

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

ELLODI PHARMACEUTICALS, LP,	:	
	:	
Plaintiff,	:	Civil Action
	:	No. 1:24-cv-01392-PTG-WEF
v.	:	
	:	
DR. FALK PHARMA GmbH,	:	October 23, 2024
	:	9:03 a.m.
	:	
Defendant.	:	
	:	
.....	:	

TRANSCRIPT OF MOTION HEARING PROCEEDINGS
BEFORE THE HONORABLE PATRICIA TOLLIVER GILES,
UNITED STATES DISTRICT COURT JUDGE

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Proceedings reported by machine shorthand, transcript produced by computer-aided transcription.

WEDNESDAY MORNING SESSION, OCTOBER 23, 2024

(9:01 a.m.)

THE COURTROOM CLERK: Court calls *Ellodi Pharmaceuticals, LP versus Dr. Falk Pharma, GmbH*, Case Number 1:24-cv-1392.

May I have appearances, please, first for the plaintiff.

MR. WIKBERG: Good morning, Your Honor. Terry Wikberg from Holland & Knight on behalf of Plaintiff Ellodi. With me are my colleagues Amy Simpson and Christian Hecht.

THE COURT: Good morning to all of you.

MR. POYNTER: Good morning, Your Honor. William Poynter of the law firm Kaleo Legal, Virginia counsel for the defendant, Dr. Falk Pharma. With me are Christy Lea and Nate Luman from the law firm Knobbe Martens. Ms. Lea will be addressing the Court this morning.

THE COURT: Okay. Good morning to all of you. And so we're on for two motions today. We have our motion for preliminary injunction, as well as the motion to dismiss.

I think I'll start with plaintiffs. And I've read everything, so I don't need you to repeat what's in your pleadings.

I will tell you I am concerned that we have a matter pending in Germany that is asking for the Court to determine whether there is a violation of the agreement in that case. And that is what's essentially at the heart of the dispute here. Okay? Because I know that there's the matter that's going on at

1 the PTAB, but I still have to make a likelihood of success on the
2 merits determination, which touches on that matter.

3 And so I don't want to hide the ball from you. I'm going
4 to let you make your arguments, but I am concerned about that.
5 Okay?

6 MR. WIKBERG: Yes, Your Honor. Ms. Simpson will --

7 THE COURT: Ms. Simpson.

8 MR. WIKBERG: -- address our --

9 THE COURT: I think I was looking --

10 MR. WIKBERG: -- opening motion.

11 THE COURT: -- at the first chair.

12 MR. WIKBERG: That's okay. That's okay. I'll take the
13 heat, and then she can pick up the slack.

14 THE COURT: Okay. All right. Ms. Simpson.

15 MS. SIMPSON: All right. May it please the Court. Good
16 morning, Your Honor.

17 THE COURT: Good morning.

18 MS. SIMPSON: Let me just jump to your exact question.
19 You know, I -- you've read the briefs, you know the facts.

20 So with respect to the likelihood of a success, our
21 position is: The only question that this Court needs to address
22 is whether to enforce the forum selection clause. This Court
23 does not need to address the threshold issues about the scope of
24 the agreement itself, and whether it applies to just European
25 patents or whether it applies to the U.S. patents as well.

1 THE COURT: Why is that, when the first element in a
2 preliminary injunction case is the likelihood of success on the
3 merits?

4 MS. SIMPSON: Our motion is based on the fact that -- an
5 argued that they had breached the forum selection clause.
6 Everybody agrees that these arguments about the scope should have
7 been brought in Germany. We articulated that position. Our
8 clients have discussed, you know, the possible -- you know, the
9 settlement agreement itself and agreed that, you know, everything
10 here -- it's undisputed that the threshold issues in the scope
11 are for a German court applying German law.

12 Here we're in a difficult spot because what Dr. Falk has
13 essentially done was circumvent that clear forum selection
14 clause, knowing that we objected and believed that the -- that we
15 interpret the scope of the agreement differently than they do,
16 and yet instead of going to the forum that they now say we should
17 be in, they come here to the U.S. with no first attempt to go to
18 Germany. I mean, I -- it's just undisputed that -- they can't
19 have their cake and eat it, too, by saying, "Hey, look, we're
20 going to ignore the forum selection clause that says everything's
21 in Germany, go to the U.S., file this, and then if we have a
22 breach of contract on a forum selection clause that has to be
23 decided in Germany."

