

1 UNITED STATES PATENT AND TRADEMARK OFFICE
2 BEFORE THE PATENT TRIAL AND APPEAL BOARD
3 Case No. IPR2024-01197

4
5 DR. FALK PHARMA GMBH,

6 Petitioner,

7 -vs-

8 ELLODI PHARMACEUTICALS, L.P.,

9 Patent Owner.
10
11

12 CORRECTED TRANSCRIPT

13 ORAL HEARING REGARDING PATENT OWNER REQUEST FOR
14 AUTHORIZATION TO FILE A MOTION TO STRIKE IN

15 IPR2024-01197

16 2:00 p.m. to 2:32 p.m.

17 August 14, 2025

18 (Remote Hearing)
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23
24 Job No. 7541125

Dr. Falk Pharma v. Ellodi Pharmaceuticals IPR2024-01197 Dr. Falk Pharma Ex. 1094
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25 REPORTED BY: Rhonda D. Tuck, RPR, CRR

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17 ALSO PRESENT:

18 Alex Wagner, Dr. Falk Pharma, for Petitioner
19 Richa Nand, Insight Patents
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I N D E X

ORAL ARGUMENT

By Attorney Agarwal.....	6
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1 (2:00 p.m., August 14, 2025)

2
3 P R O C E E D I N G S
4

5 THE COURT: Good morning, or good
6 afternoon, depending on where you are. This
7 call relates to Patent Owner's email of
8 August 4th in IPR2024-01197. And this is
9 Judge Chang. Judge Yang and Judge New are
10 also on the line.

11 So let's start with attendance.
12 Who is on the line for Petitioner?

13 ATTORNEY LUMAN: Your Honor, this
14 is Nate Luman, from Knobbe Martens, and I'm
15 joined by my partner Eric Furman, also of
16 Knobbe Martens. And I'm joined by Alex
17 Wagner. He is in-house at Dr. Falk Pharma,
18 their head of intellectual property. And I'm
19 also joined by Richa Nand, of Insight
20 Patents, for Petitioner.

21 THE COURT: Thank you. Who is on
22 the line for Patent Owner?

23 ATTORNEY AGARWAL: Your Honor,
24 this is Isha Agarwal, from Cooley LLP. I'm
25 joined by Sanya Sukduang and Jonathan Cousin,

1 also from Cooley.

2 THE COURT: Great. Thank you. Is
3 there a court reporter on the line?

4 THE COURT REPORTER: Yes, ma'am.
5 Rhonda Tuck, from Veritext.

6 THE COURT: Who engaged the court
7 reporter?

8 ATTORNEY LUMAN: That was
9 Petitioner, Your Honor.

10 THE COURT: Okay. So if you can
11 please submit a copy of the transcript as an
12 exhibit when it becomes available, we
13 appreciate that.

14 ATTORNEY LUMAN: Yes, Your Honor.

15 THE COURT: We understand that
16 Patent Owner -- Patent Owner's request for
17 authorization to file a motion to strike, and
18 as we understand it, this involves Exhibits
19 1075 to 1082 and portions of the reply
20 relying on those exhibits and then also
21 argument regarding U.S. Patent Number
22 6,139,865, and that will be exhibit I think
23 1085, and regarding -- argument regarding
24 taste masking.

25 So why don't you go ahead, Patent

1 Owners -- this is your request -- and let us
2 know why you think this is not appropriate
3 [indecipherable] reply.

4 ATTORNEY AGARWAL: Yes, Your
5 Honor, and just to clarify, we are seeking to
6 strike Exhibits 1075 to 1082 and Exhibit 1085
7 as well as Petitioner's reply that discusses
8 those exhibits and Petitioner's expert
9 declaration, the portions of Petitioner's
10 expert declarations that discuss those
11 exhibits as well.

12 Turning specifically to Exhibits
13 1075 to 1082, these are eight new exhibits
14 that Petitioner has submitted to fill in a
15 gap in the petition that Patent Owner pointed
16 out on the lack of evidence regarding
17 rapidly-dissolving lozenges and are,
18 therefore, improper reply evidence. They
19 weren't originally included in the petition,
20 and when we asked Petitioner's expert during
21 deposition whether he was aware of or had
22 looked into any references disclosing
23 rapidly-dissolving lozenges, he said no and
24 that searching for such references was not
25 relevant for his declaration.

