

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 _____

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

16
17 Wednesday, July 2, 2025

18
19 Hearing - Volume III

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21 The Hearing commenced in Courtroom B, pursuant to the
22 notice of the Judge, at 9:01 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 (9:01 a.m.)

3 JUDGE MOORE: Please be seated. Okay. On the
4 record.

5 Good morning. So I believe the exhibit list was
6 sent to the Court and to the reporter, so do we have any
7 objections to deal with?

8 MR. GANGULY: Tuhin Ganguly for Complainant.

9 Your Honor, the list has not been sent yet. We
10 have an agreed list. It hasn't been sent yet. So we're
11 working on that. And I think there are no objections, as I
12 understand it, but we could take it up after the morning
13 break to move that list in. But it hasn't -- we haven't
14 sent it to chambers or the court reporter yet.

15 JUDGE MOORE: All right.

16 MS. OKUN: Your Honor, Deanna Okun. We have no
17 objections.

18 JUDGE MOORE: Okay. All right. So I will check
19 back at the break on the list.

20 And I think that yesterday I was to get back to
21 the parties about demonstratives. The ground rules, there's
22 about three different ground rules that lay out basically
23 how demonstratives are to be handled, but I think the
24 concern was that -- how they got to the Commission. And the
25 way that happens is they go to Box, as described in the

1 ground rules, and then they are transmitted internally to
2 docketing. And docketing handles them in such a way that
3 the Commission accesses them.

4 So the Commission will have access to the
5 demonstrative exhibits, but they do not need to be entered
6 in the record the way the other exhibits are entered. So --

7 MS. OKUN: Your Honor --

8 JUDGE MOORE: Yes.

9 MS. OKUN: -- just one point of clarification.
10 On the ground rule that also describes that the
11 demonstratives would go in at the same time as the
12 post-hearing brief, is that how you'd like to handle it or
13 just do it at the same time that we do the wrap-up at the
14 end of the hearing?

15 JUDGE MOORE: Whatever the ground rules say is
16 the way to do it. Sitting here, I may not remember the
17 reason why the ground rules say to do it that way, and then
18 we run into a problem if I change, so let's just stick with
19 the way the ground rules say to do it.

20 MS. OKUN: Thank you.

21 MR. GANGULY: Thank you, Your Honor.

22 JUDGE MOORE: All right. Any other housekeeping
23 issues before we start with the witnesses?

24 MS. CHEN: Yes, Your Honor. One of our
25 witnesses, Mr. Scott Lundahl, had a medical emergency last

1 night and is in the hospital. And we've conferred with
2 Biofrontera and we would like to agree -- well, we have
3 agreed and we would like to seek your permission, Your
4 Honor, to see if we can pause the proceedings after
5 Dr. Shmuylovich is up today, and see if Mr. Lundahl might be
6 able to get out of the hospital tonight and be able to
7 testify tomorrow morning. And that would just leave one
8 other witness for tomorrow, who is Dr. Nan Jokerst.

9 JUDGE MOORE: Okay. So let me understand this.
10 So then we would end early today and then hopefully take the
11 witness tomorrow. I understand if it's not possible, but my
12 preference always would be to continue, if, I guess it's
13 Jokerst -- I don't want to pronounce his name and get it
14 wrong -- but if that witness could go in the place where the
15 other witness would go and go today, that would be my
16 preference, but maybe you can think about that and let me
17 know at the break if that would be possible.

18 But other than that, if there's going to be just
19 one witness tomorrow, then we don't have an issue of timing,
20 and I'm fine with that procedure, with the caveat that I
21 would rather go ahead and do as many witnesses as we could
22 do today, rather than doing a pause.

23 MS. CHEN: Your Honor, I believe because we're
24 moving Dr. Shmuylovich up in place of Dr. -- or Mr. Lundahl,
25 then I don't think there will be much of an early release

1 today anyway. And there's no question, even with this
2 change in order, that the proceedings will likely end by
3 midday tomorrow.

4 JUDGE MOORE: Certainly. Yeah. I understand
5 that.

6 And, as I said, I'm fine with that procedure.
7 Just to the extent that it results in ending early today, I
8 would prefer not to do that, if -- so we can, you know,
9 continue as is, but you understand my concern.

10 MS. CHEN: Yes, understood.

11 JUDGE MOORE: All right. Anything else?

12 MS. CHEN: Nothing else from Complainant, Your
13 Honor.

14 JUDGE MOORE: All right.

15 MS. OKUN: Nothing from Respondent, Your Honor.

16 JUDGE MOORE: Okay. All right. And, of course,
17 the Court sends its best wishes to the witness and hopes
18 that he recovers from whatever he is dealing with.

19 MS. CHEN: Thank you. I'll pass that along.

20 JUDGE MOORE: All right. Thank you.

21 So, you know, we've talked about timing. So we
22 should bring up the witness. And we'll go briefly off the
23 record.

24 (Discussion off the record.)

25 MR. LARIVÉE: May I proceed?

1 JUDGE MOORE: Yes.

2 MR. LARIVEE: Good morning, Your Honor. Brian
3 Larivee for the Biofrontera Respondents. Biofrontera calls
4 as its next witness Dr. Michael Ehrenreich.

