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

DR. FALK PHARMA GMBH,	) CASE NO. IPR2024-01197
	) PATENT NO. 8,771,729
PETITIONER,	)
	)
v.	)
	)
ELLODI PHARMACEUTICALS, L.P.,	)
	)
PATENT OWNER.	)
_____	)

DEPOSITION OF DR. MARTYN CHRISTOPHER DAVIES, Ph.D.

WEDNESDAY, JULY 2, 2025

NOTTHINGHAM, ENGLAND

FILE SD 7436693

REPORTED BY MARK McCLURE, CRR
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Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 001

DEPOSITION OF DR. MARTYN CHRISTOPHER DAVIES, Ph.D., 1:03 P.M., WEDNESDAY, JULY 2, 2025, VIA VERITEXT REMOTE TECHNOLOGY, BEFORE MARK McCLURE, C.S.R. #12203, CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA.

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Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 002

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Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 003

I N D E X

WITNESS	EXAMINATION	PAGE
MARTYN CHRISTOPHER DAVIES, Ph.D.		
	BY MR. LUMAN	5
	BY MS. AGARWAL	185
	BY MR. LUMAN	187

E X H I B I T S

NUMBER	DESCRIPTION	PAGE
EXHIBIT 1071	UNITED STATES PATENT APPLICATION PUBLICATION NO. US 2011/0189299 - 24 PAGES	172

PREVIOUSLY MARKED

NUMBER	PAGE
1001	13
1002	62
1005	14
1007	38
1008	140
1017	47
1020	119
1030	151
2007	9
2010	89
2015	136

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Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 004

WEDNESDAY, JULY 2, 2025, 1:03 P.M.

MR. LUMAN: This is the deposition of Dr. Davies in the matter of IPR No. 2024-01197.

My name is Nate Luman, and I'm joined by Phillip Minnick today. We're both from the law firm of Knobbe Martens, and we represent petitioner Dr. Falk Pharma in this matter.

MS. AGARWAL: I'm Isha Agarwal.

With me I have Jon Cousin and DeAnna Allen, from the law firm of Cooley LLP, and we are here representing patent owner Ellodi Pharmaceuticals.

MARTYN CHRISTOPHER DAVIES, Ph.D.
having been sworn, was examined
and testified as follows:

EXAMINATION

BY MR. LUMAN:

Q. Good afternoon. My name is Nate Luman, and I'm going to be taking the deposition today.

Can you hear me okay, Dr. Davies?

A. I can, thank you.

Q. Would you please state your full name and home address for the record.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 005

A. Martyn Christopher Davies, D-a-v-i-e-s. It's 4 Hall Grounds Drive, Colston Bassett, B-a-s-s-e-t-t, and I live in Nottingham, in the UK.

Q. Do you understand that you are under oath today?

A. I do.

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

A. No.

Q. I understand you've been deposed before, but just a few ground rules. I'm going to be asking the questions today, and the court reporter is going to be taking down my questions and your answers.

Would you agree to give verbal responses today?

A. I'll try to the best of my ability.

Q. Thanks.

And I'm going to try to not speak over you, and I would ask that you would try to not speak over me.

Is that okay?

A. Yes.

Q. And if you do not understand a question, please let me know. Otherwise, I will assume that you understood my question.

Is that fair?

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 006

A. Yes.

Q. Your attorney may object to some of my questions, but you will still need to answer the question unless you're instructed by your counsel not to answer.

Do you understand?

A. I understand.

Q. I'll probably take a break every hour or so. If you would like a break at another time, just let me know.

Is that okay?

A. Thank you.

Q. I assume you've been deposed before, is that correct?

A. That's correct.

Q. About how many times have you been deposed before?

A. I don't know the number. I've been deposed before. I don't know the number.

Q. As a rough estimate, maybe more than ten times?

A. I think so, yes.

Q. The cases where you've been deposed before, were those patent cases?

A. Excuse me. Yes, I believe so.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 007

Q. I believe you've also testified in court before, is that correct?

A. That's correct.

Q. Can you give an estimate about how many times you've testified in court before?

A. Again, I haven't counted how many times I've testified.

Q. I understand that you received a box in the mail concerning today's deposition, is that right?

A. That's correct.

Q. Do you have the box with you?

A. Yes.

Q. Would you please open the box.

A. It's already been opened, but sealed --

Q. I hope there's not too much tape on it.

A. -- by the Office of Border of Security.

Q. Okay, check the documents for security purposes. I understand.

A. There's an awful lot of tape.

I have it.

Q. Thanks.

The box contains a binder, and in the binder are exhibits. The first exhibit in the binder is your declaration, which is Exhibit 2007, and then the remaining documents in the binder, they go in order from

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 008

Exhibit 1001 and so on, up to Petitioner Exhibit 1036.

And then after that are the patent owner exhibits, starting at Exhibit 2008, which is your CV, and so forth.

So, hopefully, we won't have to go through all the exhibits today, but we have them in the binder to access, if needed.

A. Okay.

Q. Let's get started with Exhibit 2007. That would be the first exhibit in your binder.

Would you please turn there, and let me know when you have arrived.

A. I have.

Q. Exhibit 2007, just for the record, is a document that's entitled "Declaration of Martyn Christopher Davies."

Dr. Davies, do you recognize this exhibit?

A. I do.

Q. And what is it?

A. It's the declaration, my declaration in this case.

Q. Would you mind turning to the last page of the exhibit with me.

A. Yes.

Q. This is page 68.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 009

On page 68, is that your signature?

A. It is.

Q. Are there any corrections or edits you'd like to make to this declaration?

A. Not that I recall.

Q. Would you please turn with me in your declaration, Exhibit 2007, to paragraph No. 10.

A. Yes.

Q. So I'm looking at the second-to-last sentence in that paragraph. There, you state "I have extensive experience with the formulation of tablets, capsules, advanced drug delivery and controlled release systems" and so on.

Do you see that?

A. I do.

Q. And have you ever been involved with formulating an orally disintegrating tablet?

A. I have not. But I have been involved in the testing formulations, particularly those that are used and designed for the mouth. And, of course, I've taught them at the graduate course.

Q. When you said you've been involved with testing formulations, is that testing formulations of orally disintegrating tablets?

A. No, that was testing formulations which were

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 010

related to formulations that were designed for the use in the mouth for systemic absorption. I tested and characterized those formulations.

Q. So the formulations that you've tested -- what are some of the properties that you were looking at in characterizing those formulations?

MS. AGARWAL: Objection. Form.

THE WITNESS: Can I ask you what you mean by "properties"?

BY MR. LUMAN:

Q. Well, sure. Let me just ask more generally.

When you were testing formulations, what types of testings were you performing?

A. As my next sentence says, I've been actively involved in making and characterizing many pharmaceutical preparations.

It's kind of what I've been known for. So in those formulations, I'd be characterizing the distribution of the drug within the formulation, I'd be characterizing the distribution of the excipients, I'd be looking at determining their function, and also the release of the drug. Those are the kind of things that I'd be using.

A combination of advanced analytical techniques, as well as conventional pharmaceutical

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 011

techniques to do that, and I did that both in my academic work, but, of course, in the company that I cofounded, Molecular Profiles, which became Juniper Pharma Services.

Q. Dr. Davies, if I refer to orally disintegrating tablets as ODTs today, would that be okay?

A. That's fine.

Q. I'd like to discuss ODTs for a few minutes.

In your declaration, would you please turn with me to paragraph 58.

A. Yes.

Q. So, in paragraph 58, you say "Dr. Parr states that the '729 patent defines orally disintegrating tablet, orally dispersing tablet, or ODT, to refer to a solid dosage form of the present invention, which disintegrates rapidly in the oral cavity of a patient after administration, without chewing."

Do you see that?

A. I do.

Q. And based on the last sentence, in paragraph 58, I understand that you agree with this definition of an ODT.

Is that fair?

A. That's correct.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 012

Q. There's a citation in paragraph 58 to Exhibit 1001. It's to column 2, lines 41 to 44.

Do you see that?

There's a parenthetical that says "Citing Ex 1001, 2 (41-44).

A. Correct.

Q. I'd like to take a look at that exhibit together and that portion of the patent that's cited, so would you please turn in your binder to Exhibit 1001, and let me know when you've arrived.

A. I have.

MR. LUMAN: For the record, I'll state that Exhibit 1001 is U.S. Patent No. 8,771,729, and the last name of the first named inventor is Perrett.

Q. Dr. Davies, is it okay if I refer to this patent as the '729 patent today?

A. That's fine.

Q. Would you turn with me to column 2. Starting at line 41, there's a description of orally disintegrating tablet.

Do you see that?

A. I do.

Q. It says: "The terms 'orally disintegrating tablet,' 'orally dispersing tablet,' or 'ODT' refer to a solid dosage form of the present invention which

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 013

disintegrates rapidly in the oral cavity of a patient after administration, without chewing."

Do you see that?

A. I do.

Q. Is this definition of an orally disintegrating tablet consistent with how a person of ordinary skill in the art would have understood an ODT in the year 2009?

A. I believe it is.

Q. And I see that the definition refers to the oral cavity.

Would that be the mouth, in, basically, layman's terms?

A. That's correct.

Q. I'd like to take a look at another description of an ODT, specifically the description found in the FDA guidance and take a look at that, so would you mind turning with me in your binder to Exhibit 1005, and let me know when you've arrived there.

A. Okay.

MR. LUMAN: For the record, I'll state that Exhibit 1005 is a document entitled "Guidance for Industry, Orally Disintegrating Tablets."

Q. Dr. Davies, are you familiar with Exhibit 1005?

A. I am.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 014

Q. Would you turn with me to page 2 -- I'm going by the numbers at the bottom of the page -- and can you let me know when you've arrived.

A. I'm there, thank you.

Q. Thanks.

I see there's kind of, halfway through the page, a header Roman numeral III, Discussion.

Do you see that?

A. I do.

Q. And then the first sentence of section 3 says: "As briefly discussed in section 2, an ODT has previously been distinguished as a separate dosage form because of the specific, intended performance characteristics of such a product, which are rapid oral disintegration in saliva with no need for chewing or drinking liquids to ingest these products."

The next sentence: "These characteristics, which are an aid to patient use and compliance, are the primary characteristics that constitute the basis for classifying a product as an ODT."

Do you see those two sentences?

A. I do.

Q. Is the description here consistent with how a POSA, a person of ordinary skill in the art, would have understood an ODT in the year 2009?

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 015

A. I believe it is.

Q. The second sentence, it talks about primary characteristics. It says: "Primary characteristics that constitute the basis for classifying a product as an ODT."

Do you see that?

A. I do.

Q. And I understand those primary characteristics refer to the previous sentence, which would be "rapid oral disintegration in saliva with no need for chewing or drinking liquids to ingest these products."

Would you agree or disagree with me on that?

A. I think it does refer to that. And as I say, these are an aid to patient use and compliance.

Q. When you say these are made for patient use and compliance, is that ODTs you're referring to that are made for patient use and compliance?

A. I actually said "which are an aid to patient use and compliance."

So the primary characteristics of rapid oral disintegration is saliva, no need for chewing or drinking liquids to ingest these products. In other words, so that they can be swallowed, or are an aid to patient use and compliance.

Q. Thanks for the clarification.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 016

So that description refers to rapid oral disintegration in saliva, and I'd like to explore the part about the saliva there.

So my understanding of how an ODT works is that the patient's saliva contacts the ODT, and that causes the ODT to disintegrate rapidly in the oral cavity, is that correct?

A. When an ODT is placed in a patient's mouth, in their oral cavity, it will come in contact with saliva, which contains water, and that water will contact the ODT, and it will start to disintegrate rapidly. It will allow the drug to be dispersed in the saliva so it can be absorbed systemically, and if it is not dissolved in the mouth, it will be swallowed into the stomach so it can be then subsequently absorbed in the rest of the GI tract.

Q. I want to follow up on the part about dispersal in the saliva.

So the part of the ODT that's dispersed in the saliva would be the excipients from the ODT and the active ingredient from the ODT, is that right?

A. That's correct.

Q. And when we refer to dispersion, we don't necessarily mean dissolved, it could be that there's still solid particulates there, is that correct?

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 017

MS. AGARWAL: Objection to form.

THE WITNESS: It depends on what you mean. When the tablet -- when the ODT comes in contact with saliva, it will break up. It will break up, allowing the particles within the tablet, both excipient and drug, to be released into the saliva. The drug particles on contact with saliva will start to dissolve, and, therefore, they can start to be absorbed into the bloodstream through the mouth.

BY MR. LUMAN:

Q. I'd like to stay in Exhibit 1005. If you can turn back to page 1 with me, and let me know when you've arrived there.

A. Yes. Thank you.

Q. I see kind of near the sort of bottom of the page, Roman numeral II, Background.

Do you see that header there?

A. I do.

Q. And I'm looking at the second sentence of the background section on page 1 of Exhibit 1005.

It says: "The products are designed to disintegrate or dissolve rapidly on contact with saliva, thus eliminating the need to chew the tablet, swallow an intact tablet, or take the tablet with liquids."

Do you see that?

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 018

A. I do.

Q. And then the next sentence: "This mode of administration was initially expected to be beneficial to pediatric and geriatric patients, to people with conditions related to impaired swallowing, and for treatment of patients when compliance may be difficult (e.g., for psychiatric disorders.)"

Do you see that?

A. I do.

Q. I'm interested in the portion about ODTs being expected to be beneficial to people with conditions related to impaired swallowing.

Can you explain why ODTs were expected to be beneficial to people with conditions related to impaired swallowing?

A. So it talks in the context of pediatric and geriatric patients where there may be difficulty in those patients in swallowing.

Equally, there may be individuals who find it difficult to swallow tablets, and therefore, ODTs are used in those cases because, obviously, you want the treatment, you want the patient to get the drug into the bloodstream so that it can have a clinical effect, and in doing so, an ODT overcomes that compliance problem, because, when placed in the mouth, it disintegrates and,

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 019

as I discussed, it dissolves rapidly on contact with saliva, allowing the drug to be absorbed into the bloodstream very quickly, and also for the drug which is not dissolved to be swallowed and then go through the GI tract, into the small intestine and stomach, and be absorbed into the bloodstream there.

Q. So is it fair that an ODT is beneficial for patients who have impaired swallowing, as compared to an alternative tablet that needs to be swallowed? Is that a fair way to look at it?

MS. AGARWAL: Objection. Form.

THE WITNESS: I don't quite understand your question, but if you're saying that the pediatric and geriatric patients, patients where compliance is difficult, and also patients where they have a difficulty swallowing tablets, then an ODT is an alternative and ensures that you can get the drug into the bloodstream, absorbed into the bloodstream and have its clinical effect.

BY MR. LUMAN:

Q. What type of conditions do people have that are related to impaired swallowing?

A. There may be people who have a problem in swallowing. I'm not a clinician in that sense, so I'm just aware that for those patients that present with a

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 020

problem of impaired swallowing, then an ODT, which rapidly disintegrates in the saliva, is a good alternative for those individuals to ensure that they can get the drug absorbed into their bloodstream.

Q. Okay. Would you mind turning back with me to Exhibit 1001, and let me know when you have arrived there.

A. Yes.

Q. I'd like to turn to column No. 1 of Exhibit 1001. Can you let me know when you've arrived there.

A. Yes.

Q. In column 1, there's a header, Background of the Invention.

Do you see that?

A. I do.

Q. Starting at line 21, there is a description that includes eosinophilic esophagitis.

Do you see that?

A. I do.

Q. Are you familiar with eosinophilic esophagitis?

A. I am.

Q. And the text indicates that eosinophilic esophagitis is abbreviated as EE, is that right?

A. That's correct.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 021

Q. I've also seen eosinophilic esophagitis abbreviated as EoE.

Would it be okay with you if sometimes I refer to eosinophilic esophagitis as EoE?

A. Yes.

Q. When did you first become aware of EoE?

A. I don't recall when I became aware. I've been aware of it for quite some time.

Q. Have you been aware of EoE since before you began working on this case?

A. Yes.

Q. Do you recall how you became aware of EoE?

A. Just through my general reading and work. My background is in pharmacy and pharmacology, so for that reason, I am aware of this condition.

Q. Are you familiar with the symptoms of EoE?

A. Well, I was, and the patent teaches you that it's painful, leads to difficulty in swallowing and predisposes patients to food impaction and other complications.

Q. With respect to difficulty swallowing, do you know if that's a major or minor symptom of EoE?

MS. AGARWAL: Objection. Form.

THE WITNESS: I know it's one part.

BY MR. LUMAN:

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 022

Q. Do you know how commonly reported difficulty swallowing is amongst patients with EoE?

MS. AGARWAL: Objection. Form.

THE WITNESS: Again, I just know it's one of the symptoms of EE, or EoE.

BY MR. LUMAN:

Q. Do you know if difficulty swallowing is the most common symptom of EoE?

MS. AGARWAL: Objection. Form.

THE WITNESS: Again, I'm a formulator, and the formulator -- I'm from that background, and also from my pharmacy background, I know that it's one of the symptoms of EE, or EoE.

BY MR. LUMAN:

Q. I'd like to continue looking in Exhibit 1001 with you.

Would you turn with me to the claims, which begin in column 18. Can you let me know when you arrive at column 18.

A. Yes.

Q. Do you see Claim 1 in column 18?

A. Yes.

Q. Claim 1 recites: "An orally disintegrating solid pharmaceutical composition."

Do you see that?

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 023

A. That's correct.

Q. And it requires a corticosteroid and a disintegrant. It has to disintegrate within 60 seconds.

I want to look at the last limitation, starting in line 30.

Do you see that last limitation in line 30?

A. Yes.

Q. So that says: "Wherein upon administration, the corticosteroid is deposited topically in the upper gastrointestinal tract."

I'd like to understand how this orally disintegrating solid deposits the corticosteroid in the upper gastrointestinal tract.

So my understanding is that upon administration, it's the patient's saliva that causes the orally disintegrating solid to disintegrate in the oral cavity.

Do I have that right, or would you say it differently?

MS. AGARWAL: Objection. Form.

THE WITNESS: It's three different questions.

Do you mind breaking it up so that I can answer it?

BY MR. LUMAN:

Q. Yes. Let's try it this way.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 024

How does the orally disintegrating solid deposit the corticosteroid in the upper gastrointestinal tract?

A. Well, the inventors show -- they claim in this claim to use an ODT for the first time such that when it was exposed to the saliva, the ODT broke it up within 60 seconds, and they are showing that that ODT -- when the drug is both in the saliva, absorbed in saliva, and also drug particles are present within the saliva and the rest of the excipients are present within the saliva, upon swallowing that, it's administered topically in the upper gastrointestinal tract, and they claim this is essentially the first time an ODT had been used for a topical administration as opposed to systemic.

Q. I'd like to follow up on the saliva portion of your answer.

What volume of saliva is required to dissolve the orally disintegrating solid so that the corticosteroid is deposited in the upper gastrointestinal tract?

MS. AGARWAL: Objection. Form.

THE WITNESS: It will be a volume, typically -- I would agree with Dr. Parr. It would be about 1 or 2 mils in that situation, the tablet will break up and the drug will start dissolving and the

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 025

particles of the drug will be in the saliva, along with the excipients, and on swallowing, it would deposit -- this is showing for the first time that you could use this approach to deposit the corticosteroid topically in the upper gastrointestinal tract.

BY MR. LUMAN:

Q. So a volume of about 1 to 2 milliliters of saliva would be sufficient to dissolve the orally disintegrating solid for the corticosteroid to be deposited in the upper gastrointestinal tract, is that right?

A. Not quite. The 1 to 2 mils would be sufficient for the disintegration and starting the dissolution of the drug. So it dissolves, and drug particles would be deposited topically in the upper gastrointestinal tract, and the drug would continue to dissolve from the particles topically.

Q. And a volume of 1 to 2 milliliters of saliva is sufficient for allowing the corticosteroid to be deposited topically in the upper gastrointestinal tract?

A. Well, the volume clearly is sufficient volume such that the drug would be deposited topically in the upper GI tract. You know, that's what the inventors are teaching you, that they have developed a formulation for the first time which can deposit the drug topically in

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 026

the upper gastrointestinal tract.

One would not expect an ODT to be able to do that, but they are showing it has, and it's the first example I'm aware of, of ODT being used topically in the upper gastrointestinal tract.

Q. And I just wanted to follow up on the volume from your previous answer.

Is the volume of saliva, 1 to 2 milliliters, that's sufficient for depositing the corticosteroid in the upper gastrointestinal tract with an ODT, or is there a different volume that you need in order to deposit the corticosteroid in the upper gastrointestinal tract?

A. As I'm sure we'll go on to talk about, it uses 8 to 12 mils of a liquid formulation to treat and deposit topically in the upper gastrointestinal tract.

As we will discuss, I'm sure, later, Dohil shows that you can use a liquid formulation of about 8 to 12 mils of a particular viscosity to deposit the corticosteroid topically in the upper gastrointestinal tract. That's why it's surprising and innovative that the inventors have shown that you can use an ODT, because as Dr. Parr has indicated, and I agree with him, typically, you would have around 1 to 2 mils of saliva available in the circumstance for an ODT, but the

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 027

inventors have shown that this is an effective way to treat, and they have a method claim, as I'm sure you know, Claim 29 for the treatment of an inflammatory condition using this formulation.

Q. Well, let's take a look at Claim 29.

Would you please turn there. That's in column 20.

So Claim 29 is a method for treating an inflammatory condition, and it uses the composition according to Claim 1.

Do you see that?

A. I do.

Q. Would 1 to 2 milliliters of saliva be sufficient for the orally disintegrating solid of Claim 1 to treat an inflammatory condition of the gastrointestinal tract, as set here in Claim 29?

MS. AGARWAL: Objection. Form.

THE WITNESS: Again, clearly, the patentees are claiming that they can use the ODT for the first time for the topical delivery of the corticosteroid for treating an inflammatory condition of the GI tract. And I agree with Dr. Parr, typically, you would have 1 to 2 mils of liquid of saliva in the mouth at the time you took an ODT, and therefore, the inventors have shown and are claiming that they can treat the upper

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 028

gastrointestinal tract by depositing the corticosteroid using that ODT formulation. It's the first time someone has done this using an ODT as a topical administration in the upper GI tract.

BY MR. LUMAN:

Q. Can you look down at Claim 31 with me. That one is "wherein said condition is eosinophilic esophagitis, EoE."

Do you see that?

A. I do.

Q. Would 1 to 2 milliliters of saliva be sufficient to use the orally disintegrating solid of Claim 1 to treat EoE according to Claim 31?

MS. AGARWAL: Objection. Form.

THE WITNESS: Well, the patentees are claiming the ODT in column 1 can be used once it disintegrates -- one that disintegrates within 60 seconds using the USP disintegration test for the deposition of the corticosteroid topically in the upper GI tract.

Dr. Parr has said 1 to 2 mils of saliva would be present and that would allow the ODT to break up and dissolve some drug and also have some drug particles and excipient present and be deposited in the upper GI tract. And that's what the patentees are claiming is sufficient, because they claim a method for treating the

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 029

condition of the inflammatory condition of the GI tract, which include the systemic eosinphilic esophagitis, or EE.

Q. Looking at Claim 31, condition is EoE.

When the solid orally disintegrating composition mixes with the patient's saliva, does that resulting suspension formed from the saliva mixing with the ODT -- does that need to coat the esophagus to treat EoE?

MS. AGARWAL: Objection. Form.

THE WITNESS: Well, it's been deposited topically in the upper gastrointestinal tract, i.e., the esophagus. And that provides the method of treatment, it alleviates the inflammatory condition of the eosinophilic esophagitis, or EoE.

BY MR. LUMAN:

Q. In order to alleviate the inflammatory symptoms of EoE, does the solid composition mixed with the patient's saliva need to coat the esophagus?

MS. AGARWAL: Objection. Form.

THE WITNESS: Yes. That question doesn't quite make sense.

If you mean the ODT, on contact with saliva, breaks up rapidly, and that saliva, which contains the drug, dissolved drug, drug parcels, which are

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 030

dissolving, and also the excipients, that coats or is deposited, rather, topically in the upper gastrointestinal tract, and that is because this is, for the first time, not with any systemic event, as the Claim 1 says, but a topical event.

BY MR. LUMAN:

Q. And when the saliva mixes with the dissolved drug from the orally disintegrating solid, does that need to coat the entire esophagus or does it need to coat part of the esophagus or does it have to coat any of the esophagus in order to alleviate the symptoms of EoE?

MS. AGARWAL: Objection. Form.

THE WITNESS: Well, I don't think there's any question. Let's start again.

The ODT, on contact with saliva, breaks up rapidly, releasing the drug and the excipients. Some of the drug will be dissolving, some of the drug will still be drug particles. When that's swallowed it will be deposited topically in the upper gastrointestinal tract, and this -- and the patentees are saying, by that depositing in the esophagus, it really provides a method of treatment of that inflammatory condition, EoE.

BY MR. LUMAN:

Q. I want to get in what you said about it

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 031

depositing into the esophagus.

Does that depositing in the esophagus require coating the esophagus or not?

A. Depends on what you mean by "coating the esophagus," but clearly, the claim is to the ODT, which is broken up in the saliva, and the dissolved drug and the drug in the saliva, which is swallowed, will then be deposited topically in the esophagus. And that has been shown to provide relief. It's using 8 to 12 mils of a viscous solution. That solution was claimed to provide relief.

Q. As part of your answer, you'd mentioned it depends on what I mean by "coating the esophagus," and you brought up Dohil.

So do you have an understanding of when Dohil brings up coating the esophagus? Does it have to coat the entire esophagus or just part of the esophagus? Do you have an understanding of that?

MS. AGARWAL: Objection. Form.

THE WITNESS: Again, Dohil claims to provide sufficient coverage such that you get relief, you're able to treat. The same as with the ODT. For the first time, it has been shown, using an ODT, that it can deposit topically in the upper GI tract, the esophagus, such that you can treat EoE sufficiently.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 032

BY MR. LUMAN:

Q. How would we know if it's been sufficiently deposited to treat EoE? Is that 100 percent coverage of the esophagus, or something just sufficient to treat an inflamed area? Can you provide some more information on what you mean by "sufficiently deposited to treat EoE"?

MS. AGARWAL: Objection. Form.

THE WITNESS: Again, the patentees are claiming, in 29, a method for treating an inflammatory condition, like EoE, which is claimed in 31. So if you're treating it -- in other words, you're providing relief from that inflammatory condition, you are, by nature, administering sufficient corticosteroid and depositing it topically in the upper GI tract, i.e., the esophagus.

Q. I'd like to talk about the saliva volume for a minute.

Would you agree that a person typically has 1 to 2 milliliters of saliva in their oral cavity at any given time?

A. In that order. Maybe a little less, but it would be of that order. Yes, I'd agree.

Q. Are you aware that a person's saliva production rate can increase when stimulated by having a solid composition in someone's mouth?

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 033

A. Again, it depends on the context, you know. It depends on the context. If there's food in your mouth, then you may very well get saliva stimulation.

Q. How about if you place an orally disintegrating tablet in the mouth, would that increase a person's saliva production?

A. I guess the ODTs rapidly begin breaking in the mouth. So it will rapidly disintegrate within seconds, certainly within 60 seconds. They did a disintegration test, allowing the drug to be released, and it will be released into the saliva, which, when swallowed, will, for the first time, administer the drug topically to the esophagus.

Q. That process of the ODT rapidly disintegrating in the patient's saliva, does that process tend to increase the patient's saliva production rate?

MS. AGARWAL: Objection. Form.

THE WITNESS: I guess I'd agree with Dr. Parr, that you're going to have about 1 to 2 mils of saliva when the ODT is breaking up and dissolving in the mouth.

BY MR. LUMAN:

Q. So your position is that there's going to be 1 to 2 milliliters of saliva to dissolve an ODT regardless of any increase in the patient's saliva production rate that's due to stimulation by the ODT, is that fair?

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 034

MS. AGARWAL: Objection. Form.

THE WITNESS: Not quite. It's -- you will get -- when the ODT breaks up on contact with the saliva in the mouth, it will disintegrate and the drug will start to dissolve, and on swallowing, that will contain both dissolved drug, drug particles, which will deposit in the esophagus topically. A topical administration.

BY MR. LUMAN:

Q. I want to focus on the patient's saliva production rate.

Do you have an opinion if a patient's saliva production rate will increase, decrease or stay the same when an orally disintegrating tablet is placed in a patient's mouth?

A. I think there will be, certainly, 1 to 2 mils when an ODT is placed in the mouth. And, I guess -- and I've said it in my report, that you -- you know, the amount of saliva production will depend on the -- can vary, it can depend on the disease state of the patient, it depends on many factors.

And I use that comment, you know, that this clearly -- this ODT clearly works, despite the fact that you're using an ODT for the first time for topical administration.

So I'm contrasting that with what prior art

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 035

knew using a viscous solution of a defined 8 to 12 mils volume where everything was predissolved, and still, the ODT, in some ways, surprisingly, has been shown to work and treat, topically, EoE.

So whether you have 1 to 2 mils or whether that varies amongst patients, or it varies in terms of the -- you know, to some extent, you know, that adds to the surprise of the invention, because you're not having a predefined volume of liquid, which the prior art taught you worked with an ODT. You have all these variables, both inter and intrapatient, and yet, it's effective for treatment of EoE by topically administering the corticosteroid in the esophagus.

THE WITNESS: We have been going for about an hour and five minutes.

Would you mind if we took a brief break?

MR. LUMAN: Yes. Would you like five minutes? Ten minutes? Do you have a preference?

THE WITNESS: Say, ten minutes.

Would that be okay?

MR. LUMAN: Yes. We'll be back at 6:17. I suppose that's 17 after.

(A short recess was taken.)

BY MR. LUMAN:

Q. It's now 17 after, and we are back on the

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 036

record.

I wanted to follow up on your previous answer where you had said that a patient's saliva production rate depends on many factors.

Is one of the factors that increases the patient's saliva production rate the presence of an ODT in the patient's mouth?

A. Well, I've said that I agree with Dr. Parr, that when the claim -- already disintegrating composition disintegrates in 60 seconds, which Dr. Parr has admitted would only produce 1 to 2 mils of liquid, I then go on to my report. I think it's in paragraph 106. I talk about various factors impacting saliva production of a patient.

And that the amount of liquid generated when following the administration of the ODT is unpredictable and variable. And also, the viscosity could not be controlled. And I say that because it is surprising, based on the prior art, Dohil, that an ODT -- to me, and I think to a person of ordinary skill, that an ODT would work. So there are various factors impacting saliva production of a patient. And it has been shown to work.

Q. I want to take a look at page 106 of your declaration, I reference Exhibit 1007.

Looking at the sentence that brings up

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 037

unpredictable and variable.

Do you see that sentence?

It's kind of the bottom of page 46.

A. Yes.

Q. When you say that the amount of liquid generated is unpredictable and variable, is 1 to 2 milliliters the minimum amount of liquid generated in the mouth?

MS. AGARWAL: Objection. Form.

THE WITNESS: I think I agree with Dr. Parr, that he says that, on ingesting -- on taking, sorry, an ODT, disintegrating in 60 seconds, will produce 1 to 2 mils of liquid saliva.

But I go on to say that the various factors impacting saliva production in a patient may vary. It equally could be smaller than that, or larger. Because it would depend on age, time of day, hydration, disease. There are various factors that could come into play here. And I am contrasting that with Dohil, where there's a predefined, ready-made up liquid of a defined volume and viscosity.

BY MR. LUMAN:

Q. I didn't see any citation to a supporting reference in paragraph 106 for your opinion that the

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 038

amount of liquid generated is unpredictable and variable.

Do you care to comment on why there's no citation there?

A. Well, I think a person of ordinary skill would know that. I think a person of ordinary skill would know that the amount of liquid generated in the mouth following administration of an ODT is unpredictable and variable. They would have to understand that from their own personal experience.

The amount of saliva in your mouth does vary, and that contrasts significantly with the predefined volume of Dohil, that liquid formulation, and I am saying that, you know, that makes it, to me, all the more surprising that an ODT works. And I'm saying Dr. Parr does not comment on that.

Q. Is your opinion that the amount of liquid generated is unpredictable and variable based on your experience with monitoring a patient's saliva production rate after they have been administered an orally disintegrating tablet?

MS. AGARWAL: Objection. Form.

THE WITNESS: Sorry, I don't understand the question.

I'm saying that a person of ordinary skill

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 039

would understand that the amount of liquid generated in the mouth following administration of an ODT is unpredictable and variable, and I think that's a really important point in terms of the surprise that this ODT does work, because, in Dohil's case, you have a formulation, which is found to be clinically effective, where you have a predefined volume of viscosity, whereas, I would not expect the same viscosity, volume, et cetera, with an orally disintegrating tablet. So you have would no reasonable expectation of success in using that ODT.

BY MR. LUMAN:

Q. Let's turn to a different topic. I'd like to talk about lozenges for a few minutes.

Would you mind turning in your declaration to the 2007, to paragraph 83, and let me know when you have arrived.

A. Yes. Thank you.

Q. I'm looking about halfway through paragraph 83, there's a sentence that states "I'm also not aware of any fast or quick dissolving lozenges."

Do you see that?

A. Yes.

Q. Is that still true, as you sit here today?

A. Yes, I am not aware, nor is -- was Dr. Parr at

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 040

the time aware of a fast-dissolving lozenge. And I think a person of skill would understand, when the term "lozenge" is used, is that the lozenge is dissolving, it just sits in the mouth to be sucked, and the drug is released slowly over a period of time. That would be a surface drug, and it would be released quickly.

Q. Did you look for any rapidly dissolving lozenges in the prior art?

A. I do not know of any rapidly dissolving lozenges. I've been teaching and researching this field for 35 years, and I do not know -- equally, there's citations that Dr. Parr cites that describes the lozenges to be placed in the mouth and be sucked, and they stay in the mouth. That's completely different to ODT.

Q. I understand that you don't know of any rapidly dissolving lozenges, but my question was: Did you look to see if there were any rapidly dissolving lozenges in the prior art?

A. I am not aware of any. You know, I'm looking at this from the perspective of a person of ordinary skill, and I believe the person of ordinary skill would understand the text of Aulton, and other texts, dictionary definitions, and they'd understand if a document says a lozenge, and doesn't -- you know, they

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 041

would understand that a lozenge is a type of formulation that's designed not like an ODT, but to erode slowly in the mouth, releasing the drug.

Q. I understand that you're not aware of any rapidly dissolving lozenges.

My question is: Did you look to see if there are any in the prior art?

MS. AGARWAL: Objection. Form.

THE WITNESS: I did not see any rapid -- I have not seen any rapidly dissolving lozenges, to my knowledge, over 35 years. So I took the face value of the lozenge as it's used in Dohil. And I agree with Dr. Parr, I'm not aware of any, or any commercial ones.

BY MR. LUMAN:

Q. When you said you did not see any rapidly dissolving lozenges in the prior art, did you use any search terms to look into the prior art for rapidly dissolving lozenges?

MS. AGARWAL: Objection. Form.

THE WITNESS: Again, I relied on my experience and I relied on my knowledge, and I also think that's what a person of ordinary skill would understand, that a lozenge does not dissolve rapidly, like an ODT. So I relied on my knowledge. I relied on textbooks, I relied on standard references, dictionary, reviews, to come to

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 042

that review. Because I believe that is what a person of ordinary skill, if they saw a lozenge, would understand.

BY MR. LUMAN:

Q. So you did not do a search of the literature for rapidly dissolving lozenges using search terms or anything like that, is that fair?

A. I did not search because I know what a lozenge is meant -- what lozenge means. And a lozenge does not dissolve rapidly like an ODT. And, you know, I agree with Dr. Parr. He can't identify any fast dissolving lozenges. If he had found such fast dissolving lozenge, I'm surprised that he did not show them. And he also said he wasn't aware of any commercially available ODTs which were lozenges, or similar tablets.

Q. Why didn't you do a literature search for rapidly dissolving lozenges when you put together your opinion for this case?

A. It's a contradiction of terms. It goes against everything that a person of ordinary skill would understand. A person of ordinary skill, when reading about a lozenge, would understand that it does not -- is not designed to dissolve rapidly like an ODT. A lozenge is meant to be placed in the mouth and sucked, and surface drug will be released rapidly, but then gradually. As the lozenge dissolves, drug is released.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 043

That's what a person of ordinary skill would understand.

And why would you make a fast dissolving lozenge?

It's a contradiction of terms. It's for that reason I relied on my knowledge for my opinion and, you know, that's, I believe, what a person would understand.

Q. I take it, you'd be surprised if lozenges that dissolve within 60 seconds in a patient's mouth were known in the prior art.

Is that fair?

A. Not only would I be surprised, Dr. Parr would be surprised. He couldn't identify any fast dissolving lozenge of any commercially available ODTs, which constitute lozenges.

Q. You just brought up commercially available ODTs.

Is it your opinion that you would have to have a commercially available, rapidly dissolving lozenge in order to justify Dohil's description of a rapidly dissolving lozenge?

MS. AGARWAL: Objection. Form.

THE WITNESS: I'm not saying that. I'm saying that Dr. Parr could not demonstrate there were any commercially available ODTs constituting of lozenges. Equally, he was not able to identify any fast dissolving

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 044

lozenge. So in the context of somebody reading Dohil, somebody reading Dohil would understand that a lozenge is a lozenge, and, you know, they are using that description, and that description is the antithesis of an ODT.

When you look at Dohil, they say, for patients that may have difficulty with a dissolving lozenge, the lozenge may be ground or otherwise dissolved in a small volume of water. Clearly, if it was on ODT, you would not need to grind it up. If it was an ODT, it would rapidly disintegrate, but it doesn't.

And a lozenge, because it stays in the mouth for a longer period of time, will generate the kind of volumes that one would expect, anticipate in generating the kind of volume of saliva containing the drug, which are much more comparable with Dohil's 8 to 12 mils. And they talk about dissolving in a small volume of water, for example, reaching a total volume in the embodiment herein within Dohil -- in other words, the 12 mils.

BY MR. LUMAN:

Q. I understand that you didn't do a search of the prior art for rapidly dissolving lozenges.

How about including references of today, in the year 2025? Have you ever seen a rapidly dissolving lozenge anywhere in the literature?

