

UNITED STATES INTERNATIONAL TRADE COMMISSION

In the Matter of:	)	Investigation No.
CERTAIN PHOTODYNAMIC THERAPY SYSTEMS,	)	337-TA-1411
COMPONENTS THEREOF, AND	)	
PHARMACEUTICAL PRODUCTS USED IN	)	
COMBINATION WITH THE SAME	)	

OPEN SESSIONS

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1 UNITED STATES INTERNATIONAL TRADE COMMISSION
2 Washington, D.C.
3 BEFORE THE HONORABLE BRYAN F. MOORE
4 Administrative Law Judge

5 _____
6 In the Matter of:) Investigation No.
7 CERTAIN PHOTODYNAMIC THERAPY SYSTEMS,) 337-TA-1411
8 COMPONENTS THEREOF, AND)
9 PHARMACEUTICAL PRODUCTS USED IN)
10 COMBINATION WITH THE SAME)
11 _____

12
13 International Trade Commission
14 500 E Street, S.W.
15 Washington, D.C.

16
17 Tuesday, July 1, 2025

18
19 Hearing - Volume II

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21 The Hearing commenced in Courtroom B, pursuant to the
22 notice of the Judge, at 9:00 a.m. Eastern.

23
24 Reported by: Karen Brynteson, FAPR, RMR, CRR

25

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1 P R O C E E D I N G S

2 (9:00 a.m.)

3 JUDGE MOORE: Please be seated. Okay. Let's go
4 on the record.

5 Good morning. Let's start with exhibits. Were
6 the exhibits, the agreed-upon exhibits, transmitted to the
7 court reporter this morning?

8 MR. GANGULY: Yes, Your Honor. We sent a list --
9 we sent a list of exhibits that the parties do not object
10 to, with a description of what those were, and then we also
11 sent a list of the exhibits that were used during the
12 hearing yesterday, and there are no objections to those
13 either. Both of those were transmitted to chambers and to
14 the court reporter.

15 JUDGE MOORE: Okay. And we discussed yesterday
16 some exhibits that, before the trial, had been agreed-upon
17 exhibits without sponsoring witness, I guess. And those
18 type of exhibits, I had suggested that the parties re-send
19 that e-mail. Was that re-sent?

20 MR. GANGULY: Yes, Your Honor. So the e-mail
21 that was sent, there was a list attached. In that list are
22 all of the exhibits that the parties are not objecting to,
23 and that list includes all of the exhibits for which no
24 sponsoring witness is required.

25 JUDGE MOORE: Okay. All right.

1 And Respondents, no objection to the list?

2 MS. PETERSON: No objection, Your Honor.

3 JUDGE MOORE: Okay. So the list that was just
4 described is admitted into evidence.

5 (Exhibits, as submitted by counsel and reflected
6 in the attached index, were received into evidence.)

7 MR. GANGULY: And in that e-mail, Your Honor,
8 there was also -- in the body of the e-mail, there were a
9 number of exhibits that were listed that were used at the
10 hearing yesterday. They're predominantly the witness
11 statements of the witnesses that were called and I believe
12 one other exhibit that was used during an examination. We
13 understand there are no objections to those being admitted
14 either.

15 MS. PETERSON: That's correct, no objection from
16 Respondents.

17 JUDGE MOORE: Okay. Then those are also
18 admitted.

19 (Exhibits, as submitted by counsel and reflected
20 in the attached index, were received into evidence.)

21 MR. GANGULY: Thank you, Your Honor.

22 JUDGE MOORE: All right. The time, it seems like
23 we're doing well on the time, but I'll just check in. We're
24 okay with the time so far?

25 MR. GANGULY: Yes. The parties are in agreement

1 on the time allocations, and we seem to be on schedule.

2 JUDGE MOORE: All right. So with that, any
3 objections that we need to deal with this morning?

4 MR. GANGULY: No objections from Complainant, but
5 there are a couple of housekeeping matters that we'd like to
6 raise.

7 JUDGE MOORE: Okay. All right.

8 Any exhibit objections from Respondent?

9 MS. PETERSON: No, Your Honor.

10 JUDGE MOORE: Okay. All right. So continue with
11 the housekeeping.

12 MR. GANGULY: So, Your Honor, in light of your
13 instruction regarding economic prong, Complainant also moves
14 to withdraw Mr. Albert's witness statement, CX-0020C, which
15 had to do with the economic prong in this case. So we move
16 to withdraw that witness statement.

17 JUDGE MOORE: All right. Any objection?

18 MS. PETERSON: No objection, Your Honor.

19 JUDGE MOORE: Okay. The motion is granted, I
20 guess.

21 MR. GANGULY: Okay. The other housekeeping issue
22 that we wanted to raise with Your Honor had to do with
23 demonstratives. We understand, Your Honor, from Your Honor
24 that the demonstratives are not substantive evidence, but we
25 wanted some clarification on whether those demonstratives

1 will still be submitted to you and whether they will be a
2 part of the record that will eventually go to the
3 Commission.

4 You have -- there's a ground rule, 12.6.2, by
5 which we have to submit all final exhibits.

6 JUDGE MOORE: Right.

7 MR. GANGULY: To chambers. And we believe that
8 the demonstratives will go at that time. So we were looking
9 for some clarification.

10 JUDGE MOORE: Okay. This comes up from time to
11 time, and I have yet to commit to memory exactly how that
12 occurs. I believe that they go to EDIS, and so then they
13 are available to -- at least to the Commission through EDIS.
14 I don't believe they are, you know, submitted at the same
15 time as, quote/unquote, final exhibits, because they are not
16 exhibits admitted to the record. But what I'll do is, on
17 the first break, I'll get an answer to the specific
18 procedure for demonstratives.

19 And any other housekeeping from Complainants?

20 MS. PETERSON: Your Honor, to clarify, I'm
21 looking at the ground rule here, and it mentions that the
22 demonstratives used at the hearing are submitted to the ALJ
23 over Box and then are transmitted to docket services through
24 that method. So just clarifying that that's what you
25 prefer?

1 JUDGE MOORE: As I said, I haven't committed to
2 memory how that occurs. I haven't memorized that. So if
3 it's not EDIS, if it's Box, then that's what it is. But I
4 will get to the parties an official from my team explanation
5 of how that should occur. All right.

6 Anything else?

7 MR. GANGULY: Not from Complainant, Your Honor.

8 JUDGE MOORE: All right.

9 MS. PETERSON: And nothing from Respondents
10 either.

11 JUDGE MOORE: All right. Okay. So with that, we
12 have a witness.

13 I'll remind you, you're still under oath.

14 And we can go briefly off the record while we
15 prepare to continue testimony.

16 (Discussion off the record.)

17 Whereupon--

18 NAN MARIE JOKERST,
19 having been previously duly sworn/affirmed, was examined and
20 testified as follows:

21 JUDGE MOORE: All right.

22 MR. GANGULY: Tuhin Ganguly for Sun Pharma.

23 REDIRECT EXAMINATION

24 BY MR. GANGULY:

25 Q. Good morning, Dr. Jokerst.

1 A. Good morning.

2 Q. Dr. Jokerst, you were asked some questions about
3 the hinges in the RhodoLED XL yesterday. Do you recall
4 that?

5 A. Yes, I do.

6 Q. Before we get to that, I want to ask you another
7 question. You were asked yesterday whether you ever
8 disassembled the RhodoLED XL. Do you recall that?

9 A. Yes, I do.

10 Q. Now, when you were performing your analysis, did
11 you have engineering schematics that showed all the internal
12 components of the RhodoLED XL?

13 A. Yes, I did.

14 Q. Did Biofrontera also provide pictures of a
15 disassembled panel?

16 A. Yes.

17 Q. Okay. Was that information sufficient for you to
18 perform your analysis?

19 A. Yes, it was.

20 Q. Okay. So let's turn back to the hinges.

21 Dr. Jokerst, are the panels of the RhodoLED XL
22 connected by hinges?

23 A. Yes, they are.

24 Q. Can we bring up CDX-0004C.182 for reference.

25 Okay. Dr. Jokerst, can you see one of the hinges

1 on slide 182?

2 A. Yes, I can.

3 Q. What color has the hinge been highlighted on
4 slide 182?

5 A. It's a dark blue with light blue words "friction
6 hinge."

7 Q. Okay. And why did you label it "friction hinge"?

8 A. In the Biofrontera documents, there is a German
9 word that translates to English, that that component is
10 called friction hinge.

11 Q. Okay. Now, where are the friction hinges in the
12 RhodoLED XL located?

13 A. On the inner side surface of adjacent patent
14 panels.

15 Q. You mentioned the inner side surface of adjacent
16 panels in your answer, so let's talk about that. On this
17 picture in slide 182, you highlighted a number of surfaces
18 in red. Do you see that?

19 A. Yes.

20 Q. And what is the red highlighting meant to
21 indicate?

22 A. The inner side surface of the panels.

23 Q. Now, Dr. Jokerst, does each panel have a casing?

24 A. Yes, each panel has a casing.

25 Q. Okay. In this picture, did you identify any

1 portion of the panel casing as an inner side surface?

2 A. Yes.

3 Q. All right. In addition to the casing highlighted
4 in red, there's also two black structures next to the hinge.
5 Do you see that?

6 A. Yes. They look dark red, though, because I
7 highlighted them in red.

8 Q. Okay. And so those structures that you
9 highlighted in red, what are those?

10 A. Those are the hinge holders.

11 Q. And why do you call them the hinge holders?

12 A. Again, in the German documents from Biofrontera
13 regarding the structure of the panels, those were in German
14 that translated to English called hinge holders.

15 Q. Okay. During Biofrontera's opening, their
16 counsel held up the plastic housing of one of the panels,
17 which I have in my hands. Do you recall that?

18 A. Yes.

19 Q. All right. Now, how many pieces is this plastic
20 shell?

21 A. Well, the plastic shell has a front part that's
22 white and -- sorry, a front part that's black and a back
23 part that's white.

24 Q. Is there a portion of the inner side surface on
25 each of these pieces of the plastic housing?

1 A. Yes.

2 Q. Okay. Now, does the inner side surface have to
3 be one continuous piece?

4 A. No.

5 Q. Can the inner side surface of a panel be made up
6 of multiple components?

7 A. Yes.

8 Q. Looking at this disassembled shell in my hand of
9 the RhodoLED XL, are there any components from the inner
10 side surface that are missing?

11 A. Yes.

12 Q. And what is that?

13 A. The hinge holders.

14 Q. When you identified the RhodoLED XL's inner side
15 surface, did you consider the RhodoLED XL in its assembled
16 or disassembled state?

17 A. In its assembled state.

18 Q. Okay. And why did you do that?

19 A. Because that was the analysis I was asked to
20 perform for infringement.

21 Q. Now, let's turn back to CDX-004C.182, which is
22 the slide on the screen. And that's showing -- is that
23 showing panels in an assembled state?

24 A. Yes.

25 Q. Okay. Looking at this picture, can you tell me

1 what the components of the inner side surface are?

2 A. Yes. So they are the two inner side surfaces of
3 the plastic, the white and the black plastic casing, and
4 then the two hinge holders.

5 Q. Okay. And does your picture show whether the
6 friction hinge is in contact with the hinge holder?

7 A. Yes.

8 Q. Yesterday you were shown a picture of the panels
9 in a disassembled state and asked whether the hinges are
10 attached to the front side of the support structure.

11 Do you recall that?

12 A. That's correct.

13 Q. Okay. Now, looking at slide 182, does the
14 surface of the hinge holder on which the friction hinge
15 rests face an adjacent panel when the panels are in a curved
16 shape?

17 A. Yes.

18 Q. And, Dr. Jokerst, in your analysis, did you
19 review the user manual for the RhodoLED XL?

20 A. Yes, I did.

21 Q. Does the RhodoLED XL user manual instruct a user
22 to put the RhodoLED XL in a particular shape for treatment?

23 A. Yes, for treatment of the face.

24 Q. And what shape is that?

25 A. A C shape.

1 Q. Does that mean a curved shape?

2 A. Yes, a curved shape.

3 Q. All right. Regardless, in your opinion, does --
4 do all the surfaces of the inner side surface have to be
5 pointed in the same direction?

6 A. No.

7 Q. And why do you say that?

8 A. Well, the inner side surface, first of all, isn't
9 -- doesn't need to be flat. It can have portions that stick
10 in a little bit and portions that stick out. And so the
11 inner side surfaces, when the panels are tilted, will face
12 in different directions.

13 Q. Okay. Now, in addition to resting on the hinge
14 holder, does the friction hinge contact any other surface of
15 the panel?

16 A. Yes.

17 Q. And what surface is that?

18 A. It contacts the plastic shell.

19 Q. Okay. And why -- in your opinion, why does the
20 friction hinge contact the plastic shell of the panel?

21 A. Well, from a design perspective, if you have
22 components that are close but not touching, if you have
23 things like fans that might vibrate the system a little bit,
24 then that piece that isn't quite touching will actually move
25 and create a clicking sound, tck, tck, tck, and so that

1 could disturb the patient during the treatment. So it's
2 better to have everything touching and tight.

3 Q. Yesterday counsel asked you questions about the
4 fact that the flange of the friction hinge is bolted to a
5 surface inside the panel shell. Do you recall that?

6 A. Yes.

7 Q. Okay. Are you aware that Biofrontera has argued
8 that the friction hinge is not on the inner side surface of
9 the panel because the hinge flange is bolted to a surface
10 inside of the panel?

11 A. Yes.

12 Q. All right. Do any of the asserted independent
13 claims specify where or how the nested hinges or hinge
14 structures are attached to the panels?

15 A. No.

16 Q. In your opinion, could a hinge still be
17 considered a nested hinge on an inner side surface even if
18 the hinge flange is not bolted or screwed to the inner side
19 surface?

20 A. Yes.

21 Q. What, if anything, in the asserted patents
22 supports that opinion?

23 A. Well, if we look at the '512 patent, claims 17
24 and 18 have some bearing on this.

25 Q. Okay. Claims 17 and 18 are those -- are those

1 dependent claims?

2 A. Yes, those are dependent claims, dependent on
3 claim -- 17 is dependent on claim 8.

4 Q. Okay. So can we bring up claim 8 of the '512
5 patent, which is JX-0001.

6 Okay. Now, the second element of claim 8
7 recites, "the illuminator comprising at least five panels
8 connected by nested hinges on inner side surfaces of
9 adjacent panels."

10 Do you see that?

11 A. Yes.

12 Q. So does claim 8 include nested hinges on inner
13 side surfaces of adjacent panels?

14 A. Yes, it does.

15 Q. All right. Now, can we bring up claim 17 of the
16 '512 patent. Okay.

17 Now, we have claim 17 on the screen. Which
18 claim, Dr. Jokerst, does claim 17 depend from?

19 A. Claim 8.

20 Q. Okay. And claim 17 adds the limitation "wherein
21 at least one panel includes a recess configured to receive a
22 flange of one of the nested hinges."

23 Do you see that?

24 A. Yes.

25 Q. Now, can we bring up Figure 3B of the '512

1 patent.

2 Do you recall being shown this figure yesterday?

3 A. Yes.

4 Q. Okay. In this figure, what is element 50?

5 A. That's the hinge.

6 Q. Does the embodiment shown in Figure 3B show the
7 flange of the hinge in a recess?

8 A. No, it doesn't.

9 Q. Okay. Now, let's go back and take a look at
10 claim 18 of the '512 patent. And if we could bring that up
11 with claim 17 as well. All right.

12 Now, which claim does claim 18 depend from?

13 A. 17.

14 Q. Claim 18 adds the limitation "wherein the recess
15 the positioned at an inner side surface of the at least one
16 panel."

17 Do you see that?

18 A. Yes.

19 Q. Is the recess that's recited in claim 18
20 referring to the recess that's recited in claim 17?

21 A. Yes.

22 Q. All right. In light of the additional limitation
23 in claim 18, does the recess in claim 17 have to be located
24 at an inner side surface?

25 A. No.

1 Q. And why do you say that?

2 A. Well, because if 17 included the recesses
3 positioned at an inner side surface, then it would read the
4 same as claim 18. And I understand that's not allowed.

5 Q. Okay. Now, if the recess configured to receive a
6 flange of one of the nested hinges in claim 17 is not
7 required to be at an inner side surface, what, if anything,
8 does that tell you about whether the flange of a nested
9 hinge is required to be positioned at an inner side surface?

10 A. Well, if the recess configured to receive a
11 flange of one of the nested hinges can be anywhere, then the
12 flange of one of the nested hinges can be anywhere.

13 Q. So what, if anything, does that tell you about
14 where the flange of a nested hinge, as that term was
15 construed by Judge Moore, can be attached?

16 A. Anywhere.

17 Q. And why do you say that?

18 A. Well, because claim 17 doesn't stipulate where
19 the recess that's configured to receive a flange of one of
20 the nested hinges is; and so, thus, the flange of one of the
21 nested hinges could be anywhere.

22 MR. LANDMON: Objection, Your Honor, to this line
23 of questioning. Dr. Jokerst has not before ever opined on
24 whether the recess can be located at a different location
25 than an inner side surface. She has also never made,

1 essentially, the claim differentiation argument. They're
2 not in the witness statement, nor in her expert reports.
3 And I move to strike as well.

4 MR. GANGULY: Your Honor, this is in direct
5 response to counsel's cross-examination yesterday, which
6 raised the issue of where the hinge flange is connected.
7 There was a series of questions talking about the two screw
8 holes are the point where the friction attaches to the
9 support plate. The hinge -- you know, the attachment point
10 is within the shell. All of these things were raised during
11 cross-examination yesterday.

12 And in -- so I'll stop there.

13 MR. LANDMON: If I may, Your Honor. Even though
14 we asked about location of attachments, which has to do with
15 whether the hinge is actually located on an inner side
16 surface, none of those questions went to where a recess is
17 located.

18 And, you know, it was incumbent upon them to set
19 forth in her expert report and in her witness statement if
20 she had an opinion about the location of recesses and if she
21 had an opinion about claim differentiation relating to the
22 location of recesses.