5 JUDGE MOORE: All right. Raise your right hand.
6 Whereupon--

7 MICHAEL EHRENREICH,
8 having been first duly sworn/affirmed, was examined and
9 testified as follows:

10 THE WITNESS: I do.

11 JUDGE MOORE: All right. Thank you.

12 DIRECT EXAMINATION

13 BY MR. LARIVEE:

14 Q. Good morning, Dr. Ehrenreich. Could you please
15 introduce yourself on the record.

16 A. Good morning --

17 THE REPORTER: I'm sorry, your microphone is not
18 on.

19 THE WITNESS: Okay. Now it's on.

20 THE REPORTER: Thank you.

21 THE WITNESS: Okay. Good morning. I'm
22 Dr. Michael Ehrenreich. I'm a board-certified
23 dermatologist. I'm a board-certified Mohs micrographic
24 surgeon. I'm in private practice in New Jersey for the last
25 15 years. I have my practice called SOMA Skin & Laser where

1 I perform general medical, surgical cosmetic dermatology
2 with a particular focus on lasers, light-based and energy
3 devices in general.

4 Q. Abe, could we please have RX-1419.

5 Dr. Ehrenreich, do you recognize this document as
6 your CV?

7 A. I do.

8 Q. And is this an accurate and up-to-date copy of
9 your CV?

10 A. Yes, it is.

11 Q. Could you please describe your educational
12 background.

13 A. Yes, certainly. I have a Bachelor's of science
14 in finance from Yeshiva University. Subsequent to that, I
15 have a Master's in biological sciences from Columbia
16 University. Following that, at some point I got a medical
17 degree from what is now Rutgers University. At the time, it
18 was the University of Medicine and Dentistry of New Jersey.

19 Upon graduation from medical school, I completed
20 a transitional year internship at St. Barnabas Medical
21 Center in New Jersey and, after that, a dermatology
22 residency at Downstate Medical Center in Brooklyn, New York.

23 Q. And what was the subject of the courses that you
24 took in receiving your MA in biological sciences from
25 Columbia?

1 A. So this department was primarily engaged in
2 molecular biology, genetics, developmental biology. The
3 chairman at the time was Marty Chalfie, now a Nobel
4 laureate.

5 Q. And, sir, what professional credentials do you
6 hold in the field of dermatology?

7 A. So I'm a board-certified dermatologist, like I
8 said, which means I'm a fellow of the American Board of
9 Dermatology. I'm also board-certified in Mohs surgery,
10 which is a separate board certification.

11 Mohs surgery, if you're not familiar, is a
12 particularly specialized kind of cutaneous surgery for skin
13 cancer to ensure 100 percent margin control of the tumor,
14 which means that the surgeon also acts in real time more or
15 less as the pathologist, examining the margins of the tumor
16 under a microscope.

17 In order to be board certified in Mohs
18 micrographic surgery, it is beyond just surgery. You're
19 expected to be expert in all matters related to precancerous
20 cancers, the diagnosis of them, and the treatment, not only
21 with surgery but with other means, as well as adjuvant
22 therapies. In the course of performing Mohs surgery, you
23 need to have a lab in your office which has to be what is
24 called CLEA certified. It's a state -- actually, it might
25 be federal -- certification, and that requires also a

1 laboratory director which does not have to be the Mohs
2 surgeon, but in this case, I'm also the laboratory director.

3 Q. And, Dr. Ehrenreich, what is your experience
4 treating patients with photodynamic and light modalities?

5 A. So I have extensive experience doing photodynamic
6 therapy in my office for at least ten years. Prior to that,
7 I was taught and exposed to it during my residency. I also
8 perform photodiagnosis or photo -- well, we use a Wood's
9 lamp to diagnose things, which is a kind of fluorescence.
10 And I use a bunch of other light-based modalities in the
11 course of treatment and diagnosis.

12 MR. LARIVÉE: Your Honor, Biofrontera would like
13 to offer Dr. Ehrenreich as an expert in the fields of
14 dermatology, photodynamic therapy, and photodynamic
15 diagnosis.

16 MR. SHAW: Your Honor, David Shaw on behalf of
17 Sun Pharma. We object to Dr. Ehrenreich's admission as an
18 expert in this investigation. Dr. Ehrenreich's
19 qualifications do not meet the definition of a person of
20 ordinary skill in the art that you adopted in the Markman
21 order. And, therefore, he cannot be admitted as an expert
22 under Kyocera Senco in accordance with your Order Number 60
23 in the 1351 investigation, Your Honor.

24 MR. LARIVÉE: Well, here we have a very timely
25 objection, weeks after the deadline for high-priority

1 objections and motions in limine. Dr. Ehrenreich is a POSA.
2 And Your Honor's order with respect to footnote 5 is that,
3 "I find that experience in treating patients is not alone
4 sufficient to meet this proposal." The order further goes
5 on to speak to simply an M.D. and/or a Ph.D.

6 As you've just heard from Dr. Ehrenreich, he has
7 both a medical degree and a Master's, so he has education
8 beyond the educational requirements laid out in Your Honor's
9 order. And Dr. Ehrenreich is not simply treating patients.
10 He's board certified in dermatology. You've also heard that
11 he's board certified in Mohs micrographic surgery.

12 And, in addition, he is the lab director of a
13 CLEA-certified lab for diagnosing neoplastic irregularities
14 in skin, which is, of course, one of the central issues in
15 the case. He's not simply a doctor. He's also a lab
16 director.

17 And so the -- notwithstanding the ambush nature
18 of the objection, Dr. Ehrenreich qualifies as a POSA. Since
19 then, of course, Kyocera has been overturned, so it is -- as
20 we know, the Osseo Imaging case last fall distinguished
21 Kyocera. And Your Honor is familiar with decisions in which
22 -- although we maintain that Dr. Ehrenreich's capabilities
23 more than establish him as a POSA in this case, he is -- his
24 testimony will also be valuable even if you were to somehow
25 consider him not a POSA, which, of course, we would

1 strenuously object to.

2 He is being offered for claim elements for which
3 he has undisputed expertise. He has treated over 30,000
4 patients, in addition to his educational experience and his
5 work as a lab director of the CLEA lab. And he's -- has
6 experience, of course, with a number of steps that are in
7 dispute in this case. And his rebuttal witness testimony is
8 similarly rooted in his experience as a doctor, as a
9 board-certified micrographic surgeon, as a CLEA expert.