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 045

A. Again, look, Dr. Parr -- I have not seen citations in relation to that. All the reviews that Dr. Parr brought forward about ODTs, ODTs that he used for systemic administration of drugs, all those reviews do not cite a fast dissolving lozenge. And they cite all kinds of different formulations for -- you know, essentially to being rapidly disintegrating formulations in the mouth. Not one of them in that reviews -- in those reviews, in those documents, talk about a fast dissolving lozenge.

So if a person of ordinary skill knew about the fast dissolving lozenge, why isn't it in all those multiple publications that Dr. Parr brought forward about ODTs?

Because a person of ordinary skill would understand the term "lozenge" means exactly what it was. And even when some of those, like Danckwerts, who talks about different formulations for oral -- for delivery to the mouth. He talks about those ODTs and equivalents, but when he talks about lozenges, he talks specifically about lozenges which are designed, as the person of skill in the art would know, without a disintegrant so that they slowly, slowly dissolve in the mouth, releasing the drug over a period of time.

That's my point.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 046

Q. We'll be here for a long time today if you can't answer my questions.

So my question was: Have you ever seen a rapidly dissolving lozenge anywhere in the literature?

A. I have not seen a rapidly dissolving lozenge in the literature, nor have I seen it in all the publications that Dr. Parr put forward illustrating ODTs for the systemic absorption of drugs.

Q. In your previous answer, you brought up some of the review articles that Dr. Parr cited, and so still in paragraph 82 of your declaration, do you see the citation to Exhibit 1017?

It's kind of -- yeah. It's highlighted on the screen.

A. Yes, I do.

Q. Okay. Would you please turn in your binder to Exhibit 1017.

MR. LUMAN: For the record, I'll say Exhibit 1017 is a document entitled "Intraoral Drug Delivery - A Comparative Review," and the author's last name is Danckwerts.

Dr. Davies, I'm going to assume you have some familiarity with this document, is that okay?

A. Yes.

Q. Please turn to page 181.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 047

A. Yes.

Q. Let's see. Looking at -- on the right column there's a header, 2.3, "Solid Intraoral Drug Delivery Systems."

Do you see that?

A. I do.

Q. All right. The first sentence of that section says: "Oral lozenges have been used for many years and have proved to be a very popular drug delivery system for treating local mouth diseases and sore throats."

Do you see that?

A. I do.

Q. And would you agree with what the author wrote, that lozenges are typically for topical drugs that treat local mouth diseases and sore throats?

A. I agree that they are a very popular drug delivery system for treating local mouth diseases and sore throats.

Q. Can you explain a little bit how a lozenge would typically treat a sore throat?

A. A lozenge will be taken into the mouth, it will be held in the mouth, and it will gradually -- it will release drug from the surface of the lozenge, and, in that sense, the drug will be in saliva, and then over a period of time, the lozenge will gradually erode and

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 048

dissolve from the surface releasing more of the drug. The drug being in the saliva provides relief in the mouth and in the throat.

Q. Is the relief provided by the drug because the drug contacts the mouth and the throat?

A. It could be that the drug is both acting topically and also systematically, correct, in that context, but, you know, it's released over a period of time. It's not like an ODT where it's taken and it disintegrates rapidly in the mouth. It's not intended for that. It's intended to be slowly releasing the drug over a period of time.

Q. Does the patient's act of swallowing have any mechanism for providing the relief to the patient? Can you comment on that at all?

MS. AGARWAL: Objection. Form.

BY MR. LUMAN:

Q. The first sentence indicates that the lozenge is a popular drug delivery system for treating mouth and local sore throats.

Does the patient swallowing the saliva mixed with the drug have anything to do with how the lozenge treats the mouth disease and sore throats?

MS. AGARWAL: Objection. Form.

THE WITNESS: It depends on the context,

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 049

doesn't it?

But it goes on to say, in the third sentence: "The drugs that have traditionally been used have very few systemic adverse effects, and there has never really been concern about the amount of drug swallowed by the patient."

I don't know if that answers your question.

Clearly, if it's in the mouth, as it goes on to say, more potent drugs -- they are mainly used for their quicker intraoral absorption properties.

In other words, the lozenge is kept in the mouth over a period of time, the drug dissolves, and it's absorbed within the oral -- the blood stream that serves the oral cavity, providing quick absorption of the drug.

BY MR. LUMAN:

Q. When the drug is absorbed in the oral cavity, is that treating the mouth disease, or is that also treating the sore throat?

A. Well, in the context of the last section, last sentence, they talk about more potent drugs. And in that context, that's where a lozenge is useful because it can be held in the mouth, gradually releasing the drug, and the drug is being more quickly absorbed through the blood vessels of the mouth as opposed to,

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 050

say, waiting for the drug to get down to the small intestine.

Clearly, for treatment of local mouth diseases and sore throats, the drug is present locally so that it act locally in the mouth and sore throat, as well as potentially being absorbed.

Q. When the lozenge is treating the sore throat, does the patient's act of swallowing help deliver the drug to the throat? Is that fair?

MS. AGARWAL: Objection. Form.

THE WITNESS: Again, there may be -- it depends where the sore throat is and whether it's within the back of the mouth or whether it's further down in the throat. But clearly, swallowing from a lozenge over a prolonged period of time, in that context, may help. The lozenge is designed to be sucked over a period of time.

BY MR. LUMAN:

Q. I want to look at the next sentence in section 2.3 on page 181 of the Exhibit 1017.

Can you turn with me there.

A. Yes.

Q. All right. That sentence says "Most" -- it's referring to lozenges -- "Most lozenges are manufactured as candy type lozenges or tablets without

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 051

disintegrants."

Do you see that?

A. I do.

MS. AGARWAL: Objection. Form.

THE WITNESS: It also goes on to say "are intended to be sucked by patients."

BY MR. LUMAN:

Q. Are you aware of any lozenges that are made with disintegrants?

A. Typically, as it says here, most are not used with disintegrants. But even if they were to include a small amount of disintegrant, it wouldn't be designed -- it would still be designed to be present and sucked by the patient in the mouth. And I'm talking about the lozenge. But most are not made with disintegrants because that's not the point. The point is that they gradually dissolve over a period of time, releasing the drug, providing relief.

Q. Are you aware of any lozenges that are made with disintegrants?

A. I am not aware of lozenges that are made with disintegrants. I know most are made without disintegrants, but even if they did include a small amount of disintegrant, they would still be designed as a lozenge to be sucked over a period of time, because

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 052

that's, by definition, what they are meant to be doing. They are meant to be releasing the drug over a period of time by the patient sucking the lozenge and gradually eroding the lozenge, actually releasing more drug and therefore providing relief. That's very different to an ODT.

Q. Can we look at the third sentence in that section. It says: "The drugs that have traditionally been used have very few systemic adverse effects, and there has never really been concern about the amount of drug swallowed by the patient."

Do you see that?

A. I do.

Q. Would you agree with the author that lozenges are traditionally used with drugs that have very few systemic adverse effects?

A. I'd agree that locally, because you're treating with -- I'd agree that typically those drugs that are used to treat local mouth diseases and sore throats typically have few systemic adverse effects, and because there's enough locally to treat the condition, they wouldn't have a concern about the amount of drug swallowed by the patient.

But it changes when you use more potent drugs, as the next sentence indicates, and there, lozenges,

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 053

they are saying, can really affect the -- because they can be used for their quicker oral absorption properties. In other words, they get into the bloodstream quickly, and continue to be delivered over a period of time.

Q. Can you comment on why drugs that are traditionally used with lozenges tend to have very few systemic adverse effects?

A. It could be because many of those medicines are available over the counter within a pharmacy, and they can be used to treat local mouth diseases and sore throats. That's what the authors are saying, and they are -- I think, by contrast to the last sentence, they tend to be less (inaudible). Maybe that's the reason why. And also because, you know, you're treating locally.

So it's not as if you're putting in an tablet such that it would be something that could break up in the stomach and then be absorbed in the stomach, or primarily in the small intestine and having systemic effects. Here, you're looking at local mouth diseases and sore throats. So by releasing the drug slowly from the lozenge, the drug is -- a sufficient drug is acting locally to have its effect as opposed to systemic effects.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 054

Q. Let's go back up to that first sentence again about lozenges have been very popular for treating local mouth diseases and sore throats.

Do you see that one, the first sentence there?

A. I do.

Q. How about orally disintegrating tablets, are you aware of orally disintegrating tablets that have been used for treating local mouth diseases or sore throats?

A. I am only aware of orally disintegrating tablets which are used systematically. The drugs are used systematically. I'm not aware of ODTs being used for topical administration, particularly in the upper GI tract.

Q. Did you look in the literature for any orally disintegrating tablets that were used for treating local mouth diseases or sore throats?

A. Again, the ODT that I'm aware of -- they are primarily used for treating systemic activity, i.e., get the drug dissolved, the formulation disintegrates rapidly, the drug gets into solution, and the drug gets absorbed rapidly in the systemic circulation.

Q. So my question was: Did you look in the literature for any orally disintegrating tablets that were used to treat local mouth diseases or sore throats?

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 055

A. I was not aware of any that did. As I said, the ODTs that were cited in the literature that Dr. Parr cites are systemic drugs, primarily, yeah.

Q. I understand you're not aware of any, but my question is: Did you look to see if any ODTs in the prior art were used to treat local mouth diseases or sore throats?

A. I'm not aware because I don't think ODTs are primarily used for that reason, and I'm not aware that -- I suspect, if they were, Dr. Parr would have raised them in his research, and he didn't. So I'm not aware of them because ODTs would primarily be dissolved, getting systemic absorption, getting rapid absorption of the drug through the oral mucosa, into the systemic bloodstream.

Q. I understand you are not aware.

My question was: Did you look? Did you do any searching to see if ODTs in the prior art were used to treat local mouth diseases or sore throats?

A. I looked at the publications that Dr. Parr cites, and they -- they concurred with my experience about ODTs, which are for systemic absorption. So I did not look for the -- I wasn't aware of ODTs that are used locally for topical treatment, and I did not look for them because all the indicia that I knew and the news

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 056

that I knew, everything that Dr. Parr cites do not demonstrate that ODTs are for systemic absorption, particularly not for the treatment of topical diseases of the esophagus or the upper GI tract.

Q. Why didn't you do a search of the literature for prior art of orally disintegrating tablets that were used to treat local mouth diseases or sore throats?

A. The reasons I've described in my previous answers.

Q. Would you be able to search the literature for orally disintegrating tablets that were used to treat local mouth diseases or sore throats?

MS. AGARWAL: Objection. Form.

THE WITNESS: For the reasons I've described, my previous answer suffices. Equally, if Dr. Parr had come forward with an ODT which was for topical use in the -- has been shown to be useful in the topical administration of the drug in the upper GI tract, I suspect we would have seen is that. He did not, because he, like I, did not believe that ODTs have been used for that application before.

BY MR. LUMAN:

Q. Dr. Davies, do you have the capability to do a prior art literature search for orally disintegrating

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 057

tablets that might have been used to treat local mouth diseases or sore throats?

A. Again, I refer to my previous answer. I know that if an ODT had been used for topical treatment in the upper GI tract, Dr. Parr would have cited it. I'm not aware of any publications, citations from all the literature that I have read of such an ability of systemic application.

Q. My question was just simply if you wanted to, would you have the capability of doing a prior art literature search for orally disintegrating tablets that might have been used to treat local mouth diseases or sore throats? Could you do that?

MS. AGARWAL: Objection. Form.

THE WITNESS: Again, I've answered that many times. ODT are primarily, in my experience -- ODTs I've cited are for systemic use. And that systemic use could mean absorption, that systemic absorption could treat all kinds of diseases, all kinds of conditions. I'm not aware of these oral lozenges they use to treat local mouth diseases and sore throats in the way in which an oral lozenge works. An oral lozenge works by slowly releasing the drug over a period of time, and I didn't do that search for that reason.

And for the reasons I've described in my

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 058

previous answer, because I agree with Dr. Parr, you know, he could not find anything to that effect, and I believe, if he had found anything to that effect, that would be an interesting addition to his argument, but he did not.

BY MR. LUMAN:

Q. I understand you didn't do the search. I'm just asking, if you could have done that search.

Could you?

MS. AGARWAL: Objection to form.

THE WITNESS: For the reasons I've described in my previous answers, I did not do that research.

BY MR. LUMAN:

Q. I know you didn't do that research.

I'm asking, could you do it?

MS. AGARWAL: Same objection.

THE WITNESS: Again, I can do searches if I think that the issue would be addressed. I did not think -- because of my knowledge of ODTs, all the information that Dr. Parr said on ODTs, he discussed the systemic absorption, and that systemic absorption can treat all kinds of things all over the body, including the mouth and throat.

BY MR. LUMAN:

Q. When you said you can do searches, what kind

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 059

of searches would you do? Would it be Google Scholar or something else? What would you do?

A. I'd look in my textbooks, I can look at -- I could use Google Search if I so wished. But, you know, a person of ordinary skill would understand that ODTs are used -- by the very nature of rapid disintegration, achieving good systemic and quick systemic absorption for the treatment of a variety of conditions.

Q. I'd like to turn to a different topic.

If you wouldn't mind turning with me in your declaration, Exhibit 2007, to paragraph 109, please.

MR. LUMAN: And, Dr. Davies, this section is going to take a little while. We came back -- we've been on the record for about 50 minutes.

Would you like to keep going or take a break?

THE WITNESS: Let's take a break.

MR. LUMAN: Would ten minutes be good?

THE WITNESS: Yes, that would be great. Thank you very much.

(A short recess was taken.)

BY MR. LUMAN:

Q. So we are looking in Exhibit 2007, at paragraph 109. And above paragraph 109 there's a header that says "Dohil Does Not Disclose the Claimed Doses in the Context of a Solid Composition."

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 060

Do you see that, Dr. Davies?

A. I do.

Q. And then in that paragraph, underneath the header at paragraph 109, I'm looking at the fourth sentence, Dr. Parr cites to Dohil's disclosure of the doses administered to patients in Examples 1 to 3.

Do you see that?

A. I do.

Q. Then the next sentence talks about: "The patients in Examples 1-3 were given the viscous liquid formulation and a POSA would understand that doses for liquid formulations are not necessarily the same as a solid formulation."

Do you see that?

A. I do.

Q. And sitting here today, is it still your opinion that Dohil does not disclose the claimed doses in the context of a solid composition?

A. That's correct.

Q. What I'd like to do is take a look at a couple of paragraphs in Dohil and see if we can have some clarification on your opinion.

Would you turn with me in your binder to Exhibit 1002, and let me know when you get there.

A. Thank you. Yes.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 061

MR. LUMAN: For the record, I'll say Exhibit 1002 is a US Patent Publication No. 2007/00111978, and the first named inventor's last name is Dohil.

Dr. Davies, are you familiar with this exhibit?

A. I am.

Q. Would it be okay if I refer to this exhibit as Dohil?

A. Yes.

Q. And earlier in our discussion today, we had referenced Dohil.

When we were doing that earlier today, was that with reference to Exhibit 1002?

A. Yes.

Q. Would you turn with me to paragraph 15. Let me know when you arrive.

A. Yes.

Q. Paragraph 15 has the pharmaceutical composition and certain embodiments, comprises a therapeutically effective amount of corticosteroid to prevent or alleviate esophageal inflammation in certain embodiments, 1 to 2 milligrams, or 2 to 3 milligrams of corticosteroid per day is administered to said individual.

Do you see that?

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 062

A. I do.

Q. Is it your opinion that the person of ordinary skill in the art would understand that the dosage amounts in paragraph 15, of 1 to 2 milligrams or 2 to 3 milligrams, do not apply to solid formulations?

A. Sorry, I misheard you.

Could you just repeat that question?

Q. Yes.

Is it your opinion that a person of skill in the art would understand that the dosage amounts in paragraph 15, of 1 to 2 milligrams or 2 to 3 milligrams, do not apply to solid formulations?

MS. AGARWAL: Same objections.

THE WITNESS: Well, Dohil is about using liquid, viscous formulations to treat ERE. So in that context, the dosages that they're giving -- and the points I'm making back in my declaration is that you can't say, just based on a liquid formulation, that the dosage should be used within a solid formulation because they are different kinds of formulations.

BY MR. LUMAN:

Q. Would a person of skill in the art looking at paragraph 15 think these dosage amounts are limited to only liquid formulations?

A. I think a person of skill reading Dohil would

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 063

think these are about liquid formulations, that's correct. That's the extent -- for example, he talks about viscous liquid solutions -- suspensions, rather, yeah.

Q. I wanted to clarify. You'd mentioned Dohil. I'm talking about paragraph 15 particularly.

If a person of skill in the art were reading paragraph 15 of Dohil, would they think these dosages are limited to just liquid formulations?

A. A person of skill reading Dohil and understanding Dohil, would understand when they are talking about dosages, they would be talking about -- they could be talking about liquid formulations.

Q. Is there any reason you didn't include paragraph 15 in your last answer?

It seemed like you were saying Dohil generally, and I was asking about paragraph 15.

MS. AGARWAL: Objection. Form.

THE WITNESS: Again, paragraph 15 is included in Dohil, and Dohil is showing how you can use viscous liquid formulations to treat EoE.

BY MR. LUMAN:

Q. Is it your opinion that a person of skill in the art reading paragraph 15 of Dohil would think that

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 064

dosage amounts of 1 to 2 or 2 to 3 milligrams are excluded from solid formulations?

A. I think a person of ordinary skill would understand that Dohil, if you talk about solid formulations, and we talk about that in that context, ODTs -- we understand that those are very different -- that's a very different formulation to a viscous liquid solution.

So a person of ordinary skill, reading 15, would be thinking that Dohil is effectively about the use of liquid formulation, and it's giving certain embodiments. That's what it's about. But there's nothing in Dohil in which a person of ordinary skill reading this would see an ODT.

Q. How about just a solid formulation in general, not just an ODT? Would a person of skill in the art looking at paragraph 15 believe the dosage amounts of 1 to 2 milligrams or 2 to 3 milligrams exclude all solid formulations?

A. I don't think -- it certainly -- the embodiments shown in the -- shown in the examples are liquid formulations. I think a person of ordinary skill would be thinking when they read Dohil, that's what these are about.

Q. Let's look just two paragraphs up in Dohil, in

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 065

paragraph 13.

I'm looking at the sentence, it's got, "Also provided are pharmaceutical compositions." It's about halfway through the paragraph. The one that says "Also provided are pharmaceutical compositions comprising a corticosteroid."

Do you see that one?

A. I do.

Q. It's highlighted on the screen.

A. Yes.

Q. You can agree with me that that sentence discloses a dissolving tablet which is a solid formulation, right?

A. It talks about a dissolving tablet, but it gives no indication of the time it takes to dissolve, like an ODT. An ODT dissolves rapidly. It does not give any indication that that's an ODT. But right there, it's showing a tablet, a dissolving tablet, but then an immediate release tablet is a dissolving tablet, but it is not an ODT.

Q. I'll say, it seems reasonable to me that a person of skill in the art would understand that the dosage amounts in paragraph 15, just two paragraphs after paragraph 13 -- they would understand that those dosage amounts in 15, of 1 to 2 and 2 to 3 milligrams,

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 066

could apply to the solid dissolving tablet in paragraph 13.

Do you agree or disagree with that?

MS. AGARWAL: Objection. Form.

THE WITNESS: It could apply to the dissolving tablet, but the dissolving tablet is not an ODT, and therefore, there's no indication in Dohil of the time, like there is for an ODT, for an ODT to disintegrate.

So a person of skill would understand that even though there may be a dose related to be tablet, that's very different to employing an ODT, because an ODT is designed to rapidly disintegrate. And in that context, in this light, but for the reasons we discussed a moment ago, again, from all my previous answers, that's a different situation than having a predetermined dose in a volume of liquid. And that's the point I was making in the previous paragraphs.

BY MR. LUMAN:

Q. If we take out the issue of whether paragraph 13 discloses a rapidly dissolving tablet, the person of skill in the art would understand that the dosage amounts in paragraph 15 could apply to the solid tablet formulation in paragraph 13, right?

A. Could apply to that, but, you know, all the formulations that are shown are -- in that example are

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 067

liquid, viscous liquid formulations, and in that context, including -- of course, we've got the -- we've got the lozenge, which gradually releases the drug over a period of time. The drug is released quickly from the surface. So that's very different to an ODT.

Q. You just brought up the lozenges. The rapidly dissolving lozenges disclosed in paragraph 32 of Dohil -- would you mind turning with me to paragraph 32.

A. I will, thank you.

Q. So you would agree -- let's take a look here. The second sentence starts with "The lozenge or other similar tablet."

Do you see that?

Did you -- do you see the sentence, Dr. Davies?

A. I have not said anything.

Q. Okay. Let me start again, then. Sorry about that.

So do you see the second sentence refers to a lozenge or other similar tablet?

A. I do.

Q. And so you would agree with me that paragraph 32 discloses a solid lozenge or a solid similar tablet, right?

A. I agree they are solid and they are a lozenge

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 068

or similar tablet designed to release the drug over a period of time. You may get the drug dissolving rapidly from the surface, but the lozenge -- it doesn't say what rapidly means, by the way. So there's no indication of time in that sentence. But the lozenge will dissolve from the surface, rapidly leaving, allowing the drug to be released from the surface, and then gradually, over a period of time, erode, and the similar tablet would behave like a lozenge because it's a lozenge or similar tablet.

Q. I think we're going to respectfully disagree with each other on the meaning of the word "rapidly" in paragraph 32, but I think we can agree that the lozenge or similar tablet referenced there is at least a solid, right?

A. A lozenge is a solid, yeah. A lozenge is a solid. There's nothing in Dohil which explains what "rapidly" means.

Equally, if a lozenge was behaving like an ODT, rapidly breaking up, then why would children who may have difficulty with a dissolving lozenge, have it ground or otherwise dissolved in a small volume of water? Why would they do that?

Because if it was like an ODT, it would just break up very quickly in the mouth.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 069

Why would children -- they may have difficulty with a large lozenge in their mouth, which doesn't act like an ODT and disintegrate rapidly.

So the very next sentence contradicts that this could be an ODT. The very next sentence clearly contradicts it. So nowhere in Dohil is "rapidly" explained.

Q. Sure. I know we disagree on how to interpret "rapidly." I was just seeing if we could agree that this paragraph discloses a solid formulation.

Can we agree on that?

MS. AGARWAL: Objection. Form.

THE WITNESS: Well, a lozenge starts as a solid formulation, that's correct. And it releases drug from the surface and gradually erodes when it is sucked in the mouth, releasing the drug over a period of time, producing a solution that can then coat the esophagus.

BY MR. LUMAN:

Q. The immediate paragraph above paragraph 32 is paragraph 31.

Do you mind turning there with me and letting me know when you arrive.

A. 31, yeah.

Q. Yeah. Looking at that paragraph that splits the two columns, it starts with "The dosage form

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 070

contains effective amounts."

Do you see that one?

A. Yes.

Q. And so it says: "The dosage forms containing effective amounts are within the bounds of routine experimentation, and therefore, well within the scope of the instant invention."

And then the next sentence says: "In general, however, a suitable dose may be in the range of from about 10 to 400 micrograms per kilogram of body weight," and it goes on and gives several other ranges of dosages.

Do you see that?

A. I do. That's talking in the context of this invention. That's talking as it goes on to talk about liquid formulations. That's talking about viscous liquid. These -- the invention, the liquid formulation. So it's saying in the context of these liquid formulations, the viscous suspension. That's what it's talking about. It goes on to talk about that in terms of that liquid dose. Then following on.

Q. I definitely agree with you that paragraph 31 applies to liquid formulations, but my question is: Would a person of skill in the art also understand that the dosage amounts in paragraph 31 could apply to the

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 071

solid formulations in paragraph 32?

A. Depends on the solid formulations. Certainly, in a solid formulation, you're talking about a lozenge or a similar tablet. And I make the point very clearly in my report, as you know, that what you can't compare -- those liquid formulations and even that solid formulation to that of the ODT. It functions in a very different way, and somebody of ordinary skill would know that.

Q. Regardless of how we interpret paragraph 32, a person of skill in the art would understand that the dosage amounts in paragraph 31 could apply to the solid lozenge or similar tablet in paragraph 32, right?

MS. AGARWAL: Objection. Form.

THE WITNESS: They are illustrating the examples in this patent, and those formulations are very different to an ODT. So they are talking about doses which apply to a lozenge or similar tablet, which releases the drug over a period of time when it's in the mouth and it's being sucked. And that's a different approach to an ODT, which we know has a much lower volume of saliva to be dissolved into.

That's the point I'm making -- that we started this conversation, this -- that's the point I'm making about -- just because some things are solid, it doesn't

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 072

mean -- in the context of lozenge, it doesn't mean you could automatically take the doses and apply it to an ODT.

BY MR. LUMAN:

Q. It's not your opinion that a person of skill in the art would exclude the dosage amounts in paragraph 31 from the solid formulations of the lozenge and similar tablet in paragraph 32, right?

MS. AGARWAL: Objection. Form.

THE WITNESS: I don't understand the question. Sorry.

BY MR. LUMAN:

Q. Let me try it differently.

Is it reasonable that the dosage amounts discussed in paragraph 31 apply to the lozenge or other similar tablet that are disclosed in the next paragraph, paragraph 32?

MS. AGARWAL: Objection. Form.

THE WITNESS: Again, I come back to the point this is primarily a liquid formulation. They talk about the liquid dose below those doses that you -- liquid volume, sorry, below those doses. It could apply to a lozenge, which slowly releases drug over a period of time as it is sucked, or a similar tablet, which behaves in the same way, but that's a very different composition

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 073

delivery mechanism than you have with an ODT. The liquid formulations -- and also for a lozenge, it's very different to an ODT. And somebody of ordinary skill would understand that.

BY MR. LUMAN:

Q. Looking at paragraph 31, these dosage amounts -- they are not limited to just liquid formulations, right?

MS. AGARWAL: Objection. Form.

THE WITNESS: Well, looking at 31, they are looking -- it's demonstrating liquid formulations below, but as I've said, they are not, in my view, looking at -- these could apply to the lozenge or similar tablet, which releases the drug over a period of time, but they have very different compositions and very different mechanisms of release.

The liquid composition of the lozenge and similar tablet is different to an ODT. So, therefore, you apply different considerations in determining the proper dose of the drug. And a person of ordinary skill would understand that.

BY MR. LUMAN:

Q. In paragraph 32, there's the lozenge or similar tablet, and what dosage amounts would a person

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 074

of skill in the art believe should be used with that lozenge or other similar tablet?

MS. AGARWAL: Objection. Form.

THE WITNESS: Again, it's -- you know, 31 gives the guidance on dosage, but again, the lozenge -- I don't know because it doesn't describe it to you. I think a person of ordinary skill ordinary would understand that you probably need a different dose in the lozenge than you would in the liquid dose versus a different composition, different mechanism of release.

And you have other considerations to consider.

So, equally, when you talk about an ODT, you have the same argument. It's different to a liquid formulation, it's different in composition to a lozenge, and it has a different release mechanism.

And you have other considerations.

BY MR. LUMAN:

Q. If a person of skill in the art were looking at paragraph 32 and going to follow the instruction to make a lozenge or other similar tablet, would they look to paragraph 31 for selecting a dosage amount?

A. A person of ordinary skill may look at 31, but they would see that the dose -- they's see this primarily is for all liquid formulations. But, you know, it may end up that, because of the different

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 075

compositions of the lozenge to liquid formulations, or similar tablet, you would have different doses, and a person of ordinary skill wouldn't know what that is. That would have to be determined.

And equally, when you have an ODT, which has, again, a different composition to the solution, and lozenge or similar tablet, different release mechanism, different composition, different volume generated, therefore, you may have to have -- you would he -- a person of skill would not be thinking you could use this to demonstrate the dose that's needed for an ODT based on a liquid formulation.

Q. Dr. Davies, how about a person of skill in the art looking at paragraph 32 of Dohil and formulating the lozenge or similar tablet there, would they look to paragraph 15 of Dohil that has dosages of 1 to 2 milligrams or 2 to 3 milligrams for formulating the lozenge or similar tablet?

A. I don't know. I think a person -- I think a person of ordinary skill would probably look to the previous paragraph 31. And you know, albeit that, it would be different to a liquid formulation.

Q. Okay.

A. But then, you know, the lozenge or similar tablet, or an ODT. So you'd have to have a different --

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 076

you'd have a different perspective for the reasons I described in my previous answer, such that you -- Dohil doesn't disclose the dose for an ODT based on these formulations.

Q. And the reason you believe that Dohil doesn't disclose a dose for an ODT is based on your reading of paragraph 32 such that the lozenge or other similar tablet cannot disclose an ODT, right?

MS. AGARWAL: Objection. Form.

THE WITNESS: I think I've discussed this in my answers. I believe, in 32 of Dohil, that the lozenge or other similar tablet are an ODT. It doesn't dissolve rapidly, -it doesn't define what "rapidly" means, and in the next sentence, it talks about children who have difficult with lozenges. I mean, if it was an ODT, it would be dissolving rapidly in their mouth on contact.

So it's a -- clearly, it's not an ODT, clearly it's a lozenge, where a drug is released from the surface into the mouth, and using a solution that can coat the esophagus over a period of time.

BY MR. LUMAN:

Q. Are you aware that the European patent office has found that Dohil's disclosure in paragraph 32 does clearly disclose an ODT?

MS. AGARWAL: Objection. Form.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 077

THE WITNESS: I do not know. I have been told the European patent office has -- there's a European patent case, but I haven't read it. That doesn't change my view. This is this patent, and this litigation and this jurisdiction. And when I read Dohil and I read about that lozenge, a person of skill -- I believe a person of ordinary skill would understand what a lozenge is, and it's not an ODT, for all the reasons that I have described.

Q. I'd like to go to paragraph 109 of your declaration.

Would you mind turning there with me.

A. Thank you.

Q. And at the bottom of page 49, in the last full sentence, do you see where it says, "A POSA would understand that doses for liquid formulations are not necessarily the same as a solid formulation"?

A. I do.

Q. I'm going to just explore that a little bit.

Are you saying that liquid and solid formulations cannot and must not have the same dosage amount?

A. I'm just saying that a person of ordinary skill would understand the basis for liquid formulations are not necessarily the same as solid formulations. It

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 078

also depends on context. I go on to say a person would understand Dohil -- would not understand Dohil to disclose any dose of an ODT based on a liquid formulation.

So in the context of trying to teach or treat EoE, where you're trying to get coverage, what a person of ordinary skill would understand from the liquid formulations of defined volume, of defined viscosity, that's a very different formulation to an ODT, which is dissolving or dispersing rapidly in the saliva in -- for the reasons we've described for -- you know, will produce different volumes, and that can be variable. It may very well need a different dose.

So that's the point I'm making in the context of Dohil.

Q. Is it possible for Dohil's liquid formulation to have the same dosage amount as an ODT formulation?

A. I think what it is -- a person of skill wouldn't understand Dohil to disclose any dose of an ODT based on liquid formulation, because they'd understand they are very different formulations, composition, mechanism of release of drug and different volumes.

So that's the point I'm making here.

A person of skill would be thinking, look, an ODT is different to a liquid formulation, particularly

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 079

in this context and particularly in the context of trying to treat EoE in the esophagus. You wouldn't understand Dohil disclosing the dose for an ODT based on the liquid formulation on that context. Because they are a very different formulation.

Q. If a person of ordinary still in the art, hypothetically, were going to do an ODT of budesonide XX, what dosage amount would they pursue?

MS. AGARWAL: Objection. Form.

THE WITNESS: Again, I think a person of ordinary skill would think, you know, this -- a person of ordinary skill -- the reasons -- they wouldn't be thinking about doing a budesonide ODT for the reasons I've described in my report.

They would have to -- they couldn't rely on the doses, or they wouldn't understand Dohil to disclose any particular dose based on liquid formulations, because they know, for an ODT, that's different. And that's why, as I've said before, it's surprising this ODT works, and is clinically effective.

BY MR. LUMAN:

Q. So I understand your position, and I'm just saying, like, hypothetically, let's assume that a person of skill in the art were going to make an ODT of budesonide to treat EoE.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 080

What dosage amount would they start with?

MS. AGARWAL: Objection. Form.

THE WITNESS: Again, you'd have to -- that would go -- that would be a part of a decision that's part of the whole development team, where the whole development team would be thinking, well, just because Dohil discloses a dose in liquid formulation, this is going to be different for an ODT, because this is a different formulation.

You can't just expect it to work in the same way. So they would have to explore different doses and not be guided by Dohil in that context.

BY MR. LUMAN:

Q. And when Dohil discloses dosage amounts of 1 to 2 milligrams or 2 to 3 milligrams, such as in paragraph 15, would a person of skill in the art see that as a good starting point for an ODT of budesonide for treating EoE, or is there no connection there at all?

MS. AGARWAL: Objection. Form.

THE WITNESS: I don't think a person would rely on Dohil in that context. It doesn't disclose the dose for an ODT for the reasons I've described. I don't think a person would be doing this anyway, because you already had a formulation that works in Dohil.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 081

Why would you change it?

And this would be the first example of an ODT to treat topically in this particular location.

So why would a person be doing that?

And they certainly wouldn't be guided by -- or disclose a particular dose for an ODT based on the liquid formulations.

BY MR. LUMAN:

Q. Under the hypothetical, where a person of skill in the art were going to develop an ODT of budesonide to treat EoE, you would take the position that finding the dose for that ODT would be a complete start over from ground zero to figure out what the dosage amounts should be, is that fair?

MS. AGARWAL: Objection. Form.

THE WITNESS: I think it would be a very big discussion and it would not be routine or simple to do, because you are now saying to the whole of the development team, we're looking back at you as if nobody has ever used an ODT topically for the treatment of this condition.

Why can't we use the liquid formulation?

And because they're different formulations acting in different ways with different compositions, using different volumes, such -- so that you could treat

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 082

the EoE, there would be a large discussion about what doses we could use.

BY MR. LUMAN:

Q. Why is there such a disconnect --

A. -- with no reasonable expectation of success of being able to formulate a product to do that. There's an assumption in your -- there's an assumption in your hypothetical, one, that a person would do it, let's say, and the second assumption is that it would work. But you have no guarantee it would work.

Q. There's no guarantee it would work, but that's not the standard. The standard is whether there's a reasonable expectation that it would work.

Would you at least agree with that?

A. Well, I don't think there's a reasonable expectation of success. I'm surprised that the ODT -- and I've said it before today, the ODT in this -- is found to be effective in treating EoE of the esophagus, because it's a very different formulation from a viscous liquid formulation.

Q. What is so difficult --

A. Yeah, I don't think a person of skill is -- it's a hindsight argument. You know, you would not be thinking that an ODT would work. You'd be thinking liquid formulation, viscous liquid formulation, that

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 083

will work because I've seen it work, and it's proven. Let's refine that, but you wouldn't be thinking an ODT would have the same effect. That's what I view.

Q. What's so difficult about formulating a dosage amount for an ODT to treat inflammation of the esophagus?

A. Because you wouldn't even know that the formulation is able to treat and act topically on the esophagus. You wouldn't even know they are different volumes, different compositions. You wouldn't even know if it generated the same effect as the viscous liquid formulation. You just wouldn't know that.

And that's why it's surprising that it did. ODTs have been used for systemic absorption of drugs. There's no evidence that ODTs -- you'd be thinking, you have no -- you wouldn't have a reasonable expectation of success of formulating an ODT to treat a particular area of the esophagus.

And the only reason you're putting the hypothetical to me is because '729 has shown it's possible. If the '729 hadn't been here, a person of ordinary skill, Dr. Parr, and others, and me would not be thinking of using an ODT to treat that particular condition in that particular area. They'd be going after the viscous liquid formulation.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 084

Q. The difficulty in formulating an ODT to treat inflammation of the esophagus -- I mean, can you comment a little bit more about that? What's so difficult about it?

MS. AGARWAL: Objection. Form.

THE WITNESS: The difficulty has been shown. The very fact that the viscous liquid formulation worked and was shown to work and was shown to be innovative, through the Dohil patents, okay, and through publications, illustrates that people had not been able to treat that particular condition in that difficult area of the esophagus.

Then you come along and think, why would you change?

And you wouldn't -- an ODT has been designed to rapidly disintegrate in the mouth such that drugs can be absorbed into the systemic bloodstream.

Why would you think that an ODT can achieve the same effect as a preprepared 8 to 12 mils of viscous liquid formulation?

And you'd be knowing that you wouldn't be able to get the same volume. Dr. Parr has agreed to that.

And you have no guarantee that that would work. You have no guarantee that, in fact, you know, on swallowing, if it just went straight into the stomach

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 085

and wouldn't treat that area, wouldn't have the right viscous condition to treat that area -- and that's why, amongst many aspects, it's surprising that it works, that you can achieve the same effect with an ODT.

Because nobody else has done it. Nobody else is using an ODT to treat such conditions.

BY MR. LUMAN:

Q. Let's continue looking at Dohil for a few minutes.

Would you mind turning back to Exhibit 1002. And I'd like to go to paragraph 67.

Can you let me know when you're there.

A. I'm there. Thank you.

Q. I'm looking at the last sentence of paragraph 67, which says: "A larger placebo-controlled clinical trials would provide more information about dosing, efficacy and long-term safety of this treatment."

Do you see that?

A. I do.

Q. Are you familiar with placebo-controlled clinical trials?

A. Yes. But also, I'm aware that even in this publication, I think they have good statistical data of 20 people -- 20 children, I think. Children. And so -- and they also published this. So that has to go through

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 086

peer review. This comes from the -- I apologize if I mispronounce those names, ACCEVE, I think. Publications.

And look at the top, it says that: "Oral viscous budesonide would be an effective and safe treatment for individuals." "It may have advantages over other therapies in that it is palatable. Its volume (8-12 ml) provides pan-esophageal mucosal coverage and it requires only once daily administration."

And they go on to talk about a clinical trial, which provides more information about dosing. Efficacy and long-term safety of this treatment.

Q. You mentioned there were 20 children in this study.

How many people would be included in the larger placebo-controlled clinical trial referenced in paragraph 67?

MS. AGARWAL: Objection. Form.

THE WITNESS: It says "would provide," so that typically is -- that has a much larger patient base. Next stage of the clinical trials. So they've got good Example 1, example 2 of individual, children, I believe. Example 3 is on a larger group. And they're making this clear statement that it has advantages over other

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 087

therapies in that it's palatable, talks about its volume, and provides coverage.