23 MR. GANGULY: If I may respond, Your Honor.

24 So in Dr. Jokerst's opening witness statement at
25 Question 473, she was asked: Do you consider -- so, Your

1 Honor, I have on the ELM0 Dr. Jokerst's opening witness
2 statement, and at Question 473, she was asked: Do you
3 consider whether the hinges must be mounted to or affixed to
4 the inner side surface of the panels? And she answers the
5 question as we just talked about here.

6 And in -- again, she is asked at Question 474:
7 In any event, are the hinges of the RhodoLED XL mounted to
8 or affixed to the inner side surface of the panels?

9 And in Question 475, she was also asked: How, if
10 at all, does it impact your analysis that the inner side
11 surfaces of the panels may not be flat?" In which she
12 references, which this is a typo here because it should be
13 claim 17, which talks about the system of claim 1, further
14 comprising a recess at an inner side surface of the panels,
15 which is the dependent claim which Dr. Jokerst was just
16 testifying about.

17 So she did disclose this. It was raised during
18 cross-examination about where -- yes.

19 JUDGE MOORE: Okay. So, specifically, the claim
20 differentiation, I don't see -- I do see claim 17. I don't
21 see claim differentiation between 17 and 18.

22 MR. GANGULY: So she raised claim 17 as a
23 dependent -- you know, the fact that the flange can be in
24 the recess. Yesterday during cross-examination we believe
25 counsel opened the door to this line of questioning. She

1 was asked about whether the connection point of the hinge
2 flange -- about the connection point of the hinge flange in
3 the RhodoLED XL. Dr. Jokerst is just explaining why that
4 may or may not matter in -- in response.

5 JUDGE MOORE: Okay. So what we're going to do
6 here is -- just give me a moment.

7 Okay. So the testimony specifically as to claim
8 differentiation, I'm going to -- she does talk about 17.
9 She does talk about these questions about the import of
10 claim 17, but she does not talk about claim differentiation.
11 I don't believe the door was opened to a new legal theory.

12 So if we start at -- on my realtime, it's 14:04,
13 the question is: Okay. Let's go back and take a look at
14 claim 18. Okay. And then ending at 14:24, the end of the
15 answer is: "And I understand that is not allowed."

16 So we have it on the record. That is testimony
17 and questions and answers are struck. The rest --

18 MR. LANDMON: Your Honor -- I'm sorry.

19 JUDGE MOORE: Yeah. Go ahead. That's the ruling
20 so far. Do you have a question?

21 MR. LANDMON: Yeah. Just if I may, I believe the
22 next question and answer stems from her claim
23 differentiation argument. So it would go down to -- is that
24 15:07? I'm sorry. 15:11. And maybe down to 15:16, Your
25 Honor.

1 JUDGE MOORE: Yeah. Okay. So --

2 MR. GANGULY: Your Honor, we understand your
3 ruling is up to 15:11. Is that --

4 JUDGE MOORE: Right. Right. Well, that wasn't
5 the ruling before. We went to 14:24. Respondent has asked
6 to continue to 15:11. And I'm looking at her testimony
7 regarding claim 17.

8 I'm going to leave the ruling as is. She
9 testifies that the claims can be attached from the inside
10 based on claim 17. With that testimony removed, any
11 additional reliance on claim -- on claim differentiation is
12 taken out, but I don't think the further testimony is
13 inconsistent with what she said. So that's the ruling.

14 MR. LANDMON: Okay. Thank you, Your Honor.

15 MR. GANGULY: Thank you, Your Honor. Can I ask
16 for just a short break to look at what was taken out to see
17 if I have any follow-up questions?

18 JUDGE MOORE: Sure. We'll go briefly off the
19 record.

20 MR. GANGULY: Thank you.

21 (Discussion off the record.)

22 JUDGE MOORE: Back on the record.

23 MR. GANGULY: Your Honor, I was just informed
24 that when I had referenced claim 17 in the witness statement
25 as a typo, it was actually claim 7, but I understand your

1 ruling, and so I can move on.

2 JUDGE MOORE: Okay. Well, obviously, that
3 changes the situation, if she didn't testify as to claim 17.
4 Part of the basis of the ruling was that the testimony was
5 related to claim 17. So I guess give me a moment, but maybe
6 Respondents want to make a comment.

7 MR. GANGULY: And just to clarify, Your Honor --

8 JUDGE MOORE: All right. It might be helpful to
9 bring claim 7 up on the screen for context.

10 MR. GANGULY: And I -- we can bring it up. I
11 just wanted to point out one other thing before we bring
12 that up, is that Dr. Jokerst does -- in her opening witness
13 statement, beginning at Question 623, she does analyze claim
14 17, which recites the recess.

15 JUDGE MOORE: Right. But the context of the
16 comments in the other testimony were specifically about what
17 we -- the issues that you were pursuing, which was where the
18 attachment could occur at different places, based on claim
19 17. But it appears that that testimony was based on claim
20 7.

21 MR. GANGULY: And we can bring up claim 7.

22 JUDGE MOORE: All right. Okay. So what we're
23 going to do is I'm going to amend the ruling to continue to
24 -- to 15:16, just before the objection.

25 And just in order to move on, you have testimony

1 about claim 7. It may be relevant to what you were talking
2 about. You were examining her on 17. So I can't allow that
3 testimony. So it's sustained. And I'm not preventing you
4 from exploring claim 7 or proceeding with your redirect
5 however you wish, but that's the ruling, so you may
6 continue.

7 MR. GANGULY: Thank you, Your Honor.

8 MR. LANDMON: Thank you, Your Honor.

9 BY MR. GANGULY:

10 Q. All right. Can we please bring up CDX-004C.234.

11 Okay. Dr. Jokerst, yesterday you were asked
12 about the recesses, the recesses on the RhodoLED XL panel in
13 relation to claim 17. Do you recall that?

14 A. Yes.

15 Q. Okay. Now, can you explain why you believe that
16 the recess limitation is satisfied of claim 17?

17 A. So Judge Moore's claim construction was a small
18 indentation, a cleft, or -- no, a small -- an indentation, a
19 small hollow, or a cleft. And I believe that the recesses
20 that exist in the RhodoLED XL do meet Judge Moore's claim
21 construction.

22 Q. And the recesses in the RhodoLED XL, do they
23 receive a flange of the nested -- of the friction hinge?

24 A. Yes. That's shown in one of my previous graphs,
25 yes.

1 Q. And can you describe how the recesses receive the
2 flange of the friction hinge?

3 A. The flange extends into the recess.

4 Q. And where does it attach to?

5 A. The hinge flange is bolted to the inside of the
6 recess. It's -- if you look at my center figure, the red,
7 you can see the little -- the little bolt holes.

8 Q. All right. So even though the hinge flange
9 extends into the interior of the shell and bolts to the
10 panel, is it your opinion that the recess limitation is met?

11 A. Yes.

12 Q. And why do you say that?

13 A. Because the recess meets Judge Moore's claim
14 construction, and the flange of the hinge is bolted into
15 that recess.

16 Q. Does the fact that the flange of the hinge --
17 does the fact that the flange of the hinge is bolted to the
18 plate interior to the shell affect your analysis of the
19 recess limitation?

20 A. No.

21 Q. Why not?

22 A. Because the recess limitation is -- well, so the
23 recess claim construction indicates what the recess is.
24 It's an indentation, small, hollow, or cleft. And the claim
25 construction does not include what lies within the recess.

1 Q. In order for the recess limitation to be met,
2 does it matter where the flange of the hinge is bolted or
3 attached?

4 A. So the recess claim construction doesn't include
5 information about the flange. Some of the claims include
6 the relationship between the recess and the flange, but the
7 claim construction does not.

8 Q. Okay. Well, the language of claim 17 is "wherein
9 at least one panel includes a recess configured to receive a
10 flange of one of the nested hinges."

11 Do you see that?

12 A. Yes.

13 Q. So when analyzing whether this claim element is
14 met, does it matter where the flange of the hinge is bolted?

15 A. Okay. I understand. You're asking about the
16 claim, not the construction. Okay.

17 So for claim 17, the recess is configured to
18 receive a flange of one of the nested hinges. And so that
19 means that the recess needs to be or needs to be enabled to
20 receive a flange of one of the nested hinges.

21 Q. Okay. And so what I had asked was, in order to
22 determine whether -- or when analyzing whether the claim 17,
23 "wherein at least one panel includes a recess configured to
24 receive a flange of one of the nested hinges," is met by the
25 RhodoLED XL, does it matter where the flange of the hinge is

1 bolted or attached?

2 A. No, not attached.

3 Q. And why do you say that?

4 A. Because there's nothing about where it's attached
5 in this claim.

6 MR. GANGULY: Pass the witness, Your Honor.

7 MR. LANDMON: We have no further questions, Your
8 Honor.

9 JUDGE MOORE: All right. Okay.

10 So you are released now. Don't worry about the
11 folders. They will handle that.

12 THE WITNESS: Thanks.

13 JUDGE MOORE: But you can get up now.

14 MR. GANGULY: And we will be calling Dr. Jokerst
15 in our rebuttal case.

16 JUDGE MOORE: Okay. So you will return. Yes.

17 THE WITNESS: Thank you, Your Honor.

18 JUDGE MOORE: Sure.

19 (The witness stood down.)

20 JUDGE MOORE: All right. We'll go briefly off
21 the record to prepare the next witness.

22 (Discussion off the record.)

23 MS. SAFI: Your Honor, Sun Pharma calls
24 Dr. Thomas Vander Veen as its next witness. Dr. Vander
25 Veen --

1 JUDGE MOORE: Just a minute. Okay. We're back
2 on the record.

3 MS. SAFI: Sorry.

4 JUDGE MOORE: Just to be clear.

5 MS. SAFI: Your Honor, Sun Pharma calls
6 Dr. Thomas Vander Veen as its next witness.

7 JUDGE MOORE: All right. And --

8 MS. SAFI: Dr. Vander Veen is our economics
9 expert, and he's here to testify about remedy, bonding, and
10 commercial success.

11 JUDGE MOORE: All right. And let's get your name
12 on the record.

13 MS. SAFI: After apologies, Your Honor. It's
14 Atifah Safi for Sun Pharma.

15 JUDGE MOORE: All right. And we'll get him sworn
16 in.

17 All right. Raise your right hand.
18 Whereupon--

19 THOMAS VANDER VEEN,
20 having been first duly sworn/affirmed, was examined and
21 testified as follows:

22 THE WITNESS: I do.

23 JUDGE MOORE: All right. Thank you.

24 MS. SAFI: Your Honor, the parties have agreed
25 that while the economic or accounting experts have submitted

1 both direct and rebuttal witness statements, they will both
2 only testify once for efficiency. So they will both submit
3 both of their witness statements on direct testimony and
4 then be crossed on both of their witness statements in one
5 session and then also be redirected once.

6 JUDGE MOORE: All right. Thank you.

7 DIRECT EXAMINATION

8 BY MS. SAFI:

9 Q. Good morning, Dr. Vander Veen.

10 Can you please introduce yourself to the Court.

11 A. My name is Thomas Vander Veen. I'm an economist
12 and I am employed by Epsilon Economics.

13 Q. Do you see the two binders in front of you?

14 A. I see one.

15 Q. So we can start with the binder that's titled
16 Corrected Witness Statement of Dr. Thomas Vander Veen.

17 Do you see that?

18 A. Yes.

19 Q. Inside, let's turn to CX-0016C.

20 A. Okay.

21 Q. Do you recognize this document?

22 A. Yes. It's my witness statement in this
23 investigation.

24 Q. Can you briefly summarize the opinions you
25 reached in your opening witness statement?

1 A. So I'm addressing inventory related to a cease
2 and desist order. And I found that the inventories were
3 commercially significant. And in terms of bond, I've
4 concluded that no price comparison is practical in this
5 case. And there's no basis or established royalty rate.

6 Q. Can you please turn to page CX-0016C.52.

7 A. Okay.

8 Q. Do you see a signature on that page?

9 A. Yes.

10 Q. Do you recognize the signature?

11 A. It's my signature.

12 Q. Does CX-0016C contain questions from counsel and
13 your answers to those questions?

14 A. Yes, it does.

15 Q. Now, please turn to page CX-0016C.2.

16 Does that page list the exhibits to your witness
17 statement?

18 A. Yes, it does.

19 Q. Can you turn now to the tab marked CX-1315 in
20 your binder.

21 A. Okay.

22 Q. Is CX-1315 a true and correct copy of your
23 curriculum vitae?

24 A. Yes, it is.

25 Q. Dr. Vander Veen, can you tell us a little bit

1 about your academic experience, please.

2 A. My academic experience?

3 Q. Yes.

4 A. Yes. I have a Bachelor's degree in economics and
5 mathematics from Calvin College. I have a Master's degree
6 and a Ph.D. in economics, and my graduate degrees are from
7 Brown.

8 Q. And can you tell us briefly what you do for work?

9 A. Currently, I'm an economic consultant. I've been
10 an economic consultant now for over 20 years. I analyze and
11 provide economic analysis in intellectual trade and
12 intellectual -- I'm sorry, international trade and
13 intellectual property matters. I provide valuation of
14 intellectual property assets, as well as other assets.

15 I provide economic impact studies and testify in
16 matters such as this.

17 MS. SAFI: Your Honor, Sun Pharma moves to admit
18 CX-0016C, which is the Corrected Witness Statement of
19 Dr. Vander Veen, into evidence.

20 JUDGE MOORE: All right. Hearing no objection,
21 it's admitted.

22 MS. PETERSON: No objection, Your Honor.

23 (Complainant Exhibit Number CX-0016C was received
24 into evidence.)

25 BY MS. SAFI:

1 Q. Dr. Vander Veen, did you prepare any opening
2 demonstratives to help explain your testimony today?

3 A. I did.

4 Q. Please turn to the tab in your binder marked
5 CDX-0007C, Corrected Direct Demonstratives of Dr. Thomas
6 Vander Veen.

7 Do you recognize this document?

8 A. Yes. These are the demonstratives that go with
9 my witness statement.

10 MS. SAFI: Your Honor, we offer CDX-0007C into
11 the record as demonstratives.

12 JUDGE MOORE: All right. They will be handled in
13 the way demonstratives are handled.

14 BY MS. SAFI:

15 Q. Turning to the binder titled Rebuttal Witness
16 Statement of Dr. Thomas Vander Veen, can you please turn to
17 CX-0012C.

18 A. Okay.

19 Q. Do you recognize this document?

20 A. Yes. It's my rebuttal witness statement in this
21 investigation.

22 Q. Please turn now to page CX-0012C.40.

23 Do you see a signature on that page?

24 A. Yes. It's my signature.

25 Q. Does CX-0012C contain the questions from counsel

1 and your answers to those questions?

2 A. Yes, it does.

3 Q. Now, please turn to CX-0012C.2.

4 Does that page list the exhibits to your witness
5 statement?

6 A. Yes, it does.

7 MS. SAFI: Your Honor, Sun Pharma moves to admit
8 CX-0012C, the Rebuttal Witness Statement of Dr. Thomas
9 Vander Veen, into evidence.

10 JUDGE MOORE: All right. Hearing no objection,
11 it is admitted.

12 (Complainant Exhibit Number CX-0012C was received
13 into evidence.)

14 BY MS. SAFI:

15 Q. Did Vander Veen, did your prepare your rebuttal
16 demonstratives to explain your testimony?

17 A. I did.

18 Q. Can you please turn to the binder tab marked
19 CDX-0015C, the Direct Rebuttal Demonstratives of Dr. Thomas
20 Vander Veen.

21 A. Okay.

22 Q. Do you recognize this document?

23 A. Yes. These are the demonstratives that go with
24 my rebuttal witness statement.

25 MS. SAFI: Your Honor, we offer CDX-0015C into

1 the record as demonstratives, pending your ruling on the
2 matter.

3 JUDGE MOORE: Right. Yes. They will be handled
4 as demonstratives are handled.

5 MS. SAFI: Your Honor, Sun Pharma proffers
6 Dr. Vander Veen as an expert in economic analysis related to
7 Section 337 investigations.

8 JUDGE MOORE: All right. Hearing no objection,
9 he is admitted for that purpose.

10 MS. SAFI: Thank you, Your Honor. I'll pass the
11 witness.

12 JUDGE MOORE: All right.
13 When you're ready.

14 MS. PETERSON: Good morning, Your Honor. Lauren
15 Peterson for the Biofrontera Respondents.

16 CROSS-EXAMINATION

17 BY MS. PETERSON:

18 Q. Good morning, Dr. Vander Veen.

19 A. Good morning.

20 Q. As you know, I represent Biofrontera in this
21 investigation. And I want to ask you some questions about
22 the opinions set forth in your two witness statements.

23 For the purposes of bond, you testified that a
24 price comparison is not practical in this case because the
25 BLU-U 4170E is not on sale, correct?

1 A. Well, there was no price data because at the time
2 it was not on sale, that's correct.

3 Q. And as we sit here today, is there price data?

4 A. I don't believe there's any price data in the
5 record.

6 Q. Okay. And you served a -- you served a corrected
7 version of your initial witness statement on May 6th,
8 correct?

9 A. I don't recall the exact date, but yes.

10 Q. I think it's on the signature page there, if you
11 want to look at that on -- in CX-0016.

12 A. Yes, it appears to be May 6th.

13 Q. Okay. And one of the corrections you made at
14 that time was to update the fact that the FDA approval had
15 occurred on May 1st, 2025?

16 A. That the approval had occurred?

17 Q. Yes.

18 A. Yes. I believe it was May 1st.

19 Q. Okay. And on that -- in your initial witness
20 statement, CX-16C, which was dated May 6th, you testified
21 that the BLU-U 4170E had not launched at that time?

22 A. There was no record evidence of a launch as of
23 May 6th.

24 [REDACTED]
25 [REDACTED]

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]

14 Q. Okay. So just to confirm, are you aware of what
15 the final price of the 4107E will be?

16 A. I'm not -- I don't know what the final price will
17 be. I mean, that will depend on actual transaction data.

18 Q. Okay. And to be clear, are you -- have you seen
19 any actual transaction data regarding the 4170E?

20 A. I have not seen transaction data that includes
21 prices. I understand there have been sales.

22 Q. Okay. And you just mentioned you haven't seen
23 any transaction data containing prices. Have you seen other
24 documentation of these sales you just mentioned?