10 And Your Honor is also aware that, for instance,
11 similar testimony where the witness may not have met exactly
12 the letter of the POSA standard has been allowed. Of
13 course, I direct you to Certain Components for
14 Environmentally Protected LCD Digital Displays and Products
15 Containing Same, Investigation No. 337-TA-1349, Order Number
16 26. And we believe that with respect to the structural
17 elements of the light and device limitations, it's clear
18 that -- or we have been very clear that Dr. Ehrenreich is
19 not offering testimony on those issues.

20 Your Honor may recall the Markman hearing and the
21 context in which this came up, and the way note 5 came into
22 existence, which is Your Honor adopted their POSA
23 definition. And at the time, we pointed out the disjunctive
24 nature of an M.D. and/or Ph.D., such that one could have an
25 M.D. And the argument that Biofrontera made -- and I know

1 because I was the one who made it -- was that the definition
2 offered by Sun Pharma was that their definition would allow
3 an M.D. who was, for instance, an intern physician to serve
4 as a POSA in this case, who only had that experience.

5 That is very distinguishable from the expert, the
6 distinguished expert, you see in front of you who has an
7 M.D., who has a Master's from Columbia in biological
8 science, who is a board-certified Mohs micrographic surgeon,
9 who is the director of a CLEA lab. And so, Your Honor, on
10 the substance, leaving aside the ambush and the lack of
11 collegiality in this objection, we think it is wholly
12 unfounded.

13 MR. SHAW: Your Honor, may I respond?

14 JUDGE MOORE: Yes.

15 MR. SHAW: Can I have the podium and use the
16 ELMO, please?

17 Your Honor, again, David Shaw on behalf of Sun
18 Pharma.

19 So as to the timeliness of the objection, Your
20 Honor, today was the first time that Dr. Ehrenreich has been
21 proffered as an expert. They didn't make a proffer in his
22 witness statement. And so an objection before today would
23 have been premature.

24 Also, Your Honor, as I think you know, the
25 Kyocera case says unfortunately that it's an abuse of

1 discretion to let his testimony in. And you considered the
2 timing of this type of objection in the 1351 case. And you
3 said although it was, I think, unfortunate, you said, that
4 you still felt compelled to grant the motion.

5 As far as the discussion of the Osseo versus
6 Planmeca case, that did not overturn or change the ruling in
7 Kyocera. All that the Osseo court said is that it doesn't
8 matter if a person is a person of ordinary skill of the art
9 as of the date, the priority date of the patent. That's not
10 our objection to Dr. Ehrenreich. Our objection is that,
11 even sitting here today, he does not meet the definition
12 that you adopted.

13 Another thing is he is clearly offering opinions
14 on infringement and validity. The Kyocera case says that a
15 person has to meet the definition of ordinary skill in the
16 art to offer opinions on infringement and validity, so his
17 testimony is objectionable on that ground.

18 Now, Your Honor, there was some discussion of the
19 Markman order. So I do want to discuss what it says and how
20 it came about. So Your Honor might recall the definition of
21 a person of ordinary skill in the art that you adopted has
22 two aspects here, Your Honor. The first is an educational
23 aspect, M.D. or Ph.D. That's not the basis of our
24 challenge, okay? Dr. Ehrenreich has an M.D. Fine.

25 The second aspect of the person of ordinary skill

1 definition is "at least one to two years of work or research
2 experience in optical engineering, optics, optoelectronics,
3 phototherapy, photodynamic therapy, or a related field."

4 Now, Your Honor, importantly here, we've got
5 footnote 5. And as you can see, what footnote 5 says is,
6 during the Markman hearing, Biofrontera's own counsel
7 suggested that a person under this definition would lack the
8 requisite experience because it would cover someone with at
9 least two years of experience in providing phototherapy or
10 PDT. And because of that you found, Your Honor, that
11 experience in treating patients is not alone sufficient to
12 meet this proposal.

13 Now, you heard a lot of talk about Dr. Ehrenreich
14 treating patients. We don't dispute that he treats
15 patients. That's not enough.

16 And what is also interesting, Your Honor -- so
17 counsel mentioned how this definition came to be. If you
18 look back, again, at the transcript of the Markman hearing,
19 counsel was the one arguing, and so what he argued is: This
20 definition would include an M.D. with at least two years of
21 experience -- he's talking about Sun Pharma's proposed
22 definition -- and he said that that person would be a POSA.

23 Now, what he didn't talk about is the follow-up.
24 And what he said was we don't think that's right. And then
25 when you get down here to the argument, he says, "Why, why?"

1 Because these claims are specifically directed to treatment
2 including methods of treatment, and we --

3 MR. LARIVÉE: Could we -- if we're going to use
4 the ELMO, could we at least make sure it's legible? It's
5 completely -- we don't have a monitor. And this is --

6 MR. SHAW: It's the Markman order, page 32. So
7 what he said is these claims are specifically directed to
8 treatment, including methods of treatment. As we pointed
9 out in our briefing, these are claims that are directed to
10 what the FDA calls a combination product. It's a
11 combination of a pharmaceutical and a medical device. And
12 that was their complaint, is that a medical device is
13 involved, so treating patients by an M.D. is not enough.

14 Now, when we get to Dr. Ehrenreich's witness
15 statement, he talks about treating patients. And he is
16 asked: Do you believe you are qualified to offer opinions
17 on the patents and issues in this case? And he says: "Yes,
18 as explained in my expert reports, I am offering opinions on
19 the medical aspects. As we have discussed, I am a
20 board-certified dermatologist with experience in
21 photodynamically treating patients."