And then when they go to commercialization, or if they wanted to go down this route, you do larger placebo-controlled clinical trials, yeah.

BY MR. LUMAN:

Q. You mentioned a much larger patient base.

Would that be 100 patients? How many patients?

A. It could be 100 --

MS. AGARWAL: Objection to form.

THE WITNESS: It depends on the trial they are doing. It could be 100, 300, and then to the final stage, it's thousands. Yeah. If they wanted to commercialize it. So, yeah, in that context.

But you're not saying, surely, that Dohil doesn't -- isn't showing any -- an effective therapy safe for individuals, surely. It clearly has -- it has advantages, based on volume, liquids.

BY MR. LUMAN:

Q. If the larger clinical studies were conducted, do you know if that would be conducted in the United States only, or would it be likely an international study?

MS. AGARWAL: Objection. Form.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 088

THE WITNESS: Again, I've not been asked to give an opinion on this, but it depends on the stage of the clinical trials. The clinical trials could be undertaken in the states. They could equally, for the larger group of clinical trials, sometimes -- it depends on the treatment, sometimes those are multinational where the data is proved to illustrate.

BY MR. LUMAN:

Q. Would you mind turning with me to Exhibit 2010. It's kind of at the back of your binder. Let me know when you get there.

A. Yes.

MR. LUMAN: For the record, Exhibit 2010 is a Results Posted Tab from the FLUTE, F-L-U-T-E, study of a drug called APT-1011.

Dr. Davies, you cited this in your report, right?

A. I did.

Q. Would you turn with me to page 4, please.

A. Yes.

Q. There's a header, "Participant Flow," and there's "Recruitment Details."

Do you see that?

A. I do.

Q. Looking at the sentence that says "Recruitment

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 089

in 6 countries" -- looking at that sentence, so the countries in this study were the United States, Canada, Belgium, Germany, Spain and Switzerland, right?

A. Yes.

Q. And this was a study to look at EoE, correct?

A. A study to look at what?

Q. EoE.

A. Sorry, I misunderstood you.

BOE? Did you say BOE?

Q. Oh, sorry. EoE, eosinophilic esophagus.

A. Yes. It's a clinical trial, like I said, you could have different countries, and in this case, I think they had about 100 patients enrolled in part 1.

Q. Is it reasonable to assume that the study drug was shipped to each of these six countries?

MS. AGARWAL: Objection. Form.

THE WITNESS: I guess so. I wasn't involved in the trial. I guess so, yeah.

BY MR. LUMAN:

Q. Would you turn with me back to Dohil. I'd like to look at Dohil's viscous formulation for a few minutes.

So Dohil is Exhibit 1002.

Can you let me know when you get back there.

A. Are we going back to the other one? Should I

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 090

keep my finger there or not?

Q. No, I wasn't planning to.

A. Yes, thanks. Yeah.

Q. In Dohil, I'd like to turn to paragraph 46 of Exhibit 1002.

Can you let me know when you are there.

A. Yes.

Q. And I'm looking at the part where they have formulated the suspension. There's a sentence that's kind of near the bottom that says "He was placed on a regimen of twice."

Do you see that sentence?

A. I do.

Q. So the viscous oral suspension for this patient was made by taking 500 micrograms of Pulmicort and mixing that with ten packets of Splenda, right?

A. Right.

Q. Pulmicort -- that's a liquid, right?

A. It's an oral budesonide suspension.

Q. Is there a difference between a liquid and a suspension that you wanted to highlight?

A. Just wanted to be a bit more precise.

Q. Okay. So, then, the patient or caregiver has to open ten packets of Splenda and then pour the Splenda together with the Pulmicort, is that right?

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 091

MS. AGARWAL: Objection. Form.

THE WITNESS: I didn't quite hear what you said at the beginning.

He was placed on a regimen of twice daily of oral budesonide suspension mixed with about ten packet, of sucralose, Splenda, which is used to increase the fluid viscosity to be swallowed. The total volume of the preparation was about 7 to 8 mils, yeah.

BY MR. LUMAN:

Q. Yeah.

I just wanted to walk through some of the mechanics of what the patient or caregiver would have to do to make this suspension.

So they would have to open ten packets of Splenda and then mix it with the Pulmicort, is that right?

MS. AGARWAL: Objection. Form.

THE WITNESS: The oral budesonide suspension is mixed with about ten packets of sucralose, and the total volume of the preparation was about 7 to 8 mils.

BY MR. LUMAN:

Q. But the packets -- they would take the package off the ten packets and take the Pulmicort out of its container and then mix the Pulmicort contents with the contents of the Splenda packets, right?

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 092

MS. AGARWAL: Objection. Form.

THE WITNESS: I don't know what you're trying to get at, but they mix the oral budesonide suspension with about ten packets of the Splenda. And the total volume of the preparation was about 7 to 8 mils.

BY MR. LUMAN:

Q. Just trying to understand.

Like, is it the patient that does this, or the caregiver that mixes up this solution, or does that not even matter?

A. I don't think it's the patient, based on the description above. Patient 1 was a 6-year-old male with a history of abdominal pain, failure to thrive, and vomiting since infancy, and developmental delay with isolated EE diagnosed in 2011.

So I believe this was -- and this is reported -- they reported this -- the doctors reported it in a clinical journal.

So I believe this was probably made up for him by the medical team or somebody within the medical team to achieve the total volume of preparation of about 7 to 8 mils.

Q. And where is that total volume of 7 to 8 milliliters coming from? Is it the four milliliters of Pulmicort with ten packets of Splenda, and that gets you

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 093

to 7 to 8 milliliters, or do you have to add some water to it to achieve that final volume?

MS. AGARWAL: Objection. Form.

THE WITNESS: They indeed may add some water, but ultimately, they get to 7 to 8 mils.

You're not disputing, surely, Dohil, when they say 8 to 12 mils is good coverage? You're not disputing that, surely?

BY MR. LUMAN:

Q. I'm just trying to walk through the mechanics of making this solution.

And so the solution -- I guess we should call it a suspension, right?

A. Yes.

Q. So how would the person of skill in the art expect this mixing of Pulmicort with ten packets of Splenda to proceed? Is that stirring? Shaking? How is that done?

MS. AGARWAL: Objection. Form.

THE WITNESS: I think a person of ordinary skill reading this would understand. There's no confusion here. A person of ordinary skill would understand that you'd know, when it says "mixing the budesonide suspension with about ten packets," that you would mix -- take the packets, open them, and mix them

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 094

with the oral suspension. And in the end, you'd get a total volume of about 7 to 8 mils.

I think a person of ordinary skill reading this would understand that and wouldn't be -- wouldn't be challenging it, if they understood it. I mean, certainly, it wasn't challenged when it was peer reviewed and published.

BY MR. LUMAN:

Q. How long would they mix this together for? Is that a two-minute process? Ten-minute process? How would they do that?

MS. AGARWAL: Objection. Form.

THE WITNESS: Again, they mix it enough that it produced a clinical effect. You know, the sugar will mix well in with the oral suspension. They make the total volume up to about 7 to 8 mils, and they give that to the patient. And they show that, in fact, it has a clinical effect. It reduces the EoE symptoms.

BY MR. LUMAN:

Q. You'd mentioned the sugar.

The sugar is actually Splenda, right?

A. Yes. It's called a sugar, right? Nonabsorbed sugar?

Q. Sucralose?

A. Yeah.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 095

Q. Yeah.

Is the purpose of that Splenda to -- it's a sweetener.

Is that to make it sweet?

A. It will certainly do that, but it also will make sure that it increases the fluid viscosity, as it states. You know, you preprepare it, and this is within the skill of somebody within the medical team, and the POSA would understand that. You are prepreparing an viscous solution, or suspension, should I say, to about 7 to 8 mils, and they are giving that to a patient twice a day, and that shows clinical effect.

And then they go on to tell you later, as we just discussed, in paragraph 67, when talking about this, its volume of 8 to 12 mils provides pan-esophageal coverage. And it's clinically effective.

Q. You'd mentioned that this is administered twice daily.

And it's administered twice daily for three months, right?

A. Right.

Q. So if there's, like, 30 days in a month, that's about 180 administrations, is that fair?

A. Yes, about.

Q. About how long is the oral budesonide

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 096

suspension stable for? Is it stable for hours? Days? Minutes? Do you know?

MS. AGARWAL: Objection. Form.

THE WITNESS: I'd have to look at that, but I don't see what relevance that has. It would made up such that this 61-year-old man would be able to receive the viscous solution twice a day.

BY MR. LUMAN:

Q. So the stability doesn't matter because they mix it up as needed and immediately give it to the patient, is that right?

MS. AGARWAL: Objection. Form.

THE WITNESS: I didn't say that. I just didn't say it didn't matter. I'd have to look at it. But they are showing a way of making up a dose of 7 to 8 mils, and they are giving that dose twice a day for three months.

There's nothing in Dohil that causes any concern about this particular formulation, is there?

There's no concern about it, nothing in Dohil which shows the negative aspects of this formulation.

BY MR. LUMAN:

Q. If the patient wanted to store the oral budesonide suspension, how long would it be stable for

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 097

storage for?

MS. AGARWAL: Objection. Form.

THE WITNESS: Again, it depends on the suspension. It depends on how it's formulated. You would formulate -- this kind of formulation would certainly -- in the context of these two -- you know, there are many formulations out there in liquid form or suspension form that are stable. Why -- you know, a person of skill wouldn't be thinking this was an issue.

BY MR. LUMAN:

Q. Well, we have this particular suspension, which is Pulmicort mixed with Splenda.

Do you know how long that suspension would be stable for?

MS. AGARWAL: Objection. Form.

THE WITNESS: Clearly, it's stable enough when it's made such that it provides a volume of 7 to 8 mils, and it's clinically effective after three months' therapy. The six-year-old male showed abdominal pain, and vomiting was revolved, it increased appetite, with documented weight gain and complete resolution of the EoE.

So this formulation works, and that's what they're saying, and that's what they published about it, and now they're saying it in Dohil.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 098

BY MR. LUMAN:

Q. If the caregiver wanted to mix up the Pulmicort with the Splenda and store it for use in the evening, they mix it up in the morning and they want to use it in the evening, would it be stable over the course of the day?

MS. AGARWAL: Objection. Form.

THE WITNESS: Again, that's -- there are many suspensions -- oral suspensions that are stable and that are used commercially. So these are examples where they are showing this formulation works in treating EoE. This fluid viscosity formulation works. There's no reason to suspect such a formulation wouldn't work when used correctly.

BY MR. LUMAN:

Q. Yeah, I understand that there are other formulations out there. I'm asking about this formulation where you take Pulmicort, you mix it with ten packets of Splenda.

Do you have an opinion on how long that suspension would be stable for?

MS. AGARWAL: Objection. Form.

THE WITNESS: Again, you know, they are showing that it was stable enough to provide it over this period of three months. It was stable enough that

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 099

they were able to prepare the formulation, give it to the patient, and the patient showed, you know, complete resolution of EoE. So that's the point we should be taking home from here. And as I say, there are many commercial formulations out there which are oral suspensions. Yeah.

BY MR. LUMAN:

Q. Sure. And --

MS. AGARWAL: Nate, we have been going for over an hour.

Do you have more on this topic?

MR. LUMAN: I do. I'll need to get an answer on my question, and then we can take a break. Because the witness has been avoiding my question.

Q. So let me try again, Dr. Davies.

If a person of skill in the art were to make the suspension described in Dohil, paragraph 46, with Pulmicort and Splenda, do you have an opinion on how long that particular suspension would be stable for?

A. So I do have an opinion that this was made and delivered to the patient. I have an opinion on that. And it shows that it's clinically effective, and it must be stable to do that.

But as to if you were to make that formulation and -- you know, clearly, you'd need to test the

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 100

stability of it. But there's nothing in Dohil which assessed that they wouldn't be stable.

Where is there anything in Dohil which says you've got to make it this quickly and you've got to give it to the patient quickly?

There's nothing.

Q. That's my question. It doesn't say that.

So, in your opinion, as an expert in this field, if someone were to mix the Pulmicort with the Splenda, according to Dohil, paragraph 46, how long would that suspension be stable for?

MS. AGARWAL: Objection. Form.

THE WITNESS: I would say that in the context of Dohil, as it explains it, it's used on the patient and it's shown to be clinically effective. Therefore, it must be stable.

Now, if you wanted to make a solution of budesonide suspension with the Splenda, which you wanted to store over a period of time, you'd test it, but there's nothing in Dohil that would tell you that there would be a problem with that, and as I've said, many commercial -- sorry, many commercial oral suspensions are out there, and they are stable. But you test it, if that's what you wanted to do. But nothing in Dohil would suggest that it wouldn't be stable.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 101

BY MR. LUMAN:

Q. When you say --

A. There's nothing in Dohil which suggests it wouldn't be stable, and you'd be looking to an alternative formulation, which is where I think you're focused on. There's nothing that would suggest here that you would switch formulation. They are clearly showing you, use 8 to 12 mils to get good treatment and coverage of a viscous suspension.

And the person of skill would formulate -- having looked at this, would formulate that to make a stable formulation. And there's nothing here that suggests it isn't stable.

Q. When you say it's stable, do you mean stable for immediate administration or stable for administration eight hours from when it was formulated?

MS. AGARWAL: Objection. Form.

THE WITNESS: Again, I have answered that. I've answered it in the sense that they are -- these are made to be given to the patient. But having seen that this works, there's nothing in Dohil which would suggest that there's a problem with stability. There's nothing in -- a person of skill would be looking at this thinking, I can make that suspension and I can -- you now, I know suspensions are out there and --

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 102

commercially, and they're stable.

And a person of ordinary skill would be thinking, I can do that, and wouldn't be thinking, oh, my God, they can't -- you know, there's real stability issues here.

No. It's said in Dohil that they are stable.

So you wouldn't be thinking of switching formulation or going to an ODT based on this data.

Why would you be thinking that?

Because this data shows it works.

BY MR. LUMAN:

Q. All right. You seem to be, with all due respect, avoiding my question. I'm just trying to get a sense of how long this would be stable for, and you keep saying there's no problem with stability.

But do you have any opinion about how long a suspension of Pulmicort mixed with Splenda would be stable for? Is it stable for hours? For days? Minutes? Do you have -- can you provide any insight on that?

MS. AGARWAL: Objection. Form. I would just like to put an objection on the record.

The witness has answered the question.

MR. LUMAN: I disagree with that.

THE WITNESS: I believe I've answered the

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 103

question.
BY MR. LUMAN:
Q. And what was your answer?
A. I'm very happy to give it to you again.
This example and the other examples demonstrate that a viscous solution of 8 to 12 mils is effective in treating EoE. There is nothing in Dohil that suggests there could be a problem in stability.
And equally, a person of ordinary skill would be thinking, really, that's really interesting. I can make a formulation like this, which could be stable. They would be thinking that, but they would test it.
All right?
And they would be thinking there's nothing here that would suggest problems with stability, and I know that there are many commercial products out there that have no problems with stability, have long shelf lives, and frankly, that's what a person is already thinking, because the -- the person would be thinking, what is the patent teaching me?
Use a viscous suspension of 8 to 12 mils and get good, if not great results in terms of overcoming EoE.
Q. Are you willing to go on the record during this deposition and provide an opinion on whether the

oral budesonide suspension, Dohil paragraph 46, of mixing Pulmicort with Splenda is stable for a period of hours, days or minutes?

MS. AGARWAL: Objection. Form.

THE WITNESS: I'm going on the record with the answers I've described.

A person of ordinary skill would know the way this is used. There's nothing in Dohil that suggests it's a problem. And if a person of skill wanted to develop a commercial formulation, he would know that -- he or she would know that there are many oral suspensions out there with good stability, and there's nothing that would suggest, in Dohil, there were problems with stability, and they would make the formulation and test it, with the expectation of success of being able to make it.

So that's on the record for you to see.

We test it.

BY MR. LUMAN:

Q. And the testing that you're suggesting, that would determine whether the suspension was stable for a period of minutes, hours or days, is that fair?

A. This is clearly stable for minutes or hours, whatever you're talking about, because the patient has taken this and is showing complete relief from EoE.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 105

If you wanted to make the formulation such that you took multiple doses of the formulation -- I think a person of ordinary skill would think nothing in Dohil suggests problems with suspension. In fact, it's teaching you. Use them, use this 7 to 8 mils with this viscosity. It's teaching you to do that. But there's nothing in Dohil that suggests that it's going to be a problem with stability.

But then you would test it, and you'd have an expectation of success to be able to prepare a stable formulation, and you wouldn't be thinking of changing from --

Q. When you say it's stable for hours, did you mean eight hours? 24 hours? How many hours?

MS. AGARWAL: Objection. Form.

THE WITNESS: Well, a person of ordinary skill would be thinking you could make a stable formulation based on this. There is nothing that's a problem with Dohil. You could make a stable formulation, which could take multiple doses out of that. Whether that be days, weeks, whatever. But it's more likely, given the volume, days.

And you could easily make that up, and it would be stable. I don't think there's anything that would suggest it wouldn't be stable.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 106

You don't want it to be stable. You want to make the argument that you want to switch to ODTs, but there's nothing in Dohil that would suggest that. In fact, it's teaching you the opposite. It's teaching you, use 8 to 12 mils.

Anyway, I've answered your question multiple times, and I would appreciate a break now.

MR. LUMAN: I'll say that I don't feel like I have a good answer to my question. I'm willing to take a break.

Ten-minute break okay?

THE WITNESS: Fine. Thank you.

(A short recess was taken.)

BY MR. LUMAN:

Q. Dr. Davies, I'd like to turn in your declaration to paragraph 99 in Exhibit 2007.

Would you let me know when you do arrive there.

A. Thank you. I have it, paragraph 99.

Q. And the first sentence, there's a bolded underline, "ODTs are specifically designed for easy swallowing."

Do you see that?

MR. LUMAN: Let's go off the record.

(Discussion off the record.)

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 107

BY MR. LUMAN:

Q. Let's start over again, Dr. Davies. Sorry about that.

Paragraph 99, I see there's -- the first sentence has some bold underlining that says "ODTs are specifically designed for easy swallowing?"

Do you see that?

A. Yes.

Q. And then later in that paragraph, there's another bold underline where it says: "Orally disintegrating compositions are specifically designed for easy swallowing."

Do you see that?

A. Yes.

Q. And just -- I just want a little clarification on what that means.

ODTs -- the ODT itself is not swallowed, right?

A. I think you know, but I'm happy to explain it in the context of that sentence. I'm talking about a distinction between a lozenge and a similar tablet.

And to answer your question, that the ODT will disintegrate within 60 seconds, as claimed -- such orally disintegrating ODTs are specifically designed for easy swallowing, i.e., when they get in the mouth, they

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 108

disintegrate. And it's in the context, of course -- I'm answering -- Dohil and the lozenge and the fact that you grind the lozenge, because that's a different kind of formulation.

BY MR. LUMAN:

Q. Right.

So when you say ODTs are specifically designed for easy swallowing, you're not saying the tablet is swallowed, it's the resulting mixture of saliva and disintegrate that are swallowed? Do you want to say it that way, or do you want to say it differently?

MS. AGARWAL: Objection. Form.

THE WITNESS: I'm saying, I think a person reading this would understand what I'm saying. I'm talking about -- I'm distinguishing between -- a lozenge or similar tablet is not an orally disintegrating composition that disintegrates within 60 seconds as claimed, because such orally disintegrating compositions are specifically designed for easy swallowing, i.e., they disintegrate in the mouth.

And, you know, they're used for -- in the past, for people who have trouble with swallowing tablets and the like, and they are used because you can get a good systemic dose in because the tablet disintegrates, it's absorbed, and that's the reason for

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 109

it.

BY MR. LUMAN:

Q. Let's look at the second sentence of paragraph 99. This is a quotation from Dohil, Exhibit 1002, paragraph 32. And it talks about the child or other patients that may have difficulty with the dissolving lozenge.

Do you see that?

A. I do.

Q. When Dohil refers to a child or patient that may have difficulty with the dissolving lozenge, do you have any insight into what might be causing that child or patient to have difficulty with the dissolving lozenge?

A. I can only presume it's because you've got this thing in your mouth, which is like an ODT, which dissolves quickly within 60 second. With a lozenge -- with a lozenge, which is releasing over a period of time, I can only think that the patient finds that difficult in their mouth.

And so that's the reason why a lozenge isn't an ODT, because they're suggesting to grind it up, whereas an ODT would just go straight in within 60 seconds, as claimed. It will be disintegrated in your mouth. So it's not like a lozenge. That's why I've

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 110

said it.

Q. What's the underlying ailment with this child or patient that creates a difficulty with having a lozenge in their mouth? Do you have any insight into that?

MS. AGARWAL: Objection. Form.

THE WITNESS: It could be for -- other patients may have difficulty with a dissolving lozenge in his mouth. It's Dohil that is saying that. You know, if this was -- this thing -- there may be children and other patients that have difficulty with the lozenge, where the lozenge is just in the mouth and it's not like an ODT which disintegrates rapidly. Therefore, they need to grind it up.

If it was an ODT, it would just be put it in the mouth, it would dissolve rapidly, and it wouldn't be a lozenge. But it is a lozenge, and they are suggesting grinding it up, dissolving it with a small volume of water.

BY MR. LUMAN:

Q. Could the difficulty with the dissolving lozenge be like a gag reflex or dexterity issue? Is that what those might be referring to?

MS. AGARWAL: Objection. Form.

THE WITNESS: I think -- I don't know. It's

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 111

just -- I think they're just saying children and other patients who may have difficulty with a dissolving lozenge. So they may have difficulty having something in their mouth for a prolonged period of time, but if they took it ODT, that would undoubtedly go into -- disintegrate very rapidly. And that's quite different to what they're describing.

BY MR. LUMAN:

Q. Is it some type of physical or psychological problem for the child or other patient causing the difficulty with the lozenge? Do you know?

MS. AGARWAL: Objection. Form.

THE WITNESS: I think a person of skill reading would understand that it's referring to children or patients who have difficulty with a dissolving lozenge, for whatever reason. Grind it. And then I'm making the point, with an ODT, if you put it in the mouth, it would not be like a lozenge or a similar tablet, since they do not disintegrate within 60 seconds, as claimed.

BY MR. LUMAN:

Q. I'm looking for a little insight into whatever the reason is for the patient or child having difficulty with the dissolving lozenge.

Do you have any insight on what those reasons

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 112

might be?

MS. AGARWAL: Objection. Form.

THE WITNESS: There could be a number of reasons, but Dohil is explaining that children and other patients that may have difficulty with the dissolving lozenge, i.e., something in the mouth, they should grind it, and then dissolve it in a small volume of water. That's very different to an ODT. When you place an ODT in the mouth, it disintegrates rapidly, dissolving.

BY MR. LUMAN:

Q. Can you give any examples of the number of reasons that a child or other patient might have difficulty with a dissolving lozenge?

MS. AGARWAL: Objection. Form.

THE WITNESS: Again, I am just going on what Dohil says. Dohil is clearly saying that with a dissolving lozenge, there could be for -- children or other patients might have difficulty with a dissolving lozenge. You know, they wouldn't have difficulty, I believe, with an ODT because it disintegrates very quickly. The very fact that they are talking about grinding the lozenge tells you that the lozenge is not acting like an ODT, for whatever reason.

BY MR. LUMAN:

Q. And can you give a couple of examples of what

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 113

those whatever reasons might be?

A. I haven't thought about that, but I can understand that, as a POSA, they would be doing that for ODTs. They are doing it for a dissolving lozenge, because it sticks -- a lozenge sticks in the mouth. It's designed to be sucked.

Q. Let's turn to a different topic.

If you wouldn't mind, let's go to paragraph 65 of your declaration. Would you mind letting me know when you arrive there.

A. Yes, thank you.

Q. This paragraph -- I'm looking at the third sentence. It says: "There is no dispute that budesonide, fluticasone, or other topical corticosteroids could be used to treat inflammation of the upper gastrointestinal tract."

Do you see that?

A. I do.

Q. When did you first become aware of budesonide?

A. Years ago. I've known about budesonide.

Q. Is that through the literature or through another case?

A. Through the literature, but also, I've done testing on budesonide formulations.

Q. About how long ago in general terms? Ten

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 114

years? 15 years ago?

A. I can't -- it would be of the order of 10 to 15 years ago, yeah. Maybe slightly sooner. I can't remember.

Q. You mentioned you'd done some testing on budesonide formulations?

A. Yes.

Q. I don't want to get into third-party confidential, but can you just give a high level of what you were doing for the budesonide testings that you did?

A. There was a -- without getting into detail, the budesonide in the formulation was micronized, and it was micronized in a way and mixed using ordered mixing where a budesonide -- micronized budesonide particles sat on top of larger particles, and we were asked -- my company and I were asked to characterize that to show that budesonide was on the surface of the larger carrier particles, and we did that.

And we did that both as a powder and also as the tablet. We also looked at the way in which budesonide interacts with the materials that are used in inhalation products as a separate study.

Q. For the first study you mentioned, can you give me an approximate time frame for that? 1990s? 2000s?

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 115

A. It would have been about -- approximately 10 to 15 years ago.

Q. And are there any publication -- public publications that came out of that work you were doing on micronized budesonide?

A. No, there were not. It was done for clients. It was confidential.

Q. And then you mention a second one was the powder and the inhalation study.

Can you give an approximate time frame on that? How many years ago?

A. Similar time. And that was -- again, we were looking at the -- it was again done in the company, and we were looking at the way in which budesonide interacts with the materials that he used, both the excipient, but also the materials that are used with an inhaler. There could be issues of sticking and the like.

We did that not only for budesonide, for the client, but also, we looked at other drugs as well.

Q. Is it fair to say that you have a pretty good familiarity with budesonide?

A. Depends on what you mean by "good familiarity." I've studied it in specific formulations. It's a corticosteroid.

Q. Okay. How about fluticasone? When did you

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 116

first become aware of fluticasone?

A. Again, similar time period. I've known of fluticasone, I've also known that the -- yeah, fluticasone, alclometasone, mometasone. I've known of those for quite some time. Maybe even longer than 10 to 15 years.

Q. Okay. Did you do any studies with fluticasone?

A. Yes. Again, doing studies, looking at inhalation products, looking at the way in which it interacts with the excipient, and also the actual materials they use to make the inhaler. That was work we did both -- that we did in our company. We also published some academic papers on the use and the kind of techniques we were using to study interactions between drug particles and the surface of inhalation products as well.

Q. In paragraph 65, you'd referred to budesonide, fluticasone, or other topical corticosteroids.

What are the other topical steroids you're referring to?

A. They could be the ones that are quoted in Claim 3, like mometasone and beclomethasone.

And really, what I'm saying here is that Dr. Parr has spent a number of pages talking about the

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 117

desirability of budesonide to treat inflammation of the upper gastrointestinal tract. But none of the references he cited were orally disintegrating compositions. But there's no dispute that those compound, budesonide and the other compounds could be used to treat inflammation of the upper GI tract. In fact, the patent tells you that.

Q. I see.

So the other topical corticosteroids refer to at least those listed in Exhibit 1001, column 3, lines 24 to 28, column 7, lines 6 through 10, right?

Doctor, are you waiting for me?

A. Did I miss a question? I apologize.

Q. Sure.

I see the citation at the end of paragraph 65 to Exhibit 1001. There's column 3, lines 24 to 28, and column 7 --

A. Right.

Q. Yeah.

So the other topical corticosteroids referred to in this paragraph 65 include at least the ones listed in Exhibit 1001, with the citation you have there of the column 3, lines 24 to 28, and column 7, lines 6 to 10, is that right?

A. Correct.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 118

Q. I'd like to switch to the topic of taste-masking for a little bit.

Give me one second.

Would you turn with me in your declaration to paragraph 129, please. This is Exhibit 2007.

Will you let me know when you get there.

A. Yes.

Q. The header in this section is "Venkatesh is Directed to General ODT Formulations and Taste-Masking."

Do you see that?

A. Yes.

Q. And in paragraph 129, I'm seeing the second sentence, kind of similar wording: "Venkatesh is more generally directed to ODTs and taste-masking of bitter drug particles."

Do you see that?

A. I do.

Q. I'd like to take a look at some of Venkatesh's disclosures.

Would you turn in your binder with me to Exhibit 1020.

A. Yes.

MR. LUMAN: For the record, I'll say Exhibit 1020 is US Patent Publication No. 2005/0232988, and the last name of the first inventor is Venkatesh.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 119

Q. Dr. Davies, would it be okay if I referred to Exhibit 1020 as Venkatesh?

A. Yes. Thank you.

Q. Would you turn with me to paragraph 12 of Venkatesh, please.

A. Yes.

Q. The first sentence: "U.S. Pat. No. 6,139,865 assigned to Eurand discloses a method of taste-masking."

Do you see that?

A. Yes.

Q. And then way over to the last sentence of paragraph 12, there's a citation to a number of patent documents there. There's US Patent No. 5,700,492, EP65826, US Patent Application No. 2011/00149 -- sorry, 2001/0014340, and EP0914818.

Do you see those citations?

Dr. Davies, did you hear my question?

A. I did. I thought I said "yes." I'm sorry, I apologize.

Q. No worries.

In preparing your declaration in this case, did you review any of the patent documents cited in Venkatesh paragraph 12?

A. Well, I reviewed Venkatesh. I also reviewed, i.e., the one we're looking at now, the Venkatesh 988,

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 120

because that is in paragraph 8 of the '729 patent.

I also reviewed '340, US -- patent ending in '340 that's shown here on the screen.

Again, that is -- and the '988, which we're looking at, was cited by the '729 patent, because the '729 patent says "rapidly dispersing microgranules can be prepared," as described in the US 2005/0232988, which is the patent on the screen, or the US 2001/0014340, which is cited in the second part of 0012 on the screen.

BY MR. LUMAN:

Q. Just give me a second. Okay.

I understand you've reviewed -- from paragraph 12 of Venkatesh, you reviewed one of the patent applications, which was 2001/0014340, right?

A. I reviewed that one, and also the patent that we were looking at, which ends in 988, because those are cited in the '729 patent, column 8, lines 1 through 5 or 6. Those are cited for rapidly dispersing microgranules.

Q. Okay. And did you review any of the other patent documents cited in paragraph 12 in preparing your declaration?

A. I don't recall if I did look at the other ones. I focused on what the '729 patent was teaching me, that it used the rapid dispersing microgranules as

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 121

described in the two patents, the '988 patent and the '340 patent, which I believe are both Venkatesh patents.

Q. Okay. Would you turn with me to paragraph 23 of your declaration, Exhibit 2007, please.

A. Paragraph 23.

Q. And this is under a heading, "Materials Considered." I didn't see there US Patent No -- publication No. 2001/0014340, so I just -- my follow-up question is, other than the documents described here and US 2001/0014340, did you rely on any other documents in preparing your declaration?

A. I believe both the two patents were -- they are not in Dr. Parr's list of documents?

Q. They may be. I'll just check.

A. But I don't know of any other documents that I have --

Q. Okay.

A. Yeah.

Q. That's fair.

Would you turn with me to paragraph 130 of your declaration, please. Can you let me know when you arrive.

A. Yes, thank you. Yep.

Q. I'm looking at the third sentence: "Taste-masking consists of coating the topically active

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 122

corticosteroid with a water-insoluble polymer."

Do you see that?

A. I do.

Q. And after seeing the last sentence of that same paragraph, it says: "A person of skill in the art would understand that these polymer coatings would prevent the corticosteroid from topically contacting the inflamed esophagus gel tissue."

Do you see that?

A. I do.

Q. So I want to understand this a little bit better.

Is it your opinion that Venkatesh's taste-masking with a water-insoluble polymer will always prevent a drug from contacting the esophageal tissue?

MS. AGARWAL: Objection. Form.

THE WITNESS: It depends on what you mean by "always." Clearly, taste-masking by Venkatesh is not claimed in the '729 patent claims, in Claim 1. I mean, some of these coatings, for example, are PH responsive coatings. So they will not dissolve, releasing the drug, until they are in the small intestine. Equally, the ethylcellulose coating is not water soluble.

So I think a person of ordinary skill would understand that such taste-masking approach, which is

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 123

intended to taste-mask is -- you would not be using that technology in an ODT as the '729 teaches you, and that is claimed in Claim 1.

BY MR. LUMAN:

Q. Are there some water-insoluble polymer coatings with ethylcellulose that would allow a drug in an ODT to contact esophageal tissue?

MS. AGARWAL: Objection. Form.

THE WITNESS: Why would you do it?

The whole point is to provide -- to relieve the EoE, and certainly, for these kind of rapidly dispersing formulations, why would you taste-mask in this context for budesonide? Why would you do that?

You want the drug to be intact topically with the inflamed tissue.

BY MR. LUMAN:

Q. I mean, we can set aside the why, but the last sentence of paragraph 130 in your declaration seems to take a strong stance that a polymer coating would prevent the corticosteroid from topically contacting the inflamed esophageal tissue.

Is that true for all of the types of polymer coatings you're referencing there?

MS. AGARWAL: Objection. Form.

THE WITNESS: Well, I can't understand why

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 124

someone would use a water-insoluble polymer like ethylcellulose, because this taste-masking is used for ODTs which are intended for systemic effects, okay? They're intended to go -- to be -- go down into the stomach and into the small intestine and release the drug there. And the ethylcellulose coating that is there, which the drug will leach out of over a period of time, that protects the drug from contacting the taste buds in the mouth.

That's intended -- all these Venkatesh formulations are intended for systemic absorption, trying to get down into the stomach and beyond such that the coatings with the PH responsive coatings can allow the drug to be released, and also, the ethylcellulose can start to release the drug over a period of time.

BY MR. LUMAN:

Q. All right. So I understand your position on why, which is a motivational thing. But I want to know if you're taking the position that these water-insoluble polymer coatings are always going to prevent a corticosteroid from topically contacting esophageal tissue when used in an ODT.

Where do you fall on that?

MS. AGARWAL: Objection. Form.

THE WITNESS: I'm taking -- if I read my

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 125

sentence, I'm saying a person skilled would understand if you're designing an ODT, that these polymer coatings would prevent the corticosteroid from topically contacting the inflamed esophageal tissue, because, in the case of the enteric coatings, they -- it just won't dissolve. In the case of the ethylcellulose, it will take time for the drug to leach out.

And I think somebody of skill would understand that -- a person of skill would understand that, as far as claimed, these rapidly dissolving formulations, I believe, would not use this kind of taste-masking technology.

BY MR. LUMAN:

Q. Could you kind of provide a little bit of, like, a high level explanation of how this taste-masking with a water insoluble coating works? If you had to explain it to the judge quickly, how would you do it?

MS. AGARWAL: Objection. Form.

THE WITNESS: Well, the taste-masking works because the drug is coated with a water-insoluble polymer, like ethylcellulose, which will prevent the drug from contacting the oral cavity. And when the patient -- so the ODT will break up in the mouth and the ethylcellulose coating will stop the drug contacting the oral cavity and giving that bad taste effect. When

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 126

swallowed, this ethylcellulose coating, coated drug, will go into the stomach and into the small intestine and it will gradually release drug through the ethylcellulose coating.

BY MR. LUMAN:

Q. How does that release from the ethylcellulose coating -- how does that happen?

MS. AGARWAL: Objection. Form.

THE WITNESS: So, water in the stomach and in the small intestine permeates through the polymer. It then dissolves the drug on the surface, the drug itself will then diffuse back out through the ethylcellulose coating, and then subsequently be systemically absorbed into the bloodstream.

BY MR. LUMAN:

Q. How does the water permeate the water-insoluble polymer?

A. These polymer formulations are designed such that they allow the -- such as ethylcellulose, that allow the permeation of water through the coating. And then they don't dissolve in water, but they allow the permeation of water.

Q. How does the water permeate? Are there holes in the ethylcellulose coating or something?

A. Yes.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 127

MS. AGARWAL: Objection. Form.

THE WITNESS: They can be pores and -- correct.

BY MR. LUMAN:

Q. Do you know if there's ways of performing Venkatesh's taste-masking with a water-insoluble polymer that would allow the release of the drug to allow the drug to contact the esophageal tissue?

A. I don't know. I'd have to think about that. I think, from a person of skill perspective, if you're trying to treat this topically, first of all, you wouldn't be thinking about using an ODT. And you certainly wouldn't be thinking of restricting the access of the drug -- restricting the access of the drug to the topically -- contacting or coating the inflamed tissue.

It would prevent that by placing a coating. And, in fact, when it's -- since he's referring to these Venkatesh patents, is talking about the rapidly dispersing microgranules.

Q. How about, is it possible to adjust the holes in the water insoluble coating so that the drug would be released after it passes through the mouth, and then allow the drug to contact the esophageal tissue?

MS. AGARWAL: Objection. Form.

THE WITNESS: You wouldn't be motivated to

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 128

using this, would you?

As I've explained in the paragraphs that we talked about, you wouldn't be motivated to do that, based on Venkatesh.

Because why would you use taste-masking? Or why would you use a polymer, which would restrict and prevent the corticosteroid from contacting the inflamed esophageal tissue?

BY MR. LUMAN:

Q. So aside from whether someone would be motivated to do it, is it possible to adjust the holes in the water insoluble coating so that the drug would be released after it passes through the mouth and allow the drug to contact the esophageal tissue?

MS. AGARWAL: Objection. Form.

THE WITNESS: I don't know. To be frank, whether it would possible, I'd have to think about that. Given this is different to Venkatesh taste-mask -- and goes into the stomach and goes into the small intestine and releases its drug. This is different, because you're targeting a very specific region of the esophagus. And there's no reason to expect why you would use an ODT to do that for the reasons I've described.

But, equally, you'd have to think about why

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 129

would you use such a coating?

You want the drug to access that topically, contacting inflamed esophageal tissue.

BY MR. LUMAN:

Q. I'd like to take a look at some of the taste coating in the '729 patent.

Would you turn with me to Exhibit 1001, please. We are going to go to column 13, please. I'm looking at column 13 of the '729 patent, starting at line 59.

Do you see the paragraph starting there?

A. Yes.

Q. It says -- it describes taste-masking with a water-insoluble polymer.

Do you see that?

A. Yes. It's an example of one way you can use taste-masking, but I personally don't believe that is what's claimed in Claim 1.