24 THE COURT: Why do you -- because your most -- your case
25 in Germany seeks -- part of it seeks to enjoin them from acting

1 here, does it not?

2 MS. SIMPSON: It does in a way. What we seek in Germany
3 is simply an interpretation of the contract --

4 THE COURT: But I thought that was one of the things that
5 you specifically requested as a form of relief there, was it not?

6 MS. SIMPSON: It is --

7 THE COURT: Now, the --

8 MS. SIMPSON: It is a form of relief because the IPR has
9 already been filed.

10 THE COURT: And so, if that was one of your requested
11 forms of relief, why didn't you request that report for immediate
12 relief or preliminary -- you know, the equivalent there?

13 MS. SIMPSON: Right, a preliminary injunction in the U.S.

14 THE COURT: Um-hmm.

15 MS. SIMPSON: For two reasons. We absolutely investigated
16 that as an option.

17 THE COURT: Okay.

18 MS. SIMPSON: First there was an issue of timing. The PI
19 decision in -- or a rendering of a decision in Germany, you know,
20 we couldn't put any real timeline around it, especially when you
21 take into consideration the fact that most likely, regardless of
22 how the decision goes, the losing party is going to appeal. And
23 so from what we could tell, that was a very long timeline.

24 Even if that decision from Germany comes down, you know,
25 quickly, the losing party most likely will appeal.

1 The second issue is that there was no assurances that the
2 German court would actually have power to reach over and force a
3 German company to take a specific action in a U.S. case. So
4 that's why we're asking for a temporary injunction on the PTAB,
5 so we can let these issues play out in the German court, and if
6 we win in Germany, then, yes, they would have to withdraw their
7 IPR petition. So that's why we're asking -- our resolution would
8 be if we win in Germany because the scope is, as we think it is,
9 they could not challenge these patents in the U.S., then they
10 would have to withdraw their petition.

11 But, you know, we're in a crunch of timeline here because
12 the USPTO moves very fast on those IPRs.

13 THE COURT: Oh, really? I don't think so, because it
14 takes at least six months for them to decide whether or not they
15 even are going to initiate proceedings --

16 MS. SIMPSON: That's true.

17 THE COURT: -- right?

18 MS. SIMPSON: That's true. And then from there it's --

19 THE COURT: And then there's more time --

20 MS. SIMPSON: Then it's a year.

21 THE COURT REPORTER: One at a time. I'm sorry. I didn't
22 hear you, Judge.

23 THE COURT: And after that, there is more time -- he's
24 very particular, so don't -- please don't speak over me.

25 So, even after that, there is an amount of time for them

1 to actually resolve it, so this -- it's not a quick process. And
2 in fact, we don't even know -- they may decide that they're not
3 even going to initiate at all.

4 MS. SIMPSON: Absolutely. That decision will be in --

5 THE COURT: January.

6 MS. SIMPSON: -- January, correct. So right, if we -- if
7 we defeat institution, I assume that they will file for rehearing
8 or director's review, which is probably another few months, so,
9 if we win, this matter could be over, you know, in May or April.
10 But the fact that we're having to do this in the first place
11 after resolving our prior disagreements, that the parties were
12 going to basically stand down on all their patents related to
13 this specific technology --

14 THE COURT: But that in --

15 MS. SIMPSON: -- you know, we've been harmed by the --

16 THE COURT: That is -- even that in and of itself is an
17 open question, because there are two competing interpretations --

18 MS. SIMPSON: Correct --

19 THE COURT: -- on whether or not this is even covered by
20 your agreement.

21 MS. SIMPSON: Correct.

22 THE COURT: Okay.

23 MS. SIMPSON: Correct.

24 THE COURT: All right. Thank you. Okay. Did you have
25 more?

1 MS. SIMPSON: No. I just wanted to -- that's why we're
2 here today is because that interpretation should be done in
3 Germany, but we think it's fundamentally unfair to allow the PTAB
4 proceeding to go forward while we wait -- you know, while they
5 skipped over Germany and we filed in Germany seeking -- you know,
6 honoring the forum selection clause and seeking them to give the
7 parties an answer about the scope before anyone challenges anyone
8 else's patents.