22 And he's asked later at Question 70 whether he
23 meets the definition of a POSA. And he says: "Yes, I
24 believe I would have qualified. The definition says a POSA
25 could have had an M.D. and at least two years of experience

1 in phototherapy, photodynamic therapy or a related field.
2 As I explained earlier, I completed my M.D., was a
3 board-certified dermatologist and had been treating patients
4 with PDT for several years before 2015."

5 That's the same thing he said today. He talked
6 about his experience in his clinic diagnosing and treating
7 patients. He doesn't have any laboratory research
8 experience or any of the other type of experience that would
9 qualify him under the second element of the POSA definition,
10 and that's the basis for our objection, Your Honor.

11 JUDGE MOORE: All right.

12 MR. LARIVÉE: Your Honor, may I respond?

13 JUDGE MOORE: Yes, of course.

14 MR. LARIVÉE: Abe, can we have the claim
15 construction order up?

16 I think as Your Honor can see, Sun Pharma clearly
17 had time to write a brief on this. Let's look at the POSA
18 section.

19 Chris, can you direct Abe to the relevant
20 section? And is there something wrong with the monitor
21 today over here?

22 JUDGE MOORE: It looks like we're having a
23 technical difficulty. We have smaller monitors around. I
24 would suggest that we just have to deal with this. I'd
25 rather not stop to try and fix that issue right now.

1 MR. SHAW: Your Honor, the monitors at counsel's
2 table are working and that monitor is working as well.

3 JUDGE MOORE: Yes. That's what I suggested.

4 MR. LARIVÉE: Well, I don't have one up here.

5 Your Honor, directing your attention to page 13
6 of your claim construction order, I think you're going to
7 find that Sun Pharma has mischaracterized your claim
8 construction order. And it says, "Accordingly, I find a
9 person of ordinary skill in the art would have an M.D.
10 and/or" -- and then it goes on for certain Ph.D. fields --
11 "and at least one or two years of work, work, or research
12 experience in optical engineering, optics, optoelectronics,
13 phototherapy, photodynamic therapy, or a related field."

14 Here in front of you, you have Dr. Ehrenreich who
15 has -- meets this definition. Footnote 5, I think, is
16 responsive to the argument that was made at claim
17 construction about, for instance, an intern physician who
18 has, you know, perhaps only completed an intern in, for
19 instance, pediatrics, as was the case of Sun Pharma's expert
20 that we will see later today.

21 And this -- the plain language of your order
22 includes M.D. and at least one or two years of work or
23 research experience in phototherapy, photodynamic therapy,
24 or a related field. Dr. Ehrenreich, by the priority date of
25 the patent, had more than two years' work experience in

1 phototherapy and photodynamic therapy. And that -- that
2 work experience was beyond just treating patients. It was
3 also running his CLEA-certified Mohs surgery lab.

4 And so, Your Honor, I don't know how one gains
5 work experience in photodynamic therapy without doing
6 photodynamic therapy or how one gains experience, work
7 experience, in a related field without running a medical
8 laboratory related to Mohs micrographic surgery and, you
9 know, running a CLEA-certified lab to diagnose and
10 understand the margins on the tumor.

11 You know, so -- in addition, I'd just point out
12 that the -- that one of the ways in which Osseo clarifies
13 the Kyocera ruling is that it is not up for disqualifying an
14 expert from testifying on issues within their background.
15 And I think the testimony that you're going to hear from
16 Dr. Ehrenreich in his background is more than enough to
17 cover it.

18 So, Your Honor, we think on the plain language of
19 Your Honor's claim construction order, Dr. Ehrenreich's
20 medical degree, his Master's from Columbia University in
21 biological sciences, which he just discussed, which is a
22 qualification above and beyond what is in the educational
23 qualifications in Your Honor's order, but, most importantly,
24 the experience that he has in phototherapy and photodynamic
25 therapy and his qualifications running a CLEA lab more than

1 qualify him as a POA under Your Honor's order.

2 And I would just say, Your Honor, that it's very
3 clear, whatever their reasons, that Sun Pharma had the
4 opportunity to essentially write a brief on this topic
5 before this morning, and the -- if Your Honor is -- only if
6 Your Honor is inclined to consider granting this motion,
7 this belated motion, we would respect that Your Honor
8 entertain written testimony on the order.

9 JUDGE MOORE: All right. Okay. So first point,
10 as to timeliness, I have to say that I am -- I'm looking for
11 the right word -- disappointed -- that might not be the
12 right word -- for the way this comes before the Court. We
13 have one week to do these trials. We bring all these people
14 across the country, and we have to complete these trials
15 within the time period.

16 This is a dispute that could -- I disagree with
17 Complainant's suggestion that they could not bring this
18 until now. I believe that it was strategically brought now
19 to put the Court in a position where it has to make a
20 certain decision. So that is my belief. Of course, that
21 belief does not bias in any way how I will handle this
22 situation.

23 I am going to voir dire the witness on a couple
24 questions. I would appreciate the parties -- the case that
25 you mentioned that comes after Kyocera, I need you to put on

1 the record the citation for that case. And then we will
2 take a break and I will consider this issue. So that's how
3 we're going to proceed.

4 So when you get the citation to the case, feel
5 free to give it to me so that I can have it. Now, the
6 citation -- yes, you mentioned a case that came after
7 Kyocera. I need the citation to that case.

8 MR. SHAW: I have it, Your Honor, if I may.

9 JUDGE MOORE: Yes.

10 MR. SHAW: It is 116 F.4th 1335, Your Honor.

11 JUDGE MOORE: All right. Okay.

12 All right. Somewhat unusual, but I'm sure that
13 you can help us get through this.

14 So the question I have for you is that, in your
15 work experience in phototherapy or photodynamic therapy,
16 other than directly treating patients, what other activities
17 do you perform at your practice?