1 Petitioner is now using these
2 references as secondary references to support
3 its grounds to fill in the gaps in its
4 petition, which is improper.

5 It is patent -- excuse me. It is
6 Petitioner's burden to identify with
7 particularity its grounds for unpatentability
8 and any evidence to support its grounds for
9 unpatentability in the petition itself, and
10 Petitioner failed to do that.

11 Patent Owner in its response
12 pointed out these gaps. And Petitioner is
13 now improperly bringing this new evidence in
14 its reply that should have been in the
15 petition.

16 Turning to Exhibit 1085,
17 similarly, Petitioner is seeking to fill in a
18 gap in the petition that Patent Owner pointed
19 out regarding taste masking, and Patent
20 Owner's response would include how the taste
21 masking disclosed in Venkatesh would prevent
22 a POSA from using the process disclosed in
23 Venkatesh to achieve the claimed invention,
24 and Petitioner in its reply is now improperly
25 adding Exhibit 1085 as a secondary or

1 tertiary reference to support its grounds
2 along with Venkatesh.

3 We submit that Patent Owner is
4 prejudiced by this new evidence and
5 Petitioner's expert declaration on this new
6 evidence because we don't have the same
7 opportunity to have our expert opine on this
8 new evidence, and we also get a limited
9 amount of space to respond in the reply.

10 And so we are seeking to strike
11 Petitioner's evidence for these new -- these
12 nine new references as well as portions of
13 Petitioner's reply and portions of
14 Petitioner's expert declaration that discuss
15 this new evidence.

16 Also, to the extent that these
17 exhibits are not excluded and struck, we
18 would like to request an extension to 7,500
19 words for the sur-reply as well as a short
20 declaration addressing these nine exhibits.

21 THE COURT: So let me ask, is it
22 Patent Owner's position that these exhibits
23 are not usable in the reply for any reason or
24 just for specific arguments?

25 ATTORNEY AGARWAL: We believe that

1 these references are not usable for any
2 reason in the reply. Petitioner is using
3 these exhibits in the reply in order to fill
4 in these gaps that Patent Owner pointed out
5 in the petition. So it's not being used --
6 these exhibits aren't being used in any other
7 way in the reply, regardless.

8 THE COURT: Okay. And then also,
9 you mentioned prejudice. As you know, I
10 think in our Trial Practice Guide we mention
11 that you do have opportunity to cross-examine
12 the expert. So what is -- is there really
13 any significant prejudice in this case, as
14 opposed to the general cases where additional
15 exhibits are submitted during the reply?

16 ATTORNEY AGARWAL: Yes, we do
17 believe there is. Our expert is not able to
18 opine on these exhibits that Petitioner is
19 saying that a POSA would read in a particular
20 way. Patent Owner does not have the
21 opportunity to put in its own declaration to
22 say that a POSA would read these exhibits in
23 the field in this art in a particular way.

24 Also, like I mentioned, we have a
25 very limited space in our sur-reply to

1 respond to this, and we have to dedicate a
2 significant amount to respond to these new --
3 to this new evidence and, frankly, from new
4 arguments as well.

5 THE COURT: Mr. Luman, would you
6 like to respond to that?

7 ATTORNEY LUMAN: Yes. Thank you,
8 Your Honor. So as a first point,
9 Petitioner's request should be denied because
10 it's untimely. The 2019 Consolidated Trial
11 Practice Guide, it says that motions to
12 strike should be requested within one week.
13 That's at Page 81. And here, the
14 Petitioner's reply was filed on July 14th,
15 and Patent Owner's email to the Board admits
16 that it didn't reach out to Petitioner until
17 July 31st, and Patent Owner didn't reach out
18 to the Board until August 4th. That's three
19 weeks after the reply was filed. So the
20 request is untimely and should be denied.

21 But I'd like to address the two
22 issues that were raised by Patent Owner and
23 make some closing points then after.