9 THE COURT: I understand. Thank you.

10 MS. SIMPSON: Okay.

11 THE COURT: Miss -- is it "Lee"?

12 MS. LEA: Lea.

13 THE COURT: Lea.

14 MS. LEA: Good morning, Your Honor.

15 THE COURT: Good morning.

16 MS. LEA: So I would be happy to respond. Your Honor is
17 right on track here with your initial analysis of the PI motion.
18 They absolutely have to show a likelihood of success on their
19 cause of action, which is breach of the contract, and so they
20 have to actually show a breach. They have to actually show that
21 the IPR even relates to this agreement, and it doesn't. This is
22 an agreement to settle European patent litigation. It relates to
23 European patents only, meaning patents in other countries of the
24 European patent organization. It's a German contract subject to
25 German law with German jurisdiction. There's no mention of U.S.

1 patents in this contract whatsoever. U.S. products, not
2 mentioned.

3 But what we do have in the contract is we have an
4 agreement between the parties not to sue each other for patent
5 infringement in those European countries that are members of the
6 European patent organization, and, of course, we have --

7 THE COURT: Okay. Let's not get to our merits of what
8 should be where. Let's just focus on forum selection.

9 MS. LEA: Okay. But the problem with the forum selection,
10 focusing on that at the level that they want to focus on, is they
11 want to just assume that anything related to a U.S. patent is
12 arising under that agreement, and it doesn't because it's a
13 European agreement limited to European patents.

14 THE COURT: Yes, but to the extent that they are
15 attempting to assert that this agreement does cover it, and that
16 there is a foreign selection clause in there that is mandatory,
17 don't you want to address that?

18 MS. LEA: Sure. So, just because they have created a
19 dispute, they're trying to argue that this European patent covers
20 U.S. patents, doesn't prevent Dr. Falk Pharma from performing
21 actions in the United States related to the U.S. patents. I
22 mean, quite frankly, it's a frivolous position. They filed suit
23 in Germany and the German courts are going to litigate it
24 quickly. They've set a hearing for February 13th and will issue
25 a decision either on that day or within a week, and that's in a

1 declaration from our German law expert.

2 So they're going to get a decision quickly, 11 months
3 before the IP -- before the Patent Office would ever issue an
4 order invalidating their patent. So, plenty of time there,
5 plenty of time to go make their case in Germany. They could have
6 filed a preliminary injunction in Germany. That's also in our
7 German law expert declaration. That's the only evidence on that
8 point here. They could have gone there. They could have filed a
9 PI. They chose not to, chose not to give us an opportunity to
10 respond in Germany on that PI under German law, that we believe
11 we could have easily defeated there. Instead, they're coming to
12 this court where we don't even have jurisdiction over my client
13 here in Virginia.

14 THE COURT: Thank you.

15 MS. SIMPSON: Okay. In response, there's -- it's
16 undisputed that the scope here of the agreement is at issue. And
17 Dr. Falk is asking this Court to apply German law to get to these
18 threshold issues. That basically eviscerates the forum selection
19 clause in the contract itself. If the U.S. court has to make all
20 these decisions applying German law just because Dr. Falk decided
21 to rush over to the U.S. instead of honoring its own forum
22 selection clause, then there's zero meaning to that -- to that
23 provision, if this Court has to do the work that Germany was
24 bargained for and the parties agreed to.

25 Here we simply are asking that the IPR be stayed so we're

1 not being -- you know, incur additional harm. We're trying to
2 defend ourself in a forum that we thought we were protected
3 against.

4 And, yes, the parties agree -- or they disagree on that
5 very point, but the function for this Court is to determine
6 whether that forum selection clause -- that's the breach of
7 contract saying Dr. Falk breached the forum selection clause, and
8 that's what the Court has to determine. We have to win on the
9 merits. And it's undisputed that forum selection clause is both
10 mandatory, because it has very exclusive language that said all
11 issues that arise out of this settlement agreement along with
12 Germany, they have not challenged that it's not enforceable, so
13 it's mandatory enforceable, and those are really the two factors
14 that count as to determining whether a party's going to win on
15 the merits when somebody breaches the forum selection clause.

