry. Let me start again.

"Another mechanism of release, which is believed to occur, is breakage of the coating," correct?

A. Yes, ma'am.

Q. And if we go to column 1 of the '865 Patent, starting at line 62, it states: "In contrast to prior microencapsulation techniques, the present invention makes use of materials and process parameters which enable preparation of uniform, impervious coatings, and involves preparation and formulations of having high coating levels."

Do you see that?

A. Yes, ma'am.

Q. "impervious coating" indicates that the drug is completely coated by the taste-masking coating, correct?

A. Yeah, but if you continue on at paragraph -- up to 2, it talks -- "taste-masking while providing for release of drug shortly after the drug passes through the mouth."

So is it impervious? Does it protect taste-masking? It does. We've discussed that, and I

agree with that.

But it also discusses that it provides for the release of the drug shortly after it passes the mouth, so it passes very quickly, and -- and this inventor indicated a possible couple of mechanisms by which that occurs.

Q. Impervious would indicate there are no pores, correct?

A. No, not necessarily. Impervious could mean you can't go through the -- you can't go through the polymer itself, but you can -- you could go through the pores, which is how they indicated their mechanism of action -- one of the two mechanisms of actions that they propose.

Q. There is no example of the mechanism of action working in the way that they propose through the pores, correct, in the '865 Patent?

MR. LUMAN: Form.

THE WITNESS: They -- they're the authors. They proposed two possible mechanisms. I think they -- if we go back to -- remind me what that paragraph is.

BY MS. AGARWAL:

Q. In column 9.

A. They may have indicated there were other ones. And they say here -- I think they also said somewhere in there irrespective -- regardless of the reason for these

effects, these -- it can be adjusted to adjust the release rate of the drug.

So, again, the patent indicates we can effectively taste-mask it, but we can have virtually immediate release of the drug after it leaves the mouth.

So, you know, how they define impervious and then the fact that they can release the drug rapidly based on these mechanisms is what the patent entails.

MS. AGARWAL: I have no further questions.

THE WITNESS: Thank you.

MR. LUMAN: We have no further question, either. So we can go off the record.

(The deposition adjourned at 11:36 a.m.)

* * *

I declare under penalty of perjury, under the laws of the State of California, that the foregoing testimony, as corrected, is the truth, the whole truth, and nothing but the truth.

_____

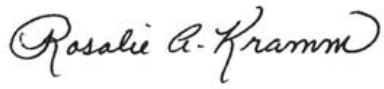
ALAN PARR, PHARM.D

REPORTER'S CERTIFICATE

I, Rosalie A. Kramm, Certified Shorthand Reporter for the State of California, do hereby certify:

That the witness named in the foregoing deposition was by me duly sworn; that the deposition was then taken before me at the time and place herein set forth; that the testimony and proceedings were reported stenographically by me and were transcribed through computerized transcription by me; that the foregoing is a true record of the testimony and proceedings taken at that time; and that I am not interested in the event of the action.

Witness my hand dated August 28, 2025.



ROSALIE A. KRAMM

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Nathanael Luman, Esq.
nate.luman@knobbe.com
August 29, 2025
RE: Pharma, Falk GMBH v. Ellodi Pharmaceuticals LP
8/25/2025, Alan Parr , Pharm.D (#7534844)

The above-referenced transcript is available for review.

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Alan Parr , Pharm.D Date

Pharma, Falk GMBH v. Ellodi Pharmaceuticals LP

Alan Parr , Pharm.D (#7534844)

ACKNOWLEDGEMENT OF DEPONENT

I, Alan Parr , Pharm.D, do hereby declare that I have read the foregoing transcript, I have made any corrections, additions, or changes I deemed necessary as noted above to be appended hereto, and that the same is a true, correct and complete transcript of the testimony given by me.

_____ _____

Alan Parr , Pharm.D Date

*If notary is required

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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