24 So I'd like to start with Patent
25 Owner's second issue. That's Patent Owner's

1 request to strike U.S. 6,139,865, and that's
2 Exhibit 1085. This is really an astonishing
3 request in view of the '865 Patent being
4 Patent Owner's own patent. The '865 Patent
5 explains that a polymeric coating allows an
6 orally disintegrating tablet to release its
7 drug to the upper gastrointestinal tract.
8 And it's appropriate rebuttal material
9 because it directly responds to arguments
10 raised in Patent Owner's response.

11 Patent Owner argued that such
12 polymeric coating prohibits tablet from
13 depositing the drug in the upper
14 gastrointestinal tract. And they didn't just
15 make that argument once. It's throughout the
16 Patent Owner response at Pages 2, 33 to 34,
17 36 to 37, 39 to 41, 50, and 52.

18 And the '865 Patent is
19 incorporated by a reference into the '729
20 Patent. That's Exhibit 1001, which is the
21 patent being challenged in this proceeding,
22 and it's also incorporated by reference into
23 Patent Owner's Venkatesh reference. That's
24 Exhibit 1020, which is the very reference
25 that Patent Owner contends prevents drug

1 release due to a polymeric coating.

2 And so it would not be a good use
3 of Board or Petitioner resources to allow
4 Patent Owner to file a motion to strike its
5 own '865 Patent when it previously told the
6 Patent Office that the '865 Patent should be
7 considered when evaluating the patentability
8 of the challenged patent by incorporating it
9 by reference into the challenged patent.

10 Now I'd like to turn to Patent
11 Owner's first request, which is seeking to
12 strike Exhibit 1075 to 1082. These exhibits
13 disclose rapidly-dissolving lozenges.

14 A major theme of Patent Owner's
15 response is that a lozenge, allegedly by
16 definition, must dissolve slowly and,
17 further, that they allege that the prior art
18 doesn't disclose rapidly-dissolving lozenges.
19 Throughout the Patent Owner response at
20 Pages 13 to 14, 20, 25 to 27, 30, and 36, and
21 Patent Owner's expert stated he's not aware
22 of any fast- or quick-dissolving lozenge in
23 the prior art. That's Exhibit 2007 at
24 Paragraph 83.

25 The Petitioner is entitled to

1 reply by introducing evidence and arguments
2 demonstrating that the prior art does
3 disclose rapidly-dissolving lozenges. The
4 Petitioner's Exhibit 1075 to 1082
5 appropriately responds to Patent Owner's
6 arguments on lozenges and are permissible.

7 I'd like to make a few closing
8 points. Petitioner asserted that the
9 arguments and exhibits should have been
10 included in the petition. Petitioners,
11 however, we can't refute every possible
12 argument that was made by a Patent Owner in
13 the petition.

14 An IPR proceeding, it's a trial
15 during which argument and an evidentiary
16 record will be developed, and Petitioners are
17 entitled to provide arguments and evidence in
18 reply to the arguments raised in Patent
19 Owner's response, which is what we've done
20 here.

21 I'll also say that a motion to
22 strike is an exceptional remedy that the
23 Board rarely grants, and for good reason.
24 The proceeding, it doesn't have a jury. It's
25 essentially a bench trial. And the Trial

1 Practice Guide explains that Your Honors are
2 well-positioned to evaluate arguments and
3 evidence including whether the arguments and
4 evidence are within the proper scope of
5 reply.

6 I'll mention that Patent Owner,
7 they're already authorized to file a
8 sur-reply. They have already scheduled a
9 deposition of Petitioner's expert on the
10 arguments and evidence that they're seeking
11 to strike, and they're already authorized to
12 file a motion to exclude. And these
13 pre-authorized briefings and depositions
14 provide Patent Owner with more than
15 sufficient opportunity to respond, and
16 there's no prejudice to Patent Owner.

17 From our perspective, there's no
18 need to waste the Board's or the parties'
19 time with additional motions to practice --
20 with additional motion practice such as a
21 motion to strike that would cover the same
22 arguments and exhibits. The better course
23 would be to have a complete record of the
24 arguments and evidence that's going to
25 facilitate public access as well as appellate

1 review.