16 As to the -- whether this arises out of the patent
17 settlement agreement, I believe Ms. Lea said their position is it
18 doesn't. But, again, that goes to a very threshold question
19 about the scope, and these -- the agreement talks about national
20 equivalence and legal constructs in the U.S. that are not
21 available in Europe. So there is an absolute dispute on the
22 scope, but then again, this is for Germany to decide, and a
23 simple stay of the IPR doesn't harm them at all. If they win,
24 they can always refile. There's no bar. The PTAB -- they can
25 refile their position with the PTAB. But, at the same time, if

1 they're not enjoined, we're forced to fight, you know, contrary
2 to all the bargained-for rights we sought -- we saw it in the
3 settlement agreement itself.

4 THE COURT: Thank you. Let's move on to the motion to
5 dismiss.

6 MS. LEA: Okay, Your Honor. So, Ellodi should never have
7 sued Dr. Falk Pharma in Virginia. Ellodi is a Pennsylvania
8 company. Dr. Falk Pharma is a German company with absolutely no
9 ties to Virginia whatsoever and no contacts. And we're here on a
10 breach of contract claim against a German contract with a German
11 law provision and a German forum selection clause, so there's no
12 reason for us to be here. And there's three reasons why this
13 Court should dismiss this case, and they're all independent
14 reasons.

15 So, first of all, the mandatory forum selection clause
16 says we should be in Germany. They're admittedly violating that
17 clause when they filed this lawsuit here in Virginia. They agree
18 it's a mandatory forum selection clause. They agree they have
19 the heavy burden to show that it would be unreasonable to enforce
20 it in this case.

21 They claim it's unreasonable because they would be denied
22 their day in court. They have their day in court. They've
23 already sued Dr. Falk Pharma in Germany. That is fully briefed.
24 They have a hearing set for February 13th, way before the PTAB
25 will ever rule in this case. They could have sought a PI in

1 Germany. They chose not to.

2 This case should absolutely dismiss -- be dismissed for
3 forum non conveniens. It should be dismissed for a lack of
4 personal jurisdiction. The only -- the sole contact that
5 Dr. Falk Pharma has ever had in Virginia is with the United
6 States government when it filed its IPR petition. That contact
7 is accepted, meaning under the government contact exception, it's
8 not considered for the personal jurisdiction analysis. We've
9 cited five different cases applying it. Four of those are being
10 applied in the Fourth Circuit, one of them here in the Eastern
11 District of Virginia that absolutely controls that if that is
12 your sole contact with the state of Virginia, it does not count
13 for personal jurisdiction. There are no other contacts. We sell
14 no products in the state of Virginia. We have no property in the
15 state of Virginia. There is nothing else.

16 And finally, failure to state a claim, 12(b)(6).

17 THE COURT: I don't need to hear anything on 12(b)(6).
18 Thank you.

19 MS. LEA: Okay. Well, then, in that case, Your Honor, we
20 ask that you dismiss the case for at least one of those three
21 reasons.

22 THE COURT: Thank you.

23 MR. WIKBERG: Your Honor, Terry Wikberg on behalf of the
24 plaintiff, Ellodi, and I'll respond to counsel's comments. But
25 before I do, it's, essentially, the theme of the motion to

1 dismiss that they don't feel they should be litigating in the
2 state of Virginia. It's a rather curious position, in that they
3 are litigating in the state of Virginia. I mean, IPRs are often
4 referred to as mini patent litigations.

5 This is not merely a petition for a trademark application
6 that's referenced in some of the cases that counsel's referred
7 to. This is an adversarial proceeding. There are expert
8 declarations. There are depositions. There are discoveries.
9 There are hearings.

10 The IPR is not simply the filing of a patent application
11 and engaging in -- with the government on some application level.
12 It is a disputed, contested proceeding. It's, in essence, a
13 litigation. Is it before an Article III court? No, it is not,
14 but they will be here in the state of Virginia or in the U.S.
15 taking a deposition, defending a deposition of their expert
16 declarant. They will be serving discovery, responding to
17 discovery, if this IPR is to proceed. And they will be attending
18 an oral argument and hearing to suggest that they shouldn't be
19 litigating in Virginia when they're litigating in Virginia seems
20 a bit of a stretch.

