

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. FALK PHARMA GMBH,
Petitioner

v.

ELLODI PHARMACEUTICALS, L.P.,
Patent Owner

Case No. 1PR2024-01197

Patent No. 8,771,729

DEPOSITION OF ALAN F. PARR, PHARM.D., PH.D.

San Diego, California

Wednesday, April 9, 2025

Volume 1

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DEPOSITION OF ALAN F. PARR, PHARM.D., PH.D.,
Volume 1, taken on behalf of Patent Owner, at 3579 Valley
Centre Drive, Suite 300, San Diego, California, beginning
at 8:54 a.m. and ending at 12:02 p.m., on Wednesday,
April 9, 2025, before LESLIE JOHNSON, Certified Shorthand
Reporter No. 11451.

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I N D E X

WITNESS

EXAMINATION

ALAN F. PARR, PHARM.D., PH.D.

Volume 1

BY MS. AGARWAL

6

BY MR. LUMAN

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EXHIBITS

ALAN F. PARR, PHARM.D., PH.D.

NUMBER	DESCRIPTION	PAGE
Exhibit 1	Petition for Inter Partes Review of U.S. Patent No. 8,771,729	9
Exhibit 1001	U.S. Patent 8,771,729	24
Exhibit 1002	United States Patent Application Publication 2007/0111978	60
Exhibit 1005	Guidance for Industry Orally Disintegrating Tablets	52
Exhibit 1008	International Patent Application, "Fast Dispersing Dosage Forms Free of Gelatin"	74
Exhibit 1010	"Eosinophilic gastroenteritis treated with non-enteric-coated budesonide tablets"	30
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EXHIBITS (Cont.)

ALAN F. PARR, PHARM.D., PH.D.

NUMBER	DESCRIPTION	PAGE
Exhibit 1030	Declaration of Alan F. Parr, Pharm.D, Ph.D., In Support of Petition for Inter Partes Review of U.S. Patent No. 8,771,729	11

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215-241-1000 ~ 610-434-8588 ~ 302-571-0510 ~ 202-803-8830

1 San Diego, California; Wednesday, April 9, 2025

2 8:54 a.m.

3
4 ALAN PARR, PHARM.D., PH.D.,
5 having been first duly sworn, was examined and testified
6 as follows:
7

8 EXAMINATION

9 BY MS. AGARWAL:

10 Q Hi, Dr. Parr. My name is Isha Agarwal. I'll
11 be taking your deposition today.

12 A Okay.

13 Q Could you please state your name and address
14 for the record.

15 A Yeah. My name is Alan Frank Parr. My address
16 is 23 Glenmore Court in Acworth, Georgia. And the ZIP
17 is 30101.

18 Q Do you understand that you're here today for
19 the cross-examination on the declaration testimony that
20 you submitted in IPR 2024-01197?

21 A Yes, ma'am.

22 Q Have you ever been deposed before?

23 A Yes, ma'am.

24 Q About how many times would you say?

25 A Four or five maybe.

1 Q So you likely have an idea of the process, but
2 I'll just go through it with you.

3 A Thank you.

4 Q So I will be asking you questions today. You
5 should answer them to the best of your ability.

6 Do you understand that you just took an oath
7 with the court reporter to tell the truth here today?

8 A Yes, ma'am, I do.

9 Q And is there any reason why you cannot
10 completely and truthfully answer my questions today?

11 A Not that I'm aware of.

12 Q And do you understand that, even if an
13 attorney objects during the deposition, you must still
14 answer the question, unless he instructs you not to do
15 so on the basis of privilege?

16 A Yes, ma'am.

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

20 Do you understand that?

21 A Yes, ma'am.

22 Q If you don't understand a question, please let
23 me know. Otherwise, we will assume that you understood
24 my question.

25 Is that okay?

1 A Yes, ma'am, that is.

2 Q We'll take breaks about every hour, but if you
3 need a break, just let me know. I just ask that you
4 don't do so while a question is pending.

5 Is that okay?

6 A Yes, ma'am.

7 Q And do you understand that under the rules,
8 you are not allowed to speak with any of the attorneys
9 here about your testimony or anticipated testimony
10 during the breaks?

11 A Yes, ma'am.

12 Q And just to be certain, you're not in
13 communication with anyone via text or chat functions or
14 anything like that, correct?

15 A No. If you'd like, I can turn my phone off.

16 Q Yes. That would be great. Thank you.

17 A I silenced it, but I'll turn it off
18 completely.

19 Q Have you had any discussions with anyone
20 employed at Dr. Falk about your deposition?

21 A No, ma'am.

22 Q Have you had any discussions with any
23 individuals employed by Dr. Falk about the subject
24 matter of your declaration?

25 A No, ma'am.

1 Q Do you understand that the '729 patent is
2 being challenged in this IPR?

3 A Yes, ma'am.

4 Q And did you read Dr. Falk's IPR petition in
5 this matter?

6 A I don't know if I did or not.

7 (Exhibit 1 marked for identification.)

8 BY MS. AGARWAL:

9 Q I'll give you a copy of the IPR petition
10 marked as Exhibit 1.

11 Just looking at it briefly, do you remember if
12 you read this?

13 A I've got to be honest, I don't -- I may have,
14 but I don't recall.

15 Q Okay. That's okay.

16 Do you remember if you read Ellodi's POPR, the
17 preliminary response or surreply in this matter?

18 A I don't recall reading that, but I may have.
19 It didn't seem relevant to what I wrote, so . . .

20 Q Do you remember reading Dr. Falk's reply in
21 this matter?

22 A No, ma'am.

23 Q Did you read the Board's institution decision
24 in this matter?

25 A That I did read, yes, ma'am.

1 Q You're currently employed by BioCeuticals LLC,
2 correct?

3 A Yes, ma'am.

4 Q When did you first become aware that there was
5 a patent dispute between Dr. Falk and Ellodi?

6 A When I was contacted by this client.

7 Q And when was that?

8 A Over a year ago, but I couldn't tell you
9 exactly when.

10 Q Did you have any involvement in the decision
11 by Dr. Falk to file an IPR against the '729 patent?

12 A No, ma'am.

13 Q How many discussions did you have with
14 Dr. Falk's counsel at any point in time prior to
15 submitting your declaration?

16 A Well, prior to submitting -- wow, that's a
17 while back. It's going to be a gross estimate, but I'd
18 say maybe three or four times.

19 Q And you said that you were contacted over a
20 year ago for this matter?

21 A Uh-huh.

22 Q Was that in 2003 [sic] then?

23 A Again, I'm only going by -- I signed this on
24 April 2024. So I don't know how far -- whether it was
25 in the end of 2023 or early 2024. That I don't know. I

1 don't recall. Sorry.

2 (Exhibit 1030 marked for identification.)

3 BY MS. AGARWAL:

4 Q We're going to -- I'm going to hand you a copy
5 of your declaration now, which is Exhibit 1030. I know
6 you have a copy in front of you as well. I'll just mark
7 it for the record.

8 A Okay.

9 MR. LUMAN: Just for housekeeping, we're going
10 to keep it as 1030, right?

11 MS. AGARWAL: Yes.

12 MR. LUMAN: Okay. Thank you.

13 BY MS. AGARWAL:

14 Q This is your declaration, correct?

15 A Yes, ma'am. It appears to be.

16 Q And it's signed on the last page by you,
17 correct?

18 A Yes, ma'am.

19 Q April 17, 2024?

20 A Yes, ma'am.

21 Q Did you personally draft the first draft of
22 your declaration?

23 A It was done in combination. We had a series
24 of discussions, and then it was drafted. So I added
25 some; they added some.

1 Q Did you personally type the first draft of
2 your declaration?

3 A I took what they had and added my stuff in, to
4 the best of my knowledge.

5 Q Was anything that you wanted to add in not
6 added to your declaration?

7 A Not that I recall, no.

8 Q Was anything taken out?

9 A Not that I recall, no.

10 Q Did the statements in your declaration change
11 significantly from the first draft?

12 MR. LUMAN: Hold on. I think you're getting
13 into discussions between Dr. Parr and counsel, and so
14 I'm going to instruct him not to answer on the grounds
15 of privilege.

16 BY MS. AGARWAL:

17 Q We can move on.

18 Did you personally write any portion of your
19 declaration?

20 A Yes. I said a second ago, I think I wrote
21 some -- added some sentences to some paragraphs, but I
22 can't recall exactly which ones or what.

23 Q How many drafts were there of your declaration
24 before you signed it?

25 A Again, that would be a guess. It would be a

1 pure guess if I gave you a number.

2 Q Ballpark, less than 10?

3 A Yeah. Definitely less than 10.

4 Q How long did you spend overall working on your
5 declaration?

6 A Again, I don't have exact timings and
7 everything. Actual time, again, would be an estimate.
8 I don't have that off the top of my head.

9 Q And you stated in your declaration that you
10 considered the materials listed in the petition for your
11 declaration, correct?

12 A Yes, ma'am.

13 MR. LUMAN: Mischaracterizes the document.

14 BY MS. AGARWAL:

15 Q Who first identified the documents listed in
16 the "Materials Considered" section of your declaration?

17 A The majority of them came from counsel. I
18 think the one question was around the USP dissolution.
19 And I don't remember if I submitted that or if they did.

20 Q So, just to clarify, most of the materials
21 considered came from counsel, and you may or may not
22 have provided the USP dissolution test, correct?

23 A Yes, ma'am.

24 Q And when was the patent identified to you?

25 A I'm not sure I understand your question.

1 Q So was the art -- the materials considered,
2 was that identified to you at the same time as when the
3 patent was identified to you, or did you read the patent
4 before?

5 A I'm sorry. I'm trying to think what you're
6 asking. Could I ask you to ask it one more time?

7 Q Sure.

8 Was the prior art given to you the same time
9 that the patent was given to you?

10 A I got a series of prior arts, but I can't
11 recall whether the patent was before that, part way
12 through that, or at the end of it.

13 Q Do you recall if you reviewed the claims of
14 the '729 patent before reviewing the prior art?

15 A Again, I don't have a clear answer on that. I
16 don't recall the timings of whether I saw the patent in
17 its entirety or whether it was part way through getting
18 documents or towards the end. I just don't recall that.
19 Sorry.

20 Q Prior to submitting your declaration
21 testimony, did you review any documents other than those
22 that are listed in your declaration?

23 A No, ma'am. I just went through the ones that
24 were listed.

25 Q Did you review any other documents prior to

1 submitting your declaration testimony?

2 A That wasn't in my document?

3 Q Yes.

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

5 Q And besides those materials considered that
6 are in your declaration, you're not relying on any other
7 documentary evidence to support your declaration,
8 correct?

9 A Other than the common knowledge of a POSA.

10 Q In preparation for today's deposition, who did
11 you meet with?

12 A I met with the three attorneys -- Mr. Luman,
13 Minnick, and Mr. Furman.

14 Q How long did you meet with them?

15 A We met Monday and Tuesday of this week.

16 Q A whole day, half the day?

17 A It was probably somewhere between six and
18 seven hours per day.

19 Q Did you review any documents during your
20 preparation?

21 A We reviewed my report and the associated
22 documents, yes.

23 Q And what do you mean by "the associated
24 documents"?

25 A The ones listed in the exhibits.

1 Q Did you review anything else?

2 A No, ma'am.

3 Q Have you done any further investigation of
4 documents or other evidence since April 17, 2024 related
5 to your declaration testimony?