25 A. I saw the testimony that indicated that there

1 have been sales. I have not seen documents or price data
2 for those sales.

3 Q. Okay. Changing gears a little bit, the list
4 price for the -- for Biofrontera's RhodoLED XL is \$18,500,
5 correct?

6 A. I believe that's the list price.

7 Q. Okay. And you understand that Biofrontera offers
8 discounts on the XL and the price therefore varies, correct?

9 A. That's correct.

10 Q. Okay.

11 MS. PETERSON: Your Honor, I believe we need to
12 go on the confidential record.

13 JUDGE MOORE: Okay.

14 MS. PETERSON: And --

15 JUDGE MOORE: We need to clear the --

16 MS. PETERSON: It will be Biofrontera,
17 Biofrontera's confidential record.

18 JUDGE MOORE: All right. Let's go off the record
19 for a moment while we clear the courtroom.

20 (Discussion off the record.)

21 (Whereupon, the hearing proceeded in confidential
22 session.)

23

24

25

1 O P E N S E S S I O N

2 JUDGE MOORE: Okay. Let's give it just a moment.

3 All right. It's taking a moment, so --

4 MS. SAFI: I can go ahead.

5 JUDGE MOORE: We're on the public record. You
6 can go ahead.

7 BY MS. SAFI:

8 Q. Dr. Vander Veen, you were asked by Biofrontera's
9 counsel about the fact that Sun Pharma has now begun selling
10 its BLU-U 4170E device. Do you recall that?

11 A. I recall questions along those lines, yes.

12 Q. Does the fact that the BLU-U 4170E is now being
13 sold change your opinions regarding bond in this case?

14 A. No, it does not. Again, we don't have
15 transaction data to make a comparison for prices. So there
16 still isn't a price that I can calculate a price comparison.

17 Q. You were also asked by Biofrontera's counsel
18 whether non-PDT treatments compete with PDT treatments. Do
19 you recall that?

20 A. Yes.

21 Q. Did you consider the non-PDT treatments competing
22 with the PDT treatments in your analysis?

23 A. I did. Certainly, I believe that the primary
24 analysis, the one that's most informative, is to look at the
25 PDT treatment and the products tied to that. But I did

1 discuss the broader AK treatment. And, for example, we
2 talked about the differences in market share, the 2 percent
3 and the 11 percent, for example.

4 Q. What, if anything, does that tell you about the
5 relevant market, the fact that 2 percent of AKs are treated
6 by AP but the revenue of PDT -- by revenue, PDT is
7 11 percent of the AK market? What, if anything, does that
8 tell you about the relevant market?

9 A. Yeah, I think it indicates that the PDT
10 treatment, the PDT procedures are differentiated from AK
11 treatments, that they are -- customers or physicians are
12 willing to pay approximately five times as much for the PDT
13 treatment compared to the average AK treatment.

14 And that's -- I think that's consistent with the
15 fact that there's a submarket for PDT treatments.

16 Q. Okay. You were also asked some questions about
17 some of the features of the RhodoLED XL in the context of
18 commercial success. And I want to talk about some of them
19 with you.

20 So Biofrontera's counsel asked you some questions
21 about whether the RhodoLED XL has a better touchscreen or a
22 touchscreen compared to the RhodoLED. Do you recall that?

23 A. Yes.

24 Q. Can we please pull up CDX-0015C.5.

25 Dr. Vander Veen, looking at this slide, can you

1 explain what is on this slide?

2 A. Yes. So this slide is -- includes two exhibits,
3 JX-75 -- from JX-75, that show the RhodoLED XL on the left
4 and the prior version on the right and how they're being
5 marketed.

6 Q. So if we can zoom in to bullet point number 3 on
7 both devices, which one of the Biofrontera devices has a
8 touchscreen, Dr. Vander Veen?

9 A. According to this, they both had touchscreens or
10 have touchscreens.

11 Q. Have you seen any evidence that RhodoLED XL sales
12 are being driven by a touchscreen or user interface or a
13 better touchscreen or user interface?

14 A. I have not, no.

15 Q. Biofrontera's counsel also asked you some
16 questions about whether the RhodoLED XL sales are being
17 driven by preference for Ameluz. Do you recall that?

18 A. Yes, I do.

19 Q. Have you seen any evidence that Ameluz is what
20 drives RhodoLED XL sales over the RhodoLED?

21 A. No. And, in fact, both the RhodoLED and the
22 RhodoLED XL would have the same indication, that they're
23 tied to Ameluz. So if there's a preference for Ameluz,
24 physicians could select the RhodoLED or the RhodoLED XL.
25 The fact that they're selecting the RhodoLED XL tells us

1 there's something about that product that's different than
2 the RhodoLED and that the choice is being driven not by
3 Ameluz, since they could do that with either, but by other
4 aspects of the XL.

5 And those turn out to be the patented features.

6 Q. You testified that in your witness statement that
7 the RhodoLED XL is priced higher than the RhodoLED, correct?

8 A. Correct.

9 Q. If both of the devices, the RhodoLED XL and the
10 RhodoLED, provide only --

11 THE REPORTER: I'm sorry, could you start that
12 over again? I didn't understand something.

13 MS. SAFI: Yeah, of course.

14 BY MS. SAFI:

15 Q. If both the RhodoLED XL and the RhodoLED provide
16 on-label use with Ameluz, is it economically reasonable in
17 your opinion to conclude that a preference for Ameluz is
18 what drives the sales of the RhodoLED XL?

19 A. No. Again, Ameluz is used with both RhodoLED and
20 the RhodoLED XL. The fact that there's a higher price for
21 the XL indicates that that's being driven by features other
22 than Ameluz, and, as I discuss in my expert report -- or in
23 my witness statement, that's tied to the patented features.

24 Q. Okay.

25 MS. SAFI: I have no further questions, Your

1 Honor.

2 JUDGE MOORE: All right. And, actually, what do
3 you anticipate? We're at 10:45. We're at the morning
4 break. If it's just a few questions, but if you think it's
5 going to go on a ways, maybe we should take the break.

6 MS. PETERSON: It is just a few questions, Your
7 Honor --

8 JUDGE MOORE: Okay.

9 MS. PETERSON: -- but I'm also fine to take a
10 break, if you prefer.

11 JUDGE MOORE: All right. Well, why don't we
12 continue, see if we can finish.

13 MS. PETERSON: Okay.

14 RECROSS-EXAMINATION

15 BY MS. PETERSON:

16 Q. If we could please pull up JX-229C again.

17 Dr. Vander Veen, you were -- oh, sorry.

18 MS. PETERSON: Yeah, sorry, this will be CBI
19 again. I forgot we went back on the public record. This
20 will be probably -- you know, just -- let's just say it will
21 be both.

22 JUDGE MOORE: All right.

23 (Whereupon, the hearing proceeded in confidential
24 session.)

25

1 O P E N S E S S I O N

2 JUDGE MOORE: Please be seated.

3 Okay. Back on the record.

4 MR. LARIVEE: Your Honor, Biofrontera calls as
5 its first witness Dr. Hermann Luebbert.

6 JUDGE MOORE: All right.

7 THE WITNESS: Good morning, Your Honor.

8 JUDGE MOORE: Good morning. And just -- we know
9 who you are, but just for procedure, get your name back on
10 the record.

11 MR. LARIVEE: Your Honor, for Respondents
12 Biofrontera -- for the Biofrontera Respondents, Brian
13 Larivee.

14 JUDGE MOORE: All right. And we will get you
15 sworn in. Raise your right hand.
16 Whereupon--

17 HERMANN LUEBBERT,
18 having been first duly sworn/affirmed, was examined and
19 testified as follows:

20

21 THE WITNESS: I swear.

22 JUDGE MOORE: All right. Thank you.

23 DIRECT EXAMINATION

24 BY MR. LARIVEE:

25 Q. Good morning, Dr. Luebbert. Can we please have

1 your name for the record.

2 A. My name is Hermann Luebbert.

3 Q. Have you testified in court before, Dr. Luebbert?

4 A. No.

5 Q. What is your first language?

6 A. It is German.

7 Q. Dr. Luebbert, what is your educational
8 background?

9 A. I am, by training, a scientist. I got a Ph.D. in
10 molecular biology from the University of Cologne. And then
11 I went to the California Institute of Technology for three
12 and a half years. And from there on I moved to Sandoz,
13 later Novartis, and I stayed there for ten years. And then
14 I started Biofrontera.

15 Q. Sir, there are two Biofrontera entities that are
16 Respondents in this investigation. Which Biofrontera entity
17 do you presently work for?

18 A. I am presently the CEO and chairman of
19 Biofrontera Inc.

20 Q. And what is your responsibility in those roles?

21 A. As CEO, I have overall responsibility for all
22 aspects of the business. And due to my background, I pay
23 particular attention, of course, to medical affairs and
24 research and development.

25 Q. And how long have you held the role of CEO of

1 Biofrontera Inc.?

2 A. I stepped into this role in 2023.

3 Q. And, sir, what was your role in the founding of
4 Biofrontera?

5 A. Well, initially we founded Biofrontera as
6 Biofrontera AG, in Germany. And I was CEO of Biofrontera AG
7 until 2021. And in 2021, we split off the two companies,
8 split off the former subsidiary, U.S. subsidiary, into a
9 separate nonstock-listed entity. And at that point I
10 dropped all my positions at Biofrontera AG and switched
11 initially as executive chairman and later as CEO and
12 chairman to Biofrontera Inc.

13 So since '21, I'm only working for Biofrontera
14 Inc. Until then, I was responsible for all of Biofrontera.

15 Q. And, sir, your company made an announcement
16 yesterday related to corporate structure. What was the
17 substance of that announcement?

18 A. That is a contract or an agreement between the
19 two entities that we have been discussing since a long time.
20 Because so far, the U.S. entity was responsible for
21 distribution of Ameluz and the lamps in the U.S., but all
22 the manufacturing, all regulatory, and the pharmacovigilance
23 and all of that was done by the German entities.

24 And now we continued splitting the U.S. entity
25 off, so all these basic functions of manufacturing and

1 pharmacovigilance, regulatory, and quality control, all of
2 that comes over to Biofrontera Inc. And with that,
3 Biofrontera Inc. is now fully separated from Biofrontera AG,
4 which is a process that we wanted to do since we split it
5 off and brought it to Nasdaq.

6 Q. Dr. Luebbert, did you offer testimony in the form
7 of a written witness statement in this investigation?

8 A. Yes.

9 Q. And do you have a binder in front of you?

10 A. Yes.

11 Q. Could you please turn to RX-4C.

12 A. Yes.

13 Q. Sir, is this your written witness statement in
14 this investigation?

15 A. Yes.

16 Q. Could you please turn to page 40. It should be
17 the second-to-last page.

18 A. Yes.

19 Q. Does this reflect your signature?

20 A. Yes.

21 Q. Does this witness statement contain your answers
22 to questions from counsel in this investigation?

23 A. Yes.

24 Q. Would you like to make any corrections to your
25 witness statement before you get started?

1 A. Yes. When I read it again, I saw that there is
2 one statement in there which I made which isn't quite
3 correct. It says we did -- or it describes the three
4 clinical pivotal trials we did to get approval for Ameluz on
5 the U.S. market by the FDA. And it says these trials have
6 been done between 2007 and 2010.

7 Now, that is true for two of them. And at that
8 time, we did the first two pivotal trials with a variety of
9 different lamps, which one of them was actually a five-panel
10 LED lamp, very similar to that one, but then we had to
11 develop our own lamp for the U.S. market. And with our own
12 lamp and Ameluz, we performed the third clinical trial. And
13 that was later. So that was between 2013 and 2015.

14 So one of the three trials was actually later
15 than what I said as a too-quick answer here.

16 JUDGE MOORE: Okay. We have an objection or
17 something.

18 MS. CHEN: Your Honor, I would move to strike
19 that portion. That's a belated effort to try to move to
20 correct the witness statement without having informed us or
21 meet and conferred. And perhaps we would agree, but we
22 haven't had a chance to discuss that because this is the
23 first time we're hearing about it.

24 JUDGE MOORE: All right. I think what we're
25 going to do is I'm going to strike the testimony. And what

1 we're going to do is at the lunch break, why don't you meet
2 and confer and figure out a reasonable agreement or
3 something else we have to discuss. But why don't we just
4 hold that testimony. And I understand it. So, you know, it
5 may be out of turn, et cetera, but we will deal with it at
6 the lunch break.

7 MS. CHEN: Thank you.

8 BY MR. LARIVEE:

9 Q. Pending that meet and confer, Dr. Luebbert, are
10 the answers in your witness statement accurate and truthful
11 to the best of your knowledge?

12 A. Yes.

13 MR. LARIVEE: And, Your Honor, Biofrontera would
14 like to move Dr. Luebbert's witness statement into evidence.

15 JUDGE MOORE: All right.

16 MS. CHEN: No objection.

17 JUDGE MOORE: It's so moved.

18 (Respondents Exhibit Number RX-0004C was received
19 into evidence.)

20 MR. LARIVEE: We pass the witness.

21 JUDGE MOORE: All right.

22 MS. CHEN: Betty Chen for Sun Pharma.

23 And the parties have reached an agreement that
24 for Dr. Luebbert, Sun Pharma is also calling him in Sun
25 Pharma's case.

1 JUDGE MOORE: All right.

2 MS. CHEN: May I proceed?

3 JUDGE MOORE: Yes.

4 MS. CHEN: Thank you.

5 CROSS-EXAMINATION

6 BY MS. CHEN:

7 Q. Dr. Luebbert, I didn't take your deposition in
8 this case, but I believe we have met before. It is good
9 seeing you again.

10 A. Nice to see you.

11 Q. So as for -- as -- you had testified just now
12 that you are Biofrontera, Inc.'s CEO, correct?

13 A. Correct.

14 Q. Okay. And for the deposition in this case, you
15 were a corporate designee for all of the Biofrontera
16 Respondents in this case, right?

17 A. To the extent that I can do that, yes.

18 Q. Okay. And you understand that Biofrontera has
19 taken a position in this case that Biofrontera's sales have
20 not reached a level sufficient to conclude that the RhodoLED
21 XL has been commercially successful. Do you understand
22 that?

23 A. I never talked to that, but we certainly did not
24 sell as many units of the Bio -- of the XL as we had hoped,
25 but you may want to ask our CFO, Fred Leffler, tomorrow. Or

1 today, later today.

2 Q. Okay. So are you aware that Biofrontera has
3 taken the position in this case that the RhodoLED XL has not
4 even sold anywhere near what it was projected?

5 A. Yes.

6 Q. And as Biofrontera's CEO, you've provided
7 statements to investors and to the press about the XL,
8 right?

9 A. Correct.

10 Q. Okay. And let's take a look at some of those
11 statements. Let's pull up CX-356.

12 Now, CX-356 is a press release from Biofrontera
13 on December 23rd, 2024.

14 Do you see that?

15 A. Yes.

16 Q. Okay. And in this press release, Biofrontera
17 announced that it placed a total of 100 RhodoLED XL in the
18 U.S. market, right?

19 A. Right.

20 Q. Okay. And Biofrontera has called this as a rapid
21 uptake in the U.S. market since launch for the RhodoLED XL,
22 right?

23 A. Right.

24 Q. Okay. And since it has seen rapid adoption by --
25 since then, it has seen rapid adoption by offices that have

1 previously used Ameluz and those who are also new to the
2 market with the product, right?

3 A. Right.

4 Q. And Biofrontera has stated that the main
5 difference between the company's existing RhodoLED XL and
6 the new RhodoLED -- I'm sorry, the existing RhodoLED and the
7 new RhodoLED XL is the number of LED panels which allow a
8 larger surface area to be illuminated during a single PDT
9 treatment with Ameluz; is that correct?

10 A. That is correct.

11 Q. And let's go to the third paragraph of the press
12 release. You're quoted here in this third paragraph, right?

13 A. Yes.

14 Q. Okay. And you state, "We are delighted that the
15 XL lamp has had such an enthusiastic reaction from
16 dermatologists who perform PDT." Correct?

17 A. Correct.

18 Q. And you have stated that "It's remarkable to have
19 placed this many in such a short span of time post-launch."
20 Right?

21 A. Right.

22 Q. Okay. And let's look at the fourth paragraph.
23 Okay. And this fourth paragraph contains a quote from
24 Biofrontera's customer, who evaluated and purchased the XL,
25 right?

1 A. Yes.

2 Q. And your customer stated they were thoroughly
3 impressed by the lamp's robust yet elegant design, as well
4 as its exceptional maneuverability and adjustability, which
5 made it ideal for photodynamic therapy, correct?

6 A. Correct.

7 Q. And that same customer said, "The larger
8 illumination area has significantly increased our patient
9 throughput."

10 Do you see that?

11 A. Yes.

12 Q. Let's turn to CX-1307. And this is a press
13 release from Biofrontera dated March 21st, 2025. Right?

14 A. Right.

15 Q. Okay. And let's look at the first bullet. All
16 right.

17 With the first bullet here, Biofrontera stated
18 that "The revenue growth was primarily driven in increases
19 by Ameluz sales volume and unit price, and the successful
20 launch of our RhodoLED XL lamp."

21 Do you see that?

22 A. I see that.

23 Q. Okay. And the fifth bullet, if we can go there,
24 states that Biofrontera placed 52 XL lamps in the fourth
25 quarter and 100 since launch, right?

1 A. Correct.

2 Q. Okay. Let's take a look at the bottom of this
3 document. And you're quoted here again, right?

4 A. Correct.

5 Q. Okay. And let's take a look at the next page,
6 where it continues your quote. Okay.

7 You state here, "We are encouraged by the sales
8 of RhodoLED XL, which has a considerable advance over
9 previous FDA-approved photodynamic therapy devices." Right?