2 They mentioned that, for the first
3 time, that they're going to alternatively
4 seek an extension of their sur-reply up to
5 7,500 words and a reply declaration. This is
6 the first time we're hearing of that.

7 Petitioner's reply complied with the Board's
8 word count requirement and didn't seek extra
9 briefing, even though Patent Owner's response
10 was up to 14,000 words, up to 14,000 words.

11 We were able to respond within the
12 word limit, and we feel that Patent Owner
13 should be allowed to do that as well. They
14 need to comply with the rule.

15 If they get to submit a short
16 declaration, then we would need to have
17 Petitioner be able to depose their declarant,
18 and we would ask for a sur-sur-reply so we
19 get a chance to respond on that issue because
20 that would only be the fair thing to do.

21 With that, Your Honor, I'll stop.
22 Thank you.

23 THE COURT: Thank you. Patent
24 Owner, if you can just quickly first address
25 the issue about timeliness. I think

1 Petitioner is correct that our Trial Practice
2 Guide is that generally a motion should be
3 sought within one week of the filing of the
4 material that you are seeking to strike.

5 So is there any reason why Patent
6 Owner could not have done that?

7 ATTORNEY AGARWAL: Yes, Your
8 Honor. I'm happy to address that.

9 The Trial Practice Guide does say
10 generally motion -- request for authorization
11 for motion to strike should be filed within
12 one week, but there is no specific rule or
13 deadline for authorizations for motions to
14 strike.

15 Also, in its reply, Petitioner
16 added about 22 new exhibits, and Patent Owner
17 was diligently analyzing the reply materials.
18 In doing so, that's when we determined that
19 these exhibits were improper and should be
20 struck.

21 We wanted to make sure that we
22 were properly going to seek authorization to
23 move to strike and make sure that we're not
24 going to move to strike exhibits that were
25 near responses to Patent Owner's arguments.

1 And so in analyzing these 23
2 exhibits and a lot of the argument and
3 [indecipherable] analysis that Petitioner put
4 in its reply, we were diligent, and we were
5 also in the process of negotiating extensions
6 of time for briefing for some of the other
7 IPR proceedings that are occurring between
8 the parties.

9 So in between that and analyzing
10 the exhibits, we were diligent. And
11 Petitioner is also not prejudiced in any way
12 for our slight delay in reaching out to the
13 Board.

14 THE COURT: Okay. Thank you.

15 Now if you can address the issues.
16 We have looked at the reply brief and
17 exhibits that was at issue in your request.
18 It does seem -- if we start with the
19 taste-masking argument first, it does seem
20 that Patent Owner would make an argument that
21 it's not -- the references were not
22 combinable because one of them -- taste
23 masking would prevent deposition of the drug.
24 It doesn't seem that that will be something
25 that Petitioner will be able to predict

1 during the filing of the petition, that this
2 is an argument that Patent Owner will make.

3 So how would you respond to that?

4 ATTORNEY AGARWAL: Sure. I would
5 just like to say for all of these exhibits,
6 not just for Exhibit 1085, in the absence of
7 all of these references, the petition would
8 fail based on the gaps that Patent Owner has
9 identified in the petition.

10 Regarding the '865 Patent
11 specifically, Petitioner pointed out that
12 this patent is incorporated by reference in
13 Venkatesh and the '729 Patent. Venkatesh
14 says what it says. It says that it is
15 directed to taste masking. This was very
16 clear just from the reference. And the
17 '865 Patent is now being used as an
18 additional reference to buttress the grounds
19 for Venkatesh.

20 It's not that Petitioner could not
21 have anticipated this. They have Venkatesh.
22 They chose to use it as an asserted ground or
23 use it in their asserted grounds. And so the
24 fact that it's incorporated into these
25 references is neither here nor there, and

1 they should have known, and they should have
2 been able to put this taste masking argument
3 into their petition.

4 THE COURT: Well, it seems that --
5 Venkatesh doesn't say that taste masking will
6 prevent deposition of the drug on the GI
7 tract and that, I think as Petitioner is
8 arguing, that they incorporated, Venkatesh
9 incorporated the patents that's at issue in
10 this motion, that -- in your request, that
11 specifically says that it does not.