6 A No, ma'am.

7 Q Have you done any further investigation of
8 documents or other evidence related to today's
9 deposition?

10 A No, ma'am.

11 Q And so you're not relying on any additional
12 information that isn't in your declaration or the listed
13 exhibits to support your testimony here today, correct?

14 A Other than POSA -- the knowledge that a POSA
15 would have, no.

16 Q Have you had any conversations with
17 nonattorneys regarding the deposition testimony today?

18 A No, ma'am.

19 Q Orally disintegrating tablets are called ODTs
20 correct?

21 A Yes, ma'am.

22 Q So, if I say "ODT," you'll understand what I'm
23 saying?

24 A Yes, ma'am.

25 Q And ODTs dissolve in the mouth, correct?

1 A They disintegrate/dissolve in the mouth, yes.

2 Q And generally speaking, ODTs' mechanism of
3 action is traditionally to deliver systemically active
4 drugs, correct?

5 A No. I don't agree with that.

6 They could be systemic or they could be
7 topical.

8 Q Are you aware of any drugs that have been
9 developed as an ODT for topical administration?

10 A I don't know all drugs that are an ODT, so I
11 don't think I can answer that question. I'm not aware
12 of any, but doesn't mean there aren't any.

13 Q Did you investigate for this case whether
14 there are any ODTs that contain topical drugs?

15 A No, ma'am, I did not.

16 In my report, there -- I quoted, I think, a
17 paper by Fu that had a list of products that are on the
18 market using ODTs.

19 Q Are any of those drugs listed in Fu topical?

20 A I'd have to go back and look and see. I
21 didn't divide them out in that order. I'd have to look
22 at that.

23 Q If any were topical that were listed in Fu,
24 you would have listed those out in your report, correct?

25 A I don't know if I would have. I didn't -- I

1 looked at Fu just as a reference document and just
2 generally the number the products that were ODTs. I
3 didn't interrogate each and every compound and their
4 mechanism of action.

5 Q Are you aware of any drugs that have been
6 developed as an ODT for topical administration of the
7 esophagus?

8 A No, I do not. But I haven't practiced
9 pharmacy for quite a while, so it could be out there and
10 I just haven't seen it in the last 12 years.

11 Q You didn't do any investigation into that for
12 this declaration, correct?

13 A No, ma'am.

14 Q Have you ever tried to develop a drug where
15 the site of action is the esophagus?

16 A No, I have not.

17 Q Have you ever developed a drug using topicals?

18 A Topicals, yes.

19 Q What kind of formulation were those?

20 A In this case, it was a topical cream.

21 Q And what was the drug in that topical cream?

22 A Oh, golly. Acyclovir.

23 Q What class of drugs is that?

24 A It's an antiviral. I think it was acyclovir.
25 I'm pretty sure it was acyclovir. It was for a client a

1 while back. I haven't worked on it for quite a while.

2 Q And does acyclovir have systemic activity or
3 localized activity?

4 A It can have both. We were developing it to
5 have a local activity to some herpes viruses.

6 Q Have you ever developed a drug involving
7 corticosteroids?

8 A Let me think about that.

9 No. I don't recall.

10 Q Have you ever developed a drug using topical
11 corticosteroids?

12 A No. I don't believe I have.

13 Q Did you ever work on any ODT formulations?

14 A Yes, ma'am.

15 Q How many would you say?

16 A Three.

17 Q And what drugs did those involve?

18 A One was ondansetron. Another one was Lamictal
19 or lamotrigine. And the third one was sumatriptan.

20 Q What class of drugs are those?

21 A The ondansetron is to treat -- it's an
22 anti-emetic to treat postoperative nausea or vomiting or
23 chemotherapy-induced nausea or vomiting.

24 Q So that's systemic acting, correct?

25 A That one is, yes.

1 Q And then lamotrigine?

2 A Lamotrigine is to treat epilepsy.

3 Q That's also systemic acting, correct?

4 A Yes, ma'am.

5 Q And the last one?

6 A Sumatriptan.

7 Q Sumatriptan.

8 A That's for migraines. And that's systemic as
9 well.

10 Q You developed all of these while you were at
11 GSK, correct?

12 A Yes, ma'am.

13 Q What other types of formulations did you
14 develop at GSK?

15 A A number of sustained-release formulations, a
16 number of immediate-release tablets and capsules, soft
17 gelatin capsule. I did some IV premixed mini-bags a
18 long, long time ago.

19 Q None of these involved corticosteroids,
20 correct?

21 A No, they did not.

22 Q And did any of them involve topical drug
23 activity, other than the acyclovir?

24 A I do not believe so, no.

25 Q At GSK, you were also charged with designing

1 and developing novel pharmacokinetic studies and
2 methods, correct?

3 A Yes, ma'am.

4 Q Pharmacokinetic studies are not very relevant
5 to topical formulations, correct?

6 A Actually, that's not true. Because you can
7 still get drugs absorbed topically into the systemic
8 circulation. You have to measure PK to determine how
9 much is absorbed into the systemic circulation.

10 Q But for topical efficacy, pharmacokinetics are
11 not very relevant, correct?

12 A I disagree. You still have to do the PK to
13 make sure that nothing gets through the abraded tissue
14 and into the systemic circulation. You have to prove
15 that to the FDA, that it doesn't get in systemically.

16 Q So the pharmacokinetic studies there are
17 relevant to prove that the drug is not systemically
18 active, correct?

19 A It depends on what we were studying.

20 If they were topical, it was to prove it was
21 not there. If they were systemic, we used the animals
22 and the PK to determine could we change the PK profile
23 of the formulation that we just developed.

24 Q While you were doing these evaluations at GSK,
25 did you evaluate any oral dosage forms?

1 A Yes.

2 Q Did you evaluate any ODTs?

3 A Not in the animals. I don't recall doing it
4 in the animals, no, sir -- no, ma'am.

5 Q What type of oral dosage forms did you
6 evaluate?

7 A We evaluated sustained release, immediate
8 release, and inhaled, IVs, and some gastric retentive
9 dosage forms. That would probably cover pretty much all
10 of them.

11 Q Did any of these oral dosage forms that you
12 evaluated have any topically acting drugs?

13 A Not that I recall.

14 Q So they were all systemic, correct?

15 A Yes, ma'am.

16 Q Would your evaluation have differed between a
17 systemic versus a topical drug?

18 A I'm sorry. Could you ask the question again?

19 Q When you were evaluating these dosage forms in
20 your role at GSK, would your evaluation methodology have
21 differed between a systemic versus a topical drug?

22 A The development process for a formulation is
23 fairly standard routine of do A, B, C, D, E, kind of
24 thing. So, no, I don't believe that it would have
25 changed based on whether it was systemic or topically.

1 We still needed to know what PK was going to do for that
2 particular formulation.

3 Q You'll understand, if I say "EoE," that means
4 eosinophilic esophagitis, right?

5 A Yes, ma'am.

6 Q Did you know about EoE before you were hired
7 for this matter?

8 A Yes, I did.

9 Q What did you know about EoE?

10 A Just the general disease state. I have a
11 particular interest in GI over my years, so I spent a
12 lot of time reading about GI, trying to control movement
13 and dosage forms through the GI tract.

14 Q What does it mean for a composition to have no
15 significant systemic glucocorticoid or mineralocorticoid
16 activity after oral administration?

17 MR. LUMAN: Incomplete hypothetical.

18 THE WITNESS: What that means is that the drug
19 doesn't elicit systemic responses within that human or
20 the animal that it's administered to. And the
21 mineralocorticoids and glucocorticoids hit a lot of
22 receptors that cause a lot of problems. Long-term
23 systemic steroid leads to a lot of not nice
24 side-effects.

25 / / / /

1 BY MS. AGARWAL:

2 Q None of the prior art you cite to in your
3 declaration contained a topical corticosteroid, correct?

4 A I'm sorry?

5 Q None of the prior art that you cite to in your
6 declaration contains a topical corticosteroid containing
7 ODT, correct?

8 MR. LUMAN: Mischaracterizes the documents.

9 THE WITNESS: No. I -- there were a number of
10 patents that talked about ODTs with budesonide as well
11 as other drugs for the topical treatment of GI issues.

12 (Exhibit 1001 marked for identification.)

13 BY MS. AGARWAL:

14 Q We'll go through them.

15 I'm going to hand you Exhibit 1001, which is
16 the '729 patent.

17 A Thank you.

18 Q If you'd go to claim 1, please.

19 Just read claim 1 to yourself, and let me know
20 when you're done.

21 A Okay. I've read it.

22 Q The mechanism of action of the pharmaceutical
23 composition in claim 1 is topical administration,
24 correct?

25 A It says "no systemic mineral glucocorticoid

1 activity." And it says it's topically administered,
2 yes, ma'am.

3 Q And the drug is deposited on a localized site
4 of action, correct?

5 A Yes. On a deposit on a -- topically on an
6 upper GI tract. In the upper GI tract.

7 Q So the upper GI tract is the localized site of
8 action, correct?

9 A Yes.

10 Q You said that claim 1 reads that there is no
11 systemic glucocorticoid activity, and so it's topically
12 administered, correct?

13 MR. LUMAN: Mischaracterizes his testimony.

14 THE WITNESS: What I said was there is no
15 significant systemic corticosteroids.

16 And then you asked about whether it was
17 topically deposited. And I read down and where it said
18 that it's deposited topically in the upper GI contract.

19 BY MS. AGARWAL:

20 Q So there's no systemic activity, according to
21 claim 1, correct?

22 MR. LUMAN: Mischaracterizes.

23 THE WITNESS: No. What it says is "no
24 significant systemic activity," glucocorticoid or
25 mineralocorticoid activities.

1 BY MS. AGARWAL:

2 Q So absorption of the drug would play an
3 insignificant role in the mechanism of action, correct?

4 A Well, that's what they're proposing.

5 So I'm not sure if that answers your question,
6 but . . .

7 Q What would you define as significant systemic
8 activity?

9 MR. LUMAN: Calls for a legal conclusion.

10 THE WITNESS: As for -- I'm sorry. Repeat the
11 question again.

12 BY MS. AGARWAL:

13 Q What would you define as significant systemic
14 activity?

15 MR. LUMAN: Same objection.

16 THE WITNESS: It would be the EIC biological
17 responses to the levels of the drug that are in there.

18 BY MS. AGARWAL:

19 Q So when claim 1 says "no significant systemic
20 glucocorticoid or mineralocorticoid activity," that
21 would mean that you would not see significant biological
22 responses?

23 A Yes, ma'am.

24 MR. LUMAN: Calls for a legal conclusion.

25 Mischaracterizes the document.

1 BY MS. AGARWAL:

2 Q If you could go to column 3 of the '729 patent
3 starting on line 10 or 11, it states "The term 'having
4 no significant systemic glucocorticoid or
5 mineralocorticoid activity,' as used herein refers to
6 corticosteroid steroid compositions which no do not
7 provide a generalized effect in the body through
8 absorption into the circulation but do provide local
9 effects through topical contact with the diseased
10 tissue."

11 Do you see that?

12 A Yes, ma'am.

13 Q And so the mechanism of claim 1, "having no
14 significant systemic glucocorticoid or mineralocorticoid
15 activity," means that absorption of the drug plays no
16 role in the mechanism of action, correct?