Q. Is the type of water-insoluble polymer coating described in column 13, beginning at line 59, incompatible with the orally disintegrating solid in Claim 1?

MS. AGARWAL: Objection. Form.

THE WITNESS: I don't believe Claim 1 -- I believe -- don't believe Claim 1 covers taste-masking,

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 130

and uses the polymers.

BY MR. LUMAN:

Q. And is your belief based on the taste-masking being incompatible with an ODT topically delivering a corticosteroid to the upper gastrointestinal tract?

MS. AGARWAL: Objection. Form.

THE WITNESS: My point is that when I look at Claim 1 -- having that disintegration time of 60 seconds -- administration, the corticosteroid is deposited topically in the upper GI tract. I believe that is not a coated formulation, i.e., the drug crystals are not taste-masked and coated. That's just what I believe.

BY MR. LUMAN:

Q. Why do you believe that Claim 1 does not include taste-masking with a water-insoluble polymer?

A. For the reason I just described in my previous answer.

Q. Is it because the water-insoluble polymer prohibits the disintegration time of 60 seconds and depositing the corticosteroid in the upper gastrointestinal tract?

MS. AGARWAL: Objection. Form.

THE WITNESS: I believe it's for the reasons I described in my previous answer.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 131

BY MR. LUMAN:

Q. It's a little bit unclear, so can you articulate what it is about the polymer coating that you believe would cause someone not to use that with Claim 1?

MS. AGARWAL: Objection. Form.

THE WITNESS: I believe Claim 1 is directed to an orally disintegrating -- and that solid -- and which disintegrates within 60 second, whereupon the administration of the corticosteroid is deposited directly -- topically in the upper gastrointestinal tract.

I personally think that means that the drug is deposited topically in the upper gastrointestinal tract. I don't believe that covers the taste-mask formulations or the polymer-coated formulations that are described in column 13. Equally, it doesn't cover other formulations, other formulations that are described in the patent. Such as liquid formulations that are not covered by this Claim 1.

BY MR. LUMAN:

Q. I hear that you don't believe it's covered. What I'm missing is the explanation why.

Can you provide any insight on what the disconnect is between a water-insoluble polymer coating

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 132

in Claim 1?

A. I believe the coating, for the reasons I've described in my -- and I cited in my report, and you drew me to the paragraph, was talking about different polymers from Venkatesh. I believe that when you coat in that way, you are not depositing the corticosteroid topically in the upper gastrointestinal tract, because you've got it coated. All right?

And that's the reason why I think -- because it's coated, I believe you will not -- this is not in the spirit of what is in Claim 1. Claim 1, you know, teaches you about Venkatesh, it teaches you about using these rapidly dispersing granules. That's employed. But equally, it shows here you could have, in certain embodiments, taste-masking.

But I don't believe, in the context of Claim 1, that's what it covers. Claim 1. Because I believe that it's an ODT, it disintegrates. And surprisingly found, when you administer that, you get the corticosteroid deposited topically in the upper gastrointestinal tract. So I believe the coating would inhibit that in the context of Claim 1.

Q. It must be just like second nature to you, but what's the -- the problem with the coating is that it's around the drug, and so because there's a coating in the

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 133

way, the drug can't contact the esophageal tissue?

A. Well, if you did have a coating, I don't believe it's in the spirit of Claim 1, because the coating would inhibit the deposition of the corticosteroid topically in the upper gastrointestinal tract. That's what I believe. So I believe that, in the context of Claim 1, it would not be covered.

Q. Okay. So let's stay in Exhibit 1001, '729 patent.

Would you turn with me to column 14, please. And can you let me know when you arrive.

A. Yes, thank you.

Q. I'm looking at line 44. It says: "Examples of such a coacervation process are disclosed in U.S. Patent Nos. 5,252,337, 5,639,475, 6,139,865, and 6,495,160."

Do you see that?

A. I do.

Q. Did you review any of those patents in preparing your opinions in this case?

A. I don't believe I did, in the context, but I understand that the patent in this column 14 is talking about using ethylcellulose to -- coacervation using ethylcellulose to -- for the taste-masking of the corticosteroid.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 134

Q. Okay.

A. It says, if you want to know more information about how you do it, you can look at those patents. And then it goes on to talk about alternatives -- solution can provide, and it goes on to a further paragraph talking about another approach that you can use, the water-insoluble ethylcellulose.

MR. LUMAN: Let's take a look at the time together. It's 5:00 p.m., Dr. Davies.

Do you want take a dinner break now, or a little bit later?

THE WITNESS: It's 6:00 p.m. my time.

MR. LUMAN: Oh, apologies. So now is a good time for a break?

THE WITNESS: Sure.

MR. LUMAN: Let's go off the record.

(A short recess was taken.)

BY MR. LUMAN:

Q. Dr. Davies, I'd like to return to your declaration, Exhibit 2007. Would you please turn back with me to paragraph 130.

A. I am there.

Q. I'm looking at the fourth sentence down. There's a reference to cellulose acetate phthalate and hydroxypropyl methylcellulose phthalate.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 135

Do you see that?

A. I do.

Q. The next sentence has a citation after it, to Exhibit 2015.

Do you see that?

A. I do.

Q. I'd like to turn to Exhibit 2015 with you, which is at the back of the binder.

A. Yes, I'm here.

MR. LUMAN: For the record, Exhibit 2015 contains some excerpts from the Handbook of Pharmaceutical Excipients.

Q. Dr. Davies, this is one of the exhibits that you cited in your report, right?

A. I do.

Q. And if you turn to page 191, this is a document that discusses cellulose acetate phthalate.

Do you see that?

A. Yes.

Q. Turning to the next page, page 192, and on the left column, there's a first header, "Moisture content."

Do you see that?

A. I do.

Q. And it says: "Cellulose acetate phthalate is hygroscopic and precautions are necessary to avoid

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 136

excessive absorption of moisture."

Do you see that?

A. I do.

Q. What does it mean, that cellulose acetate phthalate is hygroscopic?

A. It means that -- when something is hygroscopic, it absorbs surface water.

Q. And what is it about cellulose acetate phthalate that tend to absorb surface moisture?

A. Probably coming from the cellulose portion of the cellulose acetate phthalate.

Q. What about the cellulose portion would absorb surface moisture?

A. Sorry, I don't understand your question.

Q. Why did you say that the cellulose portion would tend to absorb surface moisture?

A. Cellulose is known to absorb water.

Q. Okay. Let's --

A. It doesn't stop it being an enteric coating material.

Q. Let's discuss the Grother reference for a few minutes. Let's start with your declaration, Exhibit 2007. If you'll turn with me to paragraph 118, please.

Dr. Davies, can you let me know when you arrive at paragraph 118.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 137

A. I have, thank you.

Q. I'm looking at the first sentence. "As discussed above, a POSA would understand that Grother is concerned with creating an ODT formulation that eliminates mammalian gelatin from ODT formulations and works with any class of drugs."

Do you see that?

A. I do.

Q. When you say that the person of ordinary skill in the art would understand that Grother works with any class of drugs, does that include corticosteroids?

A. Well, it's working -- ODT formulations for systemic absorption. So it's got six pages of these hundreds of different drugs, and there are corticosteroids listed among the hundreds of the other drugs.

It doesn't highlight them, but -- and he doesn't distinguish between systemic and topical corticosteroids or systemic or topical drugs. He just -- it's just a platform technology -- a new platform technology without gelatin for systemic absorption.

Q. So would a person of ordinary skill in the art understand that Grother works with corticosteroids?

A. I think a person of ordinary skill in the art

would understand that Grother is designed as an ODT for systemic absorption. He would see that there are corticosteroids listed among the hundreds of drugs. Grother doesn't particularly highlight them in any way. I think that's what he'd say.

Q. Sure.

I understand that you want to discuss that Grother doesn't highlight corticosteroids, but that wasn't my question.

My question was: Would a person of skill in the art believe that Grother's ODT would work with corticosteroids?

MS. AGARWAL: Objection to form.

THE WITNESS: I thought I answered your question. It's a -- platform technology, and he lists six pages of multiple different classes of drugs, including corticosteroids, amongst the hundreds of other drugs, but he doesn't particularly highlight them in any way.

BY MR. LUMAN:

Q. Does Grother listing corticosteroids as some of the drugs in his publication indicate that a person of skill in the art would expect corticosteroids to work with Grother's ODT formulation?

MS. AGARWAL: Objection. Form.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 139

THE WITNESS: I think a person of skill in the art would understand that Grother is just a generic platform that you can use, and it includes -- which includes, amongst six pages of multiple drugs, multiple classes, corticosteroids.

BY MR. LUMAN:

Q. Let's take a look at the Grother reference together.

Would you turn with me in your binder to Exhibit 1008, please.

MR. LUMAN: For the record, I'll say that Exhibit 1008 is a PCT Publication WO 00/44351, and the last name of the first inventor is Grother.

Q. Dr. Davies, is it okay if I refer to this exhibit as Grother?

A. Fine. Thank you.

Q. Would you turn with me to page 1 of Grother. I'm looking at line 15.

Do you see that the first listed corticosteroid is beclomethasone?

A. Yes.

Q. Would a person of ordinary skill in the art understand that Grother's ODT formulation would work with beclomethasone?

A. A person of ordinary skill would understand

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 140

you could use Grother ODT platform for any drugs for systemic absorption. And that would be the focus. You wouldn't be thinking about -- Grother doesn't even talk about different applications. Grother doesn't talk about, frankly, anything to do with using an ODT for -- to treat EoE in the esophagus.

Just because he lists a lot of drugs, a person of ordinary skill would think that you could use these drugs for that particular application, when no one in the -- has ever done that. It's, I think, very farfetched.

Q. I didn't ask anything about systemic absorption.

I just asked, would a person skilled in the art understand that Grother's ODT formulation would work with beclomethasone?

A. Can you define "work with"?

Q. Let me re-ask the question.

Would a person of ordinary skill in the art understand that beclomethasone would be used as the active ingredient in Grother's composition?

A. A person of skill in the art would understand you could use Grother for multiple drugs, but a person of ordinary skill would understand, in using them, that doesn't mean -- ODTs would be use for, i.e., systemic

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 141

absorption. A POSA reading this wouldn't be thinking that you could use these drugs in a way that is exemplified in the '729 patent, because nobody had ever done that.

Q. Sure. I didn't ask if it could be used in the '729 patent. I just asked if a person skilled in the art would have expected that beclomethasone could be used as the active ingredient in Grother's ODT composition.

MS. AGARWAL: Objection. Form.

THE WITNESS: Okay. For what application? For what?

You know, it's just a general platform technology. In that context, you'd be thinking he's swapping out the gelatin for other materials. And that's the purpose of this patent.

But could you put such a drug in it?

Yes.

Would you be thinking that would be the kind of formulation that would work as per the '729?

Absolutely no. Because no one has ever thought of doing that using the '729 platform, ODTs, for topical treatment of the esophagus.

BY MR. LUMAN:

Q. And would you give the same answer if I asked

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 142

you if a person of skill in the art would understand that fluticasone or budesonide could be use as the active ingredient in Grother's ODT composition?

A. I would, because there's nothing in the literature that would say this is just saying that you could produce an ODT based on non-gelatin formulations with these multitude of drugs. It doesn't talk about any disease, it doesn't talk about function, and, you know, that's the purpose of this.

Q. Let's return to your declaration, and if you would turn with me to paragraph 115.

Looking at the fifth sentence, it says: "A POSA would therefore understand Grother to disclose a general ODT platform, for which any drug may be used as an active. A POSA would also understand that Grother did not recognize that an ODT could be used to topically administer a corticosteroid to the upper gastrointestinal tract."

Do you see that?

A. I do.

Q. I want to know what you mean that Grother did not recognize that an ODT could be used to administer a corticosteroid.

When you say "did not recognize," is that the inventor, Mr. Grother -- Dr. Grother, didn't have it in

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 143

his mind that the corticosteroid could be used to topically administer, or are you saying something else, like, Grother just didn't write out that, in his reference, a corticosteroid could be used to topically administer a corticosteroid to the upper gastrointestinal tract?

MS. AGARWAL: Objection. Form.

THE WITNESS: I really don't understand that question. But I'll explain what the sentence means.

BY MR. LUMAN:

Q. Please.

A. This means that Grother just talks about his platform, and he lists a bunch of drugs. He doesn't talk about any disease, or it doesn't talk about any application. He doesn't talk to the fact -- you know, you have to understand, if you're talking about Grother, it's talking about general ODTs.

I couldn't find it, Dr. Parr couldn't find it -- any reference to an ODT being used to topically administer to the upper intestinal tract.

It's the first time -- the '729 explains that's the first time it's done. So somebody reading Grother would just simply see it as a new ODT platform.

It doesn't say you could use an ODT for the first time to topically administer a drug to the upper

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 144

gastrointestinal tract. That's what it saying. And I think any person of skill would -- reading that, would understand that. And they would understand that the disclosure of Grother to suggest an ODT containing topical corticosteroid to topically administer the corticosteroid to the upper GI tract, for the treatment of EoE -- a person of skill would not understand Grother to be disclosing that.

Q. When you say Grother did not recognize, you mean Grother did not write out in his publication that an ODT could be used to topically administer a corticosteroid?

MS. AGARWAL: Objection. Form.

THE WITNESS: Well, no, frankly, nobody could. Nobody, but Grother -- no citation of all the ODTs have done that. Grother is just a platform technology, and he's illustrating he's moved away from gelatin to other materials. And he doesn't recognize -- he doesn't talk about any disease, he doesn't talk any particular therapy. So Grother is just this platform, and there's nothing in Grother or any of the publications which would suggest that you could use an ODT to topically administer a corticosteroid to the upper gastrointestinal tract.

BY MR. LUMAN:

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 145

Q. I think I understand.

When you write that sentence that "Grother didn't write out." It's the word "recognize" that's kind of troubling me. Let me ask a different question.

What did you mean by using the word "recognize" in the sentence in paragraph 115 of your declaration?

MS. AGARWAL: Objection.

THE WITNESS: I think it's clear that Grother did not recognize, did not acknowledge, did not call out that an ODT could be used to topically administer a corticosteroid to the upper gastrointestinal tract.

Grother is like every other publication that's been cited. No one has said, apart from the inventors of the '729 patent, that you could use an ODT to topically administer a corticosteroid to the upper gastrointestinal tract.

Grother is simply telling you, I have developed this new ODT formulation not based on gelatin, and he's got a shocking list of drugs. He doesn't talk about any disease for these drugs. He certainly doesn't distinguish between systemic and topical absorption.

You know, somebody -- I know a person of ordinary skill would know that ODTs, to date, before the '729 patent, were used for systemic delivery, not

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 146

topical. And certainly not topically administered corticosteroid to the upper gastrointestinal tract.

That's what I'm saying.

BY MR. LUMAN:

Q. You mentioned that Grother has a shocking list of drugs.

What shocks you about it?

MS. AGARWAL: Objection.

THE WITNESS: Shocking (phonetic) -- (unintelligible - sound issues.) Sorry, my British accent.

BY MR. LUMAN:

Q. Very good. I'm glad we clarified that.

Let's go back to your declaration, back to paragraph 118. It's the next page over. Actually, it's the last sentence. It's over on page 54. Okay.

The last sentence of paragraph 118 states: "A POSA reading Grother would have no motivation to select budesonide or fluticasone from the long list of drugs."

Do you see that?

A. I do.

Q. So what would Grother have had to say in order to provide a motivation to select budesonide from the list of drugs?

MS. AGARWAL: Objection. Form.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 147

THE WITNESS: Grother doesn't say -- why would you -- based on Grother, why would you be motivated to choose budesonide from the long list of drugs? Why would you be?

It's included in this huge shopping list, or long list of drugs.

Why would you do that?

You know, certainly, Grother doesn't talk at all about topical delivery of budesonide to treat the upper gastrointestinal tract and EoE.

You know, it's just saying, here is my new platform, which isn't based on gelatin but based on other materials. And for -- that's what it's saying, ODT. So that's what it's saying.

So why would you be motivated?

You'd have no motivation. First of all, you wouldn't choose an ODT based on the prior art to treat that area of the esophagus. You'd go with a liquid solution.

Why would you switch from a formulation, which you knew worked, to a formulation based on Grother?

It makes no sense. Particularly, as no ODT had -- Dr. Parr can't point to one that's been used topically in this way. That's why there would be no motivation.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 148

BY MR. LUMAN:

Q. I mean, Grother includes budesonide in his list of drugs, so what else would a person of skill in the art need to be able to have been motivated to use budesonide in Grother's ODT formulation?

A. Well, I've already answered that question in the previous answer. A person of skill wouldn't be thinking of ODTs to treat the esophagus and EoE.

They would be thinking, let's go -- Dohil, the viscous solution, which has proved to work.

Why would you choose to move away for something that works to an ODT formulation?

Particularly as Grother doesn't talk about any disease, doesn't talk about any application. He just got this huge shopping list -- or list of drugs.

Why would a person want to move away from something that's simple, effective and easy to administer in a Dohil? Why would they want to move?

Particularly to a kind of formulation which is a -- formulation, which no -- there was no example of that being used topically.

Why would you be thinking -- there would be no motivation. You'd have no expectation of success, using -- and, in fact, the fact that it works surprised me, and I've been in the field for so long. You would

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 149

have no expectation of success. So you wouldn't be motivated. It's purely a hindsight-driven argument.

Q. It seems to me that your position is, a person reading Grother would just ignore budesonide, on page 18.

Why is it your position that the person of ordinary skill would just ignore budesonide?

MS. AGARWAL: Objection to the form.

THE WITNESS: For the reasons I described in my report. Grother is just a platform technology. There would be no motivation to select budesonide from the long list of drugs.

Why would you be motivated to do it?

The only reason you would be motivated is through the hindsight of knowing from the '729 that, for the first time, an ODT has been shown to be applied topically, and can treat EoE in the esophagus.

Why would you even go there?

Forget the '729 patent. You have something that works as a viscous liquid of a defined volume, premade of a defined viscosity.

Why would you change that and move to Grother?

You'd have no motivation to do that. That's what I'm saying.

BY MR. LUMAN:

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 150

Q. Let's move to a different topic. I'd like to turn to the Parr declaration for a few minutes.

Would you turn in your binder to Exhibit 1030, please.

MR. LUMAN: For the record, I'll state Exhibit 1030 is a declaration of Allen Parr, with respect to the '729 patent.

Q. Dr. Davies, are you familiar with Exhibit 1030?

A. I am.

Q. Would you turn with me to paragraph 29. You can let me know when you arrive, please.

A. Thank you.

Q. In the second sentence of paragraph 29, Dr. Parr explains, the person of ordinary skill in the art, that they have a Ph.D., or other advanced degree, and he goes on to further explain the characteristics of the person of skill in the art.

Do you see that?

A. I do.

Q. Do you agree with Dr. Parr's description of the person of ordinary skill in the art?

A. I believe I do. Generally, I do. Let me just double-check.

As a general thing, yes, I do.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 151

Q. Is there anything you would change about it?
A. I'd have to think about it.
Q. I'd like to change topics to the '729 patent.
Do you mind turning in your binder to Exhibit 1001, please. I'd like to look at Example 1, which starts in column 17.
Would you let me know when you arrive at column 17.
A. Yes, thank you.
Q. Are you familiar with Example 1 of the '729 patent?
A. I am.
Q. In Example 1, I see that the first ingredient in that formulation is mannitol.
Do you see that, line 14?
A. Yes.
Q. What is mannitol doing in this formulation? Is it a bulking agent, or something else?
MS. AGARWAL: Objection. Form.
THE WITNESS: It's one of the excipients that they cite in the publication that can be used. Sugar alcohol.
BY MR. LUMAN:
Q. I see there's 91.2 percent weight by weight of mannitol.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 152

Do you see that?

A. Yes.

Q. As an excipient, is mannitol the bulking agent here, or is it something else?

MS. AGARWAL: Objection. Form.

THE WITNESS: It's used as a sugar alcohol. Which would be rapidly -- undergo -- it helps it undergo rapid dissolution, together with the disintegrant.

BY MR. LUMAN:

Q. What is the disintegrant in this formulation?

A. Crospovidone XL.

Q. I see a little bit further down in Example 1, around line 34, magnesium stearate was used.

Do you see that?

A. I do.

Q. What is the purpose of magnesium stearate in this formulation?

A. It's a lubricant, a processing aid.

Q. In the formulation, Example 1, is there any binding agent that holds the formulation together?

A. It appears that the powders are blended, and water is used as the granulating agent, binding the particles together, and then they're dried.

Q. I'm looking still in Example 1.

Do you see the table in Example 1?

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 153

A. I do.

Q. So I see that the total weight of the tablet target was 100 milligrams, right?

A. Right, the target, yeah.

Q. And then, if I'm reading right, there's a range for the weight of 95 to 105 milligrams.

That's the actual weight of the ODTs that were made, right?

A. That's the acceptable range that was being used, correct.

Q. Okay. That's the acceptable range, or the range they actually measured?

A. It looks, from the weight of ten tablets below, that that's exactly -- it ranges from about 95 to 105, yeah.

Q. Then there's the thickness.

There was the target thickness of 2.4 millimeters, right?

A. Yes.

Q. And I see a range for the thickness of 2.0 to 2.8.

Does that mean the tablets that were actually made had that range, from 2.0 to 2.8 millimeters?

A. Yes. That's what produced the tablets, ranging from 95 to 105 milligrams.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 154

Q. Would a tablet in the range between 2.0 and 2.8 be a good range for the thickness of an ODT?

A. Sorry, say that again.

Q. Sure.

Is the range of 2.0 to 2.8, the thickness of an ODT -- is that a good range for an ODT?

A. It depends on how it functions.

Do all the tablets tested disintegrate in about 60 second or less?

Then, by definition, they are ODT.

Q. I'm looking now at the hardness. I see a target hardness of 28 newtons.

Do you see that?

A. Yes.

Q. Are you familiar with measuring hardness of tablets?

A. I am.

Q. Have you done that before?

A. Many times.

Q. What are some of the ways to measure tablet hardness?

A. There are machines that are commercially available that you can use where the tablet is placed in the machine, and, literally, a surface comes up to the tablet and applies pressure, and that surface has got a

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 155

way of measuring the force that is impacted during that process in terms of newtons.

Q. Does the hardness measurement depend on the rate that the pressure is applied through the surface to the tablet?

A. Usually, there's a standard approach in terms of the rate at which it's applied, but, look, whatever the rate, those tablets pass the 60 seconds or less, and they are shown to be ODTs.

Q. What's the standard approach for measuring hardness that you referenced?

A. Well, you can use the standard equipment that comes -- that is standard. I mean, frankly, whatever is measured here is measured, and it's shown that it has this particular range of hardness, and these tablets disintegrate in about 60 second or less, i.e., they are ODTs.

Q. You mentioned that hardness is measured with a surface that comes up to a tablet that applies pressure.

Does the hardness measurement depend on the rate at which the surface is brought up to the tablet to apply the pressure?

A. The hardness measurement typically comes with the standard instruments which have been calibrated. And, you know, they've measured the hardness here, and

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 156

it shows these values, but absolutely, all those tablets disintegrate within about 60 second or less.

If you wish to change the rate at which -- there are -- on the more research side, you can look at the rate at which you apply the force to the tablet to measure the force to break the tablet, but with standard equipment that is used in the pharmaceutical industry, that is done at a particular rate. And here, we're seeing the values are such, and these tablets all disintegrate in about 60 second or less, i.e., they are ODTs.

Q. How about the size of the tablet? Does the hardness measurement depend on the size of a tablet?

MS. AGARWAL: Objection. Form.

THE WITNESS: It depends. It depends on the context.

Is the hardness measurement, as shown here -- do these tablets, irrespective of the way in which they are being -- the hardness is measured, do they disintegrate within 60 second or less?

Absolutely. They're ODTs.

BY MR. LUMAN:

Q. How about the shape of the tablet? Does that impact the hardness measurement of the tablet?

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 157

MS. AGARWAL: Objection. Form.

THE WITNESS: Again, that's a kind of research aspect to that. It depends on the type of shape you would look at. Clearly, in this case, the hardness is sufficient for the integrity of the tablet, and also to -- it's sufficient that these tablets disintegrate within 60 seconds or less.

BY MR. LUMAN:

Q. And you mentioned that the hardness is sufficient for the integrity.

Is that range of 8 to 48 newtons a hardness of sufficient integrity for tablets?

A. Sure.

MS. AGARWAL: Objection. Form.

THE WITNESS: Sure. I'm certainly looking at the friability. Very good. So therefore, based on -- but also, look at the disintegration test.

Let's not talk about that. Let's not talk about the fact that these are acting like ODTs. They disintegrate in about 60 seconds when measured, using the USP disintegration.

BY MR. LUMAN:

Q. I'm looking at friability in the table. The target has NMT.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 158

Does that mean "not more than"?

A. Yeah.

Q. So the target was not more than .6 percent friability, is that right?

A. Correct.

Q. And then the range, I see 1 percent.

A. Yes.

Q. Do you see that?

That looks like just a number to me.

How is 1 percent a range?

MS. AGARWAL: Objection. Form.

THE WITNESS: I don't know, it just shows 1 percent, which is low.

BY MR. LUMAN:

Q. Are you familiar with measuring friability of tablets?

A. Yes, I am.

Q. Have you done that before?

A. Many times. Taught undergraduates to do it, like I've taught them to do hardness and tableting.

Q. Would you consider less than 1 percent a good friability for early disintegrating tablets?

MS. AGARWAL: Objection. Form.

THE WITNESS: I would consider 1 percent reasonable, a good result for friability, yes.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 159

But look, all disintegrate within 60 seconds, so they are ODTs.

BY MR. LUMAN:

Q. What is it about a friability of 1 percent that is good for ODTs?

A. It's good for tablets, full stop.

Q. Why is that?

A. It's showing that the tablets are of suitable integrity in a friability test.

Q. Does the method that a tablet is made impact its friability?

A. It depends on the context.

Are these suitably made tablets that show low friability, good weight, thickness, hardness and disintegrate within about 60 second or less?

Yeah. They're ODTs. There's nothing to suggest in the Example 1 that they are not well made.

Q. All right. A couple of other questions in the patent.

If you'll turn with me to column 9 of Exhibit 1001. And I'm looking at line 32.

Do you see where it mentions specific examples of glidants and lubricants? Do you see that?

A. I do.

Q. What's the difference between a glidant and a

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 160

lubricant?

A. A glidant is -- a glidant and lubricant attach to the surface of particles. And glidants ensure -- glidants help the particles flow within a powder bed, to improve powder flow within a powder bed.

Lubricants reduce the friction between particles, both during flow, and also when they -- the particles flow into the tablet die to a predefined volume, and then as the particles are compressed by the dies, the lubricant minimizes the friction between the particles and also between the particles and the die walls. You can add materials that can act both as lubricants and also glidants.

Q. That's what the paragraph here in column 9, lines 32 to 37 indicates, is that some of these examples of compounds can be both glidants and lubricants, right?

A. It is just listing examples of glidants and lubricants, and within that list, there are some that can act as both.

Q. Stearic acid -- is that one that can be a glidant and a lubricant?

A. It's primarily a lubricant, but it has been used, can be used as a glidant. Magnesium stearate is primarily a lubricant, but it has glidant properties as well because it reduces friction between particles.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 161

Q. How about calcium stearate or other metallic stearates, are they both glidants and lubricants?

MS. AGARWAL: Objection. Form. Beyond the scope.

THE WITNESS: I'd have to look at it. It's got nothing to do with my report. I'd have to look at it.

BY MR. LUMAN:

Q. Let's turn back to your report. If you'll turn with me to Exhibit 2007, I'd like to go to paragraph 44, please.

A. I'm there.

Q. Looking at the first sentence, it says: "The claims of the '729 patent are directed to orally disintegrating solid pharmaceutical compositions containing a topically administered corticosteroid that topically administers a therapeutically effective amount of a corticosteroid to inflamed tissue of the upper gastrointestinal tract," and then it goes on a little bit more.

Do you see that?

A. I do.

Q. I'm looking at the language "administers a therapeutically effective amount."

Do you see that?

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 162

A. I do.

Q. What did you mean, that the claimed orally disintegrating compositions administer a therapeutically effective amount to treat inflammation of the upper gastrointestinal tract?

A. I'm saying that the claims of the '729 patent are directed to these orally disintegrating solid pharmaceutical compositions, containing a topically administered corticosteroid that topically administers a therapeutically effective amount of the corticosteroid to the inflamed tissue of the upper gastrointestinal tract.

And that's what the claims do. Claim 29, onwards, talks about treatment of particular conditions. You would treat those conditions with a therapeutically effective amount of a corticosteroid.

Q. Can you give us some insight into what's happening mechanistically to deliver the therapeutically effective amount of the corticosteroid? Is it something about the saliva disintegrating the tablet, carrying the drug to the esophagus? How would you explain it?

MS. AGARWAL: Objection. Form.

THE WITNESS: As the '729 patent teaches you for the first time, you can use ODTs to topically deliver a corticosteroid, and it shows, in Claim 1, a

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 163

solid pharmaceutical composition, which is already disintegrating, whereupon -- and it does that within 60 seconds, just like the example we just saw -- whereupon, upon administration of the corticosteroid, it is deposited topically in the upper gastrointestinal tract.

So it's telling you that's the formulation, and for the reasons I've described, somebody of skill wouldn't have expected an ODT to be able to do that.

In Claim 29, a method of treatment of the inflammatory condition of the gastrointestinal tract, comprising -- administering to an individual in need thereof of a pharmaceutical composition according to Claim 1. So Claim 1 is treating, effectively, the inflammatory condition.

As it treats an inflammatory condition, you're administering a therapeutically effective dose.

BY MR. LUMAN:

Q. Right.

And you had said it's surprising that the ODT can do this.

I'm wondering, what's happening for the ODT to be able to administer the corticosteroid to the upper gastrointestinal tract? Can you explain what's going on for that to be able to happen?

A. I've explained it before. I've said multiple

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 164

answers of how the ODT works. You know that.

So I've explained that when it's in contact -- placed in the mouth, in contact with saliva, it undergoes rapid disintegration. Some of the drug is dissolved in saliva, some is in particles, and when that is swallowed, surprisingly, it's been found that it's able to topically administer a therapeutically effective amount to the -- and treat EoE within the esophagus. Treat the inflamed tissue.

And it's surprising because a person of skill wouldn't think of using an ODT to do that. They would have thought of using a liquid, like Dohil, and it's surprising, because you wouldn't have expected an ODT to be able to do what the liquid formulation, which is premade -- you know the viscosity, you know the volume. It's surprising, but it works. And it does work, and that's what they're teaching you. And it's the first time it's been done, using an ODT to topically treat the upper gastrointestinal tract.

Q. Is part of the way that Claim 1 is topically administering the particles such that the corticosteroid particles touch the upper gastrointestinal tract tissues?

MS. AGARWAL: Objection. Form.

THE WITNESS: I believe that the -- where it

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 165

says "administration of the corticosteroid is deposited topically in the upper gastrointestinal tract" -- so the corticosteroid is in contact with the inflamed tissue of the upper gastrointestinal tract. And as Claim 29 says, it's treating using the formulation of Claim 1. It's treating the inflamed tissue of the upper GI tract for the various conditions.

BY MR. LUMAN:

Q. So Claim 1 involves the corticosteroid contacting the inflamed tissue of the upper gastrointestinal tract? Is that part of it?

A. I don't understand what you mean by "is that part of it."

It's surprisingly been found that the ODT undergoes rapid disintegration in the saliva, in that limited volume that we talked about before, and that, in that limited volume, it will be dissolved into particles, and on swallowing, that is able to topically administer the drug to the upper gastrointestinal tract such that it treats the inflamed tissue. It's providing a therapeutically effective amount of the corticosteroid to the inflamed tissue in a topical way.

Q. Maybe you can explain what it means to have a topical administration.

What does it mean to have topical

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 166

administration?

A. You know what it means to have a topical administration. I think what this means is that the drug, rather than acting systematically, being absorbed in the bloodstream, is actually acting directly on the surface of the inflamed tissue. That's what "topically" means.

And that's never been done before with an ODT, and you wouldn't have any expectation of success, going from a liquid -- viscous liquid or predefined simple effective way of doing it -- predefined volume, viscosity, et cetera -- going from that to an ODT, because no one had used an ODT for topical administration in the upper gastrointestinal tract, and you wouldn't have an expectation of success in doing that.

Q. It was the '729 patent, in your opinion, that was the first to demonstrate successful topical administration of a corticosteroid to the upper gastrointestinal tract, right?

A. That's not what I said.

The '729 is the first to show that you could use an ODT to topically administer a corticosteroid to the inflamed tissue of the upper gastrointestinal tract. It's the first time that an ODT, which is used typically

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 167

for systemic absorption of drugs -- first time it's been used to topically administer -- and for all the reasons I've discussed throughout our discussion today, you wouldn't have expected an ODT to work.

You know, you wouldn't have had an expectation of success. You wouldn't have thought, I'll simply switch to an ODT, and it can work. You just wouldn't.

Why would you do that when you know there's a formulation there, which has shown to be simple and effective, like a viscous solution or suspension?

MS. AGARWAL: We've been going for about an hour.

Do you want a break?

THE WITNESS: That would be lovely, thank you.

MR. LUMAN: Shall we take a ten-minute break?

THE WITNESS: Yes, thank you very much.

(A short recess was taken.)

BY MR. LUMAN:

Q. Dr. Davies, would you turn in your declaration with me, Exhibit 2007, to paragraph 13, please.

A. I have it.

Q. In the first sentence, it says: "I have authored over 380 peer-reviewed papers, reviews, and book chapters."

Do you see that?

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 168

A. I do.

Q. I didn't see any discussion of formulating topical drugs versus systemic drugs in your publications.

Are you aware of your publications discussing topical versus systemic drugs?

MS. AGARWAL: Objection. Form.

THE WITNESS: That's just an illustration of the different -- the number of papers that I have published. Those papers are in the context of, that's my work and what I've done in the past. It doesn't stop me actually thinking, though -- you know, being able to, with all that knowledge -- with setting up a pharmaceutical company and serving all those clients in the pharmaceutical industry over those many years -- that I can come to a conclusion on whether or not something in these publications is talking about systemic or topical delivery.

BY MR. LUMAN:

Q. You are familiar, however, with formulating topical and systemic drugs, is that fair?

A. I am familiar with approaches that have been used in the past for the formulation of drugs, which are both topical -- which are topical and/or systemic. I have done that. But that doesn't mean that when it

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 169

comes to an ODT, the ODTs, before the '729 patent, were used in systemic administration. '729 is the first to use ODTs for topical delivery to the upper gastrointestinal tract.

Q. Is whether a drug acts topically or systematically -- is that a property of the drug itself, or is that based on the formulation of the drug?

MS. AGARWAL: Objection. Form.

THE WITNESS: It can be both, and it depends on the context of which you're trying to formulate.

BY MR. LUMAN:

Q. Can you explain that a little bit more. Some drugs are topical and some are systemic, but some of it depends on the particular drug.

Can you elaborate?

A. That's not what I said.

So it depends on the context.

So would you be thinking, because a drug is topical, like budesonide, that if you just placed it into an ODT, it would function and treat the upper gastrointestinal tract?

No. Because nobody had ever used an ODT to do that, for that particular application.

So in that context, it does depend on the drug, the formulation, and what you're trying to treat.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 170

Q. Is it fair to say that some drugs have topical effects and some have -- and also systemic effects?

MS. AGARWAL: Objection. Form.

THE WITNESS: It depends on the context. Give me an example.

BY MR. LUMAN:

Q. How about budesonide? Does that have systemic effects?

A. It has very low systemic effects, as we know. It's rapidly metabolized, and therefore, it has very low systematic corticosteroid function. And, you know, it's been used topically in inhalation, and topically, in enteric coated tablets to treat Crohn's disease. It's been -- it's never been used until the '729 in an ODT to treat inflamed tissue in the esophagus.

Q. How about fluticasone? Does that have systemic effects?

A. Again, it has very low systemic effects. It has very low corticosteroid activity, as do all the drugs that were cited in the '729 patent. That's why it talks to drugs, which are in the claim --

Q. Is there a way to formulate budesonide so that it acts systematically?

A. I haven't finished my answer, actually.

If I may.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 171

Q. Sorry.

A. Where in the claim it says "no significant systemic glucocorticoid or mineralocorticoid activity after oral administration." Then, in Claim 3, it lists a range of corticosteroids, which includes budesonide and fluticasone.

Q. Is that the end?

I don't want to interrupt you.

A. Yes, thank you.

Q. Is it possible to formulate fluticasone so that it has systematic effects?

A. Say that again.

Q. Is it possible to formulate fluticasone so that it has systemic effects?

A. Again, I've not been asked to consider that. I'm just considering the '729 patent, and I focused on that. And in the context of using an ODT, fluticasone can be used in an ODT, and give topical therapy for the treatment of inflammation of the gastrointestinal tract within the esophagus.

MR. LUMAN: What I'd like to do is turn to the very last tab in your binder. We will mark this as Exhibit 1071.

(Exhibit 1071 marked for identification.)

MR. LUMAN: For the record, I'll state the

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 172

document is US Patent No. 2011/0189299. It's entitled "Pharmaceutical Composition Containing Surface-Coated Microparticles." The last name of the first inventor is Okubo.

THE WITNESS: I have it.

BY MR. LUMAN:

Q. On the list of inventors, I see the name Martyn C. Davies, from Nottingham.

Is that you?

MS. AGARWAL: Where is this exhibit coming from?

We've never seen this before.

MR. LUMAN: It's the last document in the binder.

MS. AGARWAL: Yes, but you haven't produced this for us before, correct?

MR. LUMAN: No, I'm using it for the first time during this deposition.

MS. AGARWAL: And it hasn't -- it wasn't part of the petition, or in Dr. Parr's declaration, correct?

MR. LUMAN: That's correct.

MS. AGARWAL: I'm going to object to this exhibit as beyond the scope of Dr. Davies's declaration.

THE WITNESS: Sorry, I misunderstood you.

Could you restate that?

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 173

Thank you.

BY MR. LUMAN:

Q. Sure.

MS. AGARWAL: I object to this exhibit as beyond the scope, because you have no obligation to develop opinions on the fly on exhibits --

MR. LUMAN: Hold on, Counsel. There's no speaking objections like that.