12 So why would they be expected to
13 address the arguments made by the Patent
14 Owner?

15 ATTORNEY AGARWAL: Venkatesh is
16 directed to systemically acting drugs, which
17 Petitioner's expert also agreed to, and that
18 the drug is released in the lower GI tract.
19 And the '729 Patent is directed to topical
20 drugs that get deposited in upper GI tract,
21 in the esophagus. And so that in and of
22 itself, their expert reading and oppose their
23 reading Venkatesh should have realized that
24 this taste masking is a hindrance to topical
25 deposition of the drug.

1 THE COURT: Okay. Let's turn to
2 the other exhibits. It does seem, at least
3 in the reply that Petitioner filed, they are
4 citing it as in response to arguments from
5 Patent Owner, that lozenges generally are not
6 fast-dissolving. And again, this seems a
7 little bit like a claim construction issue or
8 at least understanding of a generally skilled
9 artist to what they will understand the
10 lozenges -- the properties of the lozenge.

11 So why wouldn't they be -- it
12 doesn't mean that that will be part of their
13 prima facie case, but it's, rather, something
14 in response to Patent Owner's arguments. So
15 why is that? Why is that not proper evidence
16 of what a generally skilled artisan, an
17 ordinary skilled artisan will understand?

18 ATTORNEY AGARWAL: So I believe
19 Petitioner, just now in his response,
20 basically stated that they are relying on
21 this new evidence for rapidly-dissolving
22 lozenges, which is not what was in the
23 petition, and as I mentioned earlier, in the
24 absence of these references, the petition
25 would fail, and so that's not -- Petitioner

1 has not fulfilled its burden of identifying
2 with particularity the effect -- grounds for
3 obviousness.

4 Also, I would like to point out
5 that on Page 6 of Petitioner's reply, they do
6 state that Patent Owner raised a similar
7 argument that lozenges are slow-dissolving
8 formulations, in the European Patent Office
9 proceeding, and that the EPO rejected PO's
10 argument, et cetera. But that just goes to
11 show that Petitioner itself admitted that it
12 has seen this argument from Patent Owner
13 before and so it should have been anticipated
14 that Patent Owner would make a similar
15 argument here. And we did.

16 So this should have been included
17 in the petition, particularly where
18 Petitioner has seen Patent Owner's arguments
19 on lozenges before.

20 THE COURT: Okay. I wonder -- I
21 want the parties to address a little bit in
22 terms of the timing, because we do have an
23 oral argument in late October, so that's not
24 a lot of time between now and then, in terms
25 of motion practice or if you would like to

1 have additional declarations or briefing.

2 Given that we have an oral
3 argument in two months or so, why does Patent
4 Owner think that we'd be able to fit in
5 additional reply declarations, sur-reply
6 declarations and additional depositions?
7 What is the timeline that you are
8 envisioning?

9 ATTORNEY AGARWAL: Patent Owner
10 does not need any additional time. We do
11 believe that we would be able to fit any
12 additional expert declaration, and if
13 Petitioner seeks, we would oppose any
14 sur-sur-reply from Petitioner.

15 THE COURT: Would you oppose a
16 deposition of your expert if they do submit a
17 sur-reply declaration? It seems like that
18 would be something that Petitioner should be
19 entitled to do if you submit a declaration, a
20 sur-reply declaration.

21 ATTORNEY AGARWAL: We could agree
22 to a one-hour expert deposition, and we would
23 submit the transcript -- or Petitioner would
24 submit the transcript.

25 THE COURT: Okay. And Petitioner,

1 I think you have already mentioned that you
2 are opposed to -- so are you opposed to any
3 additional declarations from the Patent
4 Owner?

5 ATTORNEY LUMAN: We are, Your
6 Honor. We think that the current -- the
7 default briefing that is allowed under the
8 rules is appropriate here because the
9 Petitioner's reply responded to what was in
10 Patent Owner's response, and the Patent Owner
11 already has authorized a reply brief. It's
12 already authorized to depose our experts and
13 includes deposition testimony of our experts
14 in their sur-reply brief. They're also
15 already authorized to file a motion to
16 exclude.