10 A. Right.

11 Q. Let's pull this down and take a look at CX-183.

12 Okay. And CX-183 reflects an earnings call
13 transcript for Biofrontera for Q3 2024 that occurred on
14 November 2024. You were on the call as a participant from
15 Biofrontera, right?

16 A. Right.

17 Q. Okay. And we can see also you as a company
18 participant. Now let's take a look at page 2.

19 And here, you're talking to investors, right?

20 A. Right.

21 Q. Okay. And so let's take a look at page 3, where
22 you continue your conversation with investors.

23 And you state that "Biofrontera will start by
24 highlighting the tremendous progress we made in previous
25 months." Correct?

1 A. Correct.

2 Q. And the fourth item that you list here at the end
3 of this paragraph is the RhodoLED XL lamp, right?

4 A. Right.

5 Q. And then you discuss the launch of the RhodoLED
6 XL lamp, right?

7 A. Probably --

8 THE REPORTER: I'm sorry. Can you repeat your
9 answer?

10 THE WITNESS: Probably, yeah. I have to read it.
11 It's quite a while ago.

12 BY MS. CHEN:

13 Q. Okay. Well, let's take a look down at the bottom
14 of page 4. Okay.

15 You talk about the lamp on this earnings call,
16 correct?

17 A. Yes.

18 Q. And you say that the lamp -- the XL lamp is an
19 alternative to doctors who want to treat larger areas of
20 skin with Ameluz, right?

21 A. Right.

22 Q. And you state that many options -- many doctors
23 have chosen this option, right?

24 A. Right.

25 Q. Okay. And to the next page, page 5, you're

1 telling investors that you're optimistic that lamp sales
2 will continue to increase at a strong pace, correct?

3 A. Correct.

4 Q. And so you have a fiduciary duty to the
5 shareholders of Biofrontera Inc., right?

6 A. Right.

7 Q. You never told investors on the earnings call
8 that XL is behind pace, right?

9 A. Well, we said in the sentence that's yellow here
10 that we are optimistic that the sales -- the speed of the
11 sales, is going to increase at a strong pace.

12 Q. Right. And so you never told the investors that
13 XL has not sold anywhere near what was projected to sell,
14 correct?

15 A. Well, the "anywhere near" is your interpretation
16 of that. We told the investors how many we sold. And that
17 is our obligation, and that fulfills our obligation. And --

18 Q. So is it -- sorry, go ahead.

19 A. And whether or not we had at some point hoped
20 that we would sell more, we have also hoped that we would
21 sell more Ameluz. And after we brought the XL to market, we
22 hardly had any goals of Ameluz in that year. So Ameluz
23 didn't grow because we brought the XL to the market.

24 Q. So is it your testimony that when you state to
25 investors, "We're optimistic that our lamp sales will

1 continue to increase at a strong pace," then that means that
2 RhodoLED XL has not even sold anywhere near what it was
3 projected?

4 A. It's -- it means what it actually says.

5 Q. Okay. And do you still stand behind the
6 statement that RhodoLED XL has not even sold anywhere near
7 what was projected?

8 A. No, we didn't state that. And that's your
9 interpretation.

10 Q. Okay. So do you agree with Biofrontera's
11 position in this case that RhodoLED XL has not even sold
12 anywhere near what was projected?

13 A. No.

14 Q. And do you agree with Biofrontera's position in
15 this case that Biofrontera's sales have not yet reached a
16 level sufficient to conclude that the XL has been
17 commercially successful?

18 A. Well, I agree that Biofrontera had hoped that we
19 would sell more lamps in the first year. I think I said
20 that before. We got very positive response about the lamp
21 from the doctors using the lamp. But we did not sell as
22 many lamps that we had hoped when we launched the lamp.

23 Q. Sir, I will just ask you a yes/no question. Do
24 you believe that RhodoLED has been commercially successful
25 to date?

1 A. I don't think I can follow your interpretation of
2 that.

3 Q. Can you answer that question yes or no?

4 A. I believe that launching the XL has been a
5 success for the company, but it hasn't been the commercial
6 success that we had hoped.

7 Q. Thank you.

8 Okay. And I would like to discuss the history
9 between -- and we can pull this down.

10 I would like to discuss the history between Sun
11 Pharma and Biofrontera. So you'll agree that there's a
12 history between the parties in this case, right?

13 A. I agree that history goes back to 2009.

14 Q. Okay. And Biofrontera entered into the U.S.
15 market in 2016, right?

16 A. That was after 2009. I understand you don't want
17 to talk about 2009. Yes, we entered the U.S. market.

18 Q. Well, let's take a look at your witness statement
19 at Question 137.

20 A. Which question?

21 Q. 137. It will be up on your screen.

22 A. Yes.

23 Q. And your answer in here, you state, "We launched
24 in the United States in 2016."

25 Do you see that?

1 A. Yes.

2 Q. Okay. And so Biofrontera entered into the U.S.
3 market in 2016, right?

4 A. That's correct.

5 Q. And you were aware of Sun Pharma's drug Levulan
6 as you were developing the Ameluz product, right?

7 A. That's correct. That's why we had invited Sun
8 Pharma to our premises already in 2009 to discuss with them
9 our plans about Ameluz and entering the U.S. market.

10 MS. CHEN: Your Honor, I would like to move to
11 strike everything behind "Yes."

12 MR. LARIVÉE: Why? He can answer the question.

13 JUDGE MOORE: The question was a yes-or-no
14 question. And my practice is I allow, on cross, yes-or-no
15 questions, and the response to a yes-or-no question is a yes
16 or no.

17 If you -- you will have an opportunity to have
18 questions from your counsel. And if you need to elaborate,
19 certainly you can.

20 So I'm going to strike the answer as -- after
21 "That's correct."

22 MS. CHEN: Thank you.

23 BY MS. CHEN:

24 Q. Okay. And when you launched in the United States
25 in 2016, you hired a team in the United States to help

1 Biofrontera commercialize and sell your products in the
2 U.S., right?

3 A. That's correct.

4 Q. You hired people who came from Sun Pharma, right?

5 A. Yes.

6 Q. And you learned at some point that the ex-Sun
7 Pharma employees brought over Sun Pharma confidential
8 documents, correct?

9 A. Correct.

10 Q. Those employees brought hundreds of Sun Pharma
11 confidential documents to Biofrontera, right?

12 A. They brought hundreds of documents. Whether they
13 were confidential, I can't know because I have never seen
14 them.

15 Q. Okay. Well, let's take a look at CX-1058. Let's
16 take a look at the second paragraph here.

17 It states, "Biofrontera, by its own admission, is
18 in possession of at least 600 DUSA documents obtained from
19 20-plus employees that have left DUSA for Biofrontera in
20 recent years." Right?

21 A. I see that.

22 Q. Okay. And it further states, "These documents
23 include an extensive target customer list, sales analysis,
24 training and marketing materials, operating procedures,
25 technical information, and unpublished clinical data."

1 Do you see that?

2 A. I see that.

3 Q. Okay. And this is part of a lawsuit between Sun
4 Pharma and Biofrontera, right?

5 A. Correct.

6 Can I say more than yes?

7 JUDGE MOORE: You will have the opportunity to
8 explain on redirect from your counsel.

9 BY MS. CHEN:

10 Q. And we can pull that down.

11 During the lawsuit, Biofrontera never stipulated
12 or agreed not to use the Sun Pharma documents, right?

13 A. Correct.

14 Q. Okay. And the FDA has approved photodynamic
15 therapy as a combination therapy. So it approves the
16 pharmaceutical product alongside a medical device, right?

17 A. That is correct.

18 Q. And for Biofrontera, that means that the FDA
19 approved the Ameluz product in combination with the XL,
20 correct?

21 A. That is partly correct.

22 Q. Okay. And -- well, the XL user manual is
23 provided to doctors when they are provided with the Ameluz
24 drug label, right?

25 A. No. It is provided to them when they buy the XL.

1 Q. Okay. Let's take a look at your question and
2 answer on -- from your answer statement, Question 87. Okay.
3 Let's look at the second paragraph.

4 You have testified, "Because this is a
5 combination label, the full prescribing information also
6 contains versions of the user manuals for the BF-RhodoLED
7 and RhodoLED XL."

8 Do you see that?

9 A. Yes.

10 Q. Okay. So when the Ameluz label is provided, the
11 RhodoLED XL user manual is provided as well, right?

12 A. That's correct. When the Ameluz label is
13 provided, that contains also the label of the lamp.

14 MS. CHEN: And, again, I move to strike
15 everything after "That's correct."

16 JUDGE MOORE: Yeah, granted.

17 BY MS. CHEN:

18 Q. Okay. And you have testified about your
19 understanding regarding on-label and off-label uses, right?

20 A. Right.

21 Q. Biofrontera is required by FDA regulations to
22 promote its product consistent with only on-label uses,
23 right?

24 A. That's correct.

25 Q. So on-label use of Ameluz requires specific

1 illuminators, the specific lamps that FDA has approved for
2 use with Ameluz, right?

3 A. Correct.

4 Q. Providing samples of Ameluz to users who don't
5 have an XL lamp is one example of off-label use, right?

6 A. I don't agree with that.

7 Q. Well, providing samples of Ameluz to users who
8 don't have an XL is an example of off-label promotion,
9 correct?

10 A. No.

11 Q. Well, you agree that Biofrontera should not
12 engage in off-label promotion of its products, right?

13 A. I agree.

14 Q. And Biofrontera is required to stick to the label
15 and promote your products consistent with the on-label
16 directions and uses, right?

17 A. Correct.

18 Q. And the Ameluz label states that it's indicated
19 for field-directed treatment of actinic keratosis, right?

20 A. Yes.

21 Q. The label does not state that Ameluz is indicated
22 for the treatment of subclinical or non-visible lesions,
23 right?

24 A. "Field therapy" means subclinical lesions.

25 Q. I'm sorry, what was that?

1 A. The scientific interpretation of a label of
2 "field therapy for AK" means subclinical lesions.

3 Q. Okay. So you believe that the Ameluz label
4 states subclinical lesions?

5 A. The Ameluz label doesn't literally say that, but
6 if you were to read the scientific literature, then in all
7 the scientific literature, it says field therapy is required
8 to treat subclinical lesions.

9 MS. CHEN: And I will move to strike everything
10 after "the label does not literally state that."

11 JUDGE MOORE: I'm going to overrule that. You
12 opened up for him to explain, so overruled.

13 BY MS. CHEN:

14 Q. Okay. Well, let's take a look at Question 55
15 from your witness statement.

16 Your answer to Question 55 states, "The label
17 states that Ameluz" -- I'm probably going to butcher this
18 pronunciation -- "a porphyrin precursor, in combination with
19 photodynamic therapy using BF-RhodoLED or RhodoLED XL lamp
20 is indicated for the lesion-directed and field-directed
21 treatment of actinic keratosis of mild to moderate severity
22 on the face and scalp."

23 Did I read that correctly?

24 A. Yes.

25 Q. Nowhere on the label does it have the words

1 "subclinical or non-visible lesions," right?

2 A. Do you see "field-directed treatment"?

3 Q. I'm sorry?

4 A. It says "field-directed treatment."

5 Q. Okay. And I'll just ask for a yes/no answer to
6 that question.

7 Does anywhere -- nowhere on the label does it
8 state "subclinical or non-visible lesions" as words, right?

9 A. Obviously not.

10 Q. Okay. When did Biofrontera begin developing the
11 device that became the RhodoLED XL?

12 A. In 2017.

13 Q. What month in 2017?

14 A. Sometime in the middle of the year.

15 Q. In the middle of the year?

16 A. Yeah.

17 Q. Does September 2017 sound right?

18 A. It could be.

19 Q. And just to not break up the CBI portions, we
20 will come back to that.

21 Let's pull up the Biofrontera 2019 annual report.

22 Is this a -- do you recognize this as
23 Biofrontera's 2019 annual report?

24 A. I only see a title page, but I believe that is
25 the correct document.

1 Q. Okay. And let's take a look at page 26 from the
2 report, under the heading Development of the BF-RhodoLED XL.

3 In this report, you have stated that the main
4 development phase of the new lamp, BF-RhodoLED XL, was in
5 2019, right?

6 A. Yes.

7 Q. And we can pull that down.

8 Now, turning to the patents at issue in this
9 case, they were brought to your attention by Biofrontera's
10 lawyers, right?

11 A. Correct.

12 Q. And when they were brought to your attention,
13 Biofrontera had not yet launched the RhodoLED XL product,
14 right?

15 A. Right.

16 Q. So you became aware of Sun Pharma's patents in
17 this case related to its five-panel LED lamps during the
18 development of the RhodoLED XL product, right?

19 A. No.

20 Q. Your deposition was taken by my colleague in this
21 case, right?

22 A. Yes.

23 Q. And you were under oath in that deposition?

24 A. Yes.

25 Q. Okay. Let's pull up your deposition transcript

1 at page 61, 5 through 18.

2 Okay. You were asked the question:

3 "Dr. Luebbert, during the development of the RhodoLED XL
4 product, did you become aware of any of Sun Pharma's patents
5 that relate to its five-panel LED lamps? And you can answer
6 that question yes or no."

7 There's an objection, but then your answer at
8 page -- line 18 is: "Yes."

9 Do you see that?

10 A. Yes.

11 Q. Okay. By the time -- you can pull that down.

12 By the time Biofrontera began working on the XL
13 lamp, Sun Pharma already had its provisional application of
14 the asserted patents in this case, right?

15 A. Yes.

16 Q. And you reviewed the asserted patents and its
17 claims, right?

18 A. I was made aware of the patents by our lawyers by
19 the end of 2023.

20 Q. Okay. So you reviewed -- you had reviewed the
21 asserted patents and its claims, right?

22 A. I read the patents.

23 Q. Okay. And when you found out about the asserted
24 patents, you decided to file an IPR on one of them, right?

25 A. Now you are asking for privileged conversations

1 with our lawyers.

2 Q. Well, let's take a look just at your witness
3 statement, Question 148.

4 The second line here, "Biofrontera decided to
5 file a petition for inter partes review against the '028
6 patent in April 2024 ahead of our anticipated launch."
7 Right?

8 A. Right.

9 Q. And that statement is accurate, correct?

10 A. I expect Sun Pharma to sue us for whatever we do
11 as long as we are on the U.S. market.

12 Q. That's a yes/no question.

13 MS. CHEN: I'll just move to strike that last
14 answer and ask -- I can ask it again.

15 JUDGE MOORE: All right. Granted. Go ahead.
16 BY MS. CHEN:

17 Q. Sir, "Biofrontera decided to file a petition for
18 inter partes review against the '028 patent in April 2024
19 ahead of our anticipated launch," that's an accurate
20 statement, correct?

21 A. That's an accurate statement.

22 Q. Okay. And before any decision was reached about
23 that IPR that was filed ahead of launch, Biofrontera went
24 ahead and launched RhodoLED XL in June 2024, right?

25 A. That was after the IPR was filed.

1 Q. I'm sorry? I just can't hear.

2 A. Can you repeat your question?

3 Q. Okay. Before any decision was reached by the
4 PTAB about the IPR that was filed before launch, Biofrontera
5 went ahead and launched the RhodoLED XL in June 2024; is
6 that correct?

7 A. That's correct.

8 Q. And Biofrontera is the entity that sells the
9 RhodoLED XL in the United States, right?

10 A. Right.

11 Q. And Biofrontera purchases the XL from Biofrontera
12 Pharma GmbH, one of the German entities; is that correct?

13 A. That's correct.

14 Q. It's Biofrontera Pharma who is responsible for
15 the production of the XL; is that right?

16 A. Yes.

17 Q. Biofrontera Inc. does not manufacture anything;
18 is that correct?

19 A. Up to now, not.

20 Q. And up until now, Biofrontera's manufacturing
21 activities with respect to the XL have all occurred outside
22 the United States, right?

23 A. Correct.

24 Q. And when -- you keep saying "up to now" because
25 there was the new restructuring deal that was announced

1 yesterday, right?

2 A. Correct.

3 (Whereupon, the hearing proceeded in confidential
4 session.)

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1 O P E N S E S S I O N

2 MR. LARIVEE: Your Honor, we'll just grab our
3 witness from the --

4 JUDGE MOORE: That's fine. We'll go off the
5 record.

6 (Discussion off the record.)

7 (A recess was taken at 1:51 p.m., after which the
8 proceedings resumed at 1:57 p.m.)

9 JUDGE MOORE: Please be seated.

10 MR. LARIVEE: May I proceed, Your Honor?

11 JUDGE MOORE: Yes.

12 MR. LARIVEE: Brian Larivee for the Biofrontera
13 Respondents. Biofrontera calls as its next witness
14 Dr. Montserrat Foguet.

15 JUDGE MOORE: All right. We'll get you sworn in.
16 So if you could raise your right hand.
17 Whereupon--

18 MONTSERRAT FOGUET,
19 having been first duly sworn/affirmed, was examined and
20 testified as follows:

21 THE WITNESS: I swear.

22 JUDGE MOORE: All right. Thank you.

23 DIRECT EXAMINATION

24 BY MR. LARIVEE:

25 Q. Good afternoon, Dr. Foguet. Could you --

1 A. Good afternoon.

2 Q. -- please tell us your name for the record.

3 A. My name is Montserrat Foguet Roca.

4 Q. And have you testified in court before,
5 Dr. Foguet?

6 A. No, this is my very first time.

7 Q. And what is your first language?

8 A. Spanish.

9 Q. Which Biofrontera entities do you work for?

10 A. I am hired by Biofrontera AG as the general
11 manager of the two subsidiaries, Biofrontera Bioscience GmbH
12 and Biofrontera Pharma GmbH. In my function as general
13 manager, I report to the board of Biofrontera AG directly.

14 Q. And what are your responsibilities in that
15 general manager role for those subsidiaries?

16 A. One side, I'm -- on one part, I'm the head of
17 regulatory affairs and also all the manufacturing, both for
18 the drug product and the medical device, they report to me.

19 Q. Dr. Foguet, what is your educational background?

20 A. I hold a degree in chemistry, focus on molecular
21 -- on biochemistry and organic chemistry of the University
22 of Barcelona. I also earned a Ph.D. in molecular and
23 cellular biology in Switzerland, the University of Basel.
24 Later I had two postdoctoral fellowships at the same
25 university and also at Standard Pharma.