You have made your objection, and now we will proceed.

MS. AGARWAL: Counsel, you're the one interjecting a completely new exhibit that neither the witness nor we have seen before.

MR. LUMAN: If you want to do a colloquy, we will have to do it off the record.

Would you like to go off the record without the witness present?

MS. AGARWAL: You know what you're doing.

BY MR. LUMAN:

Q. Dr. Davies, are you the Martyn C. Davies listed as an inventor here?

A. I believe I am, yes.

Q. If you look at the abstract, I'm looking at the second sentence, it says: "The pharmaceutical composition is for transmucosal administration and

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 174

comprises (a) a drug having a positive or negative charge at a predetermined pH."

Do you see that?

A. I do.

What on earth has this got to do with the '729 patent?

It is not an ODT.

What on earth has this got to do with that?

Q. Just a few more questions, and we'll see where this goes.

Would you mind turning with me to paragraph 44 of this document.

A. Yes.

Q. Paragraph 44: "Specific examples of the drug include, but are not limited to," and there's insulin, glucagon, and so on.

Do you see that?

A. I do.

MS. AGARWAL: It's beyond the scope.

BY MR. LUMAN:

Q. Would a person of ordinary skill in the art expect insulin to work in the pharmaceutical compositions described in this patent publication?

MS. AGARWAL: Objection. Beyond the scope.

THE WITNESS: It depends on what you mean by

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 175

"work."

What do you mean by "work"?

BY MR. LUMAN:

Q. Would you agree that insulin is a specific example of a drug that could be included in the pharmaceutical composition described in the abstract?

MS. AGARWAL: Objection. Beyond the scope. Form.

THE WITNESS: You do realize this is a completely different kind of formulation. It's got nothing to do with ODTs, but insulin could be used in this formulation. These are particles that are near to the surface of other particles.

BY MR. LUMAN:

Q. How about glucagon, would that one be an example of a drug that would be included in the pharmaceutical composition described in this patent publication?

MS. AGARWAL: Objection. Beyond the scope.

THE WITNESS: It could be, yes, for this specific application, adhering the molecule to the surface of particles for the transmucosal activity.

BY MR. LUMAN:

Q. Do you know how many drugs are listed in paragraph 44 of Exhibit 1071?

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 176

MS. AGARWAL: Objection. Form. Beyond the scope.

THE WITNESS: I don't.

BY MR. LUMAN:

Q. Does it look like a long list of drugs to you?

MS. AGARWAL: Objection. Form. Beyond the scope.

THE WITNESS: No.

BY MR. LUMAN:

Q. Does it look like a short list to you?

A. It doesn't look like five or six pages. It's specifically certain kinds of drugs. If it was five or six pages -- it's a certain type of drugs that can be used for this particular application.

Q. Are there any drugs listed in paragraph 44 that would not be used in the pharmaceutical composition described in the document?

MS. AGARWAL: Objection. Form. Beyond the scope.

THE WITNESS: Again, that's got nothing to do with what I've been talking about.

Nothing to do with my report, does it?

It's got nothing to do with the issue of the '729 patent. This is a new approach, like the '729 patent, a new approach, where the drug is immobilized on

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 177

the surface of a small particle, and it's talking about the electrostatic interaction between the polymer and the drug and the production thereof; a way that these drugs can be delivered.

BY MR. LUMAN:

Q. So that didn't answer my question.

I asked if there were any drugs listed in paragraph 44 that would not be used in the pharmaceutical composition described in the document.

MS. AGARWAL: Objection. Form. Beyond the scope.

THE WITNESS: It's beyond the scope of what I've been asked to do, but these drugs, for this specific application, could be used.

BY MR. LUMAN:

Q. Would you look at paragraph 43, please.

Do you see paragraph 43 has examples of drugs that include antihypertensive agents and antihypotensive agent and so on? Do you see that?

A. I do.

Q. How many drugs are included in the example of drugs listed in paragraph 43 of this document?

MS. AGARWAL: Objection. Form. Beyond the scope.

THE WITNESS: Again, I haven't -- I don't

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 178

know.

BY MR. LUMAN:

Q. Could it be hundreds?

A. I don't know. But you know, this example is not being used. It could not be used for ODTs. So this example is showing these drugs can be absorbed to the surface of the carrier for these different applications. But it's not going to be used -- I can't jump from this to say, okay, use it in an ODT, it will work. I can't.

Because it's got nothing to do with ODTs, got nothing to do with the '729. So this patent has not been used to contest the '729. Like the Grother patent, which lists a whole bunch of drugs for an ODT, for no specific therapy and the like, and Dr. Parr is citing that in the context of the '729 patent.

But there's nothing in here that would suggest that you could use this system for an ODT, just particularly to treat the upper gastrointestinal tract.

Q. Are there any example drugs listed in paragraph 43 that would not work with the pharmaceutical composition described in your patent publication?

MS. AGARWAL: Objection. Form. Beyond the scope.

THE WITNESS: Again, I've not been asked to comment on that.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 179

BY MR. LUMAN:

Q. I'm asking you if you can comment on it now. Do you have any comments?

MS. AGARWAL: Same objections.

THE WITNESS: You've just shown this to me in a very unfair way.

You're showing this to me without having had a chance to review this in the context of the '729 patent, aren't you?

You're just showing it to me, you know, just without giving me that chance to review it and think through it. And this is for a completely different kind of application. This is for drugs being absorbed to the surface of particles for transmucosal activity. And like that, it doesn't say which kind of trans- -- anyway.

BY MR. LUMAN:

Q. Was it important to include the example drugs in paragraphs 43 and 44 as part of your publication?

MS. AGARWAL: Objection to form. Beyond the scope.

THE WITNESS: Again, I've not been asked to comment on that, but we have included them because we believe they will work with this kind of platform technology. But this cannot be used as any kind of --

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 180

again, you've not given me the chance to look at it and think about it, but this is not going to be used in ODTs.

BY MR. LUMAN:

Q. Do you have any other comments you'd like to share on Exhibit 1071 at this time?

MS. AGARWAL: Objection. Beyond the scope.

MR. LUMAN: I'll withdraw the question.

MS. AGARWAL: And, Counsel, we are going to move to strike this exhibit and this proceeding and all related testimony to it.

MR. LUMAN: It's a fair use of a witness's publications to probe their opinions, the extent of their knowledge in the field, and so you're welcome to move to strike. I think there are multiple good reasons for Exhibit 1071 to be part of the proceeding.

MS. AGARWAL: I disagree on that, and we'll move to strike.

BY MR. LUMAN:

Q. Dr. Davies, what did you do to prepare for today's deposition?

A. I reviewed my reports -- report. I reviewed Dr. Parr's report. I reviewed the -- all the documentation that is cited in Dr. Parr's report and my report, as much as I could. I talked with counsel.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 181

Q. And you talked with counsel.

Who did you meet with? Who did you talk with?

A. I talked with Isha Agarwal, primarily. I also spoke with Jonathan Cousin.

Q. Anyone else?

A. No.

Q. Did you meet with anyone from Ellodi?

A. No.

Q. When did you meet to speak with those attorneys?

A. I believe yesterday, and I think also Tuesday, or maybe one day last week.

Q. So other than those times, did you meet with the attorneys?

A. In preparing for this? No.

Q. Can you give me an estimate of about how many hours you met in total with the attorneys to prepare for today's deposition?

A. My guess is about three hours yesterday and about three hours the previous day, and about one hour the last time.

Q. And other than the attorneys, did you talk to anyone else to prepare for your deposition today?

A. I did not.

Q. Did you review any documents to prepare for

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 182

today's deposition?

A. Yes.

Q. Did you review any documents that are not part of your declaration to prepare for today's deposition?

A. No, I don't believe so.

Q. Did you do any independent research to prepare for today's deposition?

A. No. I focused on my report and the documents contained in the report.

Q. Have you done anything to search for documents to use in this case?

A. I don't know what you mean by that. I have certainly -- in preparing my report, for instance, I tried to be -- recipients, which I have in my office. I also looked at a portion of Aulton. I copied that and sent that to Isha.

Q. Did you do any literature searches to prepare your declaration for this case? Key word searches?

That's what I'm looking for.

A. I just responded. No, I just responded to Dr. Parr.

Q. Where are you located at this moment?

A. Here? My house.

Q. In Nottingham?

A. In Colston Bassett, yeah.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 183

Q. Is anyone else in the room with you?
A. No.
Q. At any point during today's deposition, has anybody else been in the room with you?
A. In the room with me?
My wife is in the house.
Q. Okay. Anyone else?
A. No.
Q. Do you have any documents in the room with you, besides the binder that was shipped to you?
A. No.
Q. Did you look at any electronic documents, other than the ones provided to you through this Zoom meeting during today's deposition?
A. No.
Q. Did you have any form of communication with other people during today's depositions, such as email communications, text messaging or a chat line?
A. I had a phone call that -- I received a phone call from Isha over lunch, just to check I was okay. We didn't talk about anything related to this.
I also had a text message from a friend, which I responded to, but it's got nothing to do with this. It's got to do with the charity that my wife and I run.
Q. Did you have any other phone calls with Isha

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 184

or Jonathan Cousin during today's deposition?

A. No.

Q. Dr. Davies, have you ever been charged with a crime before?

A. No.

Q. Is there any reason that you're unable to travel to the United States for an in-person deposition?

A. There is, at the moment. I have idiopathic angioedema, which is an allergic reaction, which has come on since -- I've had four episode since March the 6th, and I'm undergoing tests for that, and that's the reason why I didn't travel.

Q. Thank you for sharing.

MR. LUMAN: I don't have any additional questions at this time.

MS. AGARWAL: Can we take a ten-minute break, see if we have anything for redirect, and then we'll be back.

(A short recess was taken.)

EXAMINATION

BY MS. AGARWAL:

Q. I have a couple of questions for you, Dr. Davies.

We are going to go to, I believe it is,

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 185

petitioner's Exhibit 1017, the last exhibit that you were shown.

MR. LUMAN: That's 1071.

MS. AGARWAL: I apologize. 1071. It's the publication number US 2011/0189299.

Q. Let me know when you have that. 1071. Let me know when you're there.

So opposing counsel showed you this exhibit, correct.

A. Correct.

Q. And if we go to paragraph 43 of this exhibit, opposing counsel pointed you to this list of example drugs, correct?

A. Yes.

Q. Does this paragraph disclose budesonide anywhere?

A. No, it does not.

Q. Does this paragraph disclose fluticasone anywhere?

A. No, it does not.

Q. Does this paragraph disclose corticosteroids anywhere?

A. It does not.

Q. If we go to paragraph 44, opposing counsel showed you this paragraph as well, correct?

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 186

A. That's correct.

Q. Does this paragraph disclose budesonide anywhere?

A. It does not.

Q. Does this paragraph disclose fluticasone anywhere?

A. It does not.

Q. And does this paragraph disclose corticosteroids anywhere?

A. It does not.

Q. Is this patent application directed to ODTs in any way?

A. In no way at all.

MS. AGARWAL: No further questions.

MR. LUMAN: I just have one question.

EXAMINATION

BY MR. LUMAN:

Q. Dr. Davies, did you speak with Isha or Jonathan during our last break, the one after I had finished asking questions and when you were just asked questions?

A. I did not.

MR. LUMAN: No further questions.

THE WITNESS: Thank you for doing it by

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 187

virtual. For the reasons I described, I couldn't travel, but thank you for doing it this way.

MR. LUMAN: Let's go off the record.

MS. AGARWAL: Copy of the transcript. Rough draft.

(The proceedings concluded at 8:30 p.m.)

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Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 188

DEPONENT'S DECLARATION

I, MARTYN CHRISTOPHER DAVIES, Ph.D., hereby declare:

I have read the foregoing deposition transcript and identify it as my own and approve same.

I declare under penalty of perjury under the laws of the State of California that the foregoing testimony is true and correct.

Dated this _____ day of _____, 2025, at _____, California.

_____

MARTYN CHRISTOPHER DAVIES, Ph.D.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 189

STATE OF CALIFORNIA)
COUNTY OF SANTA BARBARA) ss.

I, Mark McClure, C.S.R. No. 12203, in and for the State of California, do hereby certify:

That prior to being examined, the witness named in the foregoing deposition was by me duly sworn to testify to the truth, the whole truth, and nothing but the truth;

That said deposition was taken down by me in shorthand at the time and place therein named and thereafter reduced to typewriting under my direction, and the same is a true, correct, and complete transcript of said proceedings;

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 required.

I further certify that I am not interested in the event of the action.

Witness my hand this 7th day of July, 2025.

Certified Shorthand Reporter
State of California
CSR No. 12203

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 190

NATE LUMAN, ESQ.

nate.luman@knobbe.com

July 7, 2025

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

7/2/2025, Dr. Martyn Christopher Davies, Ph.D., (#7436693).

The above-referenced transcript has been completed by Veritext Legal Solutions and review of the transcript is being handled as follows:

__ Per CA State Code (CCP 2025.520 (a)-(e)) – Contact Veritext to schedule a time to review the original transcript at a Veritext office.

__ Per CA State Code (CCP 2025.520 (a)-(e)) – Locked .PDF Transcript - The witness should review the transcript and make any necessary corrections on the errata pages included below, notating the page and line number of the corrections. The witness should then sign and date the errata and penalty of perjury pages and return the completed pages to all appearing counsel within the period of time determined at the deposition or provided by the Code of Civil Procedure. Contact Veritext when the sealed original is required.

__ Waiving the CA Code of Civil Procedure per Stipulation of Counsel - Original transcript to be released for signature as determined at the deposition.

__ Signature Waived – Reading & Signature was waived at the time of the deposition.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 191

__ Federal R&S Requested (FRCP 30(e)(1)(B)) – Locked .PDF Transcript - The witness should review the transcript and make any necessary corrections on the errata pages included below, notating the page and line number of the corrections. The witness should then sign and date the errata and penalty of perjury pages and return the completed pages to all appearing counsel within the period of time determined at the deposition or provided by the Federal Rules.

_X_Federal R&S Not Requested - Reading & Signature was not requested before the completion of the deposition.

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 192

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1-3 61:10
10 10:7 71:10 115:2 116:1 117:5 118:11 118:23
100 33:3 88:8 88:10,13 90:13 154:3
1001 4:16 9:1 13:2,5,9,13 21:6,10 23:15 118:10,16,22 130:7 134:8 152:5 160:21
1002 4:16 61:24 62:2,13 86:10 90:23 91:5 110:4
1005 4:17 14:17,21,24 18:11,20
1007 4:17 37:24
1008 4:18 140:10,12
1011 89:15
1017 4:18 47:12,17,19 51:20 186:1
1020 4:19 119:21,24 120:2
1030 4:19 151:3,6,9
1036 9:1
105 154:6,15,25
106 37:12,23 38:25
1071 4:11 172:23,24 176:25 181:6 181:16 186:3,4 186:6
109 60:11,23,23 61:4 78:10
115 143:11 146:6
118 137:23,25 147:15,17
119 4:19
12 27:15,19 32:9 36:1 45:16,19 85:19 94:7 96:15 102:8 104:6,21 107:5 120:4,12 120:23 121:13 121:21
12203 1:25 2:3 190:4,25
129 119:5,12
1299 2:20 3:3,9
13 4:16 66:1,24 67:2,20,23 130:8,9,20 132:17 168:20
130 122:20 124:18 135:21
136 4:21
14 4:17 134:10 134:22 152:15
140 4:18
15 62:15,18 63:4,11,23 64:6,8,15,17,19 64:25 65:9,17 66:23,25 67:22 76:16 81:16 115:1,3 116:2 117:6 140:18
151 4:19
17 36:22,25 152:6,8
172 4:11
17688 190:23
18 23:18,19,21 150:5
180 96:23
181 47:25 51:20
185 4:5
187 4:6
191 136:16
192 136:20
1990s 115:24
1:03 2:2 5:1

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Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 193

2

2 1:15 2:2 5:1 13:2,5,18 15:1 15:11 25:24 26:7,12,18 27:8,24 28:13 28:22 29:11,20 33:19 34:19,23 35:15 36:5 37:11 38:6,12 62:22,22 63:4 63:4,11,11 65:1,1,18,18 66:25,25 76:16 76:17 81:15,15 87:23
2.0 154:20,23 155:1,5
2.3 48:3 51:20
2.4 154:17
2.8 154:23 155:2,5
2.8. 154:21
20 28:7 86:24 86:24 87:14
20004-2400 2:20 3:4,9
2000s 115:25
2001/0014340 120:15 121:8 121:14 122:8 122:10
2005/0232988 119:24 121:7
2007 4:20 8:24 9:9,14 10:7 40:16 60:11,22 107:16 119:5 122:4 135:20 137:23 162:10 168:20
2007/001119... 62:2
2008 9:3
2009 14:7 15:25
2010 4:20 89:10,13
2011 93:15
2011/00149 120:14
2011/0189299 4:11 173:1 186:5
2015 4:21 136:4,7,10
202.728.7079 3:4
202.776.2102 2:21
202.842.7896 3:10
2024-01197 5:4
2025 1:15 2:2 5:1 45:24 189:10 190:21 191:3
2025.520 191:9 191:12
21 21:16
23 122:3,5
24 4:12 106:14 118:11,16,23
28 118:11,16,23 155:12
29 28:3,5,8,16 33:9 151:11,14 163:13 164:9 166:4

3

3 15:10 61:6 62:22 63:4,11 65:1,18 66:25 76:17 81:15 87:24 117:23 118:10,16,23 172:4
30 24:5,6 96:22 192:1
300 2:10,14 88:13
31 29:6,13 30:4 33:10 70:20,23 71:22,25 72:12 73:7,15 74:6 74:10 75:4,21 75:22 76:21
32 68:7,8,23 69:13 70:19 72:1,10,13 73:8,17 74:24 75:19 76:14 77:7,11,23 110:5 160:21 161:15
34 153:13
340 121:2,3 122:2
35 41:11 42:11
3579 2:10,14
37 161:15
38 4:17
380 168:23

4

4 6:2 89:19
400 71:10
41 13:2,19
41-44 13:5
43 178:16,17,22 179:20 180:19 186:11
44 13:2 134:13 162:11 175:11 175:14 176:25 177:15 178:8 180:19 186:24
46 38:3 91:4 100:17 101:10 105:1
47 4:18
48 158:11
49 78:14

5

5 4:4 121:17
5,252,337 134:15
5,639,475 134:15

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 194

5,700,492 120:13
50 60:14
500 91:15
54 147:16
58 12:11,13,22 13:1
59 130:10,20
5:00 135:9

6

6 90:1 93:12 118:11,23 121:18 159:3
6,139,865 120:7 134:15
6,495,160 134:16
60 24:3 25:6 29:17 34:9 37:10 38:12 44:8 108:23 109:17 110:17 110:23 112:19 131:8,20 132:9 155:9 156:8,16 157:2,10,20 158:7,20 160:1 160:15 164:2
61 97:6
62 4:16
65 114:8 117:18 118:15 118:21
67 86:11,15 87:18 96:14
68 9:25 10:1
6:00 135:12
6:17 36:21
6th 185:11

7

7 92:8,20 93:5 93:21,23 94:1 94:5 95:2,16 96:11 97:15 98:17 106:5 118:11,17,23 191:3
7/2/2025 191:5
700 2:20 3:3,9
729 12:14 13:16 84:20,21 121:1,5,6,17,24 123:19 124:2 130:6,9 134:8 142:3,6,20,22 144:21 146:15 146:25 150:15 150:19 151:7 152:3,10 162:14 163:6 163:23 167:17 167:22 170:1,2 171:14,20 172:16 175:5 177:24,24 179:11,12,15 180:8
7436693 1:23 191:5
7th 190:21

8

8 27:15,18 32:9 36:1 45:16 85:19 92:8,20 93:5,22,23 94:1,5,7 95:2 95:16 96:11,15 97:15 98:17 102:8 104:6,21 106:5 107:5 121:1,17 158:11
8,771,729 1:4 13:13
8-12 87:8
82 47:11
83 40:16,20
858.707.4000 2:15
89 4:20
8:30 188:6

9

9 4:20 160:20 161:14
91.2 152:24
92130 2:11
92130-3316 2:15
949.760.0404 2:11
95 154:6,14,25
988 120:25 121:4,16 122:1
99 107:16,19 108:4 110:4

a

abbreviated 21:24 22:2
abdominal 93:13 98:19
ability 6:16 58:7
able 27:2 32:22 44:25 57:10 83:6 84:8 85:10,21 97:6 100:1 105:16 106:10 149:4 164:8,22,24 165:7,14 166:18 169:12
above 60:23 70:19 93:12 138:3 191:6
absolutely 142:21 157:1 157:21
absorb 137:9 137:12,16,17
absorbed 17:13 17:15 18:8 20:2,6,18 21:4 25:8 50:13,17 50:24 51:6 54:19 55:22 85:17 109:25 127:13 167:4 179:6 180:13

Veritext Legal Solutions
Calendar-CA@veritext.com 866-299-5127

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 195

absorbs 137:7
absorption 11:2 47:8 50:10,14 54:2 56:13,13,22 57:2 58:18,18 59:21,21 60:7 84:14 125:11 137:1 138:13 138:22 139:2 141:2,13 142:1 146:22 168:1
abstract 174:23 176:6
academic 12:2 117:14
accent 147:11
acceptable 154:9,11
access 9:7 128:13,14 130:2
acceve 87:2
accurate 6:8
acetate 135:24 136:17,24 137:4,8,11
achieve 85:18 86:4 93:21 94:2
achieving 60:7
acid 161:20
acknowledge 146:10
act 49:13 51:5 51:8 70:2 84:8 161:12,19
acting 49:6 54:23 82:24 113:23 158:19 167:4,5
action 190:20
active 17:21 122:25 141:21 142:8 143:3,15
actively 11:14
activity 55:19 171:19 172:3 176:22 180:14
acts 170:5 171:23
actual 117:11 154:7
actually 16:18 53:4 95:21 147:15 154:12 154:22 167:5 169:12 171:24
add 94:1,4 161:12
addition 59:4
additional 185:14
address 5:25
addressed 59:18
adds 36:7
adhering 176:21
adjust 128:20 129:11
administer 34:12 133:19 143:17,22 144:2,5,20,25 145:5,11,23 146:11,16 149:18 163:3 164:22 165:7 166:19 167:23 168:2
administered 25:11 39:20 61:6 62:23 96:17,19 147:1 162:16 163:9
administering 33:13 36:13 164:11,16 165:21
administers 162:17,23 163:9
administration 12:18 14:2 19:3 24:8,15 25:14 29:3 35:7,24 37:16 39:8 40:2 46:4 55:13 57:18 87:10 102:15 102:16 131:9 132:10 164:4 166:1,24 167:1 167:3,14,19 170:2 172:4 174:25
administrations 96:23
admitted 37:11
advanced 10:12 11:24 151:16
advantages 87:6,25 88:19
adverse 50:4 53:9,16,20 54:8
affect 54:1
afternoon 5:20
agarwal 2:19 4:5 5:9,9 11:7 18:1 20:11 22:23 23:3,9 24:20 25:21 28:17 29:14 30:10,20 31:13 32:19 33:7 34:17 35:1 38:9 39:22 42:8,19 44:21 49:16,24 51:10 52:4 57:13 58:14 59:10,16 63:13 64:18 67:4 70:12 72:14 73:9,18 74:9 75:3 77:9 77:25 80:9

Veritext Legal Solutions
Calendar-CA@veritext.com 866-299-5127

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 196

81:2,20 82:15 85:5 87:19 88:11,25 90:16 92:1,17 93:1 94:3,19 95:12 97:3,12 98:2 98:15 99:7,22 100:9 101:12 102:17 103:21 105:4 106:15 109:12 111:6 111:24 112:12 113:2,14 123:16 124:8 124:24 125:24 126:18 127:8 128:1,24 129:15 130:23 131:6,23 132:6 139:13,25 142:10 144:7 145:13 146:8 147:8,25 150:8 152:19 153:5 157:14 158:1 158:14 159:11 159:23 162:3 163:22 165:24 168:11 169:7 170:8 171:3 173:10,15,19 173:22 174:4 174:11,18 175:19,24 176:7,19 177:1 177:6,18 178:10,23 179:22 180:4 180:20 181:7,9 181:17 182:3 185:16,22 186:4 187:14 188:4

age 38:17

agent 152:18 153:3,20,22 178:19

agents 178:18

ago 67:14 114:20,25 115:1,3 116:2 116:11

agree 6:14 12:22 16:12 25:23 27:23 28:22 33:18,22 34:18 37:8 38:10 42:12 43:9 48:13,16 53:14,17,18 59:1 66:11 67:3 68:10,22 68:25 69:13 70:9,11 71:22 83:14 151:21 176:4

agreed 85:22

aid 15:18 16:14 16:18,23 153:18

ailment 111:2

albeit 76:21

alclometasone 117:4

alcohol 152:22 153:6

allen 3:8 5:10 151:6

allergic 185:9

alleviate 30:17 31:11 62:21

alleviates 30:14

allow 17:12 29:21 124:6 125:13 127:19 127:20,21 128:7,7,23 129:13

allowing 18:4 20:2 26:19 34:10 69:6

alternative 20:9,17 21:3 102:5

alternatives 135:4

amount 35:18 37:15 38:5,7 39:1,7,11,17 40:1 50:5 52:12,24 53:10 53:22 62:20 75:21 78:22 79:17 80:8 81:1 84:5 162:17,24 163:4,10,16,19 165:8 166:21

amounts 63:4 63:10,23 65:1 65:17 66:23,25 67:22 71:1,5 71:25 72:12 73:6,14 74:7 74:25 81:14 82:14

analytical 11:24

angioedema 185:9

answer 7:3,5 24:23 25:16 27:7 32:12 37:2 47:2,9 57:15 58:3 59:1 64:15 77:2 100:12 104:3 107:9 108:22 131:18 131:25 142:25 149:7 171:24 178:6

answered 58:15 102:18 102:19 103:23 103:25 107:6 139:14 149:6

answering 109:2

answers 6:13 50:7 57:9 59:12 67:14 77:11 105:6 165:1
anticipate 45:14
antihypertens... 178:18
antihypotensi... 178:18
antithesis 45:4
anybody 184:4
anyway 81:24 107:6 180:16
apart 146:14
apologies 135:13
apologize 87:1 118:13 120:19 186:4
appeal 1:2
appearances 2:7 3:1
appearing 2:9 2:13,18 3:2,7 191:18 192:7
appears 153:21
appetite 98:20
application 4:11 57:21 58:8 120:14 141:9 142:11 144:15 149:14 170:23 176:21 177:14 178:14 180:13 187:11
applications 121:14 141:4 179:7
applied 150:16 156:4,7
applies 71:23 155:25 156:19
apply 63:5,12 67:1,5,22,24 71:25 72:12,18 73:2,15,22 74:13,19 156:22 157:5
appreciate 107:7
approach 26:4 72:21 123:25 135:6 156:6,10 177:24,25
approaches 169:22
approve 189:6
approximate 115:24 116:10
approximately 116:1
apt 89:15
area 33:5 84:17 84:24 85:12 86:1,2 148:18
argument 59:4 75:13 83:23 107:2 150:2
arrive 23:18 62:16 70:22 107:17 114:10 122:22 134:11 137:25 151:12 152:7
arrived 9:12 13:10 14:18 15:3 18:13 21:6,10 40:17
art 14:7 15:24 35:25 36:9 37:19 41:8,19 42:7,16,17 44:9 45:22 46:22 56:6,18 57:6,25 58:10 63:3,10,22 64:7,25 65:16 66:22 67:21 71:24 72:11 73:6 75:1,18 76:14 80:6,24 81:16 82:10 94:15 100:16 123:5 138:10 138:23,25 139:11,23 140:2,22 141:15,19,22 142:7 143:1 148:17 149:4 151:16,18,22 175:21
articles 47:10
articulate 132:3
aside 124:17 129:10
asked 89:1 115:15,16 141:14 142:6 142:25 172:15 178:7,13 179:24 180:22 187:21
asking 6:11 59:8,15 64:17 99:17 180:2 187:21
aspect 158:3
aspects 86:3 97:21
assessed 101:2
assigned 120:8
assume 6:23 7:13 47:22 80:23 90:14
assumption 83:7,7,9
attach 161:2
attorney 7:2
attorneys 182:10,14,17 182:22
aulton 41:23 183:15
author 48:13 53:14

Veritext Legal Solutions
Calendar-CA@veritext.com 866-299-5127

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 198

author's 47:20
authored 168:23
authors 54:12
automatically 73:2
available 27:25 43:13 44:13,15 44:18,24 54:10 155:23
avenue 2:20 3:3 3:9
avoid 136:25
avoiding 100:14 103:13
aware 20:25 22:6,7,8,9,12 22:15 27:4 33:23 40:20,25 41:1,20 42:4 42:13 43:13 52:8,19,21 55:7,10,12,18 56:1,4,8,9,12 56:16,23 58:6 58:20 77:22 86:22 114:19 117:1 169:5
awful 8:19

b

b 4:9 6:2 192:1
back 18:12 21:5 36:21,25 51:13 55:1 60:13 63:17 73:19 82:19 86:10 89:10 90:20,24,25 127:12 135:20 136:8 147:14 147:14 162:9 185:18
background 18:16,20 21:12 22:14 23:11,12
bad 126:25
barbara 190:2
base 87:21 88:7
based 12:21 37:19 39:18 63:18 76:11 77:3,6 79:3,20 80:3,17 82:6 88:19 93:11 103:8 106:18 129:4 131:3 143:6 146:19 148:2,12,12,17 148:21 158:16 170:7
basically 14:11
basis 15:19 16:4 78:24
bassett 6:2 183:25
bear 2:9,13
beclomethas... 117:23 140:20 140:24 141:16 141:20 142:7
bed 161:4,5
began 22:10
beginning 92:3 130:20
behave 69:9
behaves 73:24
behaving 69:19
belgium 90:3
belief 131:3
believe 7:25 8:1 14:8 16:1 41:22 43:1 44:6 57:20 59:3 65:17 75:1 77:5,11 78:6 87:23 93:16,19 103:25 113:20 122:2,12 126:11 130:17 130:24,25,25 131:10,13,15 131:24 132:4,7 132:15,22 133:2,5,10,16 133:17,21 134:3,6,6,21 139:11 151:23 165:25 174:22 180:24 182:11 183:5 185:25
beneficial 19:3 19:11,14 20:7
best 6:16
better 123:12
beyond 125:12 162:3 173:23 174:5 175:19 175:24 176:7 176:19 177:1,6 177:18 178:10 178:12,23 179:22 180:20 181:7
big 82:16
binder 8:22,22 8:23,25 9:6,10 13:9 14:17 47:16 61:23 89:10 119:20 136:8 140:9 151:3 152:4 172:22 173:14 184:10
binding 153:20 153:22
bit 48:19 78:19 85:3 91:22 119:2 123:11 126:14 132:2 135:11 153:12 162:20 170:12
bitter 119:14
blended 153:21
blood 50:13,25
bloodstream 18:9 19:23 20:3,6,18,18 21:4 54:4

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 199

56:15 85:17 127:14 167:5
board 1:2
body 59:22 71:10
boe 90:9,9
bold 108:5,10
bolded 107:20
book 168:24
border 8:16
bottom 15:2 18:15 38:3 78:14 91:10
bounds 71:5
box 8:8,11,13 8:22
break 7:8,9 18:4,4 25:25 29:21 36:16 54:18 60:15,16 69:25 100:13 107:7,10,11 126:23 135:10 135:14 157:6 168:13,15 185:16 187:20
breaking 24:22 34:7,20 69:20
breaks 30:24 31:16 35:3
brief 36:16
briefly 15:11
brings 32:16 37:25
british 147:10
broke 25:6
broken 32:6
brought 32:14 44:15 46:3,13 47:9 68:6 156:21
budesonide 80:7,13,25 81:17 82:11 87:5 91:19 92:5,18 93:3 94:24 96:25 97:25 101:18 105:1 114:14 114:19,20,24 115:6,10,12,14 115:14,17,21 116:5,14,18,21 117:18 118:1,5 124:13 143:2 147:19,23 148:3,9 149:2 149:5 150:4,7 150:11 170:19 171:7,22 172:5 186:15 187:2
buds 125:9
bulking 152:18 153:3
bunch 144:13 179:13

c

c 173:8 174:20
c.s.r. 2:3 190:4
ca 191:9,12,21
cal 1:25
calcium 162:1
calibrated 156:24
california 2:5 2:11,15 189:8 189:11 190:1,5 190:24
call 94:12 146:10 184:19 184:20
called 89:15 95:22
calls 184:25
canada 90:2
candy 51:25
capability 57:24 58:10
capsules 10:11
care 39:3
caregiver 91:23 92:12 93:9 99:2
carrier 115:17 179:7
carrying 163:20
case 1:4 9:21 22:10 40:5 43:17 78:3 90:12 114:22 120:21 126:5,6 134:20 158:4 183:11,18 190:16
cases 7:23,24 19:21
cause 132:4
causes 17:6 24:15 97:18
causing 110:12 112:10
cavity 12:17 14:1,10 17:7,9 24:17 33:19 50:14,17 126:22,25
ccp 191:9,12
cellulose 135:24 136:17 136:24 137:4,8 137:10,11,12 137:15,17
centre 2:10,14
certain 62:19 62:21 65:11 133:14 177:12 177:13
certainly 34:9 35:15 65:20 72:2 82:5 95:6 96:5 98:6 124:11 128:13 146:21 147:1 148:8 158:15 183:13

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 200

certified 2:4 190:24
certify 190:5,19
cetera 40:9 167:12
challenged 95:6
challenging 95:5
chance 180:8 180:11 181:1
change 78:3 82:1 85:14 150:22 152:1,3 157:3
changes 53:24
changing 106:11
chapters 168:24
characteristics 15:14,17,19 16:3,3,8,20 151:17
characterize 115:16
characterized 11:3
characterizing 11:6,15,18,20
charge 175:2
charged 185:3
charity 184:24
chat 184:18
check 8:17 122:14 151:24 184:20
chew 18:23
chewing 12:18 14:2 15:15 16:10,21
child 110:5,10 110:12 111:2 112:10,23 113:12
children 69:20 70:1 77:14 86:24,24 87:14 87:23 111:10 112:1,14 113:4 113:17
choose 148:3 148:17 149:11
christopher 1:14 2:1 4:3 5:14 6:1 9:16 189:3,16 191:5
circulation 55:22
circumstance 27:25
citation 13:1 38:24 39:4 47:12 118:15 118:22 120:12 136:3 145:15
citations 41:12 46:2 58:6 120:16
cite 46:5,5 152:21
cited 13:8 47:10 56:2 58:5,17 89:16 118:3 120:22 121:5,9,17,18 121:21 133:3 136:14 146:14 171:20 181:24
cites 41:12 56:3 56:21 57:1 61:5
citing 13:4 179:14
civil 191:19,21
claim 23:21,23 25:4,5,12 28:2 28:3,5,8,10,15 28:16 29:6,13 29:13,25 30:4 31:5 32:5 37:9 117:23 123:19 124:3 130:18 130:22,24,25 131:8,15 132:5 132:7,20 133:1 133:11,11,16 133:17,22 134:3,7 163:13 163:25 164:9 164:13,13 165:20 166:4,5 166:9 171:21 172:2,4
claimed 32:10 33:10 60:24 61:17 108:23 109:18 110:24 112:20 123:19 124:3 126:10 130:18 163:2
claiming 28:19 28:25 29:15,24 33:9
claims 23:17 32:20 123:19 162:14 163:6 163:13
clarification 16:25 61:22 108:15
clarified 147:13
clarify 64:5
class 138:6,11
classes 139:16 140:5
classifying 15:20 16:4
clear 87:25 146:9
clearly 26:21 28:18 32:5 35:22,22 45:9 50:8 51:3,14 70:5 72:4 77:17,17,24 88:18 98:16 100:25 102:7

105:23 113:16 123:18 158:4
client 116:19
clients 116:6 169:14
clinical 19:23 20:19 86:15,21 87:11,17,22 88:5,21 89:3,3 89:5 90:11 93:18 95:14,18 96:12
clinically 40:6 80:20 96:16 98:18 100:22 101:15
clinician 20:24
coacervation 134:14,23
coat 30:8,19 31:9,10,10 32:16 70:17 77:20 133:5
coated 126:20 127:1 131:11 131:12 132:16 133:8,10 171:13 173:2
coating 32:3,4 32:13,16 122:25 123:23 124:19 125:6 126:16,24 127:1,4,7,13,20 127:24 128:15 128:16,21 129:12 130:1,6 130:19 132:3 132:25 133:2 133:21,24,25 134:2,4 137:19
coatings 123:6 123:20,21 124:6,23 125:13,13,20 126:2,5
coats 31:1
code 191:9,12 191:19,21
cofounded 12:3
colloquy 174:14
colston 6:2 183:25
column 13:2,18 21:9,12 23:18 23:19,21 28:6 29:16 48:2 118:10,11,16 118:17,23,23 121:17 130:8,9 130:20 132:17 134:10,22 136:21 152:6,8 160:20 161:14
columns 70:25
combination 11:24
come 17:9 38:18 42:25 57:16 73:19 85:13 169:16 185:10
comes 18:3 87:1 155:24 156:13,19,23 170:1
coming 93:24 137:10 173:10
comment 35:21 39:3,16 49:15 54:6 85:2 179:25 180:2 180:23
comments 180:3 181:5
commercial 42:13 100:5 101:22,22 104:16 105:10
commercializ... 88:3
commercialize 88:15
commercially 43:13 44:13,15 44:18,24 99:10 103:1 155:22
common 23:8
commonly 23:1
communication 184:16
communicati... 184:18
company 12:2 115:16 116:13 117:13 169:14
comparable 45:16
comparative 47:20
compare 72:6
compared 20:8
complete 82:12 98:21 100:2 105:25 190:13
completed 191:7,17 192:6
completely 41:14 174:12 176:10 180:12
completion 190:17 192:10
compliance 15:18 16:14,16 16:17,19,24 19:6,24 20:14
complications 22:20
composition 23:24 28:9 30:6,18 33:25 37:10 60:25 61:18 62:19 73:25 74:17 75:10,14 76:6 76:8 79:21 109:17 141:21 142:9 143:3