21 But with that, if we focus on the forum non conveniens
22 arguments, their position, taken to its logical extreme, means
23 that the very language of the agreement bars its enforcement, and
24 that is fundamentally unfair.

25 As Ms. Simpson pointed out, our position is that they

1 breached the forum selection clause. That couldn't be clearer.
2 It was made very clear during negotiations, long before the IPR
3 was filed, that there is a dispute as to the scope of this
4 agreement. They indicated during those negotiations that they
5 wanted to -- I assume as leverage they were going to file this
6 IPR. We told them that it is our position under the terms of the
7 agreement they cannot do that. There's a disagreement. That is
8 undisputed. Rather than resolving that disagreement about the
9 scope of the contract in Germany, as they agreed, must be done
10 based on their motion to dismiss the forum non conveniens
11 arguments and their 12(b)(6) arguments, rather than doing that,
12 they proceeded with the IPR, which has brought us here today.

13 To say that we are barred from enforcing the forum
14 agreements -- forum selection clause of that agreement, is
15 nonsensical. The agreement bars its own enforcement. Doesn't
16 make sense. And so for that reason, this -- their motion to
17 dismiss on forum non conveniens should be denied. It is
18 fundamentally unfair and fundamentally unjust to have us be
19 restricted by that language of the agreement and they can't be.

20 As to personal jurisdiction, there is some disagreement as
21 to the impact of certain cases. They heavily rely on the *Zenica*
22 case from 1999. It is our view that that case, while
23 informative, has been clarified in the *Acorda* case, I think, more
24 recently in 2016 from the Federal Circuit. In that case an ANDA
25 petition was found to be enough to satisfy personal jurisdiction.

1 Here we have, as I explained earlier, an adversarial
2 activity where parties will be litigating if -- again, if it's
3 allowed to proceed here in the state of Virginia. Depositions
4 will be taken. Hearings will be attended. Discovery will be
5 taken.

6 In addition to that, we read *Acorda* to say "the something
7 more" that was referred to in the briefing. In Mr. Walker's
8 declaration of Dr. Falk in response to the PI motion, paragraph
9 10 of his declaration expressly says that they are actively
10 pursuing bringing their product into the U.S. So, it's very
11 clear that, in addition to this proceeding, they are -- I'll use
12 his words -- "actively bringing the product to be -- "

13 THE COURT: But what does that indicate is happening in
14 Virginia, that they are actively pursuing bringing their product
15 into the United States?

16 MR. WIKBERG: That the --

17 THE COURT: Because that could be researched there; it
18 could be all kinds of things. What does that say about what's
19 happening here?

20 MR. WIKBERG: I don't imagine that they would carve out
21 the state of Virginia when they refer to the United States. So
22 that, coupled with -- in addition to their active pursuing, you
23 know, bringing a product into the United States; albeit, I agree
24 the declaration doesn't say into the state of Virginia -- I think
25 that would have been silly had they said that -- but certainly

1 Virginia being part of the United States.

2 But similarly, we also have this breach of contract. We
3 have something more. By filing the action in the U.S. Patent
4 Office, an adversarial action, that they have breached the
5 contract that very clearly says that the underlying dispute
6 should be resolved in Germany, and they agree on that.

7 By filing an adversarial proceeding, which is simply more
8 than a trademark application and it's simply more than a regular
9 ANDA application. That's not adversarial in and of itself.
10 Coupled with their clear intent and their ongoing activities,
11 not "We're going to do it some time in the future." The
12 declaration very clearly says "actively," that we feel that
13 that's sufficient to establish personal jurisdiction in the state
14 of Virginia.

15 I imagine, had we filed in Pennsylvania, they'd be saying
16 the same thing, and we have no contacts in Pennsylvania as well,
17 so the reference to that Ellodi being based in Pennsylvania, I
18 think, is a bit of a red herring.

19 As to the 12(b)(6), I think there's nothing to respond to,
20 but our position is if you look at the case law set forth in our
21 PI motion and the *Max Super Power* case, I think it addresses that
22 issue.