1 Q. And in addition to your Ph.D.s, do you have any
2 other academic training?

3 A. Well, yes. Later when the focus of Biofrontera
4 moved into clinical development, I earned a certificate of
5 the Northeastern University of Boston on international
6 regulatory affairs.

7 Q. Dr. Foguet, what was your role in the founding of
8 Biofrontera?

9 A. When Biofrontera was founded, I was senior
10 scientist at that time. At that time, we were working on
11 gene expression of several brain tissues. We were looking
12 for gene expression differences between healthy and diseased
13 brain tissues for diseases such as Alzheimer's and
14 Parkinson's. And my role was to analyze the amount of data
15 that was generated from DNA sequencing.

16 Q. Dr. Foguet, you should have a binder in front of
17 you labeled RX-002C. What is that document there?

18 A. This is my witness statement.

19 Q. And could you please turn to the second to last
20 page of the document.

21 A. Yes.

22 Q. Is that your signature there?

23 A. Yes, it is.

24 Q. Does your witness statement contain your answers
25 to questions from counsel in this investigation?

1 A. Yes.

2 MR. LARIVÉE: Your Honor, Biofrontera would like
3 to move Dr. Foguet's witness statement into evidence.

4 MR. PATNAIK: No objection, Your Honor.

5 JUDGE MOORE: All right. It's admitted into
6 evidence.

7 (Respondents Exhibit Number RX-0002C was received
8 into evidence.)

9 MR. LARIVÉE: We pass the witness.

10 MR. PATNAIK: Good afternoon, Your Honor.

11 JUDGE MOORE: Good afternoon.

12 MR. PATNAIK: Goutam Patnaik on behalf of Sun
13 Pharma.

14 JUDGE MOORE: All right.

15 CROSS-EXAMINATION

16 BY MR. PATNAIK:

17 Q. Good afternoon, Doctor.

18 A. Good afternoon. Thank you.

19 Q. You should have a binder in front of you now.

20 A. I do.

21 Q. Okay.

22 MR. PATNAIK: May I proceed?

23 JUDGE MOORE: Yes.

24 BY MR. PATNAIK:

25 Q. Turning to your witness statement, RX-2C, which

1 should be in your binder, at Question 35 you testify that
2 final manufacturing and assembly of the RhodoLED XL occurs
3 in Germany, correct?

4 A. Excuse me. I'm still opening.

5 Q. Sure, no problem.

6 A. The binder -- the binder, I apologize. Which --

7 Q. Question --

8 A. -- exhibit did you mention, please?

9 Q. Question 35.

10 A. Question 35. Oh, on my witness statement.

11 Sorry. Wrong document. Oh, I can -- sorry.

12 I have a general question, Your Honor. Do I have
13 to work with the paper form or can I just rely on the
14 information?

15 JUDGE MOORE: You can rely on the screen. If
16 you're --

17 THE WITNESS: Thank you.

18 JUDGE MOORE: -- comfortable doing that, that's
19 fine.

20 THE WITNESS: Thank you very much. Because I was
21 just --

22 BY MR. PATNAIK:

23 Q. I was trying to level-set.

24 A. Yeah.

25 Q. Let me ask the question again.

1 A. Fine.

2 Q. You testified that final manufacturing and
3 assembly of the RhodoLED XL occurs in Germany, correct?

4 A. Yes, this is correct.

5 Q. And Ameluz, the pharmaceutical product, that's
6 made in Switzerland, correct?

7 A. We have a contract manufacturer in Switzerland,
8 yes.

9 Q. Is it made anywhere else besides Switzerland?

10 A. Right now, it's the only approved manufacturer
11 that we have for Ameluz.

12 Q. The one in Switzerland, correct?

13 A. Yes.

14 Q. Prior to 2015, it was known in the scientific
15 community that Protoporphyrin IX, also known as PpIX, will
16 fluoresce in response to being exposed to certain
17 wavelengths of light. Is that correct?

18 A. Yes.

19 Q. And prior to 2015, you yourself were aware that
20 PpIX would fluoresce when exposed to certain wavelengths of
21 light, correct?

22 A. Yes, under certain wavelengths and for all kind
23 of living cells that can accumulate ALA, this could be the
24 case, yes.

25 MR. PATNAIK: Your Honor, move to strike

1 everything after "yes."

2 JUDGE MOORE: Okay, granted. Granted. Go ahead.

3 BY MR. PATNAIK:

4 Q. As of 2015, you also knew that irradiation of a
5 photosensitizer like PpIX can be used for diagnostic
6 purposes such as detecting proliferating cells, correct?

7 A. Yes.

8 Q. It was known that irradiation of a
9 photosensitizer could give rise to a characteristic
10 fluorescence radiation which could be used for diagnostic
11 purposes, correct?

12 A. Yes, this was known in the medical literature.

13 Q. Prior to 2015, correct?

14 A. Prior to 2015.

15 Q. And one example would be for detecting
16 proliferating cells; is that right?

17 A. Excuse me, can you repeat your question, please?

18 Q. Sure. And an example could be for detecting
19 proliferating cells; is that correct?

20 A. Can you please specify what you mean with
21 "proliferating cells"? All cells proliferate at a certain
22 point.

23 Q. I'm sorry. Could you repeat that?

24 A. I'm saying that proliferating, what is the -- can
25 you please specify what you mean with "proliferating cells"?

1 Q. Sure. Let me do this: Can we show you in your
2 binder, there's a patent near the back of the book. Well,
3 let me back up.

4 In your witness statement, you reference
5 nanoemulsion work that you did, correct?

6 A. Yes.

7 Q. And there were some patents that came out of that
8 nanoemulsion work. True?

9 A. Yes.

10 Q. If you turn to the back of your binder, there's a
11 copy of U.S. Patent Number 11,540,981. Do you see that?

12 A. Yes.

13 Q. And that's a patent related to nanoemulsion
14 formulation for which you're the named inventor, correct?

15 A. Correct.

16 Q. And that application for that patent was filed in
17 2007, right?

18 A. Yes.

19 Q. Looking in the background of that, of the
20 invention in that patent, column 2, lines 21 through 24,
21 could you take a look at that? Column 2, lines 21 through
22 24.

23 A. Okay.

24 Q. There it states, "Furthermore, irradiation of the
25 photosensitizer gives rise to a characteristic fluorescence

1 radiation which can be used for diagnostic purposes, for
2 example, for detecting proliferating cells."

3 Do you see that?

4 A. Yes, I see this.

5 Q. So an example that you give in your patent of
6 this diagnosis technique is for detecting proliferating
7 cells. True?

8 A. Correct, with this it means -- is meant living
9 cells that are -- that are still capable of proliferating,
10 yes.

11 Q. Let's go to column 12 of your patent, lines 40 to
12 46, please. Do you see it?

13 A. Yes.

14 Q. The detection of fluorescence is based on
15 selectively concentrating a photosensitizer like PpIX in the
16 target cells. Is that correct?

17 A. In proliferating cells, in selectively
18 concentrating the photosensitizer in proliferating cells as
19 compared to normal cells, is what I read.

20 Q. You agree with that, correct?

21 A. Sorry? Say again?

22 Q. Do you agree with that as a technique?

23 A. Yes, I agree with this.

24 Q. And the photosensitizer can be produced by the
25 metabolism of an active agent in the cells, correct?

1 A. Yes.

2 Q. And the extent to which the photosensitizer such
3 as PpIX has been concentrated can be determined by
4 photo-diagnostic methods, correct?

5 A. Yes. But I have to point out that any cell, any
6 living cell can concentrate ALA if you wait long enough.
7 It's a matter of the diagnostic or therapeutic window.
8 Cells that are fast-proliferating cells, such as diseased
9 cells, cells that are relevant for AK or maybe any other
10 skin cancer, they accumulate faster ALA into the cells and
11 produce also faster and accumulate PpIX. But any living
12 cell can do this. And, in fact, there is literature showing
13 that if you incubate for times that are long enough, then
14 also normal cells will start fluorescing, fluorescing.

15 I apologize for my English. It's not my native
16 language.

17 Q. Let me turn your attention now, Doctor, to column
18 12, lines 46 through 49. Do you see that? Your patent
19 specifies that an example of photo-diagnostic method is
20 irradiating with light having a wavelength of 405
21 nanometers. Right?

22 A. Yes.

23 Q. And then measuring the fluorescence radiation
24 generated by the photosensitizer, correct?

25 A. Yes.

1 Q. The irradiation for diagnosis could be done with
2 an artificial light source such as an LED, correct?

3 A. To my knowledge, it's usually done with a UV
4 lamp.

5 Q. Okay.

6 A. This is what I am aware of. Usually, it is done
7 with what is called the Wood's lamp, which is a UV lamp.

8 Q. So let's go in your same binder, there's a PCT
9 application near the back of the book. If you can tell me
10 when you have it. It's WO 2024/209064A1. Do you see that,
11 Doctor?

12 A. Yes, I do.

13 Q. And you're a named inventor of this PCT patent
14 application, correct?

15 A. Yes, it is.

16 Q. If you turn to page 28, lines 5 through 15, of
17 this application, please, this is -- in this application, in
18 this section, they're outlining some steps for treatment of
19 dermatological disease. Fair?

20 A. Yes.

21 Q. And one of those steps, step C, is irradiating
22 the skin area to which the formulation was administered with
23 light. Do you see that?

24 A. Yes.

25 Q. The application also notes, on that same page at

1 lines 23 through 25, the light used for irradiation in step
2 C may further be capable to induce red fluorescence of
3 accumulated porphyrins. Do you see that?

4 A. I need to read the whole sentence.

5 Q. Sure.

6 A. Give me a minute, please.

7 Q. Of course.

8 A. Yes, I read this.

9 Q. And that induction of fluorescence in this
10 application is similar to the photo-diagnostic methods we
11 just looked at in your '981 patent, true?

12 A. I would like to point out here that --

13 Q. Ma'am, it's just a yes or no.

14 A. It is difficult to answer this question
15 truthfully without explaining that Protoporphyrin IX has
16 several absorption peaks, as I think many of you may know by
17 now and have heard also on the opening. The largest peak,
18 this is the Soret band. And this is the one that is between
19 UV and blue light. And it is of course -- it is much larger
20 than the other peaks that come later in the range of 580 to
21 650. So when you are talking about fluorescence, which is a
22 very weak signal, you get the best results when working -- I
23 mean although, of course, theoretically, you can also have a
24 bit of fluorescence with the other absorption peaks. The
25 largest by far florescent signal is obtained when you work

1 with the Soret band, which is UV and blue light.

2 Q. Well, staying in your application, let's go down
3 to lines 36 through page 29, line 1, please.

4 It states that artificial light for this
5 induction may be provided by an LED, correct?

6 A. Yes.

7 Q. And artificial -- in fact, this PCT application
8 points out that the RhodoLED XL is suitable -- is a suitable
9 device for these methods. Is that fair?

10 A. I do not know the numbers of the patents by
11 heart, I have to say.

12 Q. Well, let's break it down in parts then. We
13 have --

14 A. Thank you.

15 Q. In the application, it states, "A suitable device
16 providing artificial light is described for example in U.S.
17 Patent Number 11,235,169B1 and U.S. Patent Number
18 11,219,781B2, the disclosure of which is incorporated herein
19 by reference."

20 I read that correctly?

21 A. Yes, you did.

22 Q. So let's go to your witness statement, please, at
23 Foguet witness statement at Question and Answer 86 and 87.

24 So U.S. Patent 11,235,169 is Biofrontera's method
25 of use patent involving the RhodoLED XL and Ameluz as it's

1 listed in the FDA Orange Book, correct?

2 A. Yes.

3 Q. So you did reference the Rhodo XL, RhodoLED XL in
4 your application?

5 A. If the patent number is the same, then yes.

6 Q. So you would agree that a five panel LED
7 illuminator can be used for photo-diagnostic methods as
8 disclosed in your PCT application, correct?

9 A. Again, I cannot answer with yes or no. Our --
10 on-label, our labeling for Ameluz and the approval for XL is
11 for the use of three to five panels of the XL lamp.

12 Q. But you agree that the RhodoLED XL can be used
13 for photodiagnostic methods, correct?

14 A. We do not have any approval for photodiagnostic
15 purposes of our lamp. The lamp, its intended use, and also
16 the indication, which is described on the label for Ameluz,
17 it is for the photodynamic therapy specifically and
18 exclusively.

19 Q. You'll agree, though --

20 A. Sorry, I would like to mention the label
21 completely, to make sure that there are no doubts. It is
22 the photodynamic therapy combining the use of Ameluz and the
23 BF RhodoLED and RhodoLED XL lamps for the treatment of
24 actinic keratosis, of mild to moderate actinic keratosis in
25 face and scalp. And this treatment can be lesion-directed

1 and field-directed, which is something very specific.

2 Q. I'm asking about your PCT application. I'm not
3 asking about approved use. We just went through your PCT
4 application, correct?

5 A. I understood this, but you just asked me whether
6 we are approved for this or we can use this. And this is
7 not the approved use of our lamp.

8 Q. Okay. So let me ask it a different way, then.
9 Your PCT application shows that a RhodoLED XL can be used
10 for photodiagnostic methods. True?

11 A. We don't show any data on this.

12 Q. But you reference it in the content of it. I
13 just went --

14 A. Maybe we can go back to the text because my
15 understanding is that it is referenced in -- in relation to
16 the photodynamic therapy.

17 MR. PATNAIK: Your Honor, I need to go on the
18 confidential record.

19 JUDGE MOORE: All right.

20 MR. PATNAIK: Biofrontera confidential.

21 JUDGE MOORE: Okay. Let's give it a moment.

22 (Whereupon, the hearing proceeded in confidential
23 session.)

24

25

1 O P E N S E S S I O N

2 REDIRECT EXAMINATION

3 BY MR. LARIVEE:

4 Q. Good afternoon, Dr. Foguet.

5 A. Good afternoon.

6 Q. Mr. Patnaik just asked you a number of questions
7 about Protoporphyrin IX. Do you remember that part of your
8 cross-examination?

9 A. Yes, I do.

10 Q. And he asked you about fluorescence of
11 Protoporphyrin IX --

12 MR. PATNAIK: Your Honor, can we go back on the
13 public record?

14 JUDGE MOORE: Counsel?

15 MR. LARIVEE: Yes, we can go on the public
16 record.

17 JUDGE MOORE: All right. From the beginning of
18 your examination, I assume? Yes?

19 All right. Go ahead. On the public record.

20 BY MR. LARIVEE:

21 Q. He also asked you about accumulation of
22 Protoporphyrin IX in human cells, correct?

23 A. Yes, he did.

24 Q. He asked you about your patents and your
25 experience there, right?

1 A. Sorry?

2 Q. He asked you about your patents related to
3 Protoporphyrin IX and ALA, right?

4 A. Yes, he did.

5 Q. And he also asked you about your knowledge prior
6 to 2015, right?

7 A. Yes, correct.

8 Q. What cells accumulate Protoporphyrin IX?

9 A. As I mentioned before, any cell, any living cell
10 exposed to ALA can potentially accumulate Protoporphyrin IX.
11 It's all a matter of time. This is why, typically for
12 diagnostic purposes, the incubation of the skin with ALA is
13 between one to three hours. Everything above this leads to
14 an accumulation of ALA and eventually Protoporphyrin IX also
15 in normal cells.

16 Q. So your testimony is that ALA will be converted
17 to -- pardon me. Let me ask a different question.

18 What would happen to the accumulation of ALA in
19 cells if they were left for 14 hours or more?

20 A. As I just mentioned, the longest you incubate
21 with ALA, the stronger are your chances that also normal
22 cells start accumulating PpIX, and there is literature on
23 this mentioning that after certain number of hours, then
24 also healthy cells can accumulate PpIX.

25 Q. And so what would happen under that case if you

1 -- if you incubated for 14 hours and then you exposed to
2 light, to, for instance, UV or light in the Soret band?
3 What cells would fluoresce?

4 A. Certainly, the abnormal cells, but to a certain
5 point also the normal cells surrounding the abnormal cells.

6 Q. So both the normal cells and the abnormal cells
7 would fluoresce, right?

8 A. Most likely, yes, to a certain point.

9 Q. Could we have JX-155 at column 2. Let's see the
10 first page first, Abe, cover page of the patent.

11 Dr. Foguet, is this the patent that you were
12 asked about?

13 A. This is the patent about our medical device, yes.

14 Q. Okay. Now could we have column 2, line 13. And
15 can you blow up that paragraph right there?

16 Dr. Foguet, what is photobleaching?

17 A. It's a phenomena that occurs when there is
18 insufficient amount of oxygen available during the process
19 of the photodynamic therapy. I don't know if this has been
20 explained that for photodynamic therapy to occur, you need
21 your photosensitizing agent, so Protoporphyrin IX, which is
22 synthesized from ALA; you need a certain wavelength that
23 will activate Protoporphyrin IX; but for the photodynamic
24 therapy to take place, you need a receptor molecule, which
25 is oxygen, which can accept the higher energy levels that

1 are stored in Protoporphyrin IX generating what is called
2 reactive oxygen species. And this ROS, or reactive oxygen
3 species, these are the ones that are highly toxic to the
4 cells, for the cells, and led to -- leads to cell death.

5 So photobleaching means that with time, of
6 course, the amount of protoporphyrin which is available in
7 this highly activated state is being reduced with time. So
8 you have a less active amount of Protoporphyrin IX.

9 MR. PATNAIK: Your Honor, move to strike the
10 question and answer as outside the scope of my cross-exam.
11 Photobleaching is about treatment. My questions were all
12 directed to diagnosis.

13 MR. LARIVÉE: Well, there's a relationship
14 between the two. It seems like Sun Pharma went out of their
15 way to qualify Dr. Foguet as an expert witness in this,
16 asked her all kinds of questions about the patent. I would
17 say the door is opened to this.