17 MR. LUMAN: Mischaracterizes the document.

18 THE WITNESS: Based on the definition, yes.

19 BY MS. AGARWAL:

20 Q And that's the definition that you applied in
21 your declaration, correct?

22 A I'd have to look at that to make sure.

23 Q We can go to your declaration, which is
24 Exhibit 1030. And you can go to paragraph 113.

25 In paragraph 113, you state that "The '729

1 patent defines 'having no significant systemic
2 glucocorticoid or mineralocorticoid activity'" -- that's
3 the definition that we just read -- and then you state
4 at the end of the paragraph "I have applied this
5 definition."

6 Do you see that?

7 A Yes, ma'am, I do.

8 Q So you applied this definition --

9 A Yes, ma'am.

10 Q -- in your declaration, correct?

11 Let's stay in your declaration. Let's go to
12 paragraph 34. Here, right above paragraph 35, you've
13 got a screenshot of a table describing various drug
14 dosage forms.

15 Do you see that?

16 A Yes, ma'am.

17 Q Were you aware of any of these drugs prior to
18 being hired as an expert for this IPR?

19 A Some of them are familiar to me. The first
20 three I'm familiar with, but I can't tell you where I
21 first learned about them or why.

22 Q And the remainder are new to you, correct?

23 A I'm not familiar with those, no, ma'am.

24 Q None of these drugs are ODTs comprising
25 topical corticosteroids, correct?

1 We can go through them one by one.

2 So Salofalk, is there an ODT.

3 A It just says "tablet." It doesn't define
4 whether it's an immediate release or an ODT, so I don't
5 know. It just says "tablet."

6 Q And you didn't do any investigation as to
7 whether this is an ODT?

8 A No, ma'am.

9 Q And does this contain a topical drug?

10 A I don't know, actually. The drug could have
11 both topical and systemic, but I don't know that for
12 sure.

13 Q The second drug, Budenofalk, is this an ODT?

14 A It says a "capsule." There are patents that
15 indicate ODTs for capsules. They don't delineate, so I
16 couldn't tell you if it's immediate release, sustained
17 release, an ODT capsule. All I know is it's a capsule.

18 Q Did you investigate Budenofalk for this
19 declaration?

20 A No, ma'am.

21 Q And the active substance, budesonide, is that
22 a systemic or topical drug?

23 A It's only about 10 percent absorbed, and it's
24 used more topical than systemically.

25 Q Are you aware that Budenofalk is an

1 enterically coated tablet?

2 A I don't know it's a tablet. They only list
3 capsules and rectal foams.

4 Q An enterically coated capsule then?

5 A I don't know one way or the other.

6 Q Are you aware of whether Budenofalk has been
7 used to treat EoE?

8 A I do know in one of the papers it discussed
9 using a Budenofalk tablet that they dissolved to treat
10 in one of the papers. But I don't remember any more
11 detail on that.

12 Q You don't recall whether it was in the
13 esophagus or elsewhere?

14 A I think it was the esophagus. I think it was
15 for the early GI tract.

16 Q We'll go over the papers.

17 In the paper that you're referring to,
18 Budenofalk was not topically administered to the
19 esophagus there, though, correct?

20 A Yeah, it was. They -- if I remember right,
21 the tablet was actually designed to be dissolved in
22 water and used as an enema. But the clinicians used the
23 tablet, dissolved it in water, and gave it orally.

24 (Exhibit 1010 marked for identification.)

25 / / / /

1 BY MS. AGARWAL:

2 Q Why don't we go to that paper. I believe
3 you're talking about Exhibit 1010.

4 I'm handing you Exhibit 1010, which is titled
5 "Eosinophilic gastroenteritis treated with
6 non-enteric-coated budesonide tablets" by Tan, correct?

7 A Yes, ma'am.

8 Q Do you recognize this exhibit?

9 A Yes. I remember reviewing it. I haven't read
10 it lately, but I remember reading it at one point.

11 Q Is this the exhibit that you were referencing
12 just now?

13 A Let me see.

14 It is. And I was in error. I thought they
15 dissolved it in water, but they didn't dissolve it in
16 water. But they swallowed it with water.

17 Q This is not one of the primary references that
18 you rely on for your declaration -- correct? -- for
19 obviousness?

20 A I don't believe I used Tan in any of my
21 obviousness.

22 Q This is a case study on one patient, correct?

23 A Yes, ma'am.

24 Q And the patient presented with upper abdominal
25 pain, correct?

1 A Yeah. Recurrent cramping pain in the upper
2 abdominal -- upper abdomen, yes.

3 Q And the upper abdomen is after the esophagus,
4 correct?

5 A I don't know how to answer that because the
6 abdomen is here (indicating). The esophagus goes into
7 the abdomen. So the pain radiates strangely. So I
8 would say the esophagus.

9 I guess, could you rephrase the question?

10 Q So why don't I point you to -- in the second
11 column of the first page, about halfway down, there's a
12 sentence that says "To ascertain the diagnosis of
13 eosinophilic gastroenteritis, a full thickness surgical
14 antrum biopsy was taken."

15 Do you see that?

16 A Yes, ma'am.

17 Q Where did the antrum biopsy occur?

18 A I don't know that. I'm not a physician.

19 I know the antrum is part of the upper
20 stomach, but I don't know where that biopsy would be.

21 Q So that would be in the stomach -- correct? --
22 not the esophagus?

23 A The antrum is the stomach, but the biopsy
24 could include the antrum and possibly the esophagus
25 where it goes into the stomach.

1 Again, I'm not a physician, so . . .

2 Q So you're not sure then?

3 A No. All it says is -- I'm sure where the
4 antrum is, but where they do the actual biopsy, I'm not
5 aware of that.

6 Q And the patient here was given budesonide
7 orally, correct?

8 A Yes. They were given 4 milligrams daily.

9 Q It says the tablets were taken orally -- this
10 is the bottom of the first page: "These tablets were
11 taken orally, not dissolved in fluid but swallowed with
12 water."

13 MR. LUMAN: Where are you reading from?

14 MS. AGARWAL: The bottom, last sentence of the
15 first page, onto the second page.

16 It says "These tablets were taken orally, not
17 dissolved in fluid but swallowed with water."

18 THE WITNESS: Was that a question?

19 BY MS. AGARWAL:

20 Q Do you see that?

21 A Yes, ma'am.

22 Q So the patient swallowed the tablets, correct?

23 A They swallowed them with water.

24 What I don't know with that particular
25 product, since it was designed as -- to be used as an

1 enema, typically, those tablets are rapidly
2 disintegrating. So they disintegrate quickly so you can
3 give the enema. And I don't know if that's how that
4 product works or not. So swallowing it with a little
5 bit of water could be enough where it would start to
6 disintegrate in the mouth.

7 Q If you look on page 427 of Tan, the first
8 paragraph, a little more than halfway down, it states
9 that "Budesonide is used mainly in Crohn's disease,
10 where it acts on the small bowel and the first part of
11 the colon," correct?

12 A Yes, ma'am.

13 Q And then further down in the second paragraph,
14 about halfway down, it says "In our patient, the drug
15 had to be released more proximal in the stomach and the
16 proximal small bowel."

17 Do you see that?

18 A Yes, ma'am.

19 Q So, in this patient, the budesonide was
20 released in the stomach and the proximal small bowel,
21 correct?

22 A Yes. The other thing I point out is this is
23 for eosinophilic gastritis, which is a broad category
24 term. And I think eosinophilic esophagitis is a
25 subclass of this.

1 So eosinophilic gastritis can occur -- I
2 believe one of the papers I have in my packet indicated
3 it could occur anywhere on the GI tract. And these guys
4 were focusing on a patient that had it not in the
5 esophagus but in the stomach.

6 Q But this paper -- the point of this paper is
7 that the drug was released in the stomach and the small
8 bowel, correct?

9 A It was. Because it looks like that's where
10 the patient's disease state was, where the tissue was
11 damaged at.

12 Q No more questions on this document. You can
13 set that aside.

14 I believe we were in your declaration,
15 Exhibit 1030, paragraph 34, the screenshot of a chart of
16 drugs.

17 Let me know when you're there.

18 A I'm there.

19 Q So I believe we just talked about Budenofalk.
20 Let's move on to Ursofalk.

21 Is this an ODT?

22 A Again, they don't differentiate it down to
23 that. They just say "capsules" or "film-coated
24 tablets." So I don't know if it's an ODT or not.

25 Q Did you do any investigation into --

1 A No, ma'am.

2 Q And is the active substance here a topical
3 drug or a systemic drug?

4 A I don't know for sure on that. I don't know
5 whether it's topical or systemic.

6 Q Moving on to Endofalk.

7 Is this an ODT?

8 A It says "powder for oral solution," so I would
9 say no.

10 Q Did you do any investigation as to whether
11 this is formulated as an ODT?

12 A No, I did not.

13 Q And is the active substance here topical or
14 systemic?

15 A It's topical.

16 Q And is the active substance here a
17 corticosteroid?

18 A It is not.

19 Q Moving on to Falkamin, is this an ODT?

20 A It just says "pellets." I don't know.

21 Q Did you do any investigation as to whether
22 this could be formulated as an ODT?

23 A No, ma'am.

24 Q Okay. And is the active substance here
25 topical or systemic?

1 A That I do not know.

2 Q And it's not a corticosteroid, correct?

3 A It says it's an amino acid. So I don't
4 believe it's a corticosteroid.

5 Q Moving on to Mucofalk Apple/Orange, is this an
6 ODT?

7 A It just says "granules." I don't know.

8 Q Did you do any investigation into whether or
9 not it could be formulated as an ODT?

10 A Granules are made in various papers that I
11 submitted as part of my report where they made granules
12 but -- as part of an ODT. But I don't know if this is.

13 Q Is the active substance here topical or
14 systemic?

15 A I can only look at the indications and think
16 it's topical. But I don't know that for sure.

17 Q And is this a corticosteroid?

18 A I have no idea what is all in plantago ovata
19 seed shells. So there could be steroids in there. I
20 don't know.

21 Q Moving on to Laxofalk.

22 Is this an ODT?

23 A It says "powder for preparation of an oral
24 solution." So I would say no.

25 Q Did you do any investigation as to whether

1 this could be formulated as an ODT?

2 A No, ma'am.

3 Q And the active substance here, is it topical
4 or systemic?

5 A PEG 4000. I would say it's topical.

6 Q Is this a corticosteroid?

7 A No, ma'am.

8 Q Do you think that a drug for chronic
9 constipation is a topically acting drug?

10 MR. LUMAN: Incomplete hypothetical.

11 THE WITNESS: I can only go by the PEG 4000
12 and know what it's used for. And it's marketed as a
13 laxative for chronic constipation, so . . .

14 BY MS. AGARWAL:

15 Q So yes or no?

16 A So repeat the question, please.

17 Q Would you say a drug for chronic constipation
18 is a topically acting drug?

19 MR. LUMAN: Incomplete hypothetical.

20 THE WITNESS: Based on the molecule that's in
21 it, yes, I would think it's topically active.

22 BY MS. AGARWAL:

23 Q You said you think it's topically active. You
24 don't know for sure?

25 A Well, the reason I say that is the way these

1 PEGs work, they're osmotic agents, so they pull large
2 amounts of water out of the body into the colon to cause
3 the laxative effect. I consider that a local effect.
4 Someone else may not. So I think it's a topical based
5 on the mechanism by which the PEGs work.