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 202

164:1,12 173:2 174:25 176:6 176:17 177:16 178:9 179:21
compositions 66:3,5 74:15 76:1 82:24 84:10 108:11 109:18 118:4 162:15 163:3,8 175:23
compound 118:5
compounds 118:5 161:16
compressed 161:9
comprises 62:19 175:1
comprising 66:5 164:11
concern 50:5 53:10,22 97:19 97:20
concerned 138:4
concerning 8:9
concluded 188:6
conclusion 169:16
concurred 56:21
condition 22:15 28:4,9,15,21 29:7 30:1,1,4 30:14 31:23 33:10,12 53:21 82:21 84:24 85:11 86:2 164:10,14,15
conditions 19:5 19:11,14 20:21 58:19 60:8 86:6 163:14,15 166:7
conducted 88:21,22
confidential 115:9 116:7
confusion 94:22
connection 81:18
consider 75:11 159:21,24 172:15
considerations 74:19 75:11,16
considered 122:7
considering 172:16
consistent 14:6 15:23
consists 122:25
constitute 15:19 16:4 44:14
constituting 44:24
contact 17:9,10 18:3,7,22 20:1 30:23 31:16 35:3 77:16 124:7 128:8,23 129:14 134:1 165:2,3 166:3 191:9,20
contacting 123:7,15 124:20 125:8 125:21 126:4 126:22,24 128:15 129:7 130:3 166:10
contacts 17:5 49:5
contain 35:5
contained 183:9
container 92:24
containing 45:15 71:4 145:4 162:16 163:8 173:2
contains 8:22 17:10 30:24 71:1 136:11
content 136:21
contents 92:24 92:25
contest 179:12
context 19:16 34:1,2 45:1 49:8,25 50:20 50:22 51:15 60:25 61:18 63:16 65:5 67:13 68:2 71:14,18 73:1 79:1,5,14 80:1 80:1,4 81:12 81:22 88:15 98:6 101:13 108:20 109:1 124:13 133:16 133:22 134:7 134:21 142:14 157:16 160:12 169:10 170:10 170:17,24 171:4 172:17 179:15 180:8
continue 23:15 26:16 54:4 86:8
continuing 3:1
contradiction 43:18 44:4
contradicts 70:4,6
contrast 54:13
contrasting 35:25 38:19
contrasts 39:12

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 203

controlled 10:12 37:18 86:15,20 87:17 88:5
conventional 11:25
conversation 72:24
cooley 2:19 3:2 3:8 5:11
cooley.com 2:21 3:5,10
copied 183:15
copy 188:4
correct 7:14,15 8:2,3,10 12:25 13:6 14:13 17:7,22,25 21:25 24:1 49:7 61:19 64:2 70:14 90:5 118:25 128:3 154:10 159:5 173:16 173:20,21 186:9,10,13,25 187:1 189:9 190:13
corrections 10:3 191:14,15 192:3,4
correctly 99:14
corticosteroid 24:2,9,12 25:2 25:19 26:4,9 26:19 27:9,12 27:20 28:20 29:1,19 33:13 36:13 62:20,23 66:6 116:24 123:1,7 124:20 125:21 126:3 129:7 131:5,9 131:21 132:10 133:6,20 134:5 134:25 140:20 143:17,23 144:1,4,5 145:5,6,12,23 146:12,16 147:2 162:16 162:18 163:9 163:10,16,19 163:25 164:4 164:22 165:21 166:1,3,9,21 167:19,23 171:11,19
corticosteroids 114:15 117:19 118:9,20 138:11,15,19 138:24 139:3,8 139:12,17,21 139:23 140:5 172:5 186:21 187:9
counsel 2:7 3:1 7:4 174:7,11 181:9,25 182:1 186:8,12,24 191:18,22 192:7
counted 8:6
counter 54:10
countries 90:1 90:2,12,15
county 190:2
couple 61:20 113:25 160:18 185:23
course 10:20,21 12:2 68:2 99:6 109:1
court 6:12 8:1 8:5
cousin 3:3 5:10 182:4 185:1
cover 132:17
coverage 32:21 33:3 79:6 87:9 88:2 94:7 96:16 102:9
covered 132:20 132:22 134:7
covers 130:25 132:15 133:17
creates 111:3
creating 138:4
crime 185:4
crohn's 171:13
crospovidone 153:11
crr 1:24
crystals 131:12
csr 1:25 190:25
cv 9:3

d

d 4:1 6:1
daily 87:9 92:4 96:18,19
dallen 3:10
danckwerts 46:17 47:21
data 86:23 89:7 103:8,10
date 146:24 191:16 192:5
dated 189:10
davies 1:14 2:1 4:3 5:4,14,22 6:1 9:16,17 12:5 13:15 14:23 47:22 57:24 60:12 61:1 62:4 68:15 76:13 89:16 100:15 107:15 108:2 120:1,17 135:9 135:19 136:13 137:24 140:14 151:8 168:19 173:8 174:20 174:20 181:20 185:3,24 187:19 189:3 189:16 191:5

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 204

davies's 173:23
day 38:17 62:23 96:12 97:7,16 99:6 182:12,20 189:10 190:21
days 96:22 97:1 103:18 105:3 105:22 106:20 106:22
dc 2:20 3:4,9
deanna 3:8 5:10
decision 81:4
declaration 8:24 9:15,20 9:20 10:4,7 12:10 37:24 40:15 47:11 60:11 63:17 78:11 107:16 114:9 119:4 120:21 121:22 122:4,11,21 124:18 135:20 137:22 143:10 146:7 147:14 151:2,6 168:19 173:20,23 183:4,18 189:1
declare 189:4,7
decrease 35:12
define 77:13 141:17
defined 36:1 38:20 79:8,8 150:20,21
defines 12:14
definitely 71:22
definition 12:22 14:5,9 53:1 155:10
definitions 41:24
degree 151:16
delay 93:14
deliver 51:8 163:18,25
delivered 54:4 100:21 178:4
delivering 131:4
delivery 10:12 28:20 46:18 47:19 48:3,9 48:17 49:19 74:1 146:25 148:9 169:18 170:3
demonstrate 44:23 57:2 76:11 104:6 167:18
demonstrating 74:11
depend 35:18 35:19 38:17 156:3,20 157:13 170:24
depends 18:2 32:4,13 34:1,2 35:20 37:4 49:25 51:12 72:2 79:1 88:12 89:2,5 98:3,4 116:22 123:17 155:7 157:15,15 158:3 160:12 170:9,14,17 171:4 175:25
deponent's 189:1
deposed 6:10 7:13,16,18,23
deposit 25:2 26:2,4,25 27:12,16,19 32:24 35:6
deposited 24:9 25:19 26:10,15 26:20,22 29:23 30:11 31:2,20 32:8 33:3,6 131:10 132:10 132:14 133:20 164:5 166:1
depositing 27:9 29:1 31:22 32:1,2 33:14 131:21 133:6
deposition 1:14 2:1 5:3,21 8:9 29:18 104:25 134:4 173:18 181:21 182:18 182:23 183:1,4 183:7 184:3,14 185:1,7 189:5 190:7,10,16 191:19,23,25 192:8,10
depositions 184:17
deposits 24:12
describe 75:6
described 57:8 57:14 58:25 59:11 77:2 78:9 79:11 80:14 81:23 100:17 105:6 121:7 122:1,9 129:24 130:20 131:17,25 132:16,18 133:3 150:9 164:7 175:23 176:6,17 177:17 178:9 179:21 188:1
describes 41:12 130:13
describing 112:7
description 4:10 13:19 14:14,15 15:23 17:1 21:16

Veritext Legal Solutions
Calendar-CA@veritext.com 866-299-5127

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 205

44:19 45:4,4 93:12 151:21
designed 10:20 11:1 18:21 42:2 43:22 46:21 51:16 52:12,13,24 67:12 69:1 85:15 107:21 108:6,11,24 109:7,19 114:6 127:18 139:1
designing 126:2
desirability 118:1
despite 35:22
detail 115:11
details 89:22
determine 105:21
determined 76:4 191:18,23 192:7
determining 11:21 74:19
develop 82:10 105:10 174:6
developed 26:24 146:19
development 81:5,6 82:19
developmental 93:14
dexterity 111:22
diagnosed 93:15
dictionary 41:24 42:25
die 161:8,11
diego 2:11,15
dies 161:10
difference 91:20 160:25
different 24:21 27:11 40:13 41:14 46:6,18 53:5 60:9 63:20 65:6,7 67:11,15 68:5 72:8,17,20 73:25 74:3,15 74:16,18,19 75:8,10,10,13 75:14,15,25 76:2,6,7,8,8,22 76:25 77:1 79:9,12,13,21 79:22,25 80:5 80:18 81:8,9 81:11 82:23,24 82:24,25 83:19 84:9,10 90:12 109:3 112:6 113:8 114:7 129:18,20 133:4 138:14 139:16 141:4 146:4 151:1 169:9 176:10 179:7 180:12
differently 24:19 73:13 109:11
difficult 19:6 19:20 20:15 77:15 83:21 84:4 85:3,11 110:20
difficulty 19:17 20:16 22:18,21 23:1,7 45:7 69:21 70:1 85:1,6 110:6 110:11,13 111:3,8,11,21 112:2,3,11,15 112:23 113:5 113:13,18,19
diffuse 127:12
dinner 135:10
directed 119:9 119:14 132:7 162:14 163:7 187:11
direction 190:12
directly 132:11 167:5
disagree 16:12 67:3 69:11 70:8 103:24 181:17
disclose 60:24 61:17 77:3,6,8 77:24 79:3,19 80:16 81:22 82:6 143:13 186:15,18,21 187:2,5,8
disclosed 68:7 73:16 134:14
discloses 66:12 67:20 68:23 70:10 81:7,14 120:8
disclosing 80:3 145:8
disclosure 61:5 77:23 145:4
disclosures 119:19
disconnect 83:4 132:25
discuss 12:9 27:17 137:21 139:7
discussed 15:11 20:1 59:20 67:13 73:15 77:10 96:14 138:3 168:3
discusses 136:17
discussing 169:5
discussion 15:7 62:10 82:17

83:1 107:25 168:3 169:2

disease 35:19 38:17 49:23 50:18 143:8 144:14 145:19 146:21 149:14 171:13

diseases 48:10 48:15,17 51:3 53:19 54:11,21 55:3,8,17,25 56:6,19 57:3,7 57:12 58:2,12 58:19,21

disintegrant 24:3 46:22 52:12,24 153:8 153:10

disintegrants 52:1,9,11,15,20 52:22,23

disintegrate 17:6,11 18:22 24:3,16 34:8 35:4 45:11 67:8,12 70:3 85:16 108:23 109:1,10,20 112:6,19 155:8 156:16 157:2 157:10,20 158:6,20 160:1 160:15

disintegrated 110:24

disintegrates 12:17 14:1 19:25 21:2 29:16,17 37:10 49:10 55:20 109:17,25 111:13 113:9 113:20 132:9 133:18

disintegrating 10:17,24 12:6 12:14 13:20,23 14:5,22 23:23 24:12,16 25:1 25:18 26:9 28:14 29:12 30:5 31:8 34:5 34:14 35:13 37:9 38:12 39:21 40:9 46:7 55:6,7,10 55:16,24 57:6 57:11,25 58:11 108:11,24 109:16,18 118:3 130:21 132:8 159:22 162:15 163:3,7 163:20 164:2

disintegration 15:15 16:10,21 17:2 26:13 29:18 34:9 60:6 131:8,20 158:17,21 165:4 166:15

disorders 19:7

dispersal 17:18

dispersed 17:12,19

dispersing 12:15 13:24 79:10 121:6,18 121:25 124:12 128:19 133:13

dispersion 17:23

dispute 114:13 118:4

disputing 94:6 94:7

dissolution 26:14 153:8

dissolve 18:7 18:22 25:17 26:8,17 29:22 34:23 35:5 42:23 43:9,22 44:8 46:23 49:1 52:17 66:15 69:5 77:12 111:16 113:7 123:21 126:6 127:21

dissolved 17:13 17:24 20:4 30:25 31:7 32:6 35:6 45:8 55:20 56:12 69:22 72:22 165:5 166:17

dissolves 20:1 26:14 43:25 50:12 66:16 110:17 127:11

dissolving 25:25 31:1,18 34:20 40:21 41:1,3,7,9,17 41:18 42:5,10 42:16,18 43:5 43:10,11,16 44:2,12,18,20 44:25 45:7,17 45:22,24 46:5 46:10,12 47:4 47:5 66:12,14 66:18,19 67:1 67:5,6,20 68:7 69:2,21 77:16 79:10 110:6,11 110:13 111:8 111:18,21 112:2,15,24 113:5,9,13,17 113:18 114:4 126:10

distinction 108:21

distinguish 138:18 146:22

distinguished 15:12

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 207

distinguishing 109:15
distribution 11:19,20
doctor 118:12
doctors 93:17
document 9:15 14:21 41:25 47:19,23 136:17 173:1 173:13 175:12 177:17 178:9 178:22
documentation 181:24
documented 98:21
documents 8:17,25 46:9 120:13,22 121:21 122:9 122:10,13,15 182:25 183:3,8 183:10 184:9 184:12
dohil 27:17 32:14,15,20 37:19 38:19 39:13 42:12 45:1,2,6,19 60:24 61:17,21 62:3,8,11 63:14,25 64:5 64:8,10,11,16 64:20,20,25 65:4,10,13,23 65:25 67:7 68:8 69:17 70:6 76:14,16 77:2,5,11 78:5 79:2,2,15,19 80:3,16 81:7 81:12,14,22,25 85:9 86:8 88:16 90:20,23 91:4 94:6 97:18,20 98:25 100:17 101:1,3 101:10,14,20 101:24 102:3 102:21 103:6 104:7 105:1,8 105:13 106:4,7 106:19 107:3 109:2 110:4,10 111:9 113:4,16 113:16 149:9 149:18 165:12
dohil's 40:5 44:19 45:16 61:5 77:23 79:16 90:21
doing 19:24 53:1 58:10 62:12 80:13 81:24 82:4 88:13 114:3,4 115:10 116:4 117:9 142:22 152:17 167:11 167:15 174:18 187:25 188:2
dosage 12:16 13:25 15:12 63:3,10,19,23 65:1,17 66:23 66:25 67:21 70:25 71:4,25 72:12 73:6,14 74:6,25 75:5 75:21 78:21 79:17 80:8 81:1,14 82:14 84:4
dosages 63:16 64:8,12 71:12 76:16
dose 67:10,16 71:9,21 73:21 74:20 75:8,9 75:23 76:11 77:3,6 79:3,13 79:19 80:3,17 81:7,23 82:6 82:12 97:15,16 109:24 164:16
doses 60:24 61:6,11,17 72:17 73:2,21 73:22 76:2 78:16 80:16 81:11 83:2 106:2,20
dosing 86:16 87:12
double 151:24
dr 1:4,14 2:1,8 5:4,7,22 9:17 12:5,13 13:15 14:23 25:23 27:23 28:22 29:20 34:18 37:8,10 38:10 39:16 40:25 41:12 42:13 43:10 44:11,23 46:1,3,13 47:7 47:10,22 56:2 56:10,20 57:1 57:15,24 58:5 59:1,20 60:12 61:1,5 62:4 68:15 76:13 84:22 85:22 89:16 100:15 107:15 108:2 117:25 120:1 120:17 122:13 135:9,19 136:13 137:24 140:14 143:25 144:18 148:23 151:8,15,21 168:19 173:20 173:23 174:20 179:14 181:20 181:23,24 183:21 185:3 185:24 187:19 191:4,5

draft 188:5
drew 133:4
dried 153:23
drinking 15:16 16:11,22
drive 2:10,14 6:2
driven 150:2
drug 10:12 11:19,22 17:12 18:6,6 19:22 20:2,3,17 21:4 25:8,9,25 26:1 26:14,14,16,22 26:25 29:22,22 30:25,25,25 31:8,17,18,18 31:19 32:6,7 34:10,12 35:4 35:6,6 41:4,6 42:3 43:24,25 45:15 46:24 47:19 48:3,9 48:16,23,24 49:1,2,4,5,6,11 49:19,22 50:5 50:12,15,17,24 50:24 51:1,4,9 52:18 53:2,4 53:11,22 54:22 54:23,23 55:20 55:21,21 56:14 57:18 58:23 68:3,4 69:1,2,6 70:14,16 72:19 73:23 74:14,20 77:18 79:22 89:15 90:14 117:16 119:15 123:15,22 124:6,14 125:6 125:7,8,14,15 126:7,20,22,24 127:1,3,11,11 128:7,8,14,14 128:21,23 129:12,14,20 130:2 131:11 132:13 133:25 134:1 142:17 143:14 144:25 163:21 165:4 166:19 167:4 170:5,6,7,14,18 170:25 175:1 175:14 176:5 176:16 177:25 178:3
drugs 46:4 47:8 48:14 50:3,9 50:21 53:8,15 53:18,24 54:6 55:11 56:3 84:14 85:16 116:19 138:6 138:11,14,16 138:19 139:3 139:16,18,22 140:4 141:1,7 141:9,23 142:2 143:7 144:13 146:20,21 147:6,19,24 148:3,6 149:3 149:15 150:12 168:1 169:3,3 169:6,21,23 170:13 171:1 171:20,21 176:24 177:5 177:12,13,15 178:4,7,13,17 178:21,22 179:6,13,19 180:13,18 186:13
due 34:25 103:12
duly 190:7

e

e 4:1,9 6:1,2 89:14 191:9,12 192:1
e.g. 19:7
earlier 62:10 62:12
early 159:22
earth 175:5,8
easily 106:23
easy 107:21 108:6,12,25 109:8,19 149:17
edits 10:3
ee 21:24 23:5 23:13 30:3 93:15
effect 19:23 20:19 54:24 59:2,3 84:3,11 85:19 86:4 95:14,18 96:12 126:25
effective 28:1 36:12 40:6 62:20 71:1,5 80:20 83:18 87:5 88:17 96:16 98:18 100:22 101:15 104:7 149:17 162:17,24 163:4,10,16,19 164:16 165:7 166:21 167:11 168:10
effectively 65:10 164:13
effects 50:4 53:9,16,20 54:8,21,25 125:3 171:2,2 171:8,9,17,18 172:11,14
efficacy 86:17 87:12
eight 102:16 106:14

Veritext Legal Solutions
Calendar-CA@veritext.com 866-299-5127

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 209

elaborate 170:15
electronic 184:12
electrostatic 178:2
eliminates 138:5
eliminating 18:23
ellodi 1:7 2:17 3:6 5:12 182:7 191:4
email 184:17
embodiment 45:18
embodiments 62:19,22 65:12 65:21 133:15
employed 133:13
employing 67:11
ends 121:16
england 1:16
enrolled 90:13
ensure 21:3 161:3
ensures 20:17
enteric 126:5 137:19 171:13
entire 31:9 32:17
entitled 9:15 14:21 47:19 173:1
eoe 22:2,4,6,9 22:12,16,22 23:2,5,8,13 29:8,13 30:4,9 30:15,18 31:12 31:23 32:25 33:3,6,10 36:4 36:12 64:21 79:6 80:2,25 81:18 82:11 83:1,18 90:5,7 90:10 95:18 98:22 99:11 100:3 104:7,23 105:25 124:11 141:6 145:7 148:10 149:8 150:17 165:8
eosinophilic 21:17,20,23 22:1,4 29:7 30:15 90:10
eosinphilic 30:2
ep0914818 120:15
ep65826 120:14
episode 185:10
equally 19:19 38:16 41:11 44:25 57:15 69:19 75:12 76:5 89:4 104:9 123:22 129:25 132:17 133:14
equipment 156:12 157:7
equivalents 46:19
ere 63:15
erode 42:2 48:25 69:8
erodes 70:15
eroding 53:4
errata 191:14 191:16 192:3,5
esophageal 62:21 87:8 96:15 123:15 124:7,21 125:21 126:4 128:8,23 129:8 129:14 130:3 134:1
esophagitis 21:17,21,24 22:1,4 29:8 30:2,15
esophagus 30:8 30:13,19 31:9 31:10,11,22 32:1,2,3,5,8,13 32:16,17,17,24 33:4,15 34:13 35:7 36:13 57:4 70:17 77:20 80:2 83:18 84:6,9 84:18 85:2,12 90:10 123:8 129:22 141:6 142:23 148:18 149:8 150:17 163:21 165:8 171:15 172:20
esq 2:10,14,19 3:3,8 191:1
essentially 25:13 46:7
estimate 7:20 8:4 182:16
et 40:9 167:12
ethylcellulose 123:23 124:6 125:2,6,14 126:6,21,24 127:1,4,6,12,19 127:24 134:23 134:24 135:7
eurand 120:8
european 77:22 78:2,2
evening 99:4,5
event 31:4,5 190:20
evidence 84:15
ex 13:5
exactly 46:16 154:14
examination 4:2 5:18 185:21 187:17

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 210

examined 5:15 190:6
example 27:4 45:18 64:2 67:25 82:2 87:23,23,24 104:5 123:20 130:16 149:20 152:5,10,13 153:12,19,24 153:25 160:17 164:3 171:5 176:5,16 178:21 179:4,6 179:19 180:18 186:12
examples 61:6 61:10 65:21 72:16 99:10 104:5 113:11 113:25 134:13 160:22 161:15 161:17 175:14 178:17
excerpts 136:11
excessive 137:1
excipient 18:5 29:23 116:15 117:11 153:3
excipients 11:20 17:20 25:10 26:2 31:1,17 136:12 152:20
exclude 65:18 73:6
excluded 65:2
excuse 7:25
exemplified 142:3
exhibit 4:11 8:23,24 9:1,1,3 9:9,10,14,17,23 10:7 13:1,7,9 13:13 14:17,21 14:23 18:11,20 21:6,9 23:15 37:24 47:12,17 47:18 51:20 60:11,22 61:24 62:1,5,7,13 86:10 89:9,13 90:23 91:5 107:16 110:4 118:10,16,22 119:5,21,23 120:2 122:4 130:7 134:8 135:20 136:4,7 136:10 137:22 140:10,12,15 151:3,5,8 152:4 160:20 162:10 168:20 172:23,24 173:10,23 174:4,12 176:25 181:6 181:10,16 186:1,1,8,11
exhibits 8:23 9:3,6 136:13 174:6
expect 27:2 40:8 45:14 81:10 94:16 129:22 139:23 175:22
expectation 40:10 83:5,13 83:16 84:16 105:15 106:10 149:23 150:1 167:9,15 168:5
expected 19:3 19:11,13 142:7 164:8 165:13 168:4
experience 10:11 39:10,19 42:20 56:21 58:16
experimentat... 71:6
expert 101:8
explain 19:13 48:19 108:19 126:17 144:9 151:17 163:21 164:23 166:23 170:12
explained 70:7 129:2 164:25 165:2
explaining 113:4
explains 69:17 101:14 144:21 151:15
explanation 126:15 132:23
explore 17:2 78:19 81:11
exposed 25:6
extensive 10:10
extent 36:7 64:2 181:13

f

f 89:14
face 42:11
fact 35:22 85:7 85:24 95:17 106:4 107:4 109:2 113:21 118:7 128:17 144:15 149:24 149:24 158:19
factors 35:20 37:4,5,13,21 38:14,18
failure 93:13
fair 6:25 12:24 20:7,10 34:25 43:6 44:10 51:9 82:14 96:23 105:22 116:20 122:19 169:21 171:1 181:12

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 211

falk 1:4 2:8 5:7 191:4
fall 125:23
familiar 14:23 21:20 22:16 62:4 86:20 151:8 152:10 155:15 159:15 169:20,22
familiarity 47:23 116:21 116:23
far 126:9
farfetched 141:11
fast 40:21 41:1 43:10,11 44:2 44:12,25 46:5 46:9,12
fda 14:15
federal 190:16 192:1,8,9
feel 107:8
field 41:10 101:9 149:25 181:14
fifth 143:12
figure 82:13
file 1:23
final 88:13 94:2
find 19:19 59:2 144:18,18
finding 82:12
finds 110:19
fine 12:8 13:17 107:12 140:16
finger 91:1
finished 171:24 187:21
firm 5:6,11
first 8:23 9:10 13:14 15:10 22:6 25:5,13 26:3,25 27:3 28:19 29:2 31:4 32:22 34:12 35:23 48:7 49:18 55:1,4 62:3 82:2 107:20 108:4 114:19 115:23 117:1 119:25 120:7 128:11 136:21 138:2 140:13 140:19 144:21 144:22,25 148:16 150:16 152:13 162:13 163:24 165:17 167:18,22,25 168:1,22 170:2 173:3,17
five 36:15,17 177:11,12
flow 89:21 161:4,5,7,8
fluid 92:7 96:6 99:12
flute 89:14
fluticasone 114:14 116:25 117:1,3,4,8,19 143:2 147:19 171:16 172:6 172:10,13,17 186:18 187:5
fly 174:6
focus 35:9 141:2
focused 102:6 121:24 172:16 183:8
follow 17:17 25:15 27:6 37:2 75:19 122:8
following 37:16 39:8 40:2 71:21
follows 5:16 191:8
food 22:19 34:2
force 156:1 157:5,6
foregoing 189:5,8 190:7 190:15
forget 150:19
form 11:7 12:16 13:25 15:12 18:1 20:11 22:23 23:3,9 24:20 25:21 28:17 29:14 30:10,20 31:13 32:19 33:7 34:17 35:1 38:9 39:22 42:8,19 44:21 49:16,24 51:10 52:4 57:13 58:14 59:10 64:18 67:4 70:12,25 72:14 73:9,18 74:9 75:3 77:9 77:25 80:9 81:2,20 82:15 85:5 87:19 88:11,25 90:16 92:1,17 93:1 94:3,19 95:12 97:3,12 98:2,7 98:8,15 99:7 99:22 101:12 102:17 103:21 105:4 106:15 109:12 111:6 111:24 112:12 113:2,14 123:16 124:8 124:24 125:24 126:18 127:8 128:1,24 129:15 130:23 131:6,23 132:6 139:13,25 142:10 144:7

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 212

145:13 147:25 150:8 152:19 153:5 157:14 158:1,14 159:11,23 162:3 163:22 165:24 169:7 170:8 171:3 176:8 177:1,6 177:18 178:10 178:23 179:22 180:20 184:16
formed 30:7
forms 71:4
formulate 83:6 98:5 102:10,11 170:10 171:22 172:10,13
formulated 91:9 98:4 102:16
formulating 10:17 76:14,17 84:4,17 85:1 169:2,20
formulation 10:11 11:19 26:24 27:15,18 28:4 29:2 39:13 40:6 42:1 55:20 61:11,13 63:18 63:19 65:7,11 65:15 66:13 67:23 70:10,14 71:17 72:3,7 73:20 75:14 76:12,22 78:17 79:4,9,16,17,20 79:25 80:4,5 81:7,9,25 82:22 83:19,20 83:25,25 84:8 84:12,25 85:7 85:20 90:21 97:19,21 98:5 98:23 99:11,12 99:13,18 100:1 100:24 102:5,7 102:12 103:8 104:11 105:10 105:15 106:1,2 106:11,17,19 109:4 115:12 131:11 138:4 139:24 140:23 141:15 142:20 146:19 148:20 148:21 149:5 149:12,19,20 152:14,17 153:10,17,19 153:20 164:6 165:14 166:5 168:9 169:23 170:7,25 176:10,12
formulations 10:19,23,23,25 11:1,3,4,6,12 11:18 46:6,7 46:18 61:12 63:5,12,15,20 63:24 64:1,9 64:13,21 65:2 65:5,19,22 67:25 68:1 71:16,19,23 72:1,2,6,16 73:7 74:2,8,11 75:24 76:1 77:4 78:16,21 78:24,25 79:8 79:21 80:17 82:7,23 98:7 99:17 100:5 114:24 115:6 116:23 119:9 124:12 125:11 126:10 127:18 132:15,16,18 132:18,19 138:5,12 143:6
formulator 23:10,11
forth 9:4
forward 46:3 46:13 47:7 57:16
found 14:15 40:6 43:11 59:3 77:23 83:18 133:19 165:6 166:14
four 93:24 185:10
fourth 61:4 135:23
frame 115:24 116:10
frank 129:16
frankly 104:18 141:5 145:14 156:13
frcp 192:1
friability 158:16,24 159:4,15,22,25 160:4,9,11,14
friction 161:6 161:10,25
friend 184:22
full 5:24 78:14 160:6
function 11:21 143:8 170:20 171:11
functions 72:7 155:7
further 51:13 135:5 151:17 153:12 187:14 187:24 190:19

g

gag 111:22
gain 98:21
gastrointestinal 24:10,13 25:2 25:12,20 26:5

Veritext Legal Solutions
Calendar-CA@veritext.com 866-299-5127

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 213

26:10,16,20 27:1,5,10,12,16 27:20 28:16 29:1 30:12 31:3,20 114:16 118:2 131:5,22 132:11,14 133:7,21 134:5 143:18 144:6 145:1,24 146:12,17 147:2 148:10 162:19 163:5 163:11 164:5 164:10,23 165:19,22 166:2,4,11,19 167:14,20,24 170:4,21 172:19 179:18

gel 123:8

gelatin 138:5 138:21 142:15 143:6 145:17 146:19 148:12

general 22:13 65:15 71:8 114:25 119:9 142:13 143:14 144:17 151:25

generally 11:11 64:17 119:14 151:23

generate 45:13

generated 37:15 38:6,7 39:1,7,18 40:1 76:8 84:11

generating 45:14

generic 140:2

geriatric 19:4 19:17 20:14

germany 90:3

getting 56:13 56:13 115:11

gi 17:15 20:4 26:23 28:21 29:4,19,23 30:1 32:24 33:14 55:13 57:4,18 58:5 118:6 131:10 145:6 166:6

give 6:8,14 8:4 66:17 89:2 95:16 97:10 100:1 101:5 104:4 113:11 113:25 115:9 115:24 116:10 119:3 121:11 142:25 163:17 171:4 172:18 182:16

given 33:20 61:10 102:20 106:21 129:18 181:1

gives 66:15 71:11 75:5

giving 63:16 65:11 96:11 97:16 126:25 180:11

glad 147:13

glidant 160:25 161:2,2,21,23 161:24

glidants 160:23 161:3,4,13,16 161:17 162:2

glucagon 175:16 176:15

glucocorticoid 172:3

gmbh 1:4 2:8 191:4

go 8:25 9:5 20:4 27:14 37:12 38:14 55:1 78:10 79:1 81:4 86:11,25 87:11 88:3,4 96:13 104:24 107:24 110:23 112:5 114:8 125:4,4 127:2 130:8 135:16 147:14 148:18 149:9 150:18 162:10 174:16 185:25 186:11,24 188:3

god 103:4

goes 43:18 50:2 50:8 52:5 71:11,15,20 129:19,19 135:4,5 151:17 162:19 175:10

going 5:21 6:11 6:12,18 15:1 34:19,22 36:14 47:22 60:13,15 69:11 75:19 78:19 80:7,24 81:8 82:10 84:24 90:25 100:9 103:8 105:5 106:7 113:15 125:20 130:8 164:23 167:9,12 168:11 173:22 179:8 181:2,9 185:25

good 5:20 21:2 60:7,17 81:17 86:23 87:22 94:7 102:8 104:22 105:12 107:9 109:24 116:20,22 135:13 147:13 155:2,6 158:16 159:21,25 160:5,6,14

181:15
google 60:1,4
gradually 43:25 48:22,25 50:23 52:17 53:3 68:3 69:7 70:15 127:3
graduate 10:21
granulating 153:22
granules 133:13
great 60:18 104:22
grind 45:10 109:3 110:22 111:14 112:16 113:6
grinding 111:18 113:22
grother 137:21 138:3,10,24 139:1,4,8,21 140:2,7,13,15 140:17 141:1,3 141:4,23 143:13,15,21 143:25,25 144:3,12,16,23 145:4,7,9,10,15 145:16,20,21 146:2,9,13,18 147:5,18,22 148:1,2,8,21 149:2,13 150:4 150:10,22 179:12
grother's 139:11,24 140:23 141:15 141:21 142:8 143:3 149:5
ground 6:11 45:8 69:22 82:13
grounds 6:2
group 87:24 89:5
guarantee 83:10,11 85:23 85:24
guess 34:7,18 35:16 90:17,18 94:12 182:19
guidance 14:16 14:21 75:5
guided 81:12 82:5

h

h 4:9
halfway 15:6 40:19 66:4
hall 6:2
hand 190:21
handbook 136:11
handled 191:8
happen 127:7 164:24
happening 163:18 164:21
happy 104:4 108:19
hardness 155:11,12,15 155:21 156:3 156:11,15,18 156:20,23,25 157:13,17,19 157:25 158:4,9 158:11 159:20 160:14
header 15:7 18:17 21:12 48:3 60:23 61:4 89:21 119:8 136:21
heading 122:6
hear 5:22 92:2 120:17 132:22
held 48:22 50:23
help 51:8,15 161:4
helps 153:7
high 115:9 126:15
highlight 91:21 138:17 139:4,8 139:18
highlighted 47:13 66:9
hindsight 83:23 150:2,15
history 93:13
hold 174:7
holds 153:20
holes 127:23 128:20 129:11
home 5:24 100:4
hope 8:15
hopefully 9:5
hour 7:8 36:15 100:10 168:12 182:20
hours 97:1 102:16 103:18 105:3,22,23 106:13,14,14 106:14 182:17 182:19,20
house 183:23 184:6
huge 148:5 149:15
hundreds 138:14,15 139:3,17 179:3
hydration 38:17
hydroxypropyl 135:25
hygroscopic 136:25 137:5,7
hypothetical 82:9 83:8 84:20

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 215

hypothetically 80:7,23

i

i.e. 30:12 33:14 55:19 108:25 109:19 113:6 120:25 131:11 141:25 156:16 157:10
iagarwal 2:21
identification 172:24
identify 43:10 44:12,25 189:6
idiopathic 185:8
ignore 150:4,7
ii 18:16
iii 15:7
illustrate 89:7
illustrates 85:10
illustrating 47:7 72:15 145:17
illustration 169:8
immediate 66:19 70:19 102:15
immediately 97:10
immobilized 177:25
impact 157:25 160:10
impacted 156:1
impacting 37:13,21 38:15
impaction 22:19
impaired 19:5 19:12,14 20:8 20:22 21:1
important 40:4 180:18
improve 161:5
inaudible 54:14
include 30:2 52:11,23 64:14 118:21 131:16 138:11 175:15 178:18 180:18
included 64:19 87:16 148:5 176:5,16 178:21 180:23 191:14 192:3
includes 21:17 140:3,4 149:2 172:5
including 45:23 59:22 68:2 139:17
incompatible 130:21 131:4
increase 33:24 34:5,16,24 35:12 92:6
increased 98:20
increases 37:5 96:6
independent 183:6
indicate 139:22
indicated 27:23
indicates 21:23 49:18 53:25 161:15
indication 66:15,17 67:7 69:4
indicia 56:25
individual 62:24 87:23 164:11
individuals 19:19 21:3 87:6 88:18
industry 14:22 157:7 169:15
infancy 93:14
inflamed 33:5 123:8 124:15 124:21 126:4 128:15 129:7 130:3 162:18 163:11 165:9 166:3,6,10,20 166:22 167:6 167:24 171:15
inflammation 62:21 84:5 85:2 114:15 118:1,6 163:4 172:19
inflammatory 28:3,9,15,21 30:1,14,17 31:23 33:9,12 164:10,14,15
information 33:5 59:20 86:16 87:12 135:2
ingest 15:16 16:11,22
ingesting 38:11
ingredient 17:21 141:21 142:8 143:3 152:13
inhalation 115:22 116:9 117:10,16 171:12
inhaler 116:16 117:12
inhibit 133:22 134:4
initially 19:3
innovative 27:21 85:8
insight 103:19 110:12 111:4 112:22,25 132:24 163:17

insoluble 123:1 123:14 124:5 125:1,19 126:16,20 127:17 128:6 128:21 129:12 130:14,19 131:16,19 132:25 135:7
instance 183:13
instant 71:7
instructed 7:4
instruction 75:19
instruments 156:24
insulin 175:15 175:22 176:4 176:11
intact 18:24 124:14
integrity 158:5 158:10,12 160:9
intended 15:13 49:10,11 52:6 124:1 125:3,4 125:10,11
inter 36:11
interaction 178:2
interactions 117:15
interacts 115:21 116:14 117:11
interested 19:10 190:19
interesting 59:4 104:10
interjecting 174:12
international 88:23
interpret 70:8 72:10
interrupt 172:8
intestinal 144:20
intestine 20:5 51:2 54:20 123:22 125:5 127:2,10 129:19
intraoral 47:19 48:3 50:10
intrapatient 36:11
invention 12:16 13:25 21:13 36:8 71:7,15 71:17
inventor 13:14 119:25 140:13 143:25 173:3 174:21
inventor's 62:3
inventors 25:4 26:23 27:22 28:1,24 146:14 173:7
involved 10:16 10:18,22 11:15 90:17
involves 166:9
ipr 5:4
ipr2024-01197 1:4
irrespective 157:18
isha 2:19 5:9 182:3 183:16 184:20,25 187:19
isolated 93:15
issue 59:18 67:19 98:9 111:22 177:23
issues 103:5 116:17 147:10

j

j 2:14
jcousin 3:5
joined 5:5
jon 3:3 5:10
jonathan 182:4 185:1 187:20
journal 93:18
judge 126:17
july 1:15 2:2 5:1 190:21 191:3
jump 179:8
juniper 12:3
jurisdiction 78:5
justify 44:19

k

keep 60:15 91:1 103:14
kept 50:11
key 183:18
kilogram 71:10
kind 11:17,22 15:6 18:15 38:3 45:13,15 47:13 59:25 89:10 91:10 98:5 109:3 117:14 119:13 124:11 126:11 126:14 142:19 146:4 149:19 158:2 176:10 180:12,15,24 180:25
kinds 46:6 58:19,19 59:22 63:20 177:12
knew 36:1 46:11 56:25 57:1 148:21
knobbe 2:9,13 5:7
knobbe.com 2:12,16 191:2
know 6:23 7:10 7:18,19 9:11 13:10 14:18