18 MR. PATNAIK: I don't know if he wants me to
19 respond to that or not, but I can.

20 JUDGE MOORE: Go ahead.

21 MR. PATNAIK: I mean, we asked her -- she in her
22 witness statement touts her nanoemulsion work. We asked her
23 about her nanoemulsion work and her patents related thereto.

24 MR. LARIVÉE: The next question will establish
25 the relationship between photobleaching and florescence.

1 JUDGE MOORE: Well, why don't we allow him to lay
2 a foundation, and then -- so the objection is still pending.
3 It's not overruled. But we're going to go on and see if he
4 can lay some foundation.

5 MR. PATNAIK: Thank you, Your Honor.

6 BY MR. LARIVEE:

7 Q. Dr. Foguet, when a cell is photobleached, does it
8 fluoresce?

9 A. So the photobleaching affects the Protoporphyrin
10 molecules. So they are non- -- when all Protoporphyrin --
11 sorry. I apologize. When all Protoporphyrin IX molecules
12 within the cells are photobleached, this means they are
13 inactivated permanently. Then, of course, no fluorescence
14 is possible anymore.

15 MR. LARIVEE: Your Honor, I think that clearly
16 establishes the link between the fluorescence and the
17 photobleaching. And this was -- the fluorescence and the
18 photobleaching was -- or, pardon me, the fluorescence was
19 the point of the cross-examination. I think the door is
20 opened for me to ask Dr. Foguet what she knows about this,
21 since they are so clearly interested in finding out what her
22 knowledge is.

23 MR. PATNAIK: Your Honor, once again I raise the
24 same objection. Photobleaching is about treatment and the
25 treatment process. All of our questions to her were

1 directed to diagnosis.

2 MR. LARIVÉE: Your Honor, I think this will be
3 relevant to the issues around fluorescence, which is the
4 method of diagnosis.

5 JUDGE MOORE: All right. Give me a moment.

6 Okay. I think what I'm going to do is I'm going
7 to overrule the objection, allow it to continue. It's not
8 overruled with prejudice. If later it becomes clear that
9 this area is improper, then we'll deal with it later, but
10 for now, I'm going to allow it to continue.

11 MR. PATNAIK: Thank you, Your Honor.

12 BY MR. LARIVÉE:

13 Q. Dr. Foguet, we've just been speaking about
14 photobleaching. What is the relationship between the
15 fluence -- pardon me. What is fluence?

16 A. Fluorescence?

17 Q. Fluence or light dosed.

18 A. The light dose. Okay. So the light dose -- can
19 you please specify? Are you talking about the context of --

20 Q. Joules per square centimeter.

21 A. In the context of photodynamic therapy or
22 photodiagnosing.

23 Q. Well, right now, I'm just asking about fluence in
24 the context of photodynamic therapy.

25 A. Within photodynamic therapy and specifically for

1 Ameluz, the light dose is the total amount of energy that
2 you provide within a photodynamic -- phototherapy treatment
3 to the patient in order to treat it on label for Ameluz and
4 also for our PDT lamps. This is 37 joules per square
5 centimeter.

6 Q. And at a dose of 37 joules per square centimeter,
7 is that a dose relevant for treatment?

8 A. Yes, it is. It's the total light dose that is
9 approved for Ameluz.

10 Q. And if you were to imagine -- what is -- what is
11 the relationship between light brightness or irradiance,
12 time, and fluence?

13 A. The total light dose is a consequence of
14 illuminating your skin with a certain intensity for an
15 amount of time. So you have a light intensity that you
16 apply to your skin -- in our case, this is 4 to 6 millibar
17 per square centimeters -- and you apply it to a certain
18 distance over a certain period of time. And by the end of
19 the treatment, you have applied approximately 37 joules per
20 square centimeter to your patient.

21 Q. Dr. Foguet, do you remember being asked about the
22 relationship between certain wavelengths of light and
23 fluorescence?

24 A. Yes.

25 Q. And what light wavelengths work well for causing

1 fluorescence?

2 A. The most effective light wavelength for
3 fluorescence is, as I mentioned, the one within the Soret
4 band, which is between UV and blue light.

5 Q. Dr. Foguet, you were asked about the
6 manufacturing and calibration of the RhodoLED XL. Do you
7 remember that line of questioning?

8 A. Yes, I do.

9 Q. And it's your testimony that the manufacturing
10 occurs in Germany, correct?

11 A. Yes, it is.

12 Q. What type of equipment is necessary to conduct
13 the calibration of the LEDs in the RhodoLED XL?

14 A. Well, first of all, you need the software
15 installed in the lamp in order to -- to save the parameters.
16 Also, you need an optical instrument to measure the
17 irradiance. And we use as well -- it's like a frame to hold
18 the optical instrument to the distance that you need to
19 measure compared to the panels and strands of the lamp.

20 Q. And who conducts that calibration exercise at
21 Biofrontera?

22 A. Calibration, as I mentioned before, is a part of
23 the manufacturing procedure and is performed by the trained
24 manufacturing employees.

25 Q. And is there a separate group of employees who

1 conduct end-of-line testing?

2 A. This is a separate group of employees, yes,
3 because they belong to the QM department.

4 Q. And could you remind us what a QM department is
5 in the context of a medical device?

6 A. This is quality management, Your Honor.

7 Q. And what is the relationship between quality
8 management and something else you mentioned earlier, GMP?

9 A. Our Quality Management Department is responsible
10 for making sure that at Biofrontera all the quality
11 standards required by FDA are met. For production of
12 medical devices of class 3, this means that we have to
13 comply with the -- with the guidances of good manufacturing
14 practices, GMP.

15 Q. And do your manufacturing employees have a
16 specification that they are trying to meet for the output of
17 light there?

18 A. They are specifications, yes.

19 Q. And what is the relationship between that
20 specification and the FDA approval for the RhodoLED XL?

21 A. The specification approved for the -- approved by
22 FDA is broader than what we call the in-house specification
23 used by our manufacturing employees to calibrate the lamp.
24 This is also something which is very common, done in a GMP
25 procedure, since you want to make sure, of course, that you

1 always meet your FDA-approved specification. When you test
2 it and test the medical devices at the end of line
3 manufacturing, you test with a narrower specification to
4 make sure that in any case you comply with the specification
5 that has been approved by FDA.

6 MR. LARIVÉE: We pass the witness.

7 JUDGE MOORE: All right.

8 MR. PATNAIK: May I proceed?

9 JUDGE MOORE: Yes.

10 RE-CROSS-EXAMINATION

11 BY MR. PATNAIK:

12 Q. You spoke of use of ALA to diagnose during your
13 counsel's questions. Do you recall that?

14 A. Can you please repeat the question?

15 Q. Well, let me just ask the question. The
16 principles of how to use ALA to diagnose abnormal cells were
17 well known as of 2015, correct?

18 A. This is correct, yes.

19 Q. And photodynamic treatment requires illumination
20 over a period of minutes. Fair?

21 A. Photodynamic treatment requires a longer
22 illumination period of time, yes.

23 Q. Over a period of minutes, correct?

24 A. Period of minutes, yes. Correct.

25 Q. And the patent segment that counsel showed you

1 from the '169 patent relates to photobleaching. True?

2 A. It describes the process of photobleaching.

3 Q. And that means that if you apply light for long
4 enough, the agent will cease fluorescing. Correct?

5 A. Can you please repeat the question? If you --

6 Q. And that means --

7 A. -- illuminate --

8 Q. I'll -- I'm talking about photobleaching.

9 A. Photobleaching.

10 Q. And that means that if you apply light for long
11 enough, the agent will cease fluorescing?

12 A. Sorry, I did not understand. If you irrigate --
13 what do you mean?

14 Q. If you apply light for long enough, the agent
15 will cease fluorescing?

16 A. What I said is that photobleaching involves
17 damage of the Protoporphyrin IX molecules, which are not
18 able -- because there's a covalent bond that is broken, and
19 they are not able to get excited again to a higher -- sorry
20 -- a higher level of energy. So if these molecules are not
21 available anymore or are damaged, then you cannot use them
22 for the purpose of fluorescence because they cannot get
23 excited anymore into the higher level of energy.

24 Q. It was well known, though, that if you shined the
25 light for a brief amount of time, the agent will fluoresce,

1 correct?

2 A. Please repeat.

3 MR. LARIVÉE: Objection. That's outside the
4 scope of my cross.

5 JUDGE MOORE: Overruled. Go ahead.

6 MR. PATNAIK: Thank you, Your Honor.

7 BY MR. PATNAIK:

8 Q. I'm going to ask the question again.

9 But it was well known that if you shined the
10 light for a brief amount of time, the agent will fluoresce?

11 A. The agent?

12 Q. The agent.

13 A. What do you mean by "the agent"?

14 Q. We were just talking about photobleaching.

15 Right?

16 A. We were talking about photobleaching, this is
17 correct.

18 Q. And I asked if that means that if you applied
19 light for long enough, the agent will cease fluorescing.

20 A. Again, I don't know what agent you mean. What
21 are you talking about? I'm sorry.

22 Q. The photosensitive molecule like PpIX.

23 A. PpIX. If you -- can please repeat your question.

24 Q. Sure.

25 A. Thank you so much.

1 Q. For -- and I'm going back to photobleaching. In
2 photobleaching, within that context, if you apply light long
3 enough, the PpIX will cease fluorescing, correct?

4 A. I have to think about it. Again, this is a
5 dynamic process going into living cells. During the process
6 of photodynamic diagnosis or photodynamic therapy, if the
7 cell is still exposed to ALA, it can continue to produce
8 Protoporphyrin IX. So it is a balance between having
9 Protoporphyrin IX at different stages, some Protoporphyrin
10 IX at the ground level, some other molecules which might be
11 excited at the high energy level. And some of the molecules
12 would undergo the process of photobleaching, which means
13 some molecules would get broken, to state it in an easy way,
14 will not -- will not be able to recover. So it's difficult
15 to answer with yes and no because you have a balance between
16 the Protoporphyrin IX molecules in these three stages.

17 Q. But it was well known that if you shined the
18 light for a brief amount of time, the PpIX will
19 fluorescence, correct?

20 A. Could you please specify which light are you
21 talking about?

22 Q. The same light you were talking about to your
23 answers to questions from counsel when you were looking at
24 the patent.

25 A. I'm very sorry, but I already mentioned, to my

1 knowledge, you need UV lamps in order to see the
2 fluorescence of Protoporphyrin IX. The only lamps that I
3 know for diagnostic of -- to be used for photodynamic
4 diagnostic is the so-called Wood's lamp, and this is a UV
5 irradiation lamp.

6 Q. And that's a blue lamp?

7 A. This is a UV lamp. UVA.

8 Q. Is it emitting 405 nanometers?

9 A. It's emitting at 365 nanometers.

10 Q. All right. Could we go back to your binder,
11 please, to the '981 patent. Looking at column 12, lines 46
12 through 49. I just want to refresh your recollection that
13 your patent specifies that an example of photodiagnostic
14 method --

15 MR. LARIVÉE: This is outside the scope. I want
16 to object it's outside the scope of my redirect.

17 MR. PATNAIK: I'm just following up to the last
18 answer, Your Honor.

19 JUDGE MOORE: Yeah. I'll allow this. We're
20 having some difficulty getting to the point, so I'll allow
21 this.

22 BY MR. PATNAIK:

23 Q. And this is just a true or false question,
24 Doctor. Your patent here specifies an example of
25 photodiagnostic method as irradiating with light having a

1 wavelength of 405 nanometers, correct?

2 A. Yes, this is correct.

3 MR. PATNAIK: I have no further questions, Your
4 Honor.

5 JUDGE MOORE: All right.

6 MR. LARIVÉE: No further questions.

7 JUDGE MOORE: All right. Okay.

8 So we appreciate you testifying. We understand
9 it's your first time, so it's difficult for everyone, but we
10 appreciate you doing it.

11 THE WITNESS: Thank you very much, Your Honor.

12 JUDGE MOORE: You are released.

13 (The witness stood down.)

14 JUDGE MOORE: All right. We're off the record
15 while we prepare our next witness.

16 (Discussion off the record.)

17 JUDGE MOORE: Back on the record.

18 MS. PETERSON: Good afternoon, Your Honor.

19 Lauren Peterson for Biofrontera Respondents. We'd like to
20 call our next witness.

21 JUDGE MOORE: All right.

22 MS. PETERSON: Biofrontera calls Eugene Frederick
23 Leffler to the stand.

24 JUDGE MOORE: All right. And if you would stand,
25 we'll get you sworn in.

1 Whereupon--

2 EUGENE FREDERICK LEFFLER,
3 having been first duly sworn/affirmed, was examined and
4 testified as follows:

5 THE WITNESS: Yes.

6 JUDGE MOORE: All right. Thank you.

7 DIRECT EXAMINATION

8 BY MS. PETERSON:

9 Q. Good afternoon. Would you please introduce
10 yourself for the record.

11 A. Yep. My name is Eugene Frederick Leffler, III.
12 I'm the CFO at Biofrontera Inc.

13 Q. And how long have you been with Biofrontera Inc.?

14 A. Two years and nine months.

15 Q. Could you briefly describe your educational
16 background.

17 A. Sure. So I have a finance and accounting degree
18 from Ohio State and then a graduate MBA from Duke
19 University.

20 Q. And what are your responsibilities in your role
21 as CFO of Biofrontera Inc.?

22 A. Sure. Primarily, it's overseeing the accounting
23 and finance functions of the company and ensuring that our
24 numbers, books are accurate and financial managing the
25 financial reporting. Additionally, I oversee investor

1 relation activities, our IT department, our HR department,
2 and some customer service activities.

3 Q. Thank you.

4 Mr. Ortega, could you please put RX-3 on the
5 screen.

6 Mr. Leffler, do you recognize RX-3?

7 A. Yes.

8 Q. Is this your direct testimony in this
9 investigation?

10 A. The cover page, yes, it looks like that.

11 Q. Okay. And, Mr. Ortega, if you could please turn
12 to page 11.

13 Mr. Leffler, do you recognize your signature on
14 page 11 of RX-3?

15 A. I do.

16 Q. Does RX-3 reflect your testimony in this
17 investigation?

18 A. It does.

19 Q. And does it contain your own answers to questions
20 from counsel?

21 A. Yes.

22 Q. And are those answers true and correct to the
23 best of your knowledge and understanding?

24 A. They are.

25 Q. Are there any corrections to your testimony you'd

1 like to make?

2 A. Not at this time.

3 MS. PETERSON: Your Honor, we move to admit
4 RX-003C into evidence.

5 MR. PATNAIK: No objection.

6 JUDGE MOORE: All right. It's admitted into
7 evidence.

8 (Respondents Exhibit Number RX-0003C was received
9 into evidence.)

10 MS. PETERSON: Thank you, Your Honor. I pass the
11 witness.

12 MR. PATNAIK: Your Honor, Goutam Patnaik from Sun
13 Pharma again.

14 JUDGE MOORE: All right.

15 MR. PATNAIK: May I proceed?

16 JUDGE MOORE: When you're ready, go ahead.

17 CROSS-EXAMINATION

18 BY MR. PATNAIK:

19 Q. Good afternoon.

20 A. Hello.

21 Q. Biofrontera Inc. purchases products from
22 Biofrontera AG to sell in the U.S., correct?

23 A. That's correct.

24 Q. And those products include both RhodoLED XL and
25 Ameluz, correct?

1 A. Yes.

2 Q. You testified that Biofrontera competes with Sun
3 Pharma in the PD space, PDT space, right?

4 A. I did.

5 Q. Besides Sun Pharma and Biofrontera, you're not
6 aware of any other companies that offer a lamp in
7 combination with a pharmaceutical for photodynamic therapy,
8 are you?

9 A. Not in the United States.

10 Q. Biofrontera is targeting Levulan users for
11 RhodoLED XL sales, correct?

12 A. We target many different dermatologists, and some
13 of those are -- could be Levulan users, sure.

14 Q. But Biofrontera specifically targets Levulan
15 users for RhodoLED XL sales, correct?

16 A. Considering that's the only competitor out there,
17 we target, like I said, the dermatologists who are our
18 customers, Levulan customers, and folks that are using cryo
19 as an example.

20 MR. PATNAIK: Well, unfortunately, Your Honor, I
21 am going to go on the confidential record for just a minute
22 to show a document.

23 JUDGE MOORE: That's fine. All right. We'll
24 give it a moment.

25 (Whereupon, the hearing proceeded in confidential

1 session.)
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1 O P E N S E S S I O N

2 JUDGE MOORE: On the public record. Go ahead.

3 BY MR. PATNAIK:

4 Q. You work on financial reporting and investor
5 relations in your role as CFO, correct?

6 A. Yes.

7 Q. And as CFO, you participate in earnings calls for
8 Biofrontera Inc., correct?

9 A. Every one.

10 Q. And you participated in the third quarter 2024
11 earnings call that happened in November of 2024?

12 A. I did.

13 Q. Could we pull up what has been marked as CX-183,
14 please. It's also in your binder, sir.

15 A. What was the number?

16 Q. CX-183. Let me know when you're there.

17 A. Yep. Sure.

18 Q. That's the transcript from that third quarter
19 earnings call that happened in November of '24 -- '2024,
20 correct?

21 A. Yes.

22 Q. Biofrontera Inc.'s total revenue was up in the
23 third quarter of 2024 when compared with the third quarter
24 of 2023, right? And I can turn -- if you look at point 5,
25 CX-183.5, this is where you spoke, correct? The bottom half

1 of this page?

2 A. Yes, exactly. That's what I was looking for.

3 Q. And I'm just looking at the language in the
4 second paragraph of the section under your name, total
5 revenues for the third quarter of 2024 were \$9 million
6 compared with 8.9 million for the third quarter of 2023.

7 A. Well, that's why I was confused. In my head, I
8 would, you know, call that flat.

9 Q. Well, you called it an increase, right?

10 A. Yes, a \$100,000 increase.

11 Q. And you attribute that increase to being driven
12 by sales of the RhodoLED XL lamp since its launch in June
13 2024, correct?