17 And so all of these give the
18 Patent Owner plenty of opportunity to respond
19 on the record under the Board's default rules
20 which were what is contemplated for our
21 trial.

22 When they say we should only be
23 able to depose their expert for one hour, we
24 don't even know what length of declaration is
25 going to be submitted by their expert, and we

1 don't know how long they want to -- what else
2 could be included.

3 The appropriate way to handle that
4 would be to allow another round of briefing
5 with a full, seven-hour deposition of their
6 expert, to make sure that we get a fair
7 opportunity to respond to new arguments and
8 evidence that they're going to raise.

9 I also would say I agree that the
10 schedule shouldn't be further cluttered with
11 more motions. The schedule is appropriate
12 because it's what's authorized under the
13 default rules. And the Petitioner has not
14 done anything outside of what the default
15 rules allow. We responded to arguments
16 raised by the Patent Owner in the Patent
17 Owner response.

18 We can't be able to predict every
19 single argument that Patent Owner is going to
20 raise. They said it was surprising that --
21 well, to us it was surprising that they
22 reraised arguments on lozenges that were
23 already rejected by the European Patent
24 Office. We wouldn't think that they would go
25 back and do that all over again with the

1 European Patent Office ruling in front of
2 them.

3 So that's what I have to say, Your
4 Honor. I don't think the schedule should be
5 further cluttered with additional motions and
6 deposition.

7 THE COURT: Okay. Thank you.

8 If the parties will stay on the
9 line for a moment, the panel will confer for
10 a moment, and we will be back shortly. If
11 you can just stay on the line.

12 (Break in proceedings.)

13 THE COURT: We're back. We will
14 send the parties an email shortly just
15 letting you know what we've decided with
16 regard to the Patent Owner's request.

17 I will say we have some questions
18 for the Patent Owner. We do have some
19 concerns that the Patent Owner's motion to
20 strike is seeking a pretty extreme remedy,
21 but we will discuss further among the panel,
22 and we will send you an email regarding
23 whether the request is authorized and, if
24 not, whether there's any additional extension
25 of the sur-reply.

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If that works for everybody, we
can go off the record.

ATTORNEY LUMAN: Thank you, Your
Honor.

ATTORNEY AGARWAL: Thank you, Your
Honor.

THE COURT: Thank you.

(Hearing adjourned at 2:32 p.m.)

* * * * *

1 COMMONWEALTH OF VIRGINIA AT LARGE, to wit:

2
3 I, Rhonda D. Tuck, RPR, CRR, Notary Public
4 in and for the Commonwealth of Virginia at Large,
5 and whose commission expires on May 31, 2028, do
6 certify that I was the stenographic reporter, via
7 remote videoconferencing, at the aforementioned
8 proceedings and that the foregoing is a true,
9 correct, and full transcript of the proceedings
10 herein.

11 I further certify that I am neither related
12 to nor associated with any counsel or party to this
13 proceeding, nor otherwise interested in the event
14 thereof.

15 Given under my hand and notarial seal in
16 Fluvanna County, Virginia, this 22nd day of August,
17 2025.

18
19
20 

21 Rhonda D. Tuck, RPR, CRR
22 Notary Public Registration No. 224847
23 Commonwealth of Virginia at Large
24
25

ERRATA SHEET

Case Name: *Dr. Falk Pharma GmbH v. Ellodi Pharmaceuticals, L.P.*, IPR2024-01197
Date: August 14, 2025
Hearing: Oral Hearing Regarding Patent Owner Request for Authorization to File a Motion to Strike

Page(s)	Line(s)	Errata
2	18	Mr. Wagner informed the undersigned after the hearing that he was unable to dial-in to the hearing due to technical difficulties.
4	16-18	

Dated: August 25, 2025

By: /Nathanael R. Luman/
Nathanael R. Luman (Reg. No. 63,160)
Knobbe Martens Olson & Bear, LLP

Attorney for Petitioner Dr. Falk Pharma GmbH

[& - analyzing]

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1	22nd 27:16	18:13 19:19	8:20
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