18 THE WITNESS: Well, with regard to phototherapy
19 or photodynamic therapy, those would just be treatment
20 modalities. I do also use a light source called a Wood's
21 lamp to diagnose patients, which is part of the practice of
22 dermatology. I will admit that I do not have research
23 experience or engineering experience as it relates to
24 phototherapy or photodynamic therapy.

25 I would also like to offer to the Court if I may,

1 we did not focus on it I think because my credentials as a
2 medical doctor and a Mohs surgeon seem overwhelming, but I
3 would like to focus on the last term, which is one or two
4 years, Im paraphrasing, of work or research experience in a
5 related field and go back to my Master's Degree, which we
6 didn't talk very much about, which is a work or research
7 position in addition to didactics where I work in a lab and
8 that sort of thing.

9 As I mentioned, the program director at that time
10 was a person named Marty Chalfie, now a Nobel Prize winner,
11 and what he won a Nobel Prize for was the use of something
12 called green florescent protein as a biological indicator.
13 I did not work in Dr. Chalfie's lab, but I certainly had
14 many lectures from him and read probably every paper that he
15 wrote regarding this worm system called C. elegans and using
16 green florescent protein to map biological development in
17 this worm system. So I would offer to the Court that under
18 the alternative theory of one year of related work or
19 research experience, I alternatively qualify by work done in
20 my Master's program.

21 JUDGE MOORE: All right. And can you briefly
22 describe the lab work that you did during your Master's
23 program.

24 THE WITNESS: Yes. So, like I said, I did not
25 work in Dr. Chalfie's lab, I did not work specifically on

1 green fluorescent protein, but I have a lot of background
2 material and lectures on that. I tended to rotate through
3 different labs and participate in different experiments. It
4 was primarily genetics in yeast systems.

5 JUDGE MOORE: Okay. All right. What we're going
6 to do now is we're going to take a break. It should be at
7 least 20 minutes.

8 (A recess was taken at 9:38 a.m., after which the
9 proceedings resumed at 10:02 a.m.)

10 JUDGE MOORE: Please be seated.

11 All right. Back on the record.

12 If the parties could bring up the level of
13 ordinary skill so that we have it on the screen.

14 Okay. So, for the record, the level of ordinary
15 skill is "a person of ordinary skill in the art would have
16 an M.D. and/or a Ph.D. in an electrical engineering,
17 optoelectronics, physics, optical sciences, optical
18 engineering, or related scientific or engineering field and
19 at least one or two years of work or research experience in
20 optical engineering, optics, optoelectronics, phototherapy,
21 photodynamic therapy, or a related field."

22 With the footnote, "During the Markman hearing,
23 Biofrontera's counsel suggested that a person under this
24 definition would lack the experience necessary to develop
25 the invention." And then a citation.

1 "Biofrontera suggests, for example, that this
2 proposal would cover someone with at least two years of
3 experience providing phototherapy or photodynamic therapy in
4 a dermatologist's office or a resident physician at a
5 hospital. To alleviate any such concern, I find that
6 experience in treating patients alone is not -- is not alone
7 sufficient to meet this proposal."

8 So the situation we have here is -- and I will go
9 back to the Markman, at the Markman -- so at the Markman, I
10 stated that -- and this is quoting -- "I understand that the
11 claims talk about treatment but let me sort of as devil's
12 advocate say to you that the claims are about how light is
13 received on the patient's skin or surface. I'm not sure how
14 the medical experience of knowing how to treat the patient
15 informs getting an even level of light over a surface."

16 So I think the issue that we have here is that at
17 least one side is suggesting that the footnote refers
18 directly to the second half of the definition, which is
19 defined as work experience. But the issue that the footnote
20 was trying to get at was a medical doctor whose M.D. was in
21 the medical field, not in a related field of phototherapy,
22 would simply be treating patients.

23 From the testimony that we have from the witness,
24 from the witness' experience in diagnosing patients, which
25 is outside of treatment, according to the parties, to the

1 work that the expert did in his Master's work, which is
2 outside of the area of medical and in a related field, I
3 think -- I don't think -- I find that the expert does meet
4 the definition, explicitly the definition as stated in the
5 Markman order as correctly interpreted, as I have just
6 explained on the record.

7 But I want to focus on timeliness as well. In
8 the Markman, I stated that -- and I said, because certainly
9 an expert -- and then I added what I don't want to do, and
10 went on to say: And I can just sort of be fair about this.
11 In a recent investigation, I think the Court was somewhat
12 placed in a situation where there were direct Fed Circuit
13 cases that led to a particular result. I don't want to do
14 form over substance. I know we have a second expert here.

15 So the parties were on notice of the Court's
16 concern. And I went on to say: "The purpose of what we're
17 doing here is not for 'gotcha' or to waste either side's
18 money. So level of skill, in general, is not something that
19 becomes an issue in cases. Like I said, the exception is
20 the Kyocera case and the situation that I recently faced."

21 So the parties were very aware that the Court was
22 concerned about the situation that we currently find
23 ourselves in. I understand Kyocera puts you in a situation,
24 puts the Court in a situation where it is error to accept an
25 expert who does not meet the qualifications. As I've just

1 stated, while this may be a slightly unusual case, and the
2 language in the Markman order may be at the very least open
3 to interpretation, the situation here is that we do have an
4 expert that meets the level of skill, but I also find
5 separately that the raising of the issue is untimely.

6 The purpose of motions in limine, high-priority
7 objections, motions to strike, et cetera, is to allow us to
8 perform these hearings in an efficient manner and not to
9 waste parties' time and effort during a week that should be
10 focused on the merits of the case. So to the extent that
11 that could be a basis, I do find that the motion was
12 untimely.