14 A. Yes, there was an increase in sales of \$600,000
15 because of the launch of the RhodoLED XL.

16 Q. And you state in your earnings call, this
17 increase was driven by a \$600,000 increase from sales of
18 devices, specifically the RhodoLED XL lamp since its launch
19 in June of 2024. Correct?

20 A. Correct. And that was offset by a decrease in
21 Ameluz sales of about a half million dollars.

22 Q. Okay.

23 MR. PATNAIK: Now, we're going to go, Your Honor,
24 to the confidential record for the balance of my questions.

25 JUDGE MOORE: Okay.

1 (Whereupon, the hearing proceeded in confidential
2 session.)
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1 O P E N S E S S I O N

2 MR. LANDMON: Your Honor, as we're moving things
3 around -- Chad Landmon again -- Biofrontera's next witness
4 is going to be Dr. Robert Grove.

5 JUDGE MOORE: All right. We will get him sworn
6 in, if that works.
7 Whereupon--

8 ROBERT GROVE,
9 having been first duly sworn/affirmed, was examined and
10 testified as follows:

11

12 THE WITNESS: Yes, I do.

13 JUDGE MOORE: Thank you.

14 DIRECT EXAMINATION

15 BY MR. LANDMON:

16 Q. Good afternoon, Dr. Grove. Could you please
17 introduce yourself for the record again.

18 A. Yes. My name is Robert Grove.

19 Q. And did you offer expert testimony in the form of
20 a written witness statement in this investigation?

21 A. Yes, I did.

22 Q. So you should have a copy in front of you, a
23 binder, with a document labeled RX-9C.

24 A. Yes.

25 Q. Is that your rebuttal witness statement?

1 A. Yes, it is.

2 Q. And if you turn to page 22.

3 A. Yes.

4 Q. Is that your signature?

5 A. Yes, it is.

6 Q. Does this witness statement contain your answers
7 to questions from counsel in this investigation?

8 A. I did.

9 Q. Sorry, was that a yes?

10 A. I'm sorry. Could you repeat your question?

11 Q. Yes. Does this witness statement contain your
12 answers to questions from counsel in this investigation?

13 A. Yes, it does.

14 Q. Are the answers in your rebuttal witness
15 statement accurate and truthful?

16 A. Yes.

17 Q. Would you like to make any corrections to your
18 rebuttal witness statement?

19 A. No.

20 Q. And if you could turn with me to page 23. Is
21 this the list of exhibits referenced in your witness
22 statement?

23 A. Yes, it is.

24 Q. Did you also draft a set of demonstratives to
25 assist with your testimony?

1 A. Yes, I did.

2 Q. And if we can bring up on the screen RDX-0020C.

3 Is this the set of demonstratives that you
4 prepared in relation to your rebuttal witness statement?

5 A. Yes, I believe so.

6 Q. And if we could bring up on the screen RX-1420.

7 Is this a true and correct copy of your CV?

8 A. Yes, it is.

9 Q. Dr. Grove, can you please summarize your
10 educational background for us.

11 A. Yes. I have an undergraduate degree in
12 engineering physics from Cornell University. And following
13 that, I obtained a Master's degree in aeronautics and
14 astronautics from MIT.

15 And after my Master's, I started the Ph.D.
16 program and got my Ph.D., actually, in instrumentation, with
17 an area of specialization in laser applications. And then
18 following my receipt of the doctorate, I did one year of
19 post-doc work, also at MIT.

20 Q. Can you summarize your experience with
21 photodynamic therapy and PDT devices?

22 A. Yes. After my post-doc, I spent five years at
23 Lawrence Livermore Laboratory. And after that, started my
24 first company in 1981 to develop a new type of laser
25 technology. And that technology was intended for both

1 scientific applications and, frankly, any other application
2 that we could get a sale for, including medical
3 applications.

4 And probably in '82 or '83, 1982 and 1983, I got
5 a call from Dr. Thomas Dougherty, who was at the Roswell
6 Park Cancer Institute near Buffalo, New York. And he asked
7 me if we had a light source, a laser or otherwise, that
8 might be useful for photodynamic therapy.

9 Q. And can you summarize your experience with
10 phototherapy and medical lighting devices in general?

11 A. Yes. That first company was the first of a
12 number of companies over the next 40 years, all of which
13 involved lasers or light sources for medical applications,
14 all in -- I would say essentially exclusively light sources
15 for dermatology, both for medical applications and aesthetic
16 applications.

17 Q. And have you been a founder of any technology
18 companies in the phototherapy space or that provide
19 phototherapy services?

20 A. I would say all of them. All of the companies I
21 have started have been in that space, either as a design,
22 manufacturer, and seller of those systems, or one company
23 involved the use of those light-based systems in dermatology
24 offices.

25 Q. And have you served in any leadership roles in

1 any companies related to phototherapy or medical lighting
2 devices?

3 A. I would say all of the companies between 1982 and
4 my last real job, if you will, in 2010 involved leading
5 technology companies that developed and sold light sources,
6 either light -- light sources or lasers for dermatology
7 applications.

8 Q. And were you involved in the development of the
9 technologies by those companies?

10 A. Absolutely. All of the companies were quite
11 small. And in a small company, the CEO is also the VP of
12 R&D and the chief technology officer and occasionally the
13 CFO. And so I did all those roles. But as the founder of
14 the company, I started it because I felt I understood the
15 technology well and could serve in that role while spending
16 the rest of my time raising money.

17 Q. And are you a named inventor on any patents or
18 publications?

19 A. Yes. I am a named inventor in about 25-or-so
20 patents, and have three, four, five publications in
21 peer-reviewed journal articles related to lasers and
22 light-based devices.

23 MR. LANDMON: Your Honor, we would like to move
24 Dr. Grove's rebuttal witness statement, which is RX-009C,
25 into evidence.

1 MR. GANGULY: No objection.

2 JUDGE MOORE: All right. It is moved into
3 evidence.

4 (Respondents Exhibit Number RX-0009C was received
5 into evidence.)

6 MR. LANDMON: Thank you, Your Honor.

7 We would also like to move to qualify Dr. Grove
8 as an expert in the field of photodynamic therapy devices,
9 medical lighting devices, electrical engineering,
10 optoelectronics, and the development, operation, and
11 analysis of light-emitting diodes and devices.

12 MR. GANGULY: No objection.

13 JUDGE MOORE: All right. He is admitted for that
14 purpose.

15 MR. LANDMON: Thank you, Your Honor. We pass the
16 witness.

17 THE WITNESS: If I could have you get a little
18 closer to the microphone. I can't hear any of your
19 responses. I assume they are fine, but I'm sorry, I can't
20 hear your responses.

21 JUDGE MOORE: Certainly.

22 MR. GANGULY: May I proceed, Your Honor?

23 JUDGE MOORE: Yes.

24 CROSS-EXAMINATION

25 BY MR. GANGULY:

1 Q. Good afternoon, Dr. Grove. It's nice to see you
2 again. My name is Tuhin Ganguly. We met at your
3 deposition.

4 A. Yes, I remember. Nice to see you again.

5 Q. Dr. Grove, it's your opinion that the RhodoLED XL
6 does not contain panels connected by either hinges that fit
7 on inner side surfaces of adjacent panels or hinge
8 structures that fit on inner side surfaces of adjacent
9 panels?

10 A. That's correct, they do not.

11 Q. Okay. But we can agree that the RhodoLED XL does
12 include hinges, right?

13 A. There are hinges between panels in that device,
14 correct.

15 Q. Okay. And so let's talk a little bit about what
16 those hinges are and what they do. Now, in forming your
17 opinions, you examined the RhodoLED XL, right?

18 A. I did.

19 Q. Okay. And we can see a RhodoLED XL over there in
20 the courtroom (indicating), right?

21 A. That's correct.

22 Q. Okay. And we can agree that -- maybe not that
23 one in the state it's in, but we can agree that generally
24 the RhodoLED XL can be used to photodynamically treat a
25 patient, right?

1 A. That's true.

2 Q. Okay.

3 A. Correct.

4 Q. And Biofrontera developed the RhodoLED XL for use
5 in photodynamic therapy in combination with Ameluz. Right?

6 A. That's my understanding.

7 Q. Biofrontera designed the RhodoLED XL so that it
8 can uniformly illuminate the treatment surface of a
9 patient's face or scalp. Fair?

10 A. Correct.

11 Q. Yeah. And in examining the RhodoLED XL, you
12 gained an understanding of its basic operation. Isn't that
13 true?

14 A. Yes. I didn't put it through all its paces, but
15 I believe I was able -- actually, I'm not sure if I even
16 turned it on, but I was able to certainly inspect it and do
17 some partial disassembly to understand the mechanical
18 connections.

19 Q. Okay. Now, one of the things that you reviewed
20 to gain that understanding was the RhodoLED XL's user
21 manual, right?

22 A. I have looked at it, correct.

23 Q. And the user manual that Biofrontera provides to
24 a user instructs the user on how to use the RhodoLED XL
25 during the PDT treatment, right?

1 A. Yes.

2 Q. Okay. And so by following those instructions in
3 the user manual, a healthcare provider can uniformly
4 illuminate a person's face or scalp for PDT. Is that a fair
5 statement?

6 MR. LANDMON: Objection, Your Honor. Beyond the
7 scope of his witness statement. He doesn't address issues
8 of what healthcare providers do.

9 MR. GANGULY: All right. So I can withdraw that
10 question.

11 JUDGE MOORE: You want to withdraw -- all right.

12 MR. GANGULY: We can get to the hinges.

13 BY MR. GANGULY:

14 Q. Can we bring -- you mentioned that you reviewed
15 the user manual?

16 A. I recall looking at it, yes.

17 Q. Okay. So can we bring up JX-0086.12. Page 12.
18 Okay. And that's good right there.

19 All right. Dr. Grove, on the screen in front of
20 you is the user manual showing the five panels. You have
21 seen this before?

22 A. I have.

23 Q. Okay. Now, as we can see in Figure 5,
24 Biofrontera designed the RhodoLED XL with five panels,
25 correct?

1 A. Yes.

2 Q. And when Biofrontera designed the RhodoLED XL, it
3 positioned the five LED panels next to each other in a row,
4 right?

5 A. That's correct.

6 Q. Okay. And the center panel is flanked by two
7 panels on the left and the right that can be angled into a
8 curved C shape, correct?

9 A. Yes.

10 Q. Okay. And the reason that the five panels of the
11 RhodoLED XL can be angled into a curved shape is because the
12 five panels are connected by hinges, right?

13 A. That is correct. That allows the panels to
14 either be curved into a U shape or C shape or, if necessary
15 and appropriate, an essentially planar orientation.

16 Q. All right. Do you see down near the bottom
17 there's the note that says, "The RhodoLED XL LED panels
18 should only be used in the curved shape and not in a fully
19 unfolded form."

20 Do you see that?

21 A. Yes, I do.

22 Q. Okay. So we can agree that the user manual is
23 telling users that they should use the RhodoLED XL in the
24 curved shape, which is enabled by the hinges, right?

25 MR. LANDMON: Objection, Your Honor. Also beyond

1 the scope of his witness statement. He doesn't address the
2 user manual in his witness statement, and he certainly
3 doesn't address what users do with it. He's also not a
4 medical doctor. We will have a medical doctor up next.

5 MR. GANGULY: Well -- so we were talking about
6 the hinges, Your Honor. And he said it could be in a curved
7 shape, a flat shape, different shapes. And I was just
8 pointing out that the user manual tells the users that they
9 should use it in the curved shape, which is enabled by the
10 hinges.

11 JUDGE MOORE: All right. This is an expert. It
12 is not an expert as to what the manuals tell the user. I
13 think maybe I'll sustain the objection, but maybe you can
14 get at what it shows, not what it tells.

15 MR. GANGULY: Thank you, Your Honor.

16 JUDGE MOORE: You see what I'm saying here.

17 MR. GANGULY: Yeah.

18 BY MR. GANGULY:

19 Q. So let me ask it this way. As shown in the user
20 manual, the five panels of the RhodoLED XL can be put into a
21 curved shape because there are hinges between the panels.
22 Would you agree with that?

23 A. Yes.

24 Q. Okay. So when Biofrontera manufactures the
25 RhodoLED XL, it positioned the five LED panels in a row with

1 hinge barrels in between adjacent panels so that they could
2 be placed in a curved shape. Fair?

3 A. Yes, the hinges were there to allow that
4 flexibility.

5 Q. That curved shape allows each of the panels to be
6 at approximately the same distance from the treatment
7 surface. Would you agree?

8 A. Yes, I think that's correct, that the goal is to
9 use the panels with the proper distance from the patient's
10 face and the rest of his head.

11 Q. Okay. Now, Dr. Grove, even though the panels of
12 the RhodoLED XL are connected by hinges, it's your opinion
13 that the RhodoLED XL does not infringe the asserted patents
14 because its hinges are not on inner side surfaces of
15 adjacent panels. Fair?

16 A. That the hinges are not connected to the inner
17 side surfaces of adjacent panels.

18 Q. Okay. Now, we can agree that each of the panels
19 of the RhodoLED XL has an inner side surface, right?

20 A. That is correct.

21 Q. Okay. And so let's bring up your slide
22 RDX-0020C.12.

23 Now, Dr. Grove, on the screen, we see your slide
24 12, and it has the heading Inner Side Surfaces of the
25 RhodoLED XL.

1 Do you see that?

2 A. I do.

3 Q. Okay. Now, each of the panels of the RhodoLED XL
4 has a casing, right?

5 A. Each panel has a casing consisting of two halves,
6 yes.

7 Q. Right. And the two halves, we can see there's
8 the front -- the front black portion and then the back kind
9 of white, beige portion. Right?

10 A. That's correct.

11 Q. And then those two pieces come together like a
12 clamshell, right?

13 A. That's correct.

14 Q. Now, in the image on slide 12, you highlight in
15 red what you consider to be the inner side surfaces of the
16 panels of the RhodoLED XL, right? That's what you're
17 showing?

18 A. Yes.

19 Q. Okay. And we can see on the slide you highlight
20 a portion of the front black piece of the casing and a
21 portion of the back white piece of the casing, right?

22 A. That's correct.

23 Q. When the panel is assembled, the inner side
24 surface of the panel is made up of more than one piece. Do
25 you agree with that statement?

1 A. The inner side surface, yes, has a portion, as
2 shown here, part of the white half of the panel assembly and
3 part of the black front surface.

4 Q. Okay. So just it's a yes-or-no answer,
5 Dr. Grove. When the panel is assembled, the inner side
6 surface of the panel is made up of more than one piece. Do
7 you agree with that statement, yes or no?

8 A. Yeah, the inner side surface is made up of -- of
9 the portion shown here in red, yeah.

10 MR. GANGULY: Your Honor, move to strike
11 everything after "yes." It's a yes-or-no question.

12 THE WITNESS: All right. Would you repeat the
13 question, please?

14 BY MR. GANGULY:

15 Q. We will try it one more time.

16 When the panel is assembled, the inner side
17 surface of the panel is made up of more than one piece. Do
18 you agree with that statement, yes or no?

19 A. Yes.

20 Q. Okay. Thank you.

21 Now, you agree that a hinge could be designed
22 with hinge flanges that don't happen to be flat, right?

23 A. It's possible. Unusual, but possible.

24 Q. And you agree that the claims cannot be
25 interpreted to require the inner side surfaces of the

1 adjacent panels to be planar, right?

2 A. Those words are not in the claims, but if you
3 read the specification, the hinge flanges are attached. The
4 hinges are attached by flanges to those side surfaces. And
5 to do that, the hinge flanges are undoubtedly flat, and a
6 POA would understand that. And the surface to which those
7 hinge flanges attach would also be flat.

8 Q. So, Dr. Grove, you gave a deposition. I was
9 there. You gave a deposition in this case, right?

10 A. I did.

11 Q. Now, can we -- and you gave that under oath,
12 right?

13 A. I did.

14 Q. So can we bring up Dr. Grove's deposition
15 transcript at 44, line 24 through 45, line 15.

16 Now, at your deposition I asked you:

17 "Question: I am asking do the claims require the
18 inner side surfaces of the adjacent panels to be planar?"

19 And you answered:

20 "Answer: I don't believe that's a requirement
21 that can be interpreted from the claim language." And then
22 you go on from there.

23 Were you asked that question and did you give
24 that answer?

25 A. Yes, I did.

1 Q. All right. Now, I want to take a look at your
2 slide RDX-0020C.16.

3 All right. Now, Dr. Grove, I understand that you
4 and Dr. Jokerst disagree on what is or is not part of the
5 inner side surfaces. We will get to that later. I just
6 want to talk about some of these structures here.

7 A. Okay.

8 Q. Now, if we look on the left side of your slide,
9 we see an exploded view of one of the RhodoLED XL panels,
10 right?

11 A. We do.

12 Q. And in that diagram under those green arrows, we
13 can see that there's a plate inside of the casing of the
14 panel to which various components, like fans, are attached.

15 Do you see what I'm talking about?

16 A. The planar support structure, yeah.

17 Q. Right. And as you just mentioned, you previously
18 referred to this as the planar support structure, right?

19 A. That's correct.

20 Q. Now, the planar support structure has tabs that
21 jut out and are shown in green highlighting on the exploded
22 view on the left of your slide, right?

23 A. A portion of the planar support structure extends
24 out from each of the four corners, if you will. And the
25 portion that's highlighted here is often referred to as the

1 tabs or the hinge holders.

2 Q. Right. Right. So you've highlighted those in
3 green. And above it, connected by green arrows, with green
4 text, it says "tabs/hinge holders." Right?

5 A. That's correct.

6 Q. Okay. Now, of course you're aware that
7 Biofrontera's own engineering diagrams refer to those tabs
8 as hinge holders, right?

9 A. In German, yes.

10 Q. Yes. And we can agree that the tabs labeled
11 "hinge holders" on RDX-20C.16, those are part of the panel,
12 right?

13 A. Are we looking at this same figure?

14 Q. Well, let me ask you a different question. You
15 agree that the tabs are a part of the panel of the RhodoLED
16 XL, right?