Veritext Legal Solutions
Calendar-CA@veritext.com 866-299-5127

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 217

15:3 18:12 21:6,10 22:22 22:24 23:1,4,7 23:12,18 26:23 28:3 33:2 34:1 35:17,21 36:7 36:7 39:6,7,14 40:16 41:9,11 41:16,20,25 43:7,9 44:6 45:3 46:6,22 49:8 50:7 52:22 54:15 58:3 59:2,14 60:4 61:24 62:16 67:24 70:8,22 72:5,8 72:21 75:4,6 75:25 76:3,19 76:21,24 78:1 79:11 80:11,18 83:23 84:7,9 84:10,12 85:24 86:12 88:22 89:11 90:24 91:6 93:2 94:23 95:14 96:7 97:2 98:6 98:8,13 99:23 100:2,25 102:25 103:4 104:16 105:7 105:10,11 107:17 108:19 109:21 111:10 111:25 112:11 113:19 114:9 119:6 122:15 122:21 125:18 128:5,9 129:16 133:11 134:11 135:2 137:24 142:13 143:9 143:21 144:15 146:23,23,24 148:8,11 151:12 152:7 156:25 159:12 165:1,15,15 167:2 168:5,8 169:12 171:9 171:11 174:18 176:24 179:1,4 179:4 180:10 183:12 186:6,7

knowing 85:21 150:15

knowledge 42:11,21,24 44:5 59:19 169:13 181:14

known 11:17 44:9 114:20 117:2,3,4 137:17

l

l 89:14

l.p. 1:7 2:17 3:6

language 162:23

large 70:2 83:1

larger 38:16 86:15 87:17,21 87:24 88:4,7 88:21 89:5 115:15,17

law 5:6,11

laws 189:8

layman's 14:12

leach 125:7 126:7

leads 22:18

leaving 69:6

left 136:21

legal 191:7

letting 70:21 114:9

level 115:9 126:15

light 67:13

likely 88:23 106:21

limitation 24:4 24:6

limited 63:23 64:9 74:7 166:16,17 175:15

line 13:19 21:16 24:5,6 130:10,20 134:13 140:18 152:15 153:13 160:21 184:18 191:15 192:4

lines 13:2 118:10,11,16 118:23,23 121:17 161:15

liquid 27:15,18 28:23 36:9 37:11,15 38:5 38:7,13,20 39:1,7,13,17 40:1 61:10,12 63:15,18,24 64:1,3,9,13,21 65:7,11,22 67:16 68:1,1 71:16,17,17,18 71:21,23 72:6 73:20,21,21 74:2,7,11,17 75:9,13,24 76:1,12,22 78:16,20,24 79:3,7,16,20,25 80:4,17 81:7 82:7,22 83:20 83:25,25 84:11 84:25 85:7,20 91:18,20 98:7 132:19 148:18 150:20 165:12 165:14 167:10 167:10

liquids 15:16 16:11,22 18:24 88:19

list 122:13 146:20 147:5 147:19,24 148:3,5,6 149:3,15,15 150:12 161:18 173:7 177:5,10 186:12
listed 118:10 118:21 138:15 139:3 140:19 174:21 176:24 177:15 178:7 178:22 179:19
listing 139:21 161:17
lists 139:15 141:7 144:13 172:4 179:13
literally 155:24
literature 43:4 43:15 45:25 47:4,6 55:15 55:24 56:2 57:5,10,25 58:7,11 114:21 114:23 143:5 183:17
litigation 78:4
little 33:21 48:19 60:13 78:19 85:3 108:15 112:22 119:2 123:11 126:14 132:2 135:11 153:12 162:19 170:12
live 6:3
lives 104:18
llp 2:9,13,19 3:2,8 5:11
local 48:10,15 48:17 49:20 51:3 53:19 54:11,21 55:2 55:8,16,25 56:6,19 57:7 57:12 58:1,12 58:20
locally 51:4,5 53:17,21 54:16 54:24 56:24
located 183:22
location 82:3
locked 191:12 192:1
long 47:1 86:17 87:13 95:9 96:25 97:25 98:13 99:20 100:19 101:10 103:14,16 104:17 114:25 147:19 148:3,6 149:25 150:12 177:5
longer 45:13 117:5
look 13:7 14:14 14:16 20:10 24:4 28:5 29:6 37:23 41:7,18 42:6,17 45:6 46:1 51:19 53:7 55:15,23 56:5,17,23,24 60:3,3 61:20 65:25 68:10 75:20,22 76:15 76:20 79:24 87:4 90:5,6,21 97:4,14 110:3 119:18 121:23 130:5 131:7 135:3,8 140:7 152:5 156:7 157:4 158:4,17 160:1 162:5,6 174:23 177:5 177:10,11 178:16 181:1 184:12
looked 56:20 102:11 115:20 116:19 183:15
looking 10:9 11:5,21 18:19 23:15 30:4 37:25 40:19 41:20 48:2 54:21 60:22 61:4 63:22 65:17 66:2 70:24 74:6,10 74:11,12 75:18 76:14 82:19 86:8,14 89:25 90:1 91:8 102:4,23 112:22 114:12 116:13,14 117:9,10 120:25 121:5 121:16 122:24 130:9 134:13 135:23 138:2 140:18 143:12 153:24 155:11 158:15,24 160:21 162:13 162:23 174:23 183:19
looks 154:13 159:9
lot 8:19 141:7
lovely 168:14
low 159:13 160:13 171:9 171:10,18,19
lower 72:21
lozenge 41:1,3 41:3,25 42:1 42:12,23 43:2 43:7,8,8,11,21 43:22,25 44:3 44:13,18,20 45:1,2,3,7,8,12 45:25 46:5,10 46:12,16 47:4 47:5 48:19,21

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 219

48:23,25 49:18
49:22 50:11,22
51:7,14,16
52:15,25 53:3
53:4 54:23
58:22,22 68:3
68:11,20,23,25
69:3,5,9,9,13
69:16,16,19,21
70:2,13 72:3
72:13,18 73:1
73:7,15,23
74:2,13,17,24
75:2,5,9,14,20
76:1,7,15,18,24
77:7,11,18
78:6,7 108:21
109:2,3,15
110:7,11,14,17
110:18,21,25
111:4,8,12,12
111:17,17,22
112:3,11,16,18
112:24 113:6
113:13,17,19
113:22,22
114:4,5
lozenges 40:14
40:21 41:8,10
41:13,17,19
42:5,10,16,18
43:5,11,14,16
44:7,14,24
45:22 46:20,21
48:8,14 51:24
51:24,25 52:8
52:19,21 53:14
53:25 54:7
55:2 58:20
68:6,7 77:15
lp 191:4
lubricant
153:18 161:1,2
161:10,21,22
161:24
lubricants
160:23 161:6
161:13,16,18
162:2
luman 2:10 4:4
4:6 5:3,5,19,20
11:10 13:12
14:20 18:10
20:20 22:25
23:6,14 24:24
26:6 29:5
30:16 31:6,24
33:1 34:21
35:8 36:17,21
36:24 38:23
40:12 42:14
43:3 45:20
47:18 49:17
50:16 51:18
52:7 57:23
59:6,13,24
60:12,17,21
62:1 63:21
64:23 67:18
70:18 73:4,12
74:5,23 75:17
77:21 80:21
81:13 82:8
83:3 86:7 88:6
88:20 89:8,13
90:19 92:9,21
93:6 94:9 95:8
95:19 97:8,23
98:10 99:1,15
100:7,12 102:1
103:11,24
104:2 105:19
107:8,14,24
108:1 109:5
110:2 111:20
112:8,21
113:10,24
119:23 121:10
124:4,16
125:16 126:13
127:5,15 128:4
129:9 130:4
131:2,14 132:1
132:21 135:8
135:13,16,18
136:10 139:20
140:6,11
142:24 144:10
145:25 147:4
147:12 149:1
150:25 151:5
152:23 153:9
157:23 158:8
158:23 159:14
160:3 162:8
164:17 166:8
168:15,18
169:19 170:11
171:6 172:21
172:25 173:6
173:13,17,21
174:2,7,14,19
175:20 176:3
176:14,23
177:4,9 178:5
178:15 179:2
180:1,17 181:4
181:8,12,19
185:14 186:3
187:15,18,24
188:3 191:1
lunch 184:20

m

machine
155:24
machines
155:22
made 16:15,17
38:20 52:8,15
52:19,21,22
91:15 93:19
97:5 98:17
100:20 102:20
154:8,23
160:10,13,17
174:9
magnesium
153:13,16
161:23

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 220

mail 8:9
major 22:22
make 10:4 30:22 44:2 72:4 75:20 80:24 92:13 95:15 96:4,6 100:16,24 101:4,17 102:11,24 104:11 105:14 105:16 106:1 106:17,19,23 107:2 117:12 191:14 192:3
makes 39:14 148:22
making 11:15 63:17 67:17 72:23,24 79:14 79:23 87:24 94:11 97:15 112:17
male 93:12 98:19
mammalian 138:5
man 97:6
mannitol 152:14,17,25 153:3
manufactured 51:24
march 185:10
mark 1:24 2:3 172:22 190:4
marked 4:14 172:24
martens 2:9,13 5:7
martyn 1:14 2:1 4:3 5:14 6:1 9:15 173:8 174:20 189:3 189:16 191:5
mask 124:1,12 129:18 132:15
masked 131:12
masking 119:2 119:9,14 120:8 122:25 123:14 123:18,25 125:2 126:11 126:15,19 128:6 129:5 130:13,17,25 131:3,16 133:15 134:24
material 137:20
materials 115:21 116:15 116:16 117:12 122:6 142:15 145:18 148:13 161:12
matter 5:4,8 93:10 97:9,14
mcclure 1:24 2:3 190:4
mean 11:8 17:24 18:2 30:23 32:4,13 33:6 58:18 73:1,1 77:15 85:2 95:5 102:14 106:14 116:22 123:17 123:19 124:17 137:4 141:25 143:21 145:10 146:5 149:2 154:22 156:13 159:1 163:2 166:12,25 169:25 175:25 176:2 183:12
meaning 69:12
means 43:8 46:16 69:4,18 77:13 108:16 132:13 137:6 144:9,12 166:23 167:2,3 167:7
meant 43:8,23 53:1,2
measure 155:20 157:6
measured 154:12 156:14 156:14,18,25 157:19 158:20
measurement 156:3,20,23 157:13,17,25
measuring 155:15 156:1 156:10 159:15
mechanics 92:12 94:10
mechanism 49:14 74:1 75:10,15 76:7 79:22
mechanisms 74:16
mechanistica... 163:18
medical 93:20 93:20 96:8
medicines 54:9
meet 182:2,7,9 182:13
meeting 184:14
mention 116:8
mentioned 32:12 64:5 87:14 88:7 95:20 96:17 115:5,23 147:5 156:18 158:9
mentions 160:22
message 184:22
messaging 184:18

Veritext Legal Solutions
Calendar-CA@veritext.com 866-299-5127

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 221

met 182:17
metabolized 171:10
metallic 162:1
method 28:2,8 29:25 30:13 31:22 33:9 120:8 160:10 164:9
methylcellul... 135:25
micrograms 71:10 91:15
microgranules 121:6,19,25 128:19
micronized 115:12,13,14 116:5
microparticles 173:3
milligrams 62:22,22 63:4 63:5,11,11 65:1,18,18 66:25 76:17,17 81:15,15 154:3 154:6,25
milliliters 26:7 26:18 27:8 28:13 29:11 33:19 34:23 38:7 93:24,24 94:1
millimeters 154:18,23
mils 25:24 26:12 27:15,19 27:24 28:23 29:20 32:9 34:19 35:15 36:1,5 37:11 38:13 45:16,19 85:19 92:8,20 93:5,22 94:5,7 95:2,16 96:11 96:15 97:16 98:17 102:8 104:6,21 106:5 107:5
mind 9:22 14:16 21:5 24:22 36:16 40:15 60:10 68:8 70:21 78:12 86:10 89:9 114:8,9 144:1 152:4 175:11
mineralocorti... 172:3
minimizes 161:10
minimum 38:7
minnick 2:14 5:6
minor 22:22
minute 33:17 95:10,10 107:11 168:15 185:16
minutes 12:9 36:15,17,18,19 40:14 60:14,17 86:9 90:22 97:2 103:19 105:3,22,23 137:22 151:2
misheard 63:6
mispronounce 87:2
missing 132:23
misunderstood 90:8 173:24
mix 92:15,24 93:3 94:25,25 95:9,13,15 97:10 99:2,4 99:18 101:9
mixed 30:18 49:21 92:5,19 98:12 103:17 115:13
mixes 30:6 31:7 93:9
mixing 30:7 91:16 94:16,23 105:2 115:13
mixture 109:9
ml 87:8
mode 19:2
moisture 136:21 137:1,9 137:13,16
molecular 12:3
molecule 176:21
moment 67:14 183:22 185:8
mometasone 117:4,23
monitoring 39:19
month 96:22
months 96:20 97:17 98:18 99:25
morning 99:4
motivated 128:25 129:3 129:11 148:2 148:15 149:4 150:2,13,14
motivation 147:18,23 148:16,25 149:23 150:11 150:23
motivational 125:18
mouth 10:20 11:2 14:11 17:8,14 18:9 19:25 28:23 33:25 34:3,5,8 34:20 35:4,14 35:16 37:7 38:8 39:7,11 40:2 41:4,13

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 222

41:14 42:3 43:23 44:8 45:12 46:8,19 46:23 48:10,15 48:17,21,22 49:3,5,10,19,23 50:8,12,18,23 50:25 51:3,5 51:13 52:14 53:19 54:11,21 55:3,8,17,25 56:6,19 57:7 57:12 58:1,12 58:21 59:23 69:25 70:2,16 72:20 77:16,19 85:16 108:25 109:20 110:16 110:20,25 111:4,9,12,16 112:4,18 113:6 113:9 114:5 125:9 126:23 128:22 129:13 165:3
move 149:11,16 149:18 150:22 151:1 181:10 181:15,18
moved 145:17
mucosa 56:14
mucosal 87:8
multinational 89:6
multiple 46:13 106:2,20 107:6 139:16 140:4,4 141:23 164:25 181:15
multitude 143:7

n

n 4:1
name 5:5,20,24 13:14 47:20 62:3 119:25 140:13 173:3,7
named 13:14 62:3 190:6,11
names 87:2
nate 2:10 5:5 5:20 100:9 191:1
nate.luman 2:12 191:2
nature 33:13 60:6 133:23
near 18:15 91:10 176:12
necessarily 17:24 61:12 78:17,25
necessary 136:25 191:14 192:3
need 7:3 15:15 16:10,21 18:23 27:11 30:8,19 31:9,9 45:10 75:8 79:13 100:12,25 111:14 149:4 164:11
needed 9:7 76:11 97:10
needs 20:9
negative 97:21 175:1
neither 174:12
never 50:4 53:10 167:8 171:14 173:12
new 138:20 144:23 146:19 148:11 174:12 177:24,25
news 56:25
newtons 155:12 156:2 158:11
nm 2:20 3:3,9
nmt 158:25
non 143:6
nonabsorbed 95:22
nos 134:15
notating 191:15 192:4
notthingham 1:16
nottingham 6:3 173:8 183:24
number 4:10 4:15 7:18,19 113:3,11 117:25 120:12 159:9 169:9 186:5 191:15 192:4
numbers 15:2
numeral 15:7 18:16

o

oath 6:4
object 7:2 173:22 174:4
objection 11:7 18:1 20:11 22:23 23:3,9 24:20 25:21 28:17 29:14 30:10,20 31:13 32:19 33:7 34:17 35:1 38:9 39:22 42:8,19 44:21 49:16,24 51:10 52:4 57:13 58:14 59:10,16 64:18 67:4 70:12 72:14 73:9,18 74:9 75:3 77:9,25 80:9 81:2,20 82:15 85:5 87:19 88:11,25 90:16 92:1,17 93:1 94:3,19 95:12 97:3,12 98:2,15 99:7

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 223

99:22 101:12
102:17 103:21
103:22 105:4
106:15 109:12
111:6,24
112:12 113:2
113:14 123:16
124:8,24
125:24 126:18
127:8 128:1,24
129:15 130:23
131:6,23 132:6
139:13,25
142:10 144:7
145:13 146:8
147:8,25 150:8
152:19 153:5
157:14 158:1
158:14 159:11
159:23 162:3
163:22 165:24
169:7 170:8
171:3 174:9
175:24 176:7
176:19 177:1,6
177:18 178:10
178:23 179:22
180:20 181:7

objections
63:13 174:8
180:4

obligation
174:5

obviously
19:21

odt 12:15,23
13:24 14:7,15
15:11,20,25
16:5 17:4,5,6,8
17:11,19,20,21
18:3 19:24
20:7,16 21:1
25:5,6,7,13
27:2,4,10,22,25
28:19,24 29:2
29:3,16,21
30:8,23 31:16
32:5,22,23
34:14,20,23,25
35:3,16,22,23
36:3,10 37:6
37:16,19,20
38:12 39:8,15
40:2,4,11
41:15 42:2,23
43:9,22 45:5,9
45:10 49:9
53:6 55:18
57:16 58:4,16
65:14,16 66:16
66:16,17,20
67:6,8,8,11,12
68:5 69:20,24
70:3,5 72:7,17
72:21 73:3
74:1,3,18
75:12 76:5,11
76:25 77:3,6,8
77:12,15,17,24
78:8 79:3,9,17
79:19,25 80:3
80:7,13,18,20
80:24 81:8,17
81:23 82:2,6
82:10,12,20
83:16,17,24
84:2,5,17,23
85:1,15,18
86:4,6 103:8
108:17,22
110:16,22,23
111:13,15
112:5,17 113:8
113:8,20,23
119:9 124:2,7
125:22 126:2
126:23 128:12
129:23 131:4
133:18 138:4,5
138:12 139:1
139:11,24
140:23 141:1,5
141:15 142:8
143:3,6,14,16
143:22 144:19
144:23,24
145:4,11,22
146:11,15,19
148:14,17,22
149:5,12
150:16 155:2,6
155:6,10 164:8
164:19,21
165:1,11,13,18
166:14 167:8
167:12,13,23
167:25 168:4,7
170:1,20,22
171:14 172:17
172:18 175:7
179:9,13,17

odts 12:6,9
16:16 19:10,13
19:20 34:7
43:13 44:13,16
44:24 46:3,3
46:14,19 47:7
55:12 56:2,5,8
56:12,18,22,23
57:2,20 58:16
59:19,20 60:5
65:6 84:14,15
107:2,21 108:5
108:17,24
109:7 114:4
119:14 125:3
141:25 142:22
144:17 145:15
146:24 149:8
154:7 156:9,17
157:11,21
158:19 160:2,5
160:16 163:24
170:1,3 176:11
179:5,10 181:3
187:11

office 1:1 8:16
77:22 78:2
183:14 191:11

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 224

oh 90:10 103:3 135:13
okay 5:22 6:20 7:11 8:17 9:8 12:7 13:15 14:19 21:5 22:3 36:20 47:16,23 62:7 68:17 76:23 85:9 91:23 107:11 116:25 117:7 120:1 121:11,20 122:3,17 125:3 134:8 135:1 137:18 140:14 142:11 147:16 154:11 179:9 184:7,20
okubo 173:4
old 93:12 97:6 98:19
olson 2:9,13
once 29:16 87:9
ones 42:13 117:22 118:21 121:24 184:13
onwards 163:14
ooo 188:7
open 8:13 91:24 92:14 94:25
opened 8:14
opinion 35:11 38:25 39:17 43:17 44:5,17 61:17,22 63:2 63:9 64:24 73:5 89:2 99:20 100:18 100:20,21 101:8 103:16 104:25 123:13 167:17
opinions 134:20 174:6 181:13
opposed 25:14 50:25 54:24
opposing 186:8 186:12,24
opposite 107:4
oral 12:17 14:1 14:10 15:14 16:10,20 17:1 17:6,9 24:17 33:19 46:18 48:8 50:13,14 50:17 54:2 56:14 58:20,22 58:22 87:4 91:14,19 92:5 92:18 93:3 95:1,15 96:25 97:24 99:9 100:5 101:22 105:1,11 126:22,25
172:4
orally 10:17,24 12:5,14,15 13:19,23,24 14:5,22 23:23 24:11,16 25:1 25:18 26:8 28:14 29:12 30:5 31:8 34:4 35:13 39:20 40:9 55:6,7,10 55:15,24 57:6 57:11,25 58:11 108:10,24 109:16,18 118:3 130:21 132:8 162:14 163:2,7
order 8:25 27:11 30:17 31:11 33:21,22 44:19 115:2 147:22
ordered 115:13
ordinary 14:6 15:24 37:20 39:5,6,25 41:21,22 42:22 43:2,19,20 44:1 46:11,15 60:5 63:2 65:3 65:9,13,22 72:8 74:3,20 75:7,7,22 76:3 76:20 78:7,23 79:7 80:6,11 80:12 84:22 94:20,22 95:3 103:2 104:9 105:7 106:3,16 123:24 138:9 138:23,25 140:22,25 141:8,19,24 146:24 150:7 151:15,22 175:21
original 190:15 191:10,20,22
overcomes 19:24
overcoming 104:22
own 39:10 189:6
owner 1:8 2:17 3:6 5:12 9:2

p

p.m. 2:2 5:1 135:9,12 188:6
package 92:22
packet 92:5
packets 91:16 91:24 92:14,19 92:22,23,25 93:4,25 94:16 94:24,25 99:19
page 4:2,10,15 9:22,25 10:1 15:1,2,7 18:12

18:16,20 37:23 38:3 47:25 51:20 78:14 89:19 136:16 136:20,20 140:17 147:15 147:16 150:4 191:15 192:4

pages 4:12 117:25 138:13 139:16 140:4 177:11,13 191:14,17,17 192:3,6,6

pain 93:13 98:19

painful 22:18

palatable 87:7 88:1

pan 87:8 96:15

papers 117:14 168:23 169:9 169:10

paragraph 10:7,10 12:11 12:13,21 13:1 37:12 38:25 40:16,19 47:11 60:11,23,23 61:3,4 62:15 62:18 63:4,11 63:23 64:6,8 64:15,17,19,25 65:17 66:1,4 66:23,24 67:1 67:19,22,23 68:7,8,22 69:13 70:10,19 70:19,20,24 71:22,25 72:1 72:10,12,13 73:6,8,15,16,17 74:6,24 75:19 75:21 76:14,16 76:21 77:7,23 78:10 81:16 86:11,14 87:18 91:4 96:14 100:17 101:10 105:1 107:16 107:19 108:4,9 110:3,5 114:8 114:12 117:18 118:15,21 119:5,12 120:4 120:12,23 121:1,12,21 122:3,5,20 123:5 124:18 130:11 133:4 135:5,21 137:23,25 143:11 146:6 147:15,17 151:11,14 161:14 162:11 168:20 175:11 175:14 176:25 177:15 178:8 178:16,17,22 179:20 186:11 186:15,18,21 186:24,25 187:2,5,8

paragraphs 61:21 65:25 66:23 67:17 129:2 180:19

parcels 30:25

parenthetical 13:4

parr 12:13 25:23 27:23 28:22 29:20 34:18 37:8,10 38:10 39:16 40:25 41:12 42:13 43:10 44:11,23 46:1 46:3,13 47:7 47:10 56:2,10 56:20 57:1,15 58:5 59:1,20 61:5 84:22 85:22 117:25 144:18 148:23 151:2,6,15 179:14 183:21

parr's 122:13 151:21 173:20 181:23,24

part 17:3,17,19 22:24 31:10 32:12,17 81:4 81:5 90:13 91:8 121:9 165:20 166:11 166:13 173:19 180:19 181:16 183:3

participant 89:21

particle 178:1

particles 18:5,7 25:9 26:1,15 26:17 29:22 31:19 35:6 115:14,15,18 117:16 119:15 153:23 161:3,4 161:7,8,9,11,11 161:25 165:5 165:21,22 166:18 176:12 176:13,22 180:14

particular 27:19 80:17 82:3,6 84:17 84:23,24 85:11 97:19 98:11 100:19 141:9 145:19 156:15 157:8 163:14 170:14,23 177:14

particularly 10:19 55:13 57:3 64:6 79:25 80:1

Veritext Legal Solutions
Calendar-CA@veritext.com 866-299-5127

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 226

139:4,18 148:22 149:13 149:19 179:18

particulates 17:25

party 115:8

pass 156:8

passes 128:22 129:13

past 109:22 169:11,23

pat 120:7

patent 1:1,2,4,8 2:17 3:6 4:11 5:12 7:24 9:2 12:14 13:8,13 13:16,16 22:17 62:2 72:16 77:22 78:2,3,4 104:20 118:7 119:24 120:12 120:13,14,22 121:1,2,5,6,8 121:13,15,17 121:21,24 122:1,2,7 123:19 130:6,9 132:19 134:9 134:15,22 142:3,6,16 146:15,25 150:19 151:7 152:3,11 160:19 162:14 163:6,23 167:17 170:1 171:20 172:16 173:1 175:6,23 176:17 177:24 177:25 179:11 179:12,15,21 180:8 187:11

patentees 28:18 29:15,24 31:21 33:8

patents 85:9 122:1,2,12 128:18 134:19 135:3

patient 12:17 14:1 15:18 16:14,15,17,18 16:24 19:22 35:19 37:14,22 38:15 49:14,21 50:6 52:14 53:3,11,23 87:21 88:7 91:15,23 92:12 93:8,11,12 95:17 96:11 97:11,24 100:2 100:2,21 101:5 101:14 102:20 105:24 110:10 110:13,19 111:3 112:10 112:23 113:12 126:23

patient's 17:5,8 24:15 30:6,19 34:15,16,24 35:9,11,14 37:3,6,7 39:19 44:8 49:13 51:8

patients 19:4,6 19:17,18 20:8 20:14,14,15,25 22:19 23:2 36:6 45:6 52:6 61:6,10 88:8,9 90:13 110:6 111:8,11 112:2 112:15 113:5 113:18

pct 140:12

pdf 191:12 192:1

pediatric 19:4 19:16 20:13

peer 87:1 95:6 168:23

penalty 189:7 191:16 192:5

pennsylvania 2:20 3:3,9

people 19:4,11 19:14 20:21,23 85:10 86:24 87:16 109:22 184:17

percent 33:3 152:24 159:3,6 159:10,13,21 159:24 160:4

performance 15:13

performing 11:13 128:5

period 41:5 45:13 46:24 48:25 49:8,12 50:12 51:15,16 52:17,25 53:2 54:5 58:23 68:4 69:2,8 70:16 72:19 73:23 74:14 77:20 99:25 101:19 105:2 105:22 110:18 112:4 117:2 125:7,15 191:18 192:7

perjury 189:7 191:17 192:6

permeate 127:16,23

permeates 127:10

permeation 127:20,22

perrett 13:14

person 14:6 15:24 33:18 37:20 39:5,6 39:25 41:2,21 41:22 42:22

Veritext Legal Solutions
Calendar-CA@veritext.com 866-299-5127

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 227

43:1,19,20
44:1,6 46:11
46:15,21 60:5
63:2,9,22,25
64:7,10,24
65:3,9,13,16,22
66:22 67:9,20
71:24 72:11
73:5 74:20,25
75:7,18,22
76:3,10,13,19
76:20 78:6,7
78:23 79:1,6
79:18,24 80:6
80:10,11,23
81:16,21,24
82:4,9 83:8,22
84:21 94:15,20
94:22 95:3
98:9 100:16
102:10,23
103:2 104:9,18
104:19 105:7,9
106:3,16
109:13 112:13
123:5,24 126:1
126:9 128:10
138:9,23,25
139:10,22
140:1,22,25
141:7,14,19,22
141:23 142:6
143:1 145:2,7
146:23 149:3,7
149:16 150:3,6
151:15,18,22
165:10 175:21
185:7
person's 33:23
34:6
personal 39:10
personally
130:17 132:13
perspective
41:21 77:1
128:10
pertains 190:15
petition 173:20
petitioner 1:5
2:8 5:7 9:1
petitioner's
186:1
ph 123:20
125:13 175:2
ph.d. 1:14 2:1
4:3 5:14
151:16 189:3
189:16 191:5
pharma 1:4 2:8
5:8 12:4 191:4
pharmaceutical
11:16,25 23:24
62:18 66:3,5
136:12 157:7
162:15 163:8
164:1,12
169:14,15
173:2 174:24
175:22 176:6
176:17 177:16
178:9 179:20
pharmaceutic...
1:7 2:17 3:6
5:12 191:4
pharmacology
22:14
pharmacy
22:14 23:12
54:10
phillip 2:14 5:6
phillip.minnick
2:16
phone 184:19
184:19,25
phonetic 147:9
phthalate
135:24,25
136:17,24
137:5,9,11
physical 112:9
place 34:4
113:8 190:11
placebo 86:15
86:20 87:17
88:5
placed 17:8
19:25 35:13,16
41:13 43:23
91:10 92:4
155:23 165:3
170:19
placing 128:16
planning 91:2
platform
138:20,21
139:15 140:3
141:1 142:13
142:22 143:14
144:13,23
145:16,20
148:12 150:10
180:24
play 38:18
please 5:24
6:23 8:13 9:11
10:6 12:10
13:9 28:6
47:16,25 60:11
89:19 119:5
120:5 122:4,21
130:8,8 134:10
135:20 137:23
140:10 144:11
151:4,12 152:5
162:11 168:20
178:16
point 40:4
46:25 52:16,16
67:16 72:4,23
72:24 73:19
79:14,23 81:17
100:3 112:17
124:10 131:7
148:23 184:3
pointed 186:12
points 63:17
polymer 123:1
123:6,14 124:5
124:19,22
125:1,20 126:2

Veritext Legal Solutions
Calendar-CA@veritext.com 866-299-5127

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 228

126:21 127:10 127:17,18 128:6 129:6 130:14,19 131:16,19 132:3,16,25 178:2
polymers 131:1 133:5
popular 48:9 48:16 49:19 55:2
pores 128:2
portion 13:8 19:10 25:15 137:10,12,15 183:15
posa 15:24 61:11 78:15 96:9 114:3 138:3 142:1 143:13,15 147:18
position 34:22 80:22 82:11 125:17,19 150:3,6
positive 175:1
possible 79:16 84:21 128:20 129:11,17 172:10,13
posted 89:14
potent 50:9,21 53:24
potentially 51:6
pour 91:24
powder 115:19 116:9 161:4,5 161:5
powders 153:21
precautions 136:25
precise 91:22
predefined 36:9 38:20 39:12 40:7 161:8 167:10 167:11
predetermined 67:15 175:2
predisposes 22:19
predissolved 36:2
preference 36:18
premade 150:21 165:15
preparation 92:8,20 93:5 93:21
preparations 11:16
prepare 100:1 106:10 181:20 182:17,23,25 183:4,6,17
prepared 121:7
preparing 120:21 121:21 122:11 134:20 182:15 183:13
preprepare 96:7
preprepared 85:19
prepreparing 96:9
presence 37:6
present 12:16 13:25 20:25 25:9,10 29:21 29:23 51:4 52:13 174:17
pressure 155:25 156:4 156:19,22
presume 110:15
pretty 116:20
prevent 62:21 123:7,15 124:20 125:20 126:3,21 128:16 129:7
previous 16:9 27:7 37:2 47:9 57:8,15 58:3 59:1,12 67:14 67:17 76:21 77:2 131:17,25 149:7 182:20
previously 4:14 15:12
primarily 54:20 55:19 56:3,9,12 58:16 73:20 75:24 161:22 161:24 182:3
primary 15:19 16:2,3,8,20
prior 35:25 36:9 37:19 41:8,19 42:7 42:16,17 44:9 45:22 56:6,18 57:6,25 58:10 148:17 190:6
probably 7:8 75:8 76:20 93:19 137:10
probe 181:13
problem 19:24 20:23 21:1 101:21 102:22 103:15 104:8 105:9 106:8,18 112:10 133:24
problems 104:15,17 105:14 106:4
procedure 191:19,21
proceed 94:17 174:10

Veritext Legal Solutions
Calendar-CA@veritext.com 866-299-5127

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 229

proceeding 181:10,16
proceedings 188:6 190:14 190:17
process 34:14 34:15 95:10,10 134:14 156:2
processing 153:18
produce 37:11 38:12 79:12 143:6
produced 95:14 154:24 173:15
producing 70:17
product 15:14 15:20 16:4 83:6
production 33:24 34:6,16 34:24 35:10,12 35:18 37:3,6 37:13,22 38:15 39:19 178:3
products 15:16 16:11,22 18:21 104:16 115:22 117:10,17
profiles 12:3
prohibits 131:20
prolonged 51:15 112:4
proper 74:20
properties 11:5 11:9 50:10 54:3 161:24
property 170:6
protects 125:8
proved 48:9 89:7 149:10
proven 84:1
provide 32:9,10 32:20 33:5 86:16 87:20 99:24 103:19 104:25 124:10 126:14 132:24 135:5 147:23
provided 49:4 66:3,5 184:13 191:19 192:8
provides 30:13 31:22 49:2 87:8,12 88:2 96:15 98:17
providing 33:11 49:14 50:14 52:18 53:5 166:20
psychiatric 19:7
psychological 112:9
public 116:3
publication 4:11 62:2 86:23 116:3 119:24 122:8 139:22 140:12 145:10 146:13 152:21 175:23 176:18 179:21 180:19 186:5
publications 46:13 47:7 56:20 58:6 85:10 87:3 116:4 145:21 169:4,5,17 181:13
published 86:25 95:7 98:24 117:14 169:10
pulmicort 91:15,18,25 92:15,23,24 93:25 94:16 98:12 99:3,18 100:18 101:9 103:17 105:2
purely 150:2
purpose 96:2 142:16 143:9 153:16
purposes 8:18
pursue 80:8
put 43:16 47:7 103:22 111:15 112:17 142:17
putting 54:17 84:19

q

question 6:22 6:24 7:4 20:13 30:21 31:15 39:24 41:17 42:6 47:3 50:7 55:23 56:5,17 58:9 63:7 71:23 73:10 100:13,14 101:7 103:13 103:23 104:1 107:6,9 108:22 118:13 120:17 122:9 137:14 139:9,10,15 141:18 144:9 146:4 149:6 178:6 181:8 187:15
questions 6:12 6:13 7:3 24:21 47:2 160:18 175:9 185:15 185:23 187:14 187:21,22,24
quick 40:21 50:14 60:7
quicker 50:10 54:2
quickly 20:3 41:6 50:24

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 230

54:4 68:4 69:25 101:4,5 110:17 113:21 126:17
quite 20:12 22:8 26:12 30:22 35:2 92:2 112:6 117:5
quotation 110:4
quoted 117:22

r

r&s 192:1,9
raised 56:11
range 71:9 154:6,9,11,12 154:20,23 155:1,2,5,6 156:15 158:11 159:6,10 172:5
ranges 71:11 154:14
ranging 154:25
rapid 15:14 16:9,20 17:1 42:9 56:13 60:6 121:25 153:8 165:4 166:15
rapidly 12:17 14:1 17:6,11 18:22 20:1 21:2 30:24 31:17 34:7,8 34:14 41:7,9 41:17,18 42:5 42:10,15,17,23 43:5,9,16,22,24 44:18,19 45:11 45:22,24 46:7 47:4,5 49:10 55:21,22 66:16 67:12,20 68:6 69:2,4,6,12,18 69:20 70:3,6,9 77:13,13,16 79:10 85:16 111:13,16 112:6 113:9 121:6,18 124:11 126:10 128:18 133:13 153:7 171:10
rate 33:24 34:16,24 35:10 35:12 37:4,6 39:20 156:4,7 156:8,21 157:3 157:5,8
rather 31:2 64:3 167:4
reaching 45:18
reaction 185:9
read 58:7 65:23 78:3,5,5 125:25 189:5
reading 22:13 43:20 45:1,2 63:25 64:7,10 64:25 65:9,14 77:6 94:21 95:3 109:14 112:14 142:1 144:22 145:2 147:18 150:4 154:5 191:24 192:9
ready 38:20
real 103:4
realize 176:9
really 31:22 40:3 50:4 53:10 54:1 104:10,10 117:24 144:8
reason 6:7 22:15 44:5 54:14 56:9 58:24 64:14 77:5 84:19 99:13 109:25 110:21 112:16 112:23 113:23 129:22 131:17 133:9 150:14 185:6,12
reasonable 40:10 66:21 73:14 83:5,13 83:15 84:16 90:14 159:25
reasons 57:8,14 58:25 59:11 67:13 77:1 78:8 79:11 80:12,13 81:23 112:25 113:4 113:12 114:1 129:23 131:24 133:2 150:9 164:7 168:2 181:15 188:1
recall 10:5 22:7 22:12 121:23
receive 97:6
received 8:8 184:19
recess 36:23 60:20 107:13 135:17 168:17 185:19
recipients 183:14
recites 23:23
recognize 9:17 143:16,22,24 145:9,18 146:3 146:6,10
record 5:25 9:14 13:12 14:20 37:1 47:18 60:14 62:1 89:13 103:22 104:24 105:5,17 107:24,25 119:23 135:16 136:10 140:11 151:5 172:25