13 So -- and certainly in these cases, if there is a
14 situation where one side is challenged in a particular way,
15 it's certainly not useful or helpful to, in a goose/gander
16 situation, just challenge the other side in the same way.
17 So I don't find that that is productive. I don't find
18 that's the best use of our time and the best practice for
19 our profession.

20 So with all that said, I think I have resolved
21 the objection, and we can bring the witness back to the
22 stand.

23 And one final note, which I think I said before,
24 but it's important to say, obviously the Court, myself, we
25 try our best to live up to the ethical standards. The fact

1 that I may have been not happy with something that one side
2 or the other side did in absolutely no way affects how I
3 rule on these cases. These cases are always ruled
4 exclusively on the merits, not on who is the good guy, who
5 is the bad guy. I'm sure through our discovery conferences
6 in this case, you know I don't want to know who did
7 something allegedly wrong and who said something allegedly
8 wrong. I'm 100 percent focused on the merits at all times.

9 So with that, go ahead.

10 MR. LARIVEE: Thank you, Your Honor.

11 BY MR. LARIVEE:

12 Q. Dr. Ehrenreich, you should have copies of RX-11C,
13 as well as RDX-21C in front of you.

14 A. Yes, I do.

15 Q. And what is RX-11C?

16 A. RX-11C is my rebuttal witness statement.

17 Q. And what is RDX-21C?

18 A. RDX-21C -- I'll check the number -- is the
19 demonstratives. RDX-21C is the demonstratives that go with
20 this.

21 Q. Sir, if you could please turn to RX-11C at page
22 51.

23 A. Yes.

24 Q. Is that your signature?

25 A. It is.

1 Q. And does this rebuttal witness statement contain
2 your answers to questions from counsel in this
3 investigation?

4 A. Yes, it does.

5 Q. Are the answers in your witness statement
6 accurate and truthful?

7 A. To the best of my knowledge, yes.

8 MR. LARIVÉE: Your Honor, Biofrontera would like
9 to move Dr. Ehrenreich's rebuttal witness statement into
10 evidence.

11 MR. SHAW: No objection, Your Honor.

12 JUDGE MOORE: All right. It is moved into
13 evidence.

14 (Respondents Exhibit Number RX-11C was received
15 into evidence.)

16 MR. LARIVÉE: We pass the witness.

17 JUDGE MOORE: When you're ready.

18 MR. SHAW: Thank you, Your Honor.

19 CROSS-EXAMINATION

20 BY MR. SHAW:

21 Q. Dr. Ehrenreich, are you ready?

22 A. I am.

23 Q. Great. Nice to meet you. I'm David Shaw. I
24 represent Sun Pharma.

25 A. Good morning.

1 Q. So, Dr. Ehrenreich, I want to ask you about your
2 opinions related to infringement today. Okay?

3 A. Okay.

4 Q. And you're focused on the medical and treatment
5 aspects of the asserted claims, right?

6 A. That's correct.

7 Q. And you're deferring to Dr. Grove's analysis to
8 determine whether Biofrontera practices the device and
9 structural limitations of the claims, right?

10 A. That's correct.

11 Q. Now, Doctor, as part of your analysis in this
12 investigation, you didn't meet with Dr. Grove before
13 submitting your expert reports or sitting for deposition,
14 did you?

15 A. No, I reviewed his reports, but I did not meet
16 with him.

17 Q. And, in fact, you didn't meet with any engineer
18 in coming to your opinions before your deposition in this
19 case, did you?

20 A. That's correct.

21 Q. Changing gears a little bit, Doctor, the purpose
22 and function of a user manual for a medical device like the
23 RhodoLED XL and the BLU-U is to instruct the user how to use
24 the device. That's right?

25 A. That sounds reasonable, yes.

1 Q. And on-label use of those devices requires
2 following the instructions in the user manual, doesn't it?

3 A. Not the user manual alone. If it's a device,
4 plus a pharmaceutical, it would be the user manual plus the
5 label that we would be looking at as a healthcare
6 practitioner.

7 Q. And you agree that the user manual for the
8 RhodoLED XL includes instructions on how to bend the LED
9 panels into a curved shape for treatment, don't you?

10 A. I recall that it tells you to bend it into a
11 curved shape. I don't know that it tells you specifically
12 how. I wasn't focused on the mechanical aspects of moving
13 the panels.

14 Q. And the design of the RhodoLED XL more generally
15 allows you to position the panels. You agree with that at
16 least, don't you?

17 A. To position the panels? Like to move them
18 around? Yes.

19 Q. And once you move the panels, you can place the
20 treatment surface of a patient wherever you want relative to
21 those panels. True?

22 A. Once you position the panels, you can place a
23 patient in front of the panels however you see fit. Of
24 course, you would do that in accordance with the guidance in
25 the manual and the label.

1 Q. The RhodoLED XL device is capable of operating
2 regardless of the treatment distance to the face. True or
3 false?

4 A. You could turn it on in an empty room and it
5 would work.

6 Q. And so you agree with me that you could turn it
7 on in a room at any distance from a patient's face and it
8 would work, right?

9 A. Or at no distance or with no patient present.
10 Yeah, if you turn it on, the lights go on.

11 Q. Doctor, can you try to focus on my question and
12 answer my question, please?

13 A. I thought I was, sir.

14 Q. The RhodoLED XL device is capable of operating
15 regardless of the treatment distance from a patient's face.
16 Is that true or is it false?

17 A. I think I've agreed with you already.

18 Q. Now, in the RhodoLED XL, Doctor, by default, all
19 five panels are activated when the user turns the device on.
20 True?