23 THE COURT: Thank you.

24 MR. WIKBERG: Thank you.

25 THE COURT: Ms. Lea, I have one question for you, because

1 in your pleadings you indicate that -- and you said it this
2 morning -- that they could have asked for this same relief there,
3 and so then are you conceding that they could enjoin your client
4 from proceeding in the PTAB?

5 MS. LEA: No, Your Honor. What I meant was that they
6 could move for a preliminary injunction in Germany. I don't
7 think the motion would be successful because it's meritless.

8 THE COURT: I didn't ask you whether it was -- to assess
9 the merits.

10 MS. LEA: Okay.

11 THE COURT: I asked you -- and this is a specific
12 question -- are you conceding then, because -- are you conceding
13 that if the German court did enjoin them, you all would be bound
14 by it?

15 MS. LEA: Absolutely.

16 THE COURT: You are conceding that?

17 MS. LEA: Correct.

18 THE COURT: Okay. That's all I have.

19 MS. LEA: So nothing further from me, Your Honor?

20 THE COURT: Nothing further.

21 MS. LEA: Okay.

22 THE COURT: Thank you. All right. And so --

23 MR. WIKBERG: Your Honor, may I respond to that or --

24 THE COURT: No.

25 MR. WIKBERG: Okay. Thank you.

1 THE COURT: No, you may not. I do think it's appropriate
2 to dismiss this case under the doctrine of non conveniens. I
3 know that that's a discretionary call for the Court. I am not
4 bound to do it. But when I look here and I see a mandatory forum
5 selection clause that you all have raised, I see that you are
6 asking the German court to enjoin and do the very thing you are
7 asking me to do, when there is a choice of law provision that
8 says German law. It's a forum selection clause that says a
9 German court. I think it is appropriate that that court be the
10 one to decide this issue.

11 When you have a mandatory forum selection clause, which
12 both sides concede that this is, the plaintiff's choice of forum
13 is not given any weight, and they're required to show why
14 transfer is unwarranted. And I don't think you -- according to
15 you, your position is that the parties contracted in advance that
16 that court, the German court should decide issues that arise
17 under the contract, and it's your position that this does arise
18 under the contract, that the very -- whether or not -- it's your
19 position that your agreement covers these patents, the U.S.
20 patents as well.

21 And so, I don't see how any -- public interest factors
22 also weigh against this enforcement. I think it's reasonable and
23 just for this action to be decided there, and I wanted to hear
24 and understand their position that they understand that they are
25 bound by, which was something that you raised in your briefs and

1 in your arguments today. You didn't know whether or not they
2 would be bound, but they have conceded. Okay?

3 I think also, given the way the PTAB moves and that this
4 upcoming date in Germany, that it's also reasonable that you take
5 this there, because the PTAB at this point hasn't even decided to
6 initiate. And so, even the timetable doesn't sway me in any way
7 that I think -- that gives me any reservation about this
8 decision. Okay? So I am going to grant their motion to dismiss.

9 I'm going to deny the preliminary injunction as moot,
10 then, and your exceptions are preserved.

11 Is there anything else?

12 MR. WIKBERG: There is, Your Honor. I understand, and I
13 don't want to relitigate your decision, but certainly, regardless
14 of how the German action ends, it will be appealed. And if that
15 appeal changes, we could very well be facing a situation where
16 the PTO --

17 THE COURT: You will --

18 MR. WIKBERG: -- cancels the patent, and the German action
19 hasn't been yet resolved, and that --

20 THE COURT: You will have to take that up in Germany,
21 because here's the thing: This is what the parties have
22 bargained for, that it be decided there, and I think it is
23 appropriate. Okay?

24 MR. WIKBERG: Okay. All right. Thank you.

25 THE COURT: We're adjourned.

(Proceedings adjourned at 9:32 a.m.)

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C E R T I F I C A T E

I, Scott L. Wallace, RDR-CRR,
certify that the foregoing is a correct transcript
from the record of proceedings in the above-entitled
matter.

/s/ Scott L. Wallace

10/30/24

Scott L. Wallace, RDR, CRR
Official Court Reporter

Date