Veritext Legal Solutions
Calendar-CA@veritext.com 866-299-5127

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 231

174:15,16 188:3
recruitment 89:22,25
redirect 185:17
reduce 161:6
reduced 190:12
reduces 95:18 161:25
refer 12:5,15 13:15,24 16:9 16:13 17:23 22:3 58:3 62:7 118:9 140:14
reference 37:24 38:25 62:13 135:24 137:21 140:7 144:4,19
referenced 62:11 69:14 87:17 156:11 191:6
references 42:25 45:23 118:3
referencing 124:23
referred 117:18 118:20 120:1
referring 16:16 51:24 111:23 112:14 117:21 128:17
refers 14:9 17:1 68:19 110:10
refine 84:2
reflex 111:22
regardless 34:23 72:10
regimen 91:11 92:4
region 129:21
related 11:1 19:5,12,14 20:22 67:10 181:11 184:21
relation 46:2
release 10:12 11:22 48:23 66:19 69:1 74:16 75:10,15 76:7 79:22 125:5,15 127:3 127:6 128:7
released 18:6 34:10,11 41:5 41:6 43:24,25 49:8 68:4 69:7 77:18 125:14 128:22 129:13 191:22
releases 68:3 70:14 72:19 73:23 74:14 129:20
releasing 31:17 42:3 46:24 49:1,11 50:23 52:17 53:2,4 54:22 58:23 70:16 110:18 123:21
relevance 97:5
relied 42:20,21 42:24,24,24 44:5
relief 32:9,11 32:21 33:12 49:2,4,14 52:18 53:5 105:25
relieve 124:10
rely 80:15 81:22 122:10
remaining 8:25
remember 115:4
remote 2:2
repeat 63:7
report 35:17 37:12 72:5 80:14 89:16 133:3 136:14 150:10 162:6,9 177:22 181:22 181:23,24,25 183:8,9,13
reported 1:24 23:1 93:17,17 93:17
reporter 2:4 6:12 190:24
reports 181:22
represent 5:7
representing 5:12
requested 192:1,9,10
require 32:2
required 25:17 190:18 191:20
requires 24:2 87:9
research 56:11 59:12,14 157:4 158:2 183:6
researching 41:10
resolution 98:21 100:3
respect 22:21 103:13 151:6
respectfully 69:11
responded 183:20,20 184:23
responses 6:14
responsive 123:20 125:13
rest 17:15 25:10
restate 173:25
restrict 129:6
restricting 128:13,14
result 159:25
resulting 30:7 109:9

results 89:14 104:22
return 135:19 143:10 191:17 192:6
review 43:1 47:10,20 87:1 120:22 121:20 134:19 180:8 180:11 182:25 183:3 190:17 191:8,10,13 192:2
reviewed 95:7 120:24,24 121:2,12,13,15 168:23 181:22 181:22,23
reviews 42:25 46:2,4,8,9 168:23
revolved 98:20
right 8:9 17:21 21:24 24:18 26:11 48:2,7 51:23 66:13,17 67:23 68:24 69:15 72:13 73:8 74:8 77:8 86:1 89:17 90:3 91:16,17 91:18,25 92:16 92:25 94:13 95:21,22 96:20 96:21 97:11 103:12 104:13 108:18 109:6 118:11,18,24 121:14 125:17 133:8 136:14 154:3,4,5,8,18 159:4 160:18 161:16 164:18 167:20
roman 15:7 18:16
room 184:1,4,5 184:9
rough 7:20 188:4
route 88:4
routine 71:5 82:17
rules 6:11 192:8
run 184:24

s

s 4:9 6:1,2,2
safe 87:5 88:18
safety 86:17 87:13
saliva 15:15 16:10,21 17:2 17:3,5,9,12,18 17:20 18:4,6,7 18:22 20:2 21:2 24:15 25:6,8,8,9,10 25:15,17 26:1 26:8,18 27:8 27:24 28:13,23 29:11,20 30:6 30:7,19,23,24 31:7,16 32:6,7 33:16,19,23 34:3,6,11,15,16 34:19,23,24 35:3,9,11,18 37:3,6,13,21 38:13,15 39:11 39:19 45:15 48:24 49:2,21 72:22 79:10 109:9 163:20 165:3,5 166:15
san 2:11,15
santa 190:2
sat 115:15
saw 43:2 164:3
saying 20:13 31:21 39:14,15 39:25 44:22,22 54:1,12 64:16 71:18 78:20,23 80:23 82:18 88:16 98:24,25 103:15 109:8 109:13,14 111:9 112:1 113:16 117:24 126:1 143:5 144:2 145:1 147:3 148:11 148:13,14 150:24 163:6
says 11:14 13:4 13:23 15:10 16:3 18:21 24:8 31:5 38:11 41:25 48:8 51:23 52:10 53:8 60:24 66:4 71:4,8 78:15 86:15 87:4,20 89:25 91:10 94:23 101:3 108:5,10 113:16 114:13 121:6 123:5 130:13 134:13 135:2 136:24 143:12 162:13 166:1,4 168:22 172:2 174:24
schedule 191:10
scholar 60:1
scope 71:6 162:4 173:23 174:5 175:19 175:24 176:7 176:19 177:2,7 177:19 178:11 178:12,24 179:23 180:21 181:7
screen 47:14 66:9 121:3,8,9

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 233

sd 1:23
sealed 8:14 191:20
search 42:17 43:4,5,7,15 45:21 57:5,10 57:25 58:11,24 59:7,8 60:4 183:10
searches 59:17 59:25 60:1 183:17,18
searching 56:18
second 10:9 16:2 18:19 68:11,19 83:9 110:3,17 116:8 119:3,12 121:9 121:11 132:9 133:23 151:14 155:9 156:16 157:2,10,20 160:15 174:24
seconds 24:3 25:7 29:17 34:8,9 37:10 38:12 44:8 108:23 109:17 110:24 112:20 131:9,20 156:8 158:7,20 160:1 164:3
section 15:10 15:11 18:20 48:7 50:20 51:19 53:8 60:12 119:8
security 8:16 8:17
see 10:14 12:19 13:3,21 14:3,9 15:6,8,21 16:6 18:15,17,25 19:8 21:14,18 23:21,25 24:6 28:11 29:9 38:2,24 40:22 41:18 42:6,9 42:15 47:11 48:2,5,11 52:2 53:12 55:4 56:5,18 61:1,7 61:14,21 62:25 65:14 66:7 68:13,14,19 71:2,13 75:23 75:23 78:15 81:16 86:18 89:23 91:12 97:5 105:17 107:23 108:4,7 108:13 110:8 114:17 118:8 118:15 119:10 119:16 120:9 120:16 122:7 123:2,9 130:11 130:15 134:17 136:1,5,18,22 137:2 138:7 139:2 140:19 143:19 144:23 147:20 151:19 152:13,15,24 153:1,12,14,25 154:2,20 155:11,13 159:6,8 160:22 160:23 162:21 162:25 168:25 169:2 173:7 175:3,9,17 178:17,19 185:17
seeing 70:9 119:12 123:4 157:9
seem 103:12
seemed 64:16
seems 66:21 124:18 150:3
seen 22:1 42:10 45:24 46:1 47:3,5,6 57:19 84:1 102:20 173:12 174:13
select 147:18 147:23 150:11
selecting 75:21
sense 20:24 30:22 48:24 102:19 103:14 148:22
sent 183:16
sentence 10:9 11:14 12:21 15:10,17 16:2 16:9 18:19 19:2 37:25 38:2 40:20 48:7 49:18 50:2,21 51:19 51:23 53:7,25 54:13 55:1,4 61:5,9 66:2,11 68:11,14,19 69:5 70:4,5 71:8 77:14 78:15 86:14 89:25 90:1 91:9,12 107:20 108:5,20 110:3 114:13 119:13 120:7,11 122:24 123:4 124:18 126:1 135:23 136:3 138:2 143:12 144:9 146:2,6 147:16,17 151:14 162:13 168:22 174:24
sentences 15:21
separate 15:12 115:22
serves 50:14
services 12:4

Veritext Legal Solutions
Calendar-CA@veritext.com 866-299-5127

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 234

serving 169:14
set 28:16 124:17
setting 169:13
several 71:11
shaking 94:17
shape 157:24 158:3
share 181:6
sharing 185:13
shelf 104:17
shipped 90:15 184:10
shocking 146:20 147:5,9
shocks 147:7
shopping 148:5 149:15
short 36:23 60:20 107:13 135:17 168:17 177:10 185:19
shorthand 2:4 190:11,24
show 25:4 43:12 95:17 115:16 160:13 167:22
showed 98:19 100:2 186:8,25
showing 25:7 26:3 27:3 64:20 66:18 88:17 97:15 99:11,24 102:8 105:25 160:8 179:6 180:7,10
shown 27:22 28:1,24 32:9 32:23 36:3 37:22 57:17 65:21,21 67:25 84:20 85:6,8,8 101:15 121:3 150:16 156:9 156:14 157:17 168:9 180:5 186:2
shows 27:18 96:12 97:21 100:22 103:10 133:14 157:1 159:12 163:25
side 157:4
sign 191:16 192:5
signature 10:1 190:23 191:22 191:24,24 192:9
significant 172:2
significantly 39:12
similar 43:14 68:12,20,23 69:1,8,9,14 72:4,13,18 73:8,16,24 74:13,18,25 75:2,20 76:2,7 76:15,18,24 77:7,12 108:21 109:16 112:18 116:12 117:2 119:13
simple 82:17 149:17 167:10 168:9
simply 58:9 144:23 146:18 168:6
sit 40:24
sits 41:4
sitting 61:16
situation 25:24 67:15
six 90:15 98:19 138:13 139:16 140:4 177:11 177:13
size 157:12,13
skill 14:6 15:24 37:20 39:5,6 39:25 41:2,22 41:22 42:22 43:2,19,20 44:1 46:11,15 46:22 60:5 63:3,9,22,25 64:7,10,24 65:3,9,13,16,22 66:22 67:9,21 71:24 72:8,11 73:5 74:3,20 75:1,7,18,22 76:3,10,13,20 78:6,7,24 79:7 79:18,24 80:11 80:12,24 81:16 82:10 83:22 84:22 94:15,21 94:22 95:3 96:8 98:9 100:16 102:10 102:23 103:2 104:9 105:7,9 106:3,16 112:13 123:5 123:24 126:8,9 128:10 138:9 138:23,25 139:10,23 140:1,22,25 141:8,19,22,24 143:1 145:2,7 146:24 149:3,7 150:7 151:15 151:18,22 164:7 165:10 175:21
skilled 126:1 141:14 142:6
slightly 115:3
slowly 41:5 42:2 46:23,23 49:11 54:22 58:22 73:23
small 20:5 45:8 45:17 51:1

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 235

52:12,23 54:20 69:22 111:18 113:7 123:22 125:5 127:2,10 129:19 178:1
smaller 38:16
solid 12:16 13:25 17:25 23:24 24:12,16 25:1,18 26:9 28:14 29:12 30:5,18 31:8 33:25 48:3 60:25 61:13,18 63:5,12,19 65:2,4,15,18 66:12 67:1,22 68:23,23,25 69:14,16,17 70:10,14 72:1 72:2,3,6,12,25 73:7 78:17,20 78:25 130:21 132:8 162:15 163:7 164:1
soluble 123:23
solution 32:10 32:10 36:1 55:21 65:8 70:17 76:6 77:19 93:9 94:11,12 96:10 97:7 101:17 104:6 135:4 148:19 149:10 168:10
solutions 64:3 191:7
somebody 45:1 45:2 72:8 74:3 93:20 96:8 126:8 144:22 146:23 164:7
someone's 33:25
sooner 115:3
sore 48:10,15 48:18,20 49:20 49:23 50:19 51:4,5,7,12 53:19 54:11,22 55:3,8,17,25 56:7,19 57:7 57:12 58:2,13 58:21
sorry 38:11 39:23 63:6 68:17 73:11,22 90:8,10 101:22 108:2 120:14 120:18 137:14 147:10 155:3 172:1 173:24
sort 18:15
sound 147:10
spain 90:3
speak 6:18,19 182:9 187:19
speaking 174:8
specific 15:13 116:23 129:21 160:22 175:14 176:4,21 178:14 179:14
specifically 14:15 46:20 107:21 108:6 108:11,24 109:7,19 177:12
spent 117:25
spirit 133:11 134:3
splenda 91:16 91:24,24 92:6 92:15,25 93:4 93:25 94:17 95:21 96:2 98:12 99:3,19 100:18 101:10 101:18 103:17 105:2
splits 70:24
spoke 182:4
ss 190:2
stability 97:9 101:1 102:22 103:4,15 104:8 104:15,17 105:12,14 106:8
stable 97:1,1,25 98:8,14,16 99:5,9,21,24,25 100:19,23 101:2,11,16,23 101:25 102:4 102:12,13,14 102:14,15 103:1,6,14,18 103:18 104:11 105:2,21,23 106:10,13,17 106:19,24,25 107:1
stage 87:22 88:14 89:2
stance 124:19
standard 42:25 83:12,12 156:6 156:10,12,13 156:24 157:6
start 17:11 18:7,8 25:25 31:15 35:5 68:17 81:1 82:13 108:2 125:15 137:22
started 9:9 72:23
starting 9:3 13:18 21:16 24:5 26:13 81:17 130:9,11
starts 68:11 70:13,25 152:6
state 2:4 5:24 10:10 13:12 14:20 35:19

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 236

151:5 172:25 189:8 190:1,5 190:24 191:9 191:12
statement 87:25
states 1:1 4:11 12:13 40:20 88:23 89:4 90:2 96:7 147:17 185:7
statistical 86:23
stay 18:11 35:12 41:14 134:8
stays 45:12
stearate 153:13 153:16 161:23 162:1
stearates 162:2
stearic 161:20
steroids 117:20
sticking 116:17
sticks 114:5,5
stimulated 33:24
stimulation 34:3,25
stipulation 191:21
stirring 94:17
stomach 17:14 20:5 54:19,19 85:25 125:5,12 127:2,9 129:19
stop 126:24 137:19 160:6 169:11
storage 98:1
store 97:24 99:3 101:19
straight 85:25 110:23
stream 50:13
strike 181:10 181:15,18
strong 124:19
studied 116:23
studies 88:21 117:7,9
study 87:15 88:24 89:14 90:2,5,6,14 115:22,23 116:9 117:15
subsequently 17:15 127:13
success 40:10 83:5,16 84:17 105:15 106:10 149:23 150:1 167:9,15 168:6
successful 167:18
sucked 41:4,13 43:23 51:16 52:6,13,25 70:15 72:20 73:24 114:6
sucking 53:3
sucralose 92:6 92:19 95:24
suffices 57:15
sufficient 26:8 26:13,19,21 27:9 28:14 29:12,25 32:21 33:4,13 54:23 158:5,6,10,12
sufficiently 32:25 33:2,6
sugar 95:14,20 95:21,22,23 152:21 153:6
suggest 101:25 102:6,21 104:15 105:13 106:25 107:3 145:4,22 160:17 179:16
suggesting 105:20 110:22 111:17
suggests 102:3 102:13 104:8 105:8 106:4,7
suitable 71:9 160:8
suitably 160:13
suite 2:10,14,20 3:3,9
supporting 38:24
suppose 36:22
sure 11:11 27:14,17 28:2 70:8 96:6 100:8 118:14 135:15 139:6 142:5 155:4 158:13,15 174:3
surely 88:16,18 94:6,8
surface 41:6 43:24 48:23 49:1 68:5 69:3 69:6,7 70:15 77:19 115:17 117:16 127:11 137:7,9,13,16 155:24,25 156:4,19,21 161:3 167:6 173:2 176:13 176:22 178:1 179:7 180:14
surprise 36:8 40:4
surprised 43:12 44:7,11 44:12 83:16 149:24
surprising 27:21 37:18 39:15 80:19 84:13 86:3 164:19 165:10

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 237

165:13,16
surprisingly 36:3 133:18 165:6 166:14
suspect 56:10 57:19 99:13
suspension 30:7 71:19 91:9,14,19,21 92:5,13,18 93:3 94:13,24 95:1,15 96:10 97:1,25 98:4,8 98:11,13 99:21 100:17,19 101:11,18 102:9,24 103:17 104:21 105:1,21 106:4 168:10
suspensions 64:3 99:9,9 100:6 101:22 102:25 105:12
swallow 18:23 19:20
swallowed 16:23 17:14 20:4,9 31:19 32:7 34:11 50:5 53:11,23 92:7 108:17 109:9,10 127:1 165:6
swallowing 19:5,12,15,18 20:8,16,22,24 21:1 22:18,21 23:2,7 25:11 26:2 35:5 49:13,21 51:8 51:14 85:25 107:22 108:6 108:12,25 109:8,19,22 166:18
swapping 142:15
sweet 96:4
sweetener 96:3
switch 102:7 107:2 119:1 148:20 168:7
switching 103:7
switzerland 90:3
sworn 5:15 190:7
symptom 22:22 23:8
symptoms 22:16 23:5,13 30:18 31:11 95:18
system 48:9,17 49:19 179:17
systematic 171:11 172:11
systematically 49:7 55:11,12 167:4 170:6 171:23
systemic 11:2 25:14 30:2 31:4 46:4 47:8 50:4 53:9,16 53:20 54:8,20 54:24 55:19,22 56:3,13,14,22 57:2 58:8,17 58:17,18 59:21 59:21 60:7,7 84:14 85:17 109:24 125:3 125:11 138:13 138:18,19,21 139:2 141:2,12 141:25 146:22 146:25 168:1 169:3,6,18,21 169:24 170:2 170:13 171:2,7 171:9,17,18 172:3,14
systemically 17:13 127:13
systems 10:12 48:4

t

t 4:9 6:2,2 89:14
tab 89:14 172:22
table 153:25 158:24
tablet 10:17 12:15,15 13:20 13:24,24 14:6 18:3,5,23,24,24 20:9 25:24 34:5 35:13 39:21 40:9 54:17 66:12,14 66:18,18,19,19 67:1,6,6,10,20 67:22 68:12,20 68:23 69:1,8 69:10,14 72:4 72:13,18 73:8 73:16,24 74:14 74:18,25 75:2 75:20 76:2,7 76:15,18,25 77:8,12 108:21 109:8,16,24 112:19 115:20 154:2 155:1,20 155:23,25 156:5,19,21 157:5,6,12,13 157:24,25 158:5 160:10 161:8 163:20
tableting 159:20
tablets 10:11 10:24 12:6 14:22 19:20

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 238

20:16 43:14 51:25 55:6,7 55:11,16,24 57:6,11 58:1 58:11 109:23 154:13,22,24 155:8,16 156:8 156:15 157:1,9 157:18 158:6 158:12 159:16 159:22 160:6,8 160:13 171:13

take 7:8 13:7 14:14,16 18:24 28:5 37:23 44:7 60:13,15 60:16 61:20 67:19 68:10 73:2 82:11 92:22,23 94:25 99:18 100:13 106:20 107:9 119:18 124:19 126:7 130:5 135:8,10 140:7 168:15 185:16

taken 36:23 48:21 49:9 60:20 105:25 107:13 135:17 168:17 185:19 190:10

takes 66:15

talk 27:14 33:16 37:13 40:14 45:17 46:9 50:21 65:4,5 71:15 71:20 73:20 75:12 87:11 135:4 141:3,4 143:7,8 144:14 144:14,15 145:18,19 146:20 148:8 149:13,14 158:18,18 182:2,22 184:21

talked 129:3 166:16 181:25 182:1,3

talking 52:14 64:6,12,12,13 71:14,15,16,20 72:3,17 96:14 105:24 108:20 109:15 113:21 117:25 128:18 133:4 134:22 135:6 144:16 144:17 169:17 177:21 178:1

talks 16:2 19:16 46:17,19 46:20,20 61:9 64:2 66:14 77:14 88:1 110:5 144:12 163:14 171:21

tape 8:15,19

target 154:3,4 154:17 155:12 158:25 159:3

targeting 129:21

taste 119:2,9,14 120:8 122:25 123:14,18,25 124:1,12 125:2 125:8 126:11 126:15,19,25 128:6 129:5,18 130:5,13,17,25 131:3,12,16 132:15 133:15 134:24

taught 10:20 36:10 159:19 159:20

teach 79:5

teaches 22:17 124:2 133:12 133:12 163:23

teaching 26:24 41:10 104:20 106:5,6 107:4 107:4 121:24 165:17

team 81:5,6 82:19 93:20,20 96:8

techniques 11:25 12:1 117:15

technology 2:3 124:2 126:12 138:20,21 139:15 142:14 145:16 150:10 180:25

tell 96:13 101:20

telling 146:18 164:6

tells 113:22 118:7

ten 7:20 36:18 36:19 60:17 91:16,24 92:5 92:14,19,23 93:4,25 94:16 94:24 95:10 99:19 107:11 114:25 154:13 168:15 185:16

tend 34:15 54:7 54:14 137:9,16

term 41:2 46:16 86:17 87:13

terms 13:23 14:12 36:6 40:4 42:17 43:5,18 44:4 71:20 104:22 114:25 156:2,6

test 29:18 34:10 100:25 101:19,23

104:12 105:15 105:18 106:9 158:17 160:9
tested 11:2,4 155:8
testified 5:16 8:1,5,7
testify 190:8
testimony 6:8 181:11 189:9
testing 10:19 10:23,23,25 11:12 105:20 114:24 115:5
testings 11:13 115:10
tests 185:11
text 21:23 41:23 184:18 184:22
textbooks 42:24 60:3
texts 41:23
thank 5:23 7:12 15:4 18:14 40:18 60:18 61:25 68:9 78:13 86:13 107:12,19 114:11 120:3 122:23 134:12 138:1 140:16 151:13 152:9 168:14,16 172:9 174:1 185:13 187:25 188:2
thanks 6:17 8:21 15:5 16:25 91:3
therapeutically 62:20 162:17 162:24 163:3 163:10,15,18 164:16 165:7 166:21
therapies 87:7 88:1
therapy 88:17 98:19 145:20 172:18 179:14
thereof 164:12 178:3
they's 75:23
thickness 154:16,17,20 155:2,5 160:14
thing 110:16 111:10 125:18 151:25
things 11:22 59:22 72:25
think 7:22 16:13 31:14 35:15 37:12,20 38:10 39:5,6 40:3 41:2 42:21 54:13 56:8 59:18,19 63:23,25 64:1 64:8,25 65:3 65:20,22 69:11 69:13 75:7 76:19,19 77:10 79:18 80:10,11 81:21,24 82:16 83:15,22 85:13 85:18 86:23,24 87:2 90:13 93:11 94:20 95:3 102:5 106:3,3,24 108:19 109:13 110:19 111:25 112:1,13 123:24 126:8 128:9,10 129:17,25 132:13 133:9 138:25 139:5 140:1 141:8,10 145:2 146:1,9 152:2 165:11 167:3 180:11 181:2,15 182:11
thinking 65:10 65:23 76:10 79:24 80:13 81:6 83:24,24 84:2,15,23 98:9 102:24 103:3,3,7,9 104:10,12,14 104:19,19 106:11,17 128:12,13 141:3 142:1,14 142:19 149:8,9 149:22 169:12 170:18
third 50:2 53:7 114:12 115:8 122:24
thought 114:2 120:18 139:14 142:22 165:12 168:6
thousands 88:14
three 24:21 96:19 97:17 98:18 99:25 182:19,20
thrive 93:13
throat 48:20 49:3,5 50:19 51:5,7,9,12,14 59:23
throats 48:10 48:15,18 49:20 49:23 51:4 53:20 54:12,22 55:3,9,17,25 56:7,19 57:7 57:12 58:2,13 58:21
time 7:9 22:8 25:5,13 26:3 26:25 28:20,23

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 240

29:2 31:4 32:23 33:20 34:12 35:23 38:17 41:1,5 45:13 46:24 47:1 48:25 49:9,12 50:12 51:15,17 52:17 52:25 53:3 54:5 58:23 66:15 67:7 68:4 69:2,5,8 70:16 72:19 73:24 74:14 77:20 101:19 110:19 112:4 115:24 116:10 116:12 117:2,5 125:8,15 126:7 131:8,20 135:8 135:12,14 144:21,22,25 150:16 163:24 165:18 167:25 168:1 173:18 181:6 182:21 185:15 190:11 191:10,18,25 192:7

times 7:16,21 8:4,6 58:16 107:7 155:19 159:19 182:13

tissue 123:8,15 124:7,15,21 125:22 126:4 128:8,15,23 129:8,14 130:3 134:1 162:18 163:11 165:9 166:3,6,10,20 166:22 167:6 167:24 171:15

tissues 165:23

today 5:6,21 6:5,8,12,15 9:6 12:6 13:16 40:24 45:23 47:1 61:16 62:10,12 83:17 168:3 182:23

today's 8:9 181:21 182:18 183:1,4,7 184:3,14,17 185:1

together 13:8 43:16 91:25 95:9 135:9 140:8 153:8,20 153:23

told 78:1

took 28:24 36:16 42:11 106:2 112:5

top 87:4 115:15

topic 40:13 60:9 100:11 114:7 119:1 151:1

topical 25:14 28:20 29:3 31:5 35:7,23 48:14 55:13 56:24 57:3,16 57:17 58:4 114:14 117:19 117:20 118:9 118:20 138:18 138:19 142:23 145:5 146:22 147:1 148:9 166:22,24,25 167:2,13,18 169:3,6,18,21 169:24,24 170:3,13,19 171:1 172:18

topically 24:9 25:11 26:4,15 26:17,20,22,25 27:4,16,20 29:19 30:12 31:2,20 32:8 32:24 33:14 34:12 35:7 36:4,12 49:7 82:3,20 84:8 122:25 123:7 124:14,20 125:21 126:3 128:11,15 130:2 131:4,10 132:11,14 133:7,20 134:5 143:16 144:2,4 144:19,25 145:5,11,22 146:11,16 147:1 148:24 149:21 150:17 162:16,17 163:8,9,24 164:5 165:7,18 165:20 166:2 166:18 167:6 167:23 168:2 170:5 171:12 171:12

topics 152:3

total 45:18 92:7 92:20 93:4,21 93:23 95:2,16 154:2 182:17

touch 165:22

tract 17:16 20:5 24:10,13 25:3,12,20 26:5,10,16,20 26:23 27:1,5 27:10,13,16,21 28:16,21 29:1 29:4,19,24 30:1,12 31:3 31:20 32:24 33:14 55:14 57:4,18 58:5 114:16 118:2,6 131:5,10,22 132:12,14

Veritext Legal Solutions
Calendar-CA@veritext.com 866-299-5127

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 241

133:7,21 134:6 143:18 144:6 144:20 145:1,6 145:24 146:12 146:17 147:2 148:10 162:19 163:5,12 164:5 164:10,23 165:19,22 166:2,4,6,11,19 167:14,20,24 170:4,21 172:19 179:18
trademark 1:1
traditionally 50:3 53:8,15 54:7
trans 180:15
transcript 188:4 189:6 190:13,16,17 191:6,8,10,13 191:13,22 192:2,2
transmucosal 174:25 176:22 180:14
travel 185:7,12 188:2
treat 27:15 28:2,15,25 29:13 30:8 32:22,25 33:3 33:4,6 36:4 48:15,20 53:19 53:21 54:11 55:25 56:6,19 57:7,11 58:1 58:12,18,20 59:22 63:15 64:21 79:5 80:2,25 82:3 82:11,25 84:5 84:8,17,23 85:1,11 86:1,2 86:6 114:15 118:1,6 128:11 141:6 148:9,17 149:8 150:17 163:4,15 165:8 165:9,18 170:20,25 171:13,15 179:18
treating 28:8 28:21 29:25 33:9,11 48:10 48:17 49:19 50:18,19 51:7 53:18 54:15 55:2,8,16,19 81:18 83:18 99:11 104:7 164:13 166:5,6
treatment 19:6 19:22 28:3 30:13 31:23 36:12 51:3 56:24 57:3 58:4 60:8 82:20 86:17 87:6,13 89:6 102:8 142:23 145:6 163:14 164:9 172:19
treats 49:23 164:15 166:20
trial 1:2 87:11 87:17 88:12 90:11,18
trials 86:16,21 87:22 88:5 89:3,3,5
tried 183:14
trouble 109:22
troubling 146:4
true 40:24 124:22 189:9 190:13
truth 190:8,8,9
truthful 6:8
try 6:16,18,19 24:25 73:13 100:15
trying 79:5,6 80:2 93:2,7 94:10 103:13 125:12 128:11 170:10,25
tuesday 182:11
turn 9:11 10:6 12:10 13:9,18 15:1 18:12 21:9 23:17 28:6 40:13 47:16,25 51:21 60:9 61:23 62:15 89:19 90:20 91:4 107:15 114:7 119:4,20 120:4 122:3,20 130:7 134:10 135:20 136:7,16 137:23 140:9 140:17 143:11 151:2,3,11 160:20 162:9 162:10 168:19 172:21
turning 9:22 14:17 21:5 40:15 60:10 68:8 70:21 78:12 86:10 89:9 136:20 152:4 175:11
twice 91:11 92:4 96:11,18 96:19 97:7,16
two 15:21 65:25 66:23 70:25 95:10 98:6 122:1,12
type 20:21 42:1 51:25 112:9 130:19 158:3 177:13
types 11:12 124:22

Veritext Legal Solutions
Calendar-CA@veritext.com 866-299-5127

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 242

typewriting 190:12
typically 25:23 27:24 28:22 33:18 48:14,20 52:10 53:18,20 87:21 156:23 167:25

u

u 89:14
u.s. 13:13 120:7 134:14
uk 6:3
ultimately 94:5
unable 6:7 185:6
unclear 132:2
under 6:4 82:9 122:6 189:7,7 190:12
undergo 153:7 153:7
undergoes 165:4 166:15
undergoing 185:11
undergraduates 159:19
underline 107:21 108:10
underlining 108:5
underlying 111:2
underneath 61:3
understand 6:4 6:10,22 7:6,7 8:8,18 12:22 16:8 20:12 24:11 39:9,23 40:1 41:2,16 41:23,24 42:1 42:4,22 43:2 43:20,21 44:1 44:6 45:2,21 46:16 56:4,16 59:7 60:5 61:11 63:3,10 64:11 65:4,6 66:22,24 67:9 67:21 71:24 72:11 73:10 74:4,21 75:8 78:7,16,24 79:2,2,7,19,20 80:3,16,22 93:7 94:21,23 95:4 96:9 99:16 109:14 112:14 114:3 121:12 123:6 123:11,25 124:25 125:17 126:1,8,9 134:22 137:14 138:3,10,24 139:1,7 140:2 140:23,25 141:15,20,22 141:24 143:1 143:13,15 144:8,16 145:3 145:3,7 146:1 166:12
understanding 17:4 24:14 32:15,18 64:11
understood 6:24 14:7 15:25 95:5
undertaken 89:4
undoubtedly 112:5
unfair 180:6
unintelligible 147:10
united 1:1 4:11 88:22 90:2 185:7
unpredictable 37:16 38:1,6 39:1,8,18 40:3
upper 24:9,13 25:2,12,19 26:5,10,15,20 26:23 27:1,5 27:10,12,16,20 28:25 29:4,19 29:23 30:12 31:2,20 32:24 33:14 55:13 57:4,18 58:5 114:16 118:2,6 131:5,10,21 132:11,14 133:7,20 134:5 143:17 144:5 144:20,25 145:6,23 146:12,16 147:2 148:10 162:18 163:4 163:11 164:5 164:22 165:19 165:22 166:2,4 166:6,10,19 167:14,19,24 170:3,20 179:18
use 11:1 15:18 16:14,15,17,19 16:24 25:5 26:3 27:18,22 28:19 29:12 35:21 42:16 53:24 57:16 58:17,17,20 60:4 64:20 65:11 76:10 82:22 83:2 99:3,5 102:8 104:21 106:5,5 107:5 117:12 117:14 125:1 126:11 129:5,6 129:23 130:1 130:16 132:4

Veritext Legal Solutions
Calendar-CA@veritext.com 866-299-5127

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 243

135:6 140:3 141:1,8,23,25 142:2 143:2 144:24 145:22 146:15 149:4 155:23 156:12 163:24 167:23 170:3 179:9,17 181:12 183:11

used 10:19 19:21 25:13 27:4 29:16 41:3 42:12 46:3 48:8 50:3 50:9 52:10 53:9,15,19 54:2,7,11 55:8 55:11,12,12,16 55:19,25 56:6 56:9,18,23 57:7,11,20 58:1,4,12 60:6 63:19 75:1 82:20 84:14 92:6 99:10,14 101:14 105:8 109:21,23 114:15 115:21 116:15,16 118:6 121:25 125:2,22 141:20 142:5,8 143:14,16,22 144:1,4,19 145:11 146:11 146:25 148:23 149:21 152:21 153:6,13,22 154:10 157:7 161:23,23 167:13,25 168:2 169:23 170:2,22 171:12,14 172:18 176:11 177:14,16 178:8,14 179:5 179:5,8,12 180:25 181:2

useful 50:22 57:17

uses 27:14 28:9 131:1

using 11:23 28:4 29:2,3,17 32:9,23 35:23 36:1 40:10 43:5 45:3 63:14 77:19 82:25 84:23 86:6 115:13 117:15 124:1 128:12 129:1 133:12 134:23 134:23 141:5 141:24 142:22 146:5 149:24 158:20 165:11 165:12,18 166:5 172:17 173:17

usp 29:17 158:21

usually 156:6

v

v 1:6 6:1 191:4

valley 2:10,14

value 42:11

values 157:1,9

variable 37:17 38:1,6 39:2,9 39:18 40:3 79:12

variables 36:11

varies 36:6,6

variety 60:8

various 37:13 37:21 38:14,18 166:7

vary 35:19 38:15 39:11

venkatesh 119:8,13,25 120:2,5,23,24 120:25 121:13 122:2 123:18 125:10 128:18 129:4,18 133:5 133:12

venkatesh's 119:18 123:13 128:6

verbal 6:14

veritext 2:2 191:7,9,11,20

versus 75:9 169:3,6

vessels 50:25

videoconfere... 2:9,13,18 3:2,7

view 74:12 78:4 84:3

virtual 188:1

viscosity 27:19 37:17 38:21 40:7,8 79:8 92:7 96:6 99:12 106:6 150:21 165:15 167:12

viscous 32:10 36:1 61:10 63:15 64:3,20 65:7 68:1 71:16,19 83:19 83:25 84:11,25 85:7,19 86:2 87:5 90:21 91:14 96:10 97:7 102:9 104:6,21 149:10 150:20 167:10 168:10

volume 25:17 25:22 26:7,18 26:21,21 27:6 27:8,11 33:16 36:2,9 38:21 39:13 40:7,8 45:9,15,17,18

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 244

67:16 69:22 72:22 73:22 76:8 79:8 85:22 87:8 88:2,19 92:7 92:20 93:5,21 93:23 94:2 95:2,16 96:15 98:17 106:22 111:18 113:7 150:20 161:9 165:15 166:16 166:17 167:11
volumes 45:14 79:12,22 82:25 84:10
vomiting 93:14 98:20

w

waiting 51:1 118:12
waived 191:24 191:24
waiving 191:21
walk 92:11 94:10
walls 161:12
want 17:17 19:21,22 24:4 31:25 35:9 37:23 51:19 99:4 107:1,1,2 108:15 109:10 109:11 115:8 123:11 124:14 125:18 130:2 135:2,10 139:7 143:21 149:16 149:18 168:13 172:8 174:14
wanted 27:6 37:2 58:9 64:5 88:4,14 91:21 91:22 92:11 97:24 99:2 101:17,18,24 105:9 106:1
washington 2:20 3:4,9
water 17:10,10 45:9,17 69:23 94:1,4 111:19 113:7 123:1,14 123:23 124:5 125:1,19 126:16,20 127:9,16,17,20 127:21,22,23 128:6,21 129:12 130:14 130:19 131:16 131:19 132:25 135:7 137:7,17 153:22
way 20:10 24:25 28:1 58:21 69:4 72:8 73:25 81:11 97:15 105:7 109:11 115:13,20 116:14 117:10 120:11 130:16 133:6 134:1 139:4,19 142:2 148:24 156:1 157:18 165:20 166:22 167:11 171:22 178:3 180:6 187:12 187:13 188:2
ways 36:3 82:24 128:5 155:20
we've 60:13 68:2,2 79:11 168:11 173:12
wednesday 1:15 2:2 5:1
week 182:12
weeks 106:21
weight 71:10 98:21 152:24 152:24 154:2,6 154:7,13 160:14
welcome 181:14
went 85:25
wife 184:6,24
willing 104:24 107:9
wish 157:3
wished 60:4
withdraw 181:8
witness 4:2 11:8 18:2 20:12 22:24 23:4,10 24:21 25:22 28:18 29:15 30:11,21 31:14 32:20 33:8 34:18 35:2 36:14,19 38:10 39:23 42:9,20 44:22 49:25 51:11 52:5 57:14 58:15 59:11,17 60:16,18 63:14 64:19 67:5 70:13 72:15 73:10,19 74:10 75:4 77:10 78:1 80:10 81:3,21 82:16 85:6 87:20 88:12 89:1 90:17 92:2,18 93:2 94:4,20 95:13 97:4,13 98:3,16 99:8 99:23 100:14 101:13 102:18 103:23,25 105:5 106:16 107:12 109:13 111:7,25

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 245

112:13 113:3
113:15 123:17
124:9,25
125:25 126:19
127:9 128:2,25
129:16 130:24
131:7,24 132:7
135:12,15
139:14 140:1
142:11 144:8
145:14 146:9
147:9 148:1
150:9 152:20
153:6 157:15
158:2,15
159:12,24
162:5 163:23
165:25 168:14
168:16 169:8
170:9 171:4
173:5,24
174:13,17
175:25 176:9
176:20 177:3,8
177:20 178:12
178:25 179:24
180:5,22
187:25 190:6
190:21 191:13
191:16 192:2,5

witness's 181:12
wo 140:12
wondering 164:21
word 69:12 146:3,5 183:18
wording 119:13
words 16:23 33:11 45:19 50:11 54:3
work 12:2 22:13 36:3 37:21,22 40:5 81:10 83:10,10 83:11,13,24 84:1,1 85:8,24 99:13 116:4 117:12 139:11 139:23 140:23 141:15,17 142:20 149:10 165:16 168:4,7 169:11 175:22 176:1,2 179:9 179:20 180:24
worked 36:10 85:7 148:21
working 22:10 138:12
works 17:4 35:22 39:15 58:22,22 80:20 81:25 86:3 98:23 99:11,12 102:21 103:10 126:16,19 138:6,10,24 149:12,24 150:20 165:1 165:16
worries 120:20
write 144:3 145:10 146:2,3
wrote 48:14

x

x 4:1,9 192:9
xl 153:11
xx 80:8

y

yeah 47:13 56:3 64:4 69:16 70:23,24 83:22 88:5,14 88:15 90:18 91:3 92:8,10 95:25 96:1 99:16 100:6 115:3 117:3 118:19 122:18 154:4,15 159:2 160:16 183:25
year 14:7 15:25 45:24 93:12 97:6 98:19
years 41:11 42:11 48:8 114:20 115:1,1 115:3 116:2,11 117:6 169:15
yep 122:23
yesterday 182:11,19

z

zero 82:13
zoom 184:13

Ellodi's Exhibit 2027
Falk v. Ellodi
IPR2025-00054 - Page 246