21 A. Yes.

22 Q. And you're not aware of any requirement for a
23 healthcare professional to turn panels off, are you?

24 A. A requirement? No, it's optional.

25 Q. So Biofrontera has configured the RhodoLED XL

1 device so that a healthcare professional can treat patients
2 using five panels. True or false?

3 A. You're able to use it with five panels, that's
4 correct.

5 Q. Now, can we please pull up Dr. Ehrenreich's slide
6 RDX-21C.36.

7 This is a slide that you helped create to
8 illustrate your testimony, right, Doctor?

9 A. Yes. It seems to be from RDX-021C, my
10 demonstratives.

11 Q. Right. And this slide 36 from your
12 demonstratives shows an excerpt from JX-86.17, right?

13 A. It seems to be. I don't know the number of the
14 reference, but it seems to be from the user manual.

15 Q. And this is an excerpt from the user manual of
16 Chapter 8.4.6 titled Treatment Area. True?

17 A. Yes.

18 Q. And it's not the entirety of Chapter 8.4.6 titled
19 Treatment Area, is it, Doctor?

20 A. I'd have to see the entire chapter in front of me
21 to answer that accurately.

22 Q. Great. Can we put JX-86, page 17, side-by-side
23 with Dr. Ehrenreich's slide 36, please. And zoom in on
24 Chapter 8.4.6.

25 So, Doctor, now that you have these two

1 side-by-side, you agree with me that you didn't include all
2 the language from Chapter 8.4.6 on your slide 36, did you?

3 A. That's correct. There seems to be one sentence
4 missing from the bottom of it.

5 Q. That's right. And the sentence that's missing
6 said, "If a treatment with less than five active LED panels
7 is started, a message dialogue box appears which must be
8 confirmed." Right?

9 A. Yes.

10 Q. Now, Doctor, at the time of your deposition, you
11 had never tested the RhodoLED XL device to see if that
12 dialogue box actually popped up, had you?

13 A. No, I tested the RhodoLED device in my office.
14 To be honest, I don't recall when that was relative to my
15 deposition, if it was before or afterwards, but I did use
16 the device. I turned it on in different phases.

17 Q. Can we please pull up Dr. Ehrenreich's deposition
18 transcript at page 145, lines 19 through 22. And while
19 that's happening, Doctor, you recall --

20 MR. LARIVÉE: Objection to improper impeachment.

21 MR. SHAW: Your Honor, his testimony is directly
22 contrary to what he just said, and there hasn't been an
23 attempt to impeach yet.

24 JUDGE MOORE: All right. Overruled.

25 BY MR. SHAW:

1 Q. So, Doctor, you recall that my colleague,
2 Mr. Habbaz, deposed you in this case?

3 A. I do.

4 Q. And you recall at the beginning of that
5 deposition, you took an oath to tell the truth?

6 A. I do.

7 Q. And in your deposition, the question you were
8 asked was: "Did you test the device to see if this dialogue
9 box popped up when you used it?"

10 And the answer you gave under oath was: "I did
11 not." True?

12 A. And that was the truth at that time.

13 Q. Doctor, true or false?

14 A. Yes, at the time that was the truth. And I
15 testified that I wasn't aware of -- I did not remember right
16 now whether I tested it before or after the deposition. So
17 I'm trying to answer you honestly, sir. If that's what I
18 said at the deposition, then that was true at the time that
19 I said it.

20 I could tell you that at this point, I have
21 tested it to see that pop-up. But like I said, I wasn't
22 aware at this moment if that was before or after the
23 deposition that I saw it.

24 Q. So sitting here today, you've tested the RhodoLED
25 XL device and you've seen that if a treatment with less than

1 five active LED panels is started, a message dialogue box
2 appears which must be confirmed. You've seen that, right?

3 A. I have.

4 Q. You've never seen a similar dialogue box when you
5 start a treatment with three panels turned on, have you?

6 A. I'm sorry, sir. You -- that pop-up is with three
7 panels turned on.

8 Q. Pardon me, you're right.

9 You've never seen a similar pop-up that warns you
10 that you're starting a treatment with five panels, have you?

11 A. That's correct.

12 Q. And so if a health care professional starts a
13 RhodoLED XL treatment with three panels turned on, they have
14 to take the affirmative action of confirming that dialogue
15 box before the treatment continues, right?

16 A. That's correct.

17 Q. But if a healthcare professional starts a
18 RhodoLED XL treatment with all five panels turned on,
19 there's no dialogue box they have to confirm, right?

20 A. Not that I can recall.

21 Q. Now, Doctor, switching gears a little bit, you
22 also reviewed a Biofrontera marketing video involving
23 Dr. Ted Lain. Do you recall that?

24 A. I do.

25 Q. And Dr. Lain is a dermatologist, right?

1 A. I have been told.

2 Q. And Dr. Lain's practice is located in the United
3 States. You recall that from watching the video, right?

4 A. I've been told that. I don't know Dr. Lain. I
5 don't know his practice.

6 Q. All right. And in that video, Dr. Lain and his
7 staff apply ALA to a patient, right?

8 A. I'd have to watch the video to confirm that, but
9 that's my recollection. At some point, ALA seems to have
10 been applied.

11 Q. And the ALA they apply is Ameluz, right?

12 A. I believe so.

13 Q. And in that video, Dr. Lain treats the patient
14 with the RhodoLED XL lamp; isn't that right?

15 A. Yes.

16 Q. And in that video, Dr. Lain and his staff
17 position the panels on the RhodoLED XL device to be
18 proximate the patient. That's true, isn't it?

19 A. Yes.

20 Q. And in that video, Dr. Lain treated the patient
21 using all five panels as part of the treatment, right?

22 A. As best as I can recall and tell from the angles
23 of the videos, that seems to be the case.

24 Q. And you know that when Dr. Lain and his staff
25 turned on the RhodoLED XL device for that video, all five

1 panels came on by default, don't you?

2 A. I don't know what happened in that room, but I
3 know how it's designed.

4 Q. So you know when you turn on the RhodoLED XL
5 device, all five panels come on by default?

6 A. I know -- we've discussed that. I know that
7 that's what it does. I can't say what Dr. Lain experienced.

8 Q. And you recall from the video that Dr. Lain and
9 his staff didn't down select to only use three panels in the
10 treatment, right?

11 A. I don't recall seeing that in the video.

12 Q. When Dr. Lain and his staff performed that
13 treatment using all five panels plus Ameluz, that was an
14 on-label treatment, wasn't it?

15 A. I believe so.

16 Q. All right. Now, switching gears to Sun Pharma's
17 devices, Doctor, you use the original Sun Pharma BLU-U
18 device in your practice, right?

19 A. I do.

20 Q. And you've been using the BLU-U for about 17
21 years since you finished your residency, right?

22 A. No. About 15 years since I finished my
23 residency, and then during my residency, and I acquired my
24 BLU-U about 10 years ago. So ten years in my office. The
25 first few years of my practice I did not have a BLU-U. And

1 then I had used it during my residency before I started my
2 practice.

3 Q. So let me make sure I just understand, Doctor.
4 So you used the BLU-U in your residency, right?

5 A. That's correct.

6 Q. And you got a BLU-U for your practice about ten
7 years ago and you used it ever since, right?

8 A. That's correct.

9 Q. Okay. Thank you.

10 The BLU-U is a capital investment for your
11 business, right?

12 A. Yes.

13 Q. And that's because you expect the BLU-U to have a
14 long life, right?

15 MR. LARIVÉE: Objection, outside the scope.

16 MR. SHAW: Can we pull up Dr. Ehrenreich's
17 witness statement, Question and Answer 38, where he talks
18 about the BLU-U device, please.

19 MR. LARIVÉE: Your Honor, there's nothing in
20 RX-38 about capital investment or anything that this line of
21 questioning seems to be going towards, some sort of economic
22 argument. That is -- that's outside the scope of his
23 testimony, certainly outside the scope of Question and
24 Answer 38.

25 MR. SHAW: May I, Your Honor? He's here

1 testifying as a medical expert who uses the device that is
2 allegedly, by the Respondents, very relevant to this case.
3 And I'm just asking him about his use of that device in his
4 practice. It's clearly within the scope of direct.

5 JUDGE MOORE: All right. I'm going to overrule
6 the objection. The concern seems to be about the term
7 "capital investment," so we'll see where it goes, but
8 certainly he is not here to testify about economic issues.

9 Continue.

10 MR. SHAW: Understood, Your Honor.

11 BY MR. SHAW:

12 Q. So in your practice, Dr. Ehrenreich, you don't
13 prescribe Ameluz, right?

14 A. No.

15 Q. You've exclusively prescribed Sun Pharma's
16 Levulan medicine to patients, right?

17 A. That's correct.

18 Q. And you don't use Levulan with any lamps except
19 the BLU-U, right?

20 A. That's not correct.

21 Q. You view Levulan and the BLU-U lamp as a packaged
22 unit because the approval for Levulan requires using the
23 BLU-U. True or false?

24 A. Did I view it as a packaged unit? Can you
25 clarify, please?

1 Q. So can you -- do you have your deposition
2 transcript in your binder, Doctor?

3 A. Not in the binder that was handed to me by my
4 counsel. I don't know if it's in the binders that you
5 handed me.

6 Q. It should be in there. Can you try to find it,
7 please?

8 A. Okay. Can you direct me to a tab? There's 20
9 tabs here.

10 Q. Yeah, it should be labeled deposition transcript.

11 A. Okay.

12 Q. It's probably in the back.

13 A. Give me a moment.

14 MR. SHAW: Your Honor, can I approach the witness
15 or help or if Respondents' counsel wants to do it.

16 THE WITNESS: The deposition transcript,
17 CX-1330C. I'm getting there.

18 BY MR. SHAW:

19 Q. Take your time, Doctor. We're not in a rush.

20 A. All right. Second binder. Okay. I have my
21 deposition transcript. Where would you like me to go?

22 Q. Page 59, please, Doctor.

23 A. Page 59.

24 Q. Don't put it on the screen yet, please, Jeff.

25 A. Okay. Yes.

1 Q. Can you read, please, lines 10 through 18,
2 Doctor.

3 A. Does the fact that you're already --

4 Q. Not out loud, Doctor. I'm sorry.

5 A. I'm sorry.

6 Q. No, no, it's fine.

7 A. Okay. I've read that. Yes.

8 Q. And does that refresh your recollection that you
9 view Levulan and the BLU-U as a packaged unit?

10 A. Yes, that's how I phrased it during the
11 deposition. We were talking about the context of the
12 inertia of switching system -- of switching from Levulan to
13 Ameluz, and I said that obviously they come -- well, the
14 intent; I'm not saying verbatim -- they come from one
15 company, so it's one point of sale, kind of a package in
16 terms of dealing with them, so there was a lot of inertia
17 and no real, you know, thinking about going to another, you
18 know, form of aminolevulinic acid.

19 Q. And, similarly, you would view the RhodoLED XL
20 and Ameluz as a packaged unit, right?

21 A. Yes, similar.

22 Q. Okay.

23 MR. LARIVÉE: Your Honor, this is -- I renew the
24 objection.

25 MR. SHAW: I'm moving on, Your Honor.

1 MR. LARIVÉE: This is again part of a -- of an
2 economic argument.

3 MR. SHAW: Your Honor, that line of questioning
4 is over. So...

5 MR. LARIVÉE: I'd move