6 Q Did you do any investigation as to whether a
7 POSA would consider this a topically acting drug?

8 A A think a POSA would consider it, knowing that
9 it's nonabsorbable and it pulls water into the GI tract.

10 Q Moving on to Zinkamin-Falk, is this an ODT?

11 A Again, it just says "capsule." It doesn't
12 break it down below that, so I can't tell you.

13 Q Did you do any investigation as to whether
14 this could be an ODT?

15 A No, ma'am.

16 Q And the active substance, Zink-histidin
17 complex, is that a topically or systemically active
18 drug?

19 A I have no idea on that.

20 Q Is this a corticosteroid?

21 A I do not believe it is, no, ma'am.

22 Q And Azafalk the last one, is this an ODT?

23 A It just says "film-coated tablet." So I don't
24 know if it is or it isn't.

25 Q Did you do any investigation to determine

1 whether it is an ODT?

2 A No, ma'am, I did not.

3 Q And the active substance here, is it topically
4 or systemically acting?

5 A I believe it's both. And I think in some of
6 the papers, it was listed as a potential drug. I'd have
7 to go back and check all the papers, but azathioprine, I
8 thought, was in the list -- somebody's list.

9 Q Okay. And a drug for immunosuppression, is
10 that typically a topically acting drug or a systemically
11 acting drug?

12 A It could be both, to the best of my knowledge.

13 Q Is this a corticosteroid?

14 A I don't know if it would be defined as a
15 corticosteroid. I don't know one way or the other on
16 that. It has properties along that line, but I don't
17 know if it's a corticosteroid.

18 MS. AGARWAL: Why don't we take a break here.

19 MR. LUMAN: The time is 9:51.

20 (Recess taken from 9:51 to 10:01 a.m.)

21 BY MS. AGARWAL:

22 Q Let's go into your declaration, Exhibit 1030,
23 to paragraph 47.

24 And in paragraphs 47 to 49, you rely on a
25 number of references, correct?

1 A Let's see. I rely on Kolkman, Siewert, yes,
2 ma'am.

3 Q You don't rely on any of these references as a
4 primary reference for your obviousness grounds in your
5 declaration, correct?

6 A I don't believe I did, no, ma'am.

7 Q If we go back a little bit to paragraphs 44 to
8 46, you rely -- in paragraphs 44 to 46, you cite to a
9 number of references here as well, correct?

10 A Yes.

11 Just to outline the -- what was known about
12 budesonide as a corticosteroid.

13 Q You don't rely on any of these references as a
14 primary reference for your obviousness grounds, correct?

15 A I do not.

16 Q We touched on this briefly, so I'm going to
17 ask the question again.

18 ODTs are typically formulated for absorption
19 of systemically acting drugs, correct?

20 A I'm sorry. Could you please repeat the
21 question?

22 Q Sure.

23 ODTs are typically formulated for absorption
24 of systemically acting drugs, correct?

25 A Again, I'll have to go with the response I had

1 before. They can be used for both. And I know there's
2 a list of them in my declaration from Fu. But I -- and
3 I didn't interrogate that list to see if any were -- if
4 they were all topical or they were all oral or systemic.

5 (Exhibit 1018 marked for identification.)

6 BY MS. AGARWAL:

7 Q Why don't we go to Fu. That is Exhibit 1018.

8 Actually, I don't think you have it. We'll
9 have to mark Exhibit 1018.

10 Actually, before I give you Fu, I'd like to go
11 to paragraph 81 in your declaration.

12 Is this the list that you were talking about?

13 A Yes, ma'am.

14 Q And you didn't do any investigation as to
15 whether these are topical or systemic reacting drugs in
16 these ODTs, correct?

17 A No, ma'am, I did not.

18 Q And did you do any investigation as to whether
19 any of these are corticosteroids?

20 A I didn't do any investigation, no.

21 Q Let's look at Risperdal, which is a
22 schizophrenia drug?

23 A Uh-huh.

24 Q Do you believe that's a topically acting drug?

25 A I don't know if it's topically or systemic.

1 Q In your experience as a POSA, would that be a
2 topically acting drug for schizophrenia?

3 A Again, I'm not -- based on the disease state,
4 I would think it could be systemic, but I'm not
5 100 percent confident of that.

6 Q What about Zelapar for Parkinson's disease,
7 would that be topically or systemically acting?

8 MR. LUMAN: Which one is Zelapar?

9 BY MS. AGARWAL:

10 Q The active ingredient is selegiline?

11 MR. LUMAN: Thank you.

12 THE WITNESS: Again, it could be. I don't
13 know enough about Parkinson's disease to tell you how it
14 works.

15 BY MS. AGARWAL:

16 Q In your experience as a POSA, would that --
17 would a drug for Parkinson's disease be systemic or
18 topically acting?

19 A It could be both, I guess.

20 Again, I don't know the disease well enough to
21 know if it's all systemic or if there are topical issues
22 associated with the disease state, so I couldn't tell
23 you.

24 Q So you would just be guessing?

25 A Yeah. I don't have any data to tell you if it

1 is or isn't because I don't know Parkinson's disease
2 well enough to know if they're topical treatments or if
3 it's systemic.

4 Q What about the first one on the second chart,
5 so to speak, an anti-migraine drug, Zomig ZMT? Would
6 that be topically or systemically acting?

7 A That one, I would suspect, would be systemic.

8 Q And one last one, fourth from the bottom.

9 Sorry. Why don't we look at Excedrin, which
10 is acetaminophen, a pain reliever. Is that systemic or
11 topically acting?

12 A It's systemic. And I think there are some
13 topical acetaminophens for sore throats, to treat
14 esophagus, sore throats and stuff. It's like Aspergum.
15 So the drug -- so the acetaminophen could work topically
16 or it could work systemically.

17 Q But for this Excedrin ODT, it's systemic,
18 correct?

19 A I don't know that because it's going to
20 dissolve in the mouth. It's going to go down the
21 throat. And if you've got a sore throat, it's going to
22 deal with the pain there. So it could be topically as
23 well.

24 Q Are any of these drugs corticosteroids?

25 A No, ma'am, I don't believe they are.

1 Q So none of the drugs from Table 2 from Fu are
2 corticosteroids, correct?

3 A As I look at them, I don't -- can't tell
4 100 percent sure. But none of them look to be steroids.

5 I haven't researched each and every compound
6 on that list, so I can't be absolutely sure if it is or
7 is not.

8 Q And from this Table 2 in Fu, you did not
9 investigate whether any of these drugs are topically
10 acting or systemically acting, correct?

11 A I just looked at the list of names. I didn't
12 do any additional research on any of the compounds.

13 Q Now let's go to Fu. This is titled "Orally
14 Fast Disintegrating Tablets: Developments,
15 Technologies, Taste-Masking and Clinical Studies" by Fu,
16 correct?

17 A Yes, ma'am.

18 Q Why don't we go to the top of page 434. The
19 first full sentence there states "Common complaints
20 about the difficulty in swallowing tablets in the order
21 frequency of complaints are size, surface, form, and
22 taste of tablets."

23 Do you see that?

24 A Yes, ma'am.

25 Q And the next sentence says "Geriatric and

1 pediatric patients and traveling patients who may not
2 have ready access to water are most in need of easy
3 swallowing dosage forms."

4 Do you see that?

5 A Yes, ma'am.

6 Q And in the second paragraph, second to the
7 last sentence, it states "Such a tablet disintegrates
8 into smaller granules or melts in the mouth from a hard
9 solid to a gel-like structure allowing easy swallowing
10 by patients."

11 Do you see that?

12 A Yes, ma'am.

13 Q So the tablets, these fast disintegrating
14 tablets that Fu is discussing, are used to improve
15 patient compliance to swallow the contents of the
16 tablet, correct?

17 A That's correct. They eliminate the need to
18 swallow a large dosage form because they disintegrate in
19 the mouth.

20 Q And you do not rely on Fu as a primary
21 reference for your obviousness grounds, correct?

22 A Not for obvious, but I put it in there to show
23 the extent of knowledge that there is around orally
24 disintegrating dosage forms and what a POA would know
25 at the time of the '729 patent.

1 Q What does "absorption" mean?

2 MR. LUMAN: Outside the scope.

3 THE WITNESS: Could you say the word again?

4 BY MS. AGARWAL:

5 Q Absorption.

6 A A-B.

7 Q Yes.

8 A Absorption means when a drug or anything --
9 well, we're talking about drugs in this case. When a
10 drug is given orally, it's absorbed through the GI
11 tract.

12 Now, it can be metabolized at the GI membrane
13 and it never makes it to the systemic circulation. It
14 can get through the membrane, and then it goes to the
15 liver and it could get chewed up and never makes it to
16 the systemic circulation. Or if it passes those two
17 barriers without being broken down, it gets into the
18 systemic circulation.

19 So absorption, by FDA and regulatory
20 standards, is the amount of drug that gets into the
21 bloodstream after it's administered.

22 Q Let's go back to your declaration,
23 Exhibit 1030. Paragraphs 73 to 79. You cite to a
24 number of references in these paragraphs, correct?

25 A You said -- I'm sorry -- paragraph 73 to?

1 Q To 79.

2 A Yes, I do.

3 Q And you don't rely on any of these references
4 as a primary reference for your obviousness grounds,
5 correct?

6 A I do not.

7 Again, this information was put in, as with
8 Fu, to give an understanding of what knowledge was
9 available at the time to the POSAs -- to a POSA.

10 Q Let's flip back to paragraphs 63 to 65 of your
11 declaration.

12 You cite a number of the same references here,
13 correct, as you do in paragraphs 73 to 79?

14 A 73 to 79?

15 Q Sorry.

16 In paragraphs 63 to 65, you cite to a number
17 of references, correct?

18 A Yes, ma'am.

19 Q You don't rely on any of these references for
20 your obviousness grounds, correct?

21 A I do --

22 MR. LUMAN: Mischaracterizes the document.

23 THE WITNESS: I do not.

24 Again, that information was put in to show the
25 level of knowledge available at the time for the POSAs

1 and that there was plenty of information out in the
2 marketplace around ODT products.

3 BY MS. AGARWAL:

4 Q None of the references that you cite in
5 paragraph 63 to 65 are directed to topical -- to an ODT
6 comprising a topical drug, correct?

7 A So, if you go down, I say that Shulka has the
8 unique property of rapidly disintegrating or dissolving
9 and releasing the drug as soon as it comes into contact
10 with the saliva.

11 Q Which paragraph are you in?

12 A I'm in -- must be paragraph 63, about a third
13 of the way down.

14 Q The sentence that you just read does not
15 disclose an ODT containing a topical drug, correct?

16 A It doesn't contain -- indicate a topical drug,
17 but it does indicate disintegrating or dissolving and
18 releasing the drug as soon as it comes in contact with
19 the saliva. And that makes the drug available
20 immediately from the mouth all the way through the GI
21 tract.

22 Q And the sentence continues to say "Thus
23 obviating the requirement of water during
24 administration," correct?

25 A That's correct.

1 Q So the --

2 A That's in -- I'm sorry.

3 Q So the purpose of this reference and the
4 disintegrating drug or the disintegrating tablet is
5 removing the necessity for water for swallowing,
6 correct?

7 A That's one of the reasons for it. And then,
8 again, if you know where the irritation is, and it's in
9 the esophagus, the drug has to be released before it
10 gets to the irritation. If you swallow a whole tablet,
11 you bypass it and you don't get the topical effect.

12 Q This reference doesn't say that, though,
13 correct?

14 A No. But a POSA knows that. They understand
15 what the target is they're shooting for and what the
16 dosage form has to do to deliver that.

17 Q A POSA would also know that this rapidly
18 disintegrating or dissolving tablet would disintegrate
19 quickly in the mouth and be swallowed and go straight to
20 the stomach, correct?

21 A It would. It has to go through the esophagus.
22 And it's a small volume of liquid, 1 to 2 mls. So it
23 doesn't go down as a bolus. It goes down as a very slow
24 amount.

25 Q A very slow amount?

1 A Yeah. It takes longer for that to go down
2 than if I took a tablet and swallowed it with a gulp of
3 water.

4 Q This reference, Shulka, doesn't tell you that
5 there is any topical activity for these rapidly
6 disintegrating drugs, though, correct?

7 A I'd have to go back and reread that whole
8 article. I don't recall whether it did or it didn't.
9 It may very well could have. I just didn't document it
10 in my report.

11 Q If it had said that, you would have documented
12 it in your report, correct?

13 A You know, I don't know if I would be, to be
14 honest with you. That's pretty common knowledge, so I
15 don't know if I would have put that in.

16 Q But you're relying on a POSA's common
17 knowledge, correct?

18 A Yes, ma'am.

19 Q And the Patent Office doesn't know common
20 knowledge, correct? You have to explain it to them --
21 correct? -- via your declaration?

22 A Could you rephrase -- ask the question again?

23 Q You have to explain the common knowledge to
24 the Patent Office via your declaration, correct?

25 A Yes, ma'am.

1 Q So, presumably, you would have -- if this
2 reference had that information in it, you would have put
3 it in your declaration, correct?

4 A Again, I'd have to read the paper to figure it
5 out. I don't know whether I would or would have. Some
6 of this is beyond POSA. It's just common sense. Large
7 liquids go down the esophagus faster than small volumes
8 of liquid do.

9 Q Why don't we go to paragraph 84 to -- 84.
10 And here you cite to Singh and Cherukuri.
11 Do you see that?

12 A Yes, ma'am.

13 Q You don't rely on either Singh or Cherukuri
14 for primary references in your obviousness analysis,
15 correct?

16 A I think I do.

17 I do not in my obviousness. But again, I put
18 them down under what a POSA would know. And they
19 outline the existence of ODT products for treatment of
20 the GI tract.

21 (Exhibit 1005 marked for identification.)

22 BY MS. AGARWAL:

23 Q I'm going to hand you Exhibit 1005 now.

24 This is the FDA "Guidance for Industry Orally
25 Disintegrating Tablets," correct?

1 A Yes, ma'am.

2 Q Do you recognize this exhibit?

3 A Yes, ma'am.

4 Q And you rely on this reference for a couple of
5 your obviousness grounds, correct?

6 A I rely on FDA, whether it's this document or
7 whether it's the disintegration, but yes.

8 Q This guidance does not disclose topically
9 acting ODTs, correct?

10 A I'm sorry. What was your question now?

11 Q Let me ask a different question.

12 The guidance distinguishes an ODT from a
13 chewable tablet, correct?

14 If you go to page 1, in the introduction, the
15 first paragraph states "An orally disintegrating tablet,
16 ODT, which is a different dosage form than, for example,
17 a chewable tablet."

18 Do you see that?

19 A I don't see.

20 Q It's in the --

21 A Under "Background"?

22 Q Under "Introduction," first paragraph.

23 A Okay.

24 Q "Orally disintegrating tablet, ODT."

25 A Yes, ma'am, I do see that.

1 Q So the FDA guidance distinguishes between an
2 ODT and a chewable tablet, correct?

3 A Yes, ma'am.

4 Q And in Section II, in the background, it
5 states that "In an effort to develop drug products that
6 are more convenient to use and to address
7 potential issues of patient compliance, pharmaceutical
8 manufacturers have developed products that can be
9 ingested simply by placing them on the tongue."

10 Do you see that?

11 MR. LUMAN: Mischaracterizes the document.

12 THE WITNESS: Yeah. I think there were a few
13 words you left out, but . . .

14 So it says "In an effort to develop drug
15 products that are more convenient to use and to address
16 potential issues of patient compliance for certain
17 product indications and patient populations,
18 pharmaceutical manufacturers have developed products
19 that can be ingested by simply placing them on the
20 tongue."

21 Yes, ma'am, it does say that.

22 BY MS. AGARWAL:

23 Q So ODTs were developed to -- for a more
24 convenient use of drug formulations, correct?

25 A I'm sorry. Could you please repeat that?

1 Q Yeah. Let me rephrase that.

2 ODTs were developed to be more convenient to
3 use, correct?

4 A That was one of their -- one of their
5 applications, yes, is to make dosing easier.

6 Q And another application was to address patient
7 compliance, correct?

8 A Yes, ma'am. The thought was it would improve
9 patient compliance for people that couldn't swallow.

10 Q And these were made for easier ingestion of
11 the drug, correct?

12 A Ideally for people that couldn't swallow large
13 tablets, yes.

14 Q The FDA guidance gives no guidance on
15 formulating topical-acting ODTs, correct? It doesn't
16 mention the word "topical" at all, correct?

17 A That's what I'm looking for.

18 MR. LUMAN: Objection. Form.

19 THE WITNESS: It does not. But the purpose of
20 this document by the FDA is to educate the POSAs that
21 they look at oral disintegrating tablets differently
22 than other tablets. And therefore, their expectations
23 what needs to be done will be different.

24 BY MS. AGARWAL:

25 Q So the FDA guidance -- the FDA guidance states

1 that ODTs have a disintegration time of approximately 30
2 seconds or less, correct?

3 On page 2 at the bottom, the last paragraph
4 states "Based on the original product rationale and
5 Agency experience, we recommend that, in addition to the
6 original definition, ODTs be considered solid oral
7 preparations that disintegrate rapidly in the oral
8 cavity with an in-vitro disintegration time of
9 approximately 30 seconds or less, when based on the
10 United States Pharmacopeia (USP) disintegration test
11 method."

12 It's on page 2, last paragraph.

13 A Last paragraph.

14 Okay. Yes, ma'am, that's what it states.

15 Q The FDA guidance does not disclose any sort of
16 contact time of the active drug with the mouth,
17 esophagus, or upper GI tract, correct?

18 A No, it didn't.

19 The purpose of this document was to define
20 what an ODT was so it isn't confused with the standard
21 tablet. So that wasn't the purpose of the document.

22 Q And if you go to Section IV on page 3 of the
23 document, in the middle it states that "To provide a
24 standard for and consistency in disintegration testing,
25 we recommend that applicants use the USP method for

1 disintegration testing," and then it refers to
2 Footnote 3, correct?

3 A Yes.

4 Q And that Footnote 3 refers you to USP 701
5 disintegration test, correct?

6 A Chapter 29, yes.

7 Q The '729 patent also discloses the USP 701
8 disintegration test, correct?

9 A Let me confirm that.

10 Q We can go to the patent, Exhibit 1001. Go to
11 column 1, lines 64 to 65.

12 A Yes, ma'am, it does indicate the USP 701.

13 Q And if we go to column 5, lines 3 to 5, there
14 it says also "Pharmaceutical composition disintegrates
15 within 60 seconds when tested using USP 701
16 disintegration test."

17 Do you see that?

18 A Yes, ma'am.

19 Q And then again, same column, column 5, lines 9
20 to 10, "Disintegrate within 30 seconds using the USP 701
21 disintegration test."

22 Do you see that?

23 A "Or in the oral cavity of the patient," yes,
24 ma'am.

25 Q These are all the same USP 701 disintegration

1 test referenced in the FDA guidance, correct?

2 A It's the general title of that -- of the
3 disintegration test, yes.

4 Q And the 30 seconds using the USP 701
5 disintegration test disclosed in the '729 patent is the
6 same 30 seconds as disclosed in the FDA guidance,
7 correct?

8 A Where do you have the 30 seconds in the '729
9 patent?

10 Q On column 5, lines 9 to 10.

11 A Yeah. It says in some instances it's 60, and
12 others it says 30.

13 Q And the patent examiner would have read this
14 disclosure during prosecution when examining the '729
15 patent, correct?

16 MR. LUMAN: Calls for speculation.

17 THE WITNESS: I don't know what they reviewed
18 as part of the prosecution.

19 BY MS. AGARWAL:

20 Q The patent examiner would have read the
21 specification -- correct? -- of the application?

22 A Oh, they would have read this document?

23 Q Yes.

24 A Yes.

25 Q And so the examiner would have known that the

1 '729 patent discloses this USP 701 disintegration test,
2 which is also disclosed in the FDA guidance, correct?

3 MR. LUMAN: Calls for speculation.

4 THE WITNESS: It's in the document. What the
5 patent reviewer did with the information or how they --
6 how they understood it, I have no idea. I can't answer
7 that. I'm not the patent reviewer.

8 BY MS. AGARWAL:

9 Q But they were aware that the USP 701
10 disintegration test is cited in the patent application,
11 correct?

12 A It's in the document. Whether they read it
13 completely, I can't answer to that.

14 Q You understand that a patent examiner is
15 supposed to review an application from the view of a
16 POSA, correct?

17 A I believe that. But that I -- actually, I
18 don't know. I've never reviewed -- I'm not a patent --
19 I don't work in the Patent Office. I don't know what
20 their requirements are. I know I reviewed it from the
21 view of a POSA. I don't know what they have to do.

22 Q So, in your opinion, you wouldn't know whether
23 a patent examiner would have read this same view of a
24 POSA as you do?

25 A I don't know the individual. I don't know who

1 reviewed it. I can't comment what their thought process
2 was. All I can tell you is I reviewed it from the view
3 of a POSA. What they did, I have no idea. There's no
4 way I would know that.

5 Q When you reviewed it in the view of a POSA,
6 you recognize the USP 701 disintegration test as the
7 same test that is disclosed in the FDA guidance,
8 correct?

9 A Yes. The USP 701 is the same that is
10 discussed by the FDA guidance.

11 (Exhibit 1002 marked for identification.)

12 BY MS. AGARWAL:

13 Q I'm handing you Exhibit 1002, which is titled
14 "Viscous Budesonide for the Treatment of Inflammatory
15 Diseases of the Gastrointestinal Tract." This is Patent
16 Application Publication to Dohil; is that correct?

17 A Yes, ma'am.

18 Q You rely on this reference for Grounds 1 and 3
19 of your obviousness analysis, correct?

20 A Yes, ma'am.

21 Q Dohil is mainly directed to liquid
22 formulations, correct?

23 A No. I wouldn't agree with that.

24 They list a number of excipients in various
25 paragraphs within it that are excipients that are not

1 liquid based that are used for solid or oral dosage
2 forms.

3 What they used in their clinical study, which
4 is a proof of concept study, was a liquid. And they did
5 that because they're clinicians. They wanted to test
6 whether the budesonide was going to work before they
7 made a formulation. That's common practice in the
8 industry, to do pilot studies using simple formulations
9 to test a theory.

10 Q Dohil does not disclose any ODTs, correct?

11 MR. LUMAN: Mischaracterizes the document.

12 THE WITNESS: I believe he does. He talks
13 about lozenges, tablets, capsules.

14 BY MS. AGARWAL:

15 Q Did you do any investigation as to whether
16 Dohil took the liquid formulations and made them into
17 ODTs?

18 A I did not. I just reviewed the document. But
19 the ingredients that he listed, the excipients he listed
20 are ones that are commonly used in ODT products.

21 Q Dohil doesn't disclose a fast dispersing or
22 dissolving tablet, correct?

23 MR. LUMAN: Mischaracterizes the document.

24 THE WITNESS: I'd have to read it, but I
25 thought . . .

1 No, he does talk about rapidly dispersing. He
2 talks about lozenges, tablets, capsules that would
3 dissolve rapidly in the mouth or the esophagus.

4 BY MS. AGARWAL:

5 Q So a lozenge is like a cough drop, correct?

6 A He uses the word "lozenge" or other similar
7 tablets, capsules, or other solid dosage forms. And he
8 indicates they would dissolve rapidly in the mouth or
9 the esophagus.

10 Q Does Dohil define -- or Dohil does not define
11 "dissolve rapidly," correct?

12 A No, he does -- I don't believe he does.

13 Q And a lozenge typically dissolves slowly,
14 correct?

15 A A typical lozenge does. But he identified
16 lozenges that would dissolve rapidly in the mouth. So
17 by formulating his lozenge, he could get the product to
18 dissolve rapidly in his mouth -- in the mouth.

19 Q I believe you're at paragraph 32, correct?

20 A Yes, ma'am.

21 Q If you look at the last sentence in
22 paragraph 32, it states "In other illustrative
23 embodiments of the invention, the budesonide is provided
24 in the form of a tablet, a capsule, or, for example, a
25 gel capsule, designed for slow release and delivery to

1 the esophagus."

2 Do you see that?

3 A I do.

4 Q Dohil doesn't define "slow release," correct?

5 A Not in a time frame, he does not.

6 Q Are you aware of any fast dissolving lozenges
7 on the market?

8 A I haven't done a literature search on it, so I
9 couldn't tell you if there are or there are not.

10 Q So you don't know of any fast dissolving
11 lozenges?

12 A I think what I said was I haven't done a
13 literature search, so I don't know if there are or there
14 aren't.

15 Q But you yourself are not aware, correct?

16 A Again, I haven't done a literature search, so
17 I can't tell you one way or the other.

18 Q You didn't believe that it was relevant to do
19 a literature search for a fast dissolving lozenge for
20 your declaration, correct?

21 A No, I did not.

22 Q You mentioned before that Dohil lists a number
23 of excipients, correct?

24 A Yes, ma'am.

25 Q Let's go to paragraph 37.

1 The first sentence of paragraph 37 states
2 "Pharmaceutical preparations for oral use may be
3 obtained by combining the corticosteroids with solid
4 excipients."

5 Do you see that?

6 A Yes, ma'am. It goes on to say "optional
7 grinding and resulting mixtures," blah, blah, blah.

8 Q And then it lists a number of excipients,
9 correct?

10 A Yes, it does.

11 Q These excipients can be used in any sort of
12 tablet, correct?

13 A Yes.

14 Q They're not specific to ODTs, correct?

15 A They are not. They're common -- they're
16 routine common excipients that a formulator or POSA
17 would use in formulating any product, including an ODT.

18 Q And if we go to paragraph 43 of Dohil, the
19 first sentence here states "Excipients, such as, for
20 example, those listed herein, may be included in the
21 composition to increase the viscosity of the delivery
22 composition."

23 Do you see that?

24 A Yes, ma'am.

25 Q So the excipients listed in Dohil are for the

1 purpose of increasing the viscosity, correct?

2 A Based on that statement, they are. But they
3 also are used -- a POSA would look at those and know
4 that they list fillers, they list disintegrants, they
5 list other uses for those excipients.

6 Q And those can all be used for any kind of
7 tablet, correct?

8 A In a general category, yes. But almost every
9 tablet has a filler, almost every tablet has a binder,
10 almost every tablet has a disintegrant. ODTs are no
11 different than any other standard routine formulation.

12 Q Let's go to Example 1 of Dohil. This is on
13 paragraph 46. If you go almost to the bottom of that
14 paragraph in that column, it states that the patient was
15 placed on a regimen of twice daily oral budesonide
16 suspension.

17 A I'm sorry. Which paragraph are you on?

18 Q Paragraph 46.

19 A 46. Okay.

20 Q And almost all the way at the bottom, it
21 states that the patient was placed on a regimen of twice
22 daily oral budesonide suspension Pulmicort --

23 MR. LUMAN: Are you reading the sentence that
24 starts with "He was placed"?

25 MS. AGARWAL: Yes.

1 MR. LUMAN: Okay.

2 THE WITNESS: Okay. "He was placed." Okay.

3 I'm sorry.

4 BY MS. AGARWAL:

5 Q Do you see that?

6 A I see where "He was placed."

7 If you could ask your question now, now that I
8 know where I'm at, please.

9 Q The regimen of twice daily oral budesonide
10 suspension is a liquid, correct?

11 A It's a suspension. Yeah, it's a liquid. It's
12 not a solution. It's a suspension.

13 Q It's not a tablet though, correct?

14 A It is not. It wasn't designed to. Pulmicort
15 is a metered-dose inhaler, or it could be used as a
16 nebulizer.

17 So again, they're taking -- they're trying to
18 test a theory on a patient. And they're using the
19 simplest formulation they can to see if budesonide
20 actually works to treat the patient.

21 Q And the patient is instructed to swallow it
22 twice daily, correct?

23 A Yeah. They mix it with sucralose, and then --
24 which makes the viscous fluid, and then they're asked to
25 swallow twice a day.

1 Q And about two sentences after that, it states,
2 "Following three months of therapy, repeat EGD showed a
3 normal esophagus and biopsies demonstrated complete
4 resolution of both esophageal eosinophils and basal zone
5 hyperplasia."

6 Do you see that?

7 A Yes, ma'am.

8 Q So the patient showed improvement with the
9 oral budesonide suspension, correct?

10 A Yes. The way it was -- yeah, by diluting it
11 with sucralose, yes.

12 Q And then let's move to Example 2,
13 paragraph 47.

14 Sorry. Just right above Example 2, still on
15 Example 1, it also states that "in addition, his
16 abdominal pain and vomiting resolved, resulting in
17 increased appetite with documented weight gain."

18 Do you see that?

19 A Yes, ma'am.

20 Q So the patient improved significantly on the
21 oral budesonide suspension, correct?

22 A It did. The person did, based on what was
23 written up, yes, ma'am.

24 Q Now moving on to Example 2, paragraph 47.
25 Here the patient received oral budesonide -- let me

1 orient you.

2 If you go a little bit before the end of the
3 paragraph, it states "As an alternative, she received
4 oral budesonide 500 micrograms (Pulmicort) mixed with
5 sucralose twice daily as topical esophageal therapy."

6 Do you see that?

7 A Yes, ma'am.

8 Q That is also an oral budesonide suspension,
9 correct?

10 A Yeah. They developed a simple formulation to
11 test the theory, does budesonide treat this disease
12 state? And that's the simplest way to do it.

13 Q The next sentence states "Following three
14 months of budesonide, she had improvement in her
15 abdominal pain and EGD revealed a normal appearing
16 esophagus with improved maximum eosinophil counts of 28,
17 20, and 5 per hpf," et cetera, et cetera.

18 Do you see that?

19 A Yes, ma'am.

20 Q So the patient improved using the oral
21 budesonide suspension, right?

22 A They improved with the budesonide when it was
23 delivered with the simple formulation to test the theory
24 with the suspension, yes.

25 Q Does Example 1 discuss any issues with patient

1 compliance or use with the oral suspension?

2 A I didn't see anything related to Patient 1
3 around compliance.

4 Q And Patient 1 was a 6-year-old male, correct?

5 A Yes, ma'am.

6 Q And Patient 2 was a 5-year-old girl, correct?

7 A Yes, ma'am.

8 Q And does Example 2 discuss any issues with
9 patient compliance or use of the oral budesonide
10 suspension?

11 A It does not appear, no.

12 Q Let's move to Example 3.

13 In paragraph 48, it states that "This example
14 details the efficacy and safety of once daily oral
15 viscous budesonide (OVB)."

16 Do you see that?

17 A Yes, ma'am.

18 Q Oral use budesonide is suspension, correct?

19 A Yes.

20 Q And the patients here are 20 children,
21 correct?

22 A Yes, ma'am.

23 Q Okay. And they're all given this oral viscous
24 budesonide, correct?

25 A Right. To test the theory as to whether

1 budesonide would be effective for the treatment of their
2 problem.

3 Q If you go to paragraph 53 for treatment, it
4 states that patients received OVB 0.5 to 2 milligrams
5 daily.

6 Do you see that?

7 A Yes, ma'am.

8 Q And the viscous budesonide was made by mixing
9 the Pulmicort with the sucralose.

10 Do you see that?

11 A Yeah. A very simple formulation to test
12 the -- to -- for the proof of concept study, yeah.

13 Q If you go to paragraph 60, which is on the
14 next page, in the middle, it states that the EE
15 endoscopy score fell to zero in 12 children and improved
16 in 19.

17 Do you see that?

18 A Yes, I do.

19 Q 19 of the 20 children improved in this
20 study -- correct? -- according to this sentence?

21 A Yes, ma'am. It said improved in 12 children
22 and improved in -- well, yeah, the score fell --
23 endoscopy score fell in -- to zero in 12 and improved in
24 a total of 19.

25 Q So it showed improvement in 19 of the

1 patients, correct?

2 A Yes, ma'am.

3 Q If you go to paragraph 67, which is on page 8,
4 it states that -- the first sentence states "These data
5 suggest that oral viscous budesonide would be an
6 effective and safe treatment for individuals, for
7 example, children, for example, young children, with
8 proven EE."

9 Do you see that?

10 A I do.

11 Q And it says "It may have advantages over other
12 therapies in that it is palatable, its volume provides
13 pan-esophageal mucosal coverage and it requires only
14 once daily administration."

15 Do you see that?

16 A But it also goes on to say a larger
17 placebo-controlled clinical study would provide more
18 information about dosing efficacy.

19 So what that last statement says is this was a
20 pilot study, a proof-of-concept study using this --
21 which you use a simple formulation to do, which was the
22 OVB, but he also talks about tablets, fast dissolving
23 lozenges and tablets and everything.

24 So the work that they're reporting here is
25 just to prove that the budesonide is effective at

1 treating that disease state. Indicates it is, but they
2 need a full-blown clinical study to prove that.

3 Q These examples show that the oral viscous
4 budesonide worked, though, correct?

5 A It showed that budesonide was effective at the
6 treatment in these patients, yes.

7 Q And it doesn't tell you how to switch from
8 this -- sorry. Strike that.

9 This doesn't tell you to switch dosage forms,
10 does it?

11 A It doesn't. But a POSA knows liquids are not
12 a preferred formulation. They're unstable. You have to
13 refrigerate them in many cases. They're difficult to
14 transport.

15 An oral disintegrating tablet has all the
16 volume of a solid oral. It's stable. It's easy to
17 register the correct dose in it because we make it.
18 It's easy to transportable. In the case of ODT, it
19 disintegrates quickly in the mouth, and it covers the
20 esophagus.

21 So the natural tendency is, after you prove
22 that your drug works, is then you go and develop the
23 formulation, which is what he's saying in his patent as
24 a POSA.

25 Q Is there any indication in Examples 1, 2, or 3

1 that the OVB had to be refrigerated?

2 A No. But -- and it may not be. This one might
3 not be. But it's not uncommon for solutions to have to
4 be refrigerated. This one may not be. But it still --
5 the OVB still has the disadvantages of transporting it,
6 storing it, and stability that are overcome by the ODT,
7 which is what he mentions in this patent.

8 Q The FDA has approved a liquid formulation?

9 A That I do not know.

10 Q You didn't do any investigation into that?

11 A I did not.

12 Q Is there any indication in Examples 1, 2 or 3
13 that the OVB was not stable?

14 A No. But this is written by -- all that work
15 was done by a clinician. And I'm not sure they even
16 measured it. They may have made it up and dosed it to
17 where they didn't have to do it.

18 Q But it's not disclosed, correct?

19 A It's not. But the focus of this wasn't to
20 discuss the stability of the OVB. It was to discuss
21 does budesonide work for that disease state.

22 Q There were no issues of patient compliance in
23 Example 3 either, correct?

24 A Not that I'm aware of, no. I don't recall
25 reading anything.

1 Q And there's no disclosures in any of the
2 examples that the OVB did not function the way that it
3 was supposed to, correct?

4 A No. It indicated that the budesonide was
5 effective at treating the disease state in that small
6 patient population.

7 MS. AGARWAL: Why don't we take a break now.

8 (Recess taken 11:01 to 11:09 a.m.)

9 (Exhibit 1008 marked for identification.)

10 BY MS. AGARWAL:

11 Q Let's put Dohil away. Let's go to
12 Exhibit 1008, Grother.

13 This is an international patent application
14 titled "Fast Dispersing Dosage Forms Free of Gelatin" to
15 Grother, correct?

16 A Yes, ma'am.

17 Q And you rely on this exhibit for Grounds 2 and
18 4 of your declaration, correct?

19 A I believe that's correct. Let me check just
20 to make sure.

21 Yes, ma'am.

22 Q And Grother discloses fast dispersing solid
23 dosage forms, correct? You can see that in the
24 abstract, "The present invention relates to fast
25 dispersing solid dosing forms."

1 A I don't see that specific --

2 Q The first sentence --

3 A Oh, "to fast dispersing solid dosage forms,"
4 yes, ma'am.

5 Q According to your declaration, Grother teaches
6 formulations of ODTs, correct?

7 A In general, yes.

8 Q Grother is not directed to a specific disease,
9 correct?

10 A No, ma'am. It does not.

11 Q So Grother is directed to a general disclosure
12 of ODTs, correct?

13 A Can you tell me what you mean by "general
14 disclosure"?

15 Q Sure. Why don't we go to -- why don't we go
16 to page 15 of Grother, line 19.

17 A Okay. I'm there.

18 Q Is it states "Any drug may be used as the
19 active ingredient in the composition of the present
20 invention."

21 Do you see that?

22 A Yes, ma'am.

23 Q So Grother is directed to the general
24 composition of ODTs. It's not specific to any type of
25 drug, correct?

1 A Well, he -- starting on page 16, he lists all
2 kinds of classes of drugs as well as specific drugs that
3 could be used with it. So I'm not sure how that's
4 general.

5 Q He lists different classes of drugs and the
6 drugs across pages 16, 17, 18, 19, 20, and 21, correct?

7 A Yes, ma'am.

8 Q There are over 300, 400 drugs listed here,
9 correct?

10 A Yeah. I don't know what the number is.
11 There's a number of them, yes.

12 Q So Grother is not directed to any specific one
13 of these drugs, correct?

14 A Not to any specific one, but he indicates --
15 as a POSA reads it and I read it, he's indicated his
16 technology is effective with those drugs listed, the
17 therapeutic areas as well as the specific drugs.

18 Q Any of these drugs, correct? Any of these 400
19 drugs, correct?

20 A Again, I don't know if it's 400.

21 But as a POSA reads it, these are examples of
22 suitable drugs, but not limited to those listed above,
23 in the present invention.

24 Q And as you just stated, Grother's drugs are
25 not limited to the ones listed across pages 16 to 21,

1 correct?

2 A Right. It indicates "but not limited to those
3 listed below."

4 Q So Grother discloses a general composition of
5 ODTs with regards to these drugs, correct?

6 A Again, I guess I don't -- I don't agree with
7 the "general." He lists the drugs. And he also says
8 "not limited to those below," that there are others. So
9 I don't understand your term "general."

10 If there were no drugs listed, I would say
11 yes. But he lists drugs, all kinds of drugs, so . . .

12 Q Going back to page 15, line 19, he states "any
13 drug," though, correct?

14 A Correct.

15 Q Which means any drug that may have been
16 formulated, correct?

17 A Yeah. "Any drug may be used as an active
18 ingredient in the composition of the present invention."
19 And then he lists a number of them below, both the
20 therapeutic area they fall in and the specific compound.

21 Q And they're not limited to this list of drugs,
22 correct?

23 A He indicates they're not limited, right.

24 Q So Grother discloses essentially a platform
25 ODT in which you could have any drug as the active,

1 correct?

2 A Yeah. He indicates his invention would work
3 with any of these drugs.

4 Q Grother does not distinguish between systemic
5 and topical administration of ODTs, correct?

6 A I'd have to look. I don't believe he did.

7 No, ma'am, I don't see anything where he
8 distinguishes between systemic or topical.

9 Q If we go to page 18, starting on line 15, he
10 lists a number of corticosteroids, correct?

11 A He does.

12 Q And he doesn't distinguish these
13 corticosteroids as to how many have significant systemic
14 versus topical activity, correct?

15 A He does not. But a POSA looking at it would
16 be able to know a number of them are systemically active
17 compounds and also know some that are not systemically
18 active.

19 Q And Grother does not highlight corticosteroids
20 over any other drugs in his list of drugs, correct?

21 A No. He just lists corticosteroids would work
22 with this technology.

23 Q And he lists other types of -- classes of
24 drugs would also work with his technology, correct?

25 A Yes, ma'am.

1 Q Grother does not disclose any topical drug
2 contact with the esophagus, correct?

3 A He just discusses rapidly disintegrating
4 dosage form.

5 Q And he does not disclose or discuss any
6 localized or targeted therapy of a drug in the upper
7 gastrointestinal tract, correct?

8 A I'm going to have to check on that.

9 He doesn't mention -- I don't see anything
10 where he mentions locally acting.

11 But again, a POSA would look at it, if it
12 disintegrates in a mouth and it's going to expose to the
13 esophagus to have a local effect.

14 Q If we turn to page 22 of Grother, it lists --
15 Grother lists a number of examples starting on page 22
16 to page 31, Examples 1 through 8. I'll give you a
17 chance to flip through them really quickly.

18 A Okay. I see them.

19 Q None of these examples include a
20 corticosteroid, correct?

21 A They do not. I don't think any of them
22 include a drug at all. I think they're just looking at
23 the effect of placebos.

24 Actually, I correct myself.

25 Example 8 does use two drugs -- three drugs

1 where they look at it.

2 Q Are any of these corticosteroids?

3 A One is a nonsteroidal, and the other two are
4 not. No, they're not steroidal.

5 Q Are any of them topically acting?

6 A Diclofenac can be active topically. I think
7 there's some prescription creams out for those.

8 The prevastatin, it would not -- it's
9 systemic.

10 And the phenylpropanolamine -- well, that's a
11 good one. I don't know about the phenylpropanolamine.

12 Q If we go back to page 1 of Grother.

13 MR. LUMAN: Is that the title page, or do you
14 want us to be on the -- kind of the --

15 MS. AGARWAL: The cover page, yes.

16 BY MS. AGARWAL:

17 Q Here it states that the title is "Fast
18 Dispersing Forms Free of Gelatin," correct?

19 A That's what it's supposed to be. I'm just
20 looking for the statement.

21 Yep. Essentially absolutely free of mammalian
22 gelatin.

23 Q Yes. So if we go to the second sentence of
24 the abstract on the cover page, it states "A novel
25 feature of the solid dosage forms according to the

1 invention reside in the fact that the composition is
2 essentially free or absolutely free of mammalian
3 gelatin."

4 Do you see that?

5 A You said the second sentence? Oh, "According
6 to the invention."

7 Q Yes.

8 A Yeah. So we talked about the "absolutely free
9 of mammalian gelatin."

10 So you're saying the next question "It has
11 been discovered that the use"?

12 Is that the sentence you're talking about?

13 Q No. I'm talking about the sentence right
14 before that, "A novel feature" --

15 A "A novel feature."

16 Q -- "of the solid dosage forms, according to
17 the invention, reside in the fact that the composition
18 is essentially free or absolutely free of mammalian
19 gelatin."

20 A Yes, ma'am. It says that.

21 Q And so Grother's invention -- and if we flip
22 to the first page of Grother now, in the "Background of
23 Invention" section on pages 1, 2, and 3, Grother
24 discusses issues with gelatin in tablet formulations,
25 correct?

1 A He talks about gelatin, yes, about other ways
2 of doing -- overcoming the problems.

3 Q Overcoming the problems of gelatin, correct?

4 A Yes.

5 Q And at the bottom of page 3, the last
6 paragraph, it states "According to the present invention
7 there is therefore provided a pharmaceutical composition
8 for oral administration in the form of a fast dispersing
9 dosage form designed to release an active ingredient
10 rapidly in the oral cavity characterized in that the
11 essentially gelatin free composition comprises a
12 modified starch and at least one matrix forming agent."

13 Do you see that?

14 A Yes, ma'am.

15 Q So the problem that Grother is trying to solve
16 is the issues with gelatin, correct?

17 A Yes. He's developing an ODT, a rapidly
18 dissolving dosage form, that doesn't have gelatin in it.

19 Q And the examples that we looked at on pages 22
20 to 31 are comparing dosage forms with and without
21 gelatin, correct?

22 A Yes. They did a study looking at if they made
23 the formulation with gelatin and without and using
24 starch.

25 Q And the examples show that they were

1 successfully able to make dosage forms without gelatin,
2 correct?

3 A Yeah. They showed that they had less breaking
4 of the tablets when they used the starch instead of the
5 gelatin. Less cracking and breaking it.

6 Q And if we turn to page 34 of Grother to the
7 claims. There are nine claims -- correct? -- across
8 pages 34 and 35?

9 A Yes, ma'am.

10 Q And claim 1 is the only independent claim,
11 correct?

12 A Yes, ma'am.

13 Q And claim 1 states that -- it's claiming "A
14 fast dispersing solid dosage form designed to release an
15 active ingredient in the oral cavity characterized in
16 that said dosage form is essentially free of mammalian
17 gelatin."

18 Do you see that?

19 A "And comprises," yes, ma'am.

20 Q So Grother is claiming a fast dispersing solid
21 dosage form that is essentially free of mammalian
22 gelatin, correct?

23 A Yes. With that first statement, yeah.

24 Q And claim 1 states the "solid dosage form
25 designed to release an active ingredient," correct?

1 A "A fast dispersing solid dosage form designed
2 to release an active ingredient," yes.

3 Q And none of the dependent claims specify any
4 active ingredient, correct?

5 A No, ma'am, they do not.

6 Q Let's go back to your declaration, to
7 Exhibit 1030, and paragraph 249.

8 In this paragraph, you cite to a few
9 references for administration of fluticasone, correct?

10 A The practical applications for budesonide and
11 fluticasone, yes.

12 Q You don't rely on any of these references as a
13 primary reference for your obviousness analysis,
14 correct?

15 A I do not. I put them in there just as --
16 again, to show that there was knowledge of the use of
17 budesonide, as well as, in this case, fluticasone in the
18 treatment of EE or other GI issues.

19 (Exhibit 1020 marked for identification.)

20 BY MS. AGARWAL:

21 Q Now let's turn to Exhibit 1020, Venkatesh. I
22 have not handed it to you yet.

23 This is a patent application publication
24 titled "Orally Disintegrating Tablets and Methods of
25 Manufacture" to Venkatesh, correct?

1 A Yes, ma'am.

2 Q And you rely on this reference for Grounds 3
3 and 4 of your obviousness analysis correct?

4 A Yes, ma'am.

5 Q If you go to paragraph 1 of Venkatesh, the
6 first sentence states "The present invention relates to
7 orally disintegrating tablets and a method for their
8 manufacture," correct?

9 A Yes, ma'am.

10 Q Venkatesh is not directed to any specific
11 disease, correct?

12 A Let me check on that to make sure.

13 It lists drugs that are targeted to the GI
14 tract, but I don't see a specific disease.

15 Q What paragraph are you on?

16 A If you go back to claim 21, "The method of
17 claim 20 wherein the pharmaceutically acceptable active
18 is selected from the group of H2 antagonists such as
19 ranitidine," da, da, da, as well as a number of other
20 drugs.

21 So they don't state a specification
22 indication, but they do state drugs for indications.

23 Q This is the only place that Venkatesh lists
24 any drugs, correct?

25 A I'd have to go back and look just to make

1 sure.

2 MR. LUMAN: Mischaracterizes the document.

3 THE WITNESS: I think if you go to
4 paragraph 25, it says "The term 'drug,' 'active' or
5 'active pharmaceutical ingredient'" -- it lists a number
6 of types of drugs as well as the specific names of
7 drugs.

8 BY MS. AGARWAL:

9 Q The first sentence in paragraph 25 states that
10 "The term 'drug,' 'active' or 'active pharmaceutical
11 ingredient' as used herein is meant to include any
12 therapeutic active agent indicated for oral
13 administration," correct?

14 A Yes, ma'am.

15 Q Then it says "such as" and lists a number of
16 drugs, correct?

17 A Yes, ma'am.

18 Q So Venkatesh is not limited to these drugs,
19 correct?

20 A I don't see anything. It says it is "used" --
21 "used herein is meant to include any therapeutic" -- and
22 it doesn't say it's a limited list of -- so I'm sorry.

23 Could you ask your question again? My
24 apologies.

25 Q Sure.

1 Venkatesh is not limited to the drugs listed
2 in this paragraph, correct?

3 A Yeah. It says "any therapeutic active," yes,
4 ma'am.

5 Q Are any of the drugs listed in this paragraph
6 corticosteroids?

7 A Well, let me see.

8 I don't see any of the drugs that I would say
9 are corticosteroids, but it -- again, you drew the
10 attention to include any therapeutic active agent. So
11 it would include corticosteroids.

12 Q And out of millions of possible drugs, one
13 class of drugs is corticosteroids, correct?

14 A Did you say "millions"?

15 Q Hundreds, thousands, millions of drugs.

16 A Give me a number. I mean, a million? No.

17 A thousand? No.

18 A hundred? Maybe.

19 Q Are there more than 100 drug classes out
20 there?

21 A I have no idea. I've never counted them, so I
22 couldn't tell you.

23 Q But that would include all drug classes --
24 correct? -- the "any therapeutic active agent" would
25 include all drug classes, correct?

1 A Yeah. It says -- "used herein is meant to
2 include any therapeutic active agent indicated for oral
3 administration." And then he lists some examples.

4 Q So of all the drug classes out there,
5 corticosteroids would be one, correct?

6 A Yes, ma'am.

7 Q Venkatesh does not distinguish between
8 systemic and topical drugs, correct?

9 A He just mentions the rapid oral disintegration
10 of the ODT, but I don't believe he mentions anything
11 about topical.

12 Q And going back to paragraph 25, of all the
13 drug classes that are out there, Venkatesh did not
14 specifically call out corticosteroids, correct?

15 A He didn't specifically call it out, but he
16 says "meant to include any therapeutic active agent."

17 So I'm not sure he needs to.

18 Q And no corticosteroids are listed specifically
19 in that paragraph, correct?

20 A I do not -- I do not see one in there, no,
21 ma'am.

22 Q And if we go to claim 21, of all the drug
23 classes out there, claim 21 does not list any
24 corticosteroids, correct?

25 A No, ma'am. It does not.

1 Q Would you say Venkatesh is generally directed
2 to an orally disintegrating tablet technology and their
3 method for manufacture?

4 A Well, I think it talks about orally
5 disintegrating. It talks about the use of
6 microcapsules. So it has a number of advantages.

7 Well, it adds a lot more information to it
8 than just that. It talks about particular particle size
9 needed for good mouth feel. It talks about a flavor
10 granule or a dispersing granule, all things that would
11 be of interest to a POA in developing an ODT.

12 Q So it generally discusses how to make an ODT
13 with these microgranules and microcapsules, correct?

14 A Yeah, it does. It tells you -- tells how to
15 make an ODT. And not only, again, ODT, but what
16 particle size you need, how to deal with the taste-mask.
17 It deals with a number of things. It's not just that
18 single thing.

19 Q If you turn to paragraph 3 of Venkatesh, the
20 first sentence states "There are two types of most
21 widely used dosage forms for oral administration:
22 Tablets and capsules."

23 Do you see that?

24 A Yes, ma'am.

25 Q And it goes on to state several common

1 disadvantages of tablets and capsules.

2 Do you see that?

3 A Yes, I do.

4 Q And then it distinguishes in the last sentence
5 or so solid -- it starts with "On the other hand, solid
6 medicines, which rapidly dissolve or disintegrate in the
7 buccal cavity, can be taken without water, so they may
8 be easily taken by such aged persons, children or
9 'people on the move.'"

10 Do you see that?

11 A Yes, ma'am. All advantages of an orally
12 disintegrating dosage form.

13 Q And if we go to paragraph 13 of Venkatesh, it
14 states -- starting at the first sentence, it states
15 "Microgranules suitable for microencapsulation by
16 coacervation should have sufficient strength and
17 sufficiently low friability to withstand attrition
18 caused by agitation during microencapsulation. At the
19 same time, these microcapsules following
20 microencapsulation should be capable of being compacted
21 into tablets with minimal membrane fracture, as membrane
22 fracture results in undesired drug release causing
23 bitter taste."

24 Do you see that?

25 A Yes, ma'am.

1 Q So the microencapsulation microgranules in
2 Venkatesh -- strike that.

3 So, according to this paragraph in Venkatesh,
4 we would want to avoid drug release in the mouth because
5 it would cause a bitter taste, correct?

6 A If you've got a bitter tasting drug, that
7 microgranule they make is to deal with the bitter
8 tasting drug.

9 But again, there are other things that
10 Venkatesh pushes or presents -- the particle size you
11 need to get a good mouth feel, the fact you can make it
12 in a compressed tablet. There are any number of other
13 advantages that a POSA would look at this and say it has
14 a lot of valuable information in it.

15 Q If we go to claim 1 of Venkatesh, which is on
16 page 7, it states that "What is claimed: Claim 1, a
17 tablet that rapidly disintegrates in the oral cavity
18 comprising a compressed blend of rapidly dispersing
19 microgranules."

20 Do you see that?

21 A Yes, ma'am.

22 Q And then the second limitation starts with "a
23 taste-masked microcapsule."

24 Do you see that?

25 A Yes, I see "taste-masked microcapsule."

1 Q So Venkatesh here is concerned with making
2 rapidly dispersing microgranules and taste-masked
3 microgranules that prevent bitter taste in the mouth,
4 correct?

5 A Yeah, it does, along with showing you can make
6 a rapidly dissolving tablet. You can do it by
7 compression. You've got rapidly disintegrating
8 particles or granules that aid in the disintegration.
9 All of those things give you -- and all of those also
10 lead to better mouth feel.

11 So there's a lot of things that Venkatesh
12 pushes or presents. But taste-masking is one of them,
13 but it's not the only thing.

14 Q But claim 1 in Venkatesh is addressing a
15 problem that Venkatesh is attempting to resolve,
16 correct?

17 MR. LUMAN: Mischaracterizes the document.

18 THE WITNESS: It's dealing with a bitter drug.

19 MS. AGARWAL: Let's take a break.

20 (Recess taken from 11:48 to 11:57 a.m.)

21 MS. AGARWAL: Thank you, Dr. Parr. I have no
22 further questions for you.

23 THE WITNESS: Okay.

24 MS. AGARWAL: Pass the witness.

25

EXAMINATION

BY MR. LUMAN:

Q Dr. Parr, I have a couple questions for you.
If you'll take Exhibit 1020, which is Venkatesh.

A Okay.

Q And would you turn with me to claim 1 of
Venkatesh.

A Okay.

Q Do you see the word "bitter" in claim 1 of
Venkatesh?

A I do not.

Q In your opinion, is claim 1 of Venkatesh
limited to dealing with a bitter drug, or is it broader
than that?

A Well, it could be a bitter drug. Drugs have
metallic taste. So it could be any poorly tasting drug.

Q Would you turn in Venkatesh to paragraph 15.

A Okay. I'm there.

Q And do you see that the last sentence of
paragraph 15 talks about average particle size and ends
with a smooth creamy mouth feel?

A Yes, sir.

Q Do the -- if you'll turn back to claim 1 with
me of Venkatesh.

Do you see that the first limitation about

1 rapidly dispersing microgranules calls out a particle
2 size of less than about 30 microns?

3 A Yes, sir.

4 Q Does that particle size -- in your opinion,
5 would that particle size assist with anything about a
6 creamy mouth feel, for example?

7 MS. AGARWAL: Objection. Outside the scope of
8 the cross.

9 THE WITNESS: Yeah. It does. The particle
10 size has an impact on mouth feel and texture that the
11 patient is going to feel. So a nice smooth, round
12 particle is going to have a better mouth feel than
13 something that's jagged or rough.

14 BY MR. LUMAN:

15 Q Okay. Is having a particle size of less than
16 about 30 microns limited to assisting with taste-mask in
17 a bitter drug?

18 MS. AGARWAL: Objection. Outside the scope of
19 the cross.

20 THE WITNESS: There's a size you don't want to
21 go over from a mouth feel perspective. So, if you can
22 start with a smaller particle size and build the coating
23 up, it gives you more leeway to be able to develop a
24 taste-masked drug. Or a coated particle, for that
25 matter. It doesn't even have to be a drug particle.

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MR. LUMAN: No further questions.

MS. AGARWAL: No questions.

(TIME NOTED: 12:02 P.M.)

DECLARATION UNDER PENALTY OF PERJURY

I, ALAN F. PARR, PHARM.D., PH.D., the witness herein,
declare under penalty of perjury that I have read the
foregoing in its entirety; and that the testimony
contained therein, as corrected by me, is a true and
accurate transcription of my testimony elicited at said
time and place.

Executed this _____ day of _____ 2025, at

_____, _____.

(City)

(State)

ALAN F. PARR, PHARM.D., PH.D.

REPORTER'S CERTIFICATION

I, Leslie Johnson, a Certified Shorthand Reporter of the State of California, do hereby certify:

That the foregoing proceedings were taken before me at the time and place herein set forth; that any witnesses in the foregoing proceedings, prior to testifying, were administered an oath; that a record of the proceedings was made by me using machine shorthand which was thereafter transcribed under my direction; that the foregoing transcript is a true record of the testimony given.

Further, that if the foregoing pertains to the original transcript of a deposition in a Federal Case, before completion of the proceedings, review of the transcript [] was [] was not requested. I further certify I am neither financially interested in the action nor a relative or employee of any attorney or any party to this action.

IN WITNESS WHEREOF, I have this date subscribed my name.

Dated: April 17, 2025

A handwritten signature in cursive script that reads "Leslie Johnson". The signature is written in dark ink and is positioned above the printed name.

LESLIE JOHNSON

CSR No. 11451, RPR, CCRR

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