17 A. The tabs? They're part of the planar support
18 structure, which is inside of the -- of each panel.

19 Q. Right. And so you agree that the tabs are part
20 of the panel. Do you agree with that statement?

21 A. Yes.

22 Q. Okay. And when the panel is fully assembled, the
23 tab of the inner support structures protrude from the panel,
24 right?

25 And so, actually, why don't we zoom out before I

1 ask you that question. And you can -- all right.

2 So when the -- let me ask it again. And when the
3 panel is fully assembled, the tab of the inner support
4 structure protrudes from the panel, right?

5 A. A portion of the hinge holder extends from the
6 casing, if that's what you're asking.

7 Q. Okay. Right. So a portion of the tab of the
8 inner support structure extends from the casing?

9 A. Correct.

10 Q. Okay. And so the portion of the tab or hinge
11 holder that extends from the casing can be seen in the image
12 on the right of the slide, on slide 16, as a structure
13 outlined and highlighted in green. Correct?

14 A. Yes.

15 Q. Right. And so as we can see in that image, a
16 portion of the hinge holder is exterior to the panel's
17 casing and is located in the space between adjacent panels,
18 correct?

19 A. That's correct.

20 Q. All right. And the portion of the tab that is
21 exterior to the casing is located between the front and the
22 back of the panel. You agree with that statement?

23 A. Could you repeat the question, please?

24 Q. Sure. And the portion of the tab that is
25 exterior to the casing is located between the front and the

1 back of the panel. Do you agree with that statement?

2 A. It extends out from an opening between the front
3 and the back panel, correct.

4 Q. I'm asking you a different question.

5 A. Yes.

6 Q. And it's a yes-or-no question. So let me repeat
7 it.

8 A. I thought that was the question. Sorry.

9 Q. The portion of the tab that is exterior to the
10 casing is located between the front and the back of the
11 panel. Do you agree with that statement?

12 A. I would say it extends out between the front and
13 the back portions of the panel.

14 Q. Okay. So can we bring up Dr. Grove's deposition
15 transcript. And we will start at 57, line 23. All right.
16 And it goes to 58, 3.

17 All right. So at your deposition, Dr. Grove, I
18 asked you:

19 "Question: So the portion of the tab that is
20 exterior to the casing is located between the front and the
21 back of the panel, right?

22 "Answer: Yes."

23 A. That's what I said --

24 Q. Was that the question I asked and was that the
25 answer you gave?

1 A. That was the answer I gave.

2 Q. Okay. Now, why don't we go back to -- yes, thank
3 you -- slide 16, RDX-0020C.16. All right.

4 Now, Dr. Grove, as we can see in the image on the
5 right, the hinge is in physical contact with the portion of
6 the tab which extends from the panel into the space between
7 adjacent panels. Right?

8 A. The hinge flanges are, yes.

9 Q. Now, you're aware that Dr. Jokerst testified that
10 the friction hinge is in contact with the shell of the
11 panel, right? You're aware of that?

12 A. I am.

13 Q. Okay. And you're not saying that Dr. Jokerst was
14 wrong when she saw contact between the friction hinge and
15 the shell of the panel; is that correct?

16 A. If she was referring to the flanges of the
17 friction hinge, what she said was correct.

18 I'm not disputing her statement.

19 Q. Just so we're clear, you're not disputing the
20 fact that Dr. Jokerst saw that the hinge -- the friction
21 hinge was in contact with the shell of the panel? You're
22 not disputing that, right?

23 A. If she's referring to -- depending on which
24 portion of the hinge she's referring to, I would be inclined
25 to disagree.

1 If she's referring to the friction hinge flanges
2 as they proceed into the panels, I have heard or seen her
3 testimony that she believes that the flange or flanges of
4 the hinge contact the -- in this case, it would be the black
5 front portion of the casing.

6 Q. All right. Can we bring up Dr. Grove's
7 deposition at 73, beginning at line 3 through 11.

8 So at your deposition, Dr. Grove, I asked you:

9 "Question: So just to be clear, when Dr. Jokerst
10 said that she saw contact between the friction hinge in the
11 RhodoLED XL and the shell of the panel, you're not saying
12 that she was wrong, right?"

13 And your answer was:

14 "Answer: I'm not saying she was wrong. It may
15 have, in fact, been in contact in the particular device she
16 was inspecting."

17 That was the question I asked you and the answer
18 you gave?

19 A. The answer I gave is correct.

20 Q. Now, Dr. Grove, you agree that a hinge can be
21 rested on a surface but its hinge flanges can be connected
22 to something else. You agree with that, right?

23 A. Okay, I'm sorry. Could you repeat one more time?

24 Q. Sure. You agree that a hinge can be rested on a
25 surface but its hinge flanges are connected to something

1 else, right?

2 A. If you say "a hinge," I assume you are referring
3 to the hinge flanges and the hinge barrel. So are you
4 saying that the hinge barrel can be somewhere and the hinge
5 flanges can be somewhere else?

6 Q. Sure. Let's start there. You agree that a hinge
7 barrel can be rested on a surface but its hinge flanges can
8 be connected to something else, right?

9 A. Yes.

10 Q. Okay. And so you would agree that a hinge can be
11 on a surface without it being -- without being attached to
12 that surface, right?

13 A. If it's on the surface, then it's -- then it's
14 resting -- it's being supported by that surface.

15 Q. Okay. So you agree that a hinge can be on a
16 surface but the flanges can be attached to something else.
17 You can agree to that, right?

18 A. Depending on the design, yes, it's possible.

19 Q. Okay. But it's your opinion that to meet the
20 claims, the hinge must be mounted to, attached to -- mounted
21 to or attached to the inner side surface. True?

22 A. Yes. In the claims, either the nested hinges or
23 the hinge structures need to be mounted on the inner side
24 surfaces, correct.

25 Q. Let's bring up RDX-0020C.10.

1 All right. Okay. Dr. Grove, I have on the
2 screen in front of you slide 10 from your slide deck. And
3 the title of this slide says "Hinges on Inner Side Surfaces
4 of Adjacent Panels."

5 Do you see that?

6 A. I do.

7 Q. Okay. Now, in your view, the asserted patents
8 consider hinges on inner side surfaces to be hinges laid
9 flat against and mounted to the inner side surfaces of
10 panels, right?

11 A. Yes.

12 Q. All right. And on the left of RDX-20.10, you
13 provide a drawing of your interpretation of the hinges on
14 "inner side surface" limitation, right? That's what we're
15 seeing on the left?

16 A. That's an example, yes.

17 Q. And then as we can see on this slide, you compare
18 your interpretation to Figure 3B of the '512 patent in the
19 center and the BLU-U 4170E on the right, right?

20 A. That's correct.

21 Q. Okay. And in your view, Figure 3B of the '512
22 patent depicts panels connected by hinges on inner side
23 surfaces consistent with your interpretation of the "hinges
24 on inner side surfaces" limitation, right?

25 A. Yes.

1 Q. All right. And in your view, Sun's BLU-U 4107E
2 device also contains hinges on inner side surfaces
3 consistent with your interpretation of that limitation,
4 right?

5 A. They're shown in the photograph, yes.

6 Q. All right. And the way you determine that Figure
7 3B of the '512 patent and the BLU-U 4170E depict hinges on
8 inner side surfaces consistent with your interpretation is
9 by looking at the structure of the hinges and how they
10 connect to the panels. Fair?

11 A. Looking at the hinges in the BLU-U 4170E, yes.

12 Q. Yeah. And so you -- in Figure 3B and with
13 respect to the 4170E, you were looking at the hinges
14 themselves, how they connect, their structures. Fair?

15 A. How the hinges are connected to the inner side
16 surfaces, yes.

17 Q. And so similarly, you determined in the RhodoLED
18 XL that the hinges do not meet the limitation by examining
19 the structures of the hinges in the RhodoLED XL and how they
20 connect to the panels. Fair?

21 A. They do not meet the limitation.

22 Q. Well, I was asking you what you looked at. So
23 you determined, in your opinion, that they don't meet the
24 limitation by looking at the structure of the hinges and how
25 the hinges connect to the panel. Fair?

1 A. Yes. Correct.

2 Q. All right, Dr. Grove. Let's switch gears a
3 little bit.

4 Now, you submitted a rebuttal expert report in
5 this case, right? Do you remember that?

6 A. Yes.

7 Q. All right. So stepping -- going back, you
8 submitted a rebuttal expert report in this case, right,
9 Dr. Grove?

10 A. I did.

11 Q. Okay. And I have up on the screen page 61 from
12 your rebuttal expert report that I will mark -- I will mark
13 this as CDX-1000. Okay.

14 So I have, Dr. Grove, up on the screen page 61
15 from your rebuttal expert report that I have marked as
16 CDX-1000.

17 Do you see that?

18 A. I do.

19 Q. Okay. Now, on this page you show two panels next
20 to each other connected by a hinge, right?

21 A. That's correct.

22 Q. Okay. And then the flanges of that hinge are in
23 a recess, right?

24 A. That's also correct.

25 Q. Okay. And do you recall that during your

1 deposition I asked you to annotate this figure? Do you
2 recall that?

3 A. Yes, I do.

4 Q. Okay. And the handwritten annotation next to the
5 asterisk is your notation, right?

6 A. It is.

7 Q. Now, to orient ourselves a little bit, in this
8 diagram you label the gray section that is facing the
9 adjacent panel right above the flange as inner side surface.
10 Do you see that?

11 A. I do.

12 Q. Okay. Now, in the recess, there's a longer
13 vertical section.

14 Do you see where I'm referring to?

15 A. Yes.

16 Q. Okay. And there's also a short horizontal
17 section that is marked with a red asterisk.

18 Do you see that?

19 A. Yes.

20 Q. Right there (indicating). Okay.

21 Now, below the diagram, you added a notation with
22 a black asterisk that labels the surface marked with the red
23 asterisk as "short horizontal portion of recess," and then
24 signed and dated it. Right?

25 A. Yes.

1 Q. Okay. So we're good so far? Do you recall this?

2 A. All good.

3 Q. All right. Now, Dr. Grove, it would not be
4 unreasonable to declare the inner side surface to be both
5 what's shown in this drawing as the short horizontal section
6 and the long vertical section. You agree with that
7 statement, right?

8 A. Are you referring to the long vertical section
9 that the hinge flange is touching or the side that's
10 annotated by the arrow, "inner side surface"?

11 Q. So I am referring to the short horizontal
12 section --

13 A. Yes.

14 Q. -- and then this longer horizontal section --

15 A. Yes.

16 Q. -- that the hinge flange is touching.

17 So with that in mind, let me reask my question.
18 Okay?

19 A. Yeah.

20 Q. Now, Dr. Grove, it would not be unreasonable to
21 declare that the inner side surface to be both what's shown
22 in this drawing as the short horizontal section and the
23 longer vertical section in the recess. You agree with that
24 statement?

25 A. I do.

1 Q. Okay. And as we can see in this drawing, the
2 short horizontal section marked with an asterisk is not
3 facing the adjacent panel, correct?

4 A. It is not.

5 MR. GANGULY: Your Honor, I offer CDX-1000.

6 JUDGE MOORE: All right. It will be handled as
7 other demonstratives.

8 MR. LANDMON: I'm sorry. It's just as a
9 demonstrative?

10 MR. GANGULY: Just as a demonstrative. It is not
11 coming in -- yeah, just as a demonstrative for the record.

12 JUDGE MOORE: It's not admitted.

13 MR. GANGULY: Yes. We will handle it later.

14 All right. Your Honor, I pass the witness.

15 JUDGE MOORE: All right.

16 MR. LANDMON: If I may just have a minute, Your
17 Honor?

18 JUDGE MOORE: Certainly.

19 MR. LANDMON: Thank you, Your Honor. Chad
20 Landmon again.

21 REDIRECT EXAMINATION

22 BY MR. LANDMON:

23 Q. Dr. Grove, do you recall testifying -- sorry.
24 Before we -- do you recall being asked about contact between
25 hinge flanges and the panel casing?

1 A. I do.

2 Q. Okay. And if we can pull up some of your direct
3 testimony. If I can ask that you pull up RX-009C.0013.

4 Dr. Grove, if I can focus your attention on your
5 testimony at Question and Answer 69.

6 A. Question and Answer --

7 MR. GANGULY: Objection, Your Honor. I mean, he
8 can't lead the witness with his own testimony.

9 JUDGE MOORE: Well, I will overrule it for now.
10 I'm not sure where we're going. Let's see what the question
11 is.

12 THE WITNESS: I did not see Question 69 on the
13 page.

14 BY MR. LANDMON:

15 Q. Well, we can now pull that up.

16 So, Dr. Grove, do you recall submitting testimony
17 regarding the hinge being in contact with the side surface
18 of the panels?

19 A. I do.

20 Q. Okay. And then do you recall being asked by Sun
21 Pharma's counsel about contact between a hinge flange and
22 the panel casing?

23 A. Yes, I remember this.

24 Q. All right. The fact that there's some contact
25 between the hinges on the inner side surface -- sorry -- the

1 fact that there's some contact between the hinges and the
2 panels, does that mean that the hinges are on the inner side
3 surfaces of panels?

4 A. It does not.

5 Q. And why not?

6 A. Because the -- my interpretation of the claims is
7 based on my reading of the specification. And it's clear
8 that -- from the specification and the claims that the
9 hinges need to be mounted on the inner side surfaces. And
10 so contact with the edge of a panel does not constitute, in
11 my opinion, hinges mounted on inner side surfaces.

12 MR. LANDMON: I have no further questions, Your
13 Honor.

14 JUDGE MOORE: All right.

15 MR. GANGULY: Nothing further, Your Honor.

16 JUDGE MOORE: Okay. So we are at 4:23, by my
17 clock here. So I think we lost a few minutes at the
18 afternoon break. We can go for ten minutes with the next
19 witness or we can call it a day.

20 MR. GANGULY: I think we will go with ten minutes
21 with the next witness, rather than wasting time.

22 MR. LANDMON: Your Honor, given that it is our
23 witness and we're actually, I think, ahead of schedule, I
24 would request that we call it a day and start that witness
25 off in the morning. We're actually -- by the schedule we

1 have been submitting to the Court, I think we're a witness
2 ahead. Dr. Grove, I think, was scheduled to go tomorrow
3 morning.

4 JUDGE MOORE: Right. Okay. So we have a
5 disagreement. I agree that it appears we are ahead. And
6 given that it's their witness, I think we will just call it.

7 So sorry to keep you there. You are released,
8 and you can go back and sit down, but we will have some
9 final comments with the attorneys.

10 THE WITNESS: Thank you very much, Your Honor.

11 JUDGE MOORE: Sure.

12 (The witness stood down.)

13 JUDGE MOORE: All right. As is normally the
14 case, the exhibits that have been used today should be met
15 and conferred, the agreed-upon exhibits sent to the court
16 reporter, and we will deal with any objections in the
17 morning. And as you said, it looks like we're very good on
18 time, but always discuss it.

19 Any housekeeping issues from Complainants?

20 MR. GANGULY: No, Your Honor.

21 JUDGE MOORE: Any housekeeping issues from
22 Respondents?

23 MR. LANDMON: No, Your Honor. Thank you.

24 JUDGE MOORE: All right. With that, we are
25 adjourned for the day.

1 (Whereupon, at 4:25 p.m., the hearing recessed,
2 to reconvene at 9:00 a.m. on Wednesday, July 2, 2025.)
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C O N T E N T S

WITNESS	DIRECT	CROSS	REDIRECT	RECROSS
NAN MARIE JOKERST			242	
THOMAS VANDER VEEN	263	268	290	298
HERMANN LUEBBERT	303	309	345	
MONTSERRAT FOGUET	364	367	387	396
EUGENE FREDERICK	402	404		
LEFFLER				
ROBERT GROVE	425	430	452	

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CONFIDENTIAL SESSIONS

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1	E X H I B I T S	
2	EXHIBIT NO:	RECEIVED
3	COMPLAINANTS	
4	CX-0016C	265
5	CX-0012C	267
6		
7	RESPONDENTS	
8	RX-0004C	308
9	RX-0002C	367
10	RX-0003C	404
11	RX-0009C	430
12		
13	EXHIBIT LIST SUBMITTED FOR ADMISSION:	
14	CPX-0011	
15	CPX-0012	
16	CPX-0013	
17	CX-0001	
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19	CX-0003	
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1 CERTIFICATE OF REPORTER

2 TITLE: Certain Photodynamic Therapy Systems, Components
3 Thereof

4 INVESTIGATION NO: 337-TA-1411

5 HEARING DATE: July 1, 2025

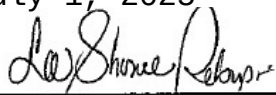
6 LOCATION: Courtroom B

7 NATURE OF HEARING: Evidentiary Hearing

8 I hereby certify that the foregoing/attached
9 transcript is a true, correct and complete record of the
10 above-referenced proceedings of the U.S. International
11 Trade Commission.

9 Date: July 1, 2025

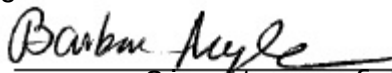
10 SIGNED:



11 Signature of the Contractor of the
12 Authorized Contractor's Representative
13 1150 Connecticut Avenue, N.W., Suite 305
Washington, D.C. 20036

14 I hereby certify that I am not the Court Reporter
15 and that I have proofread the above-referenced transcript
16 of the proceedings of the U.S. International Trade
17 Commission, against the aforementioned Court Reporter's
18 notes and recordings, for accuracy in transcription in the
19 spelling, hyphenation, punctuation and speaker
20 identification and did not make any changes of a
21 substantive nature. The foregoing/attached transcript is a
22 true, correct and complete transcription of the
23 proceedings.

19 SIGNED:

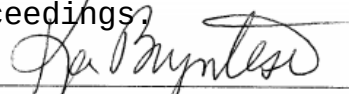


Signature of Proofreader

20

21 I hereby certify that I reported the above-referenced
22 proceedings of the U.S. International Trade Commission and
23 caused to be prepared from my tapes and notes of the
24 proceedings a true, correct and complete verbatim recording
25 of the proceedings.

23 SIGNED:



24 Signature of the Court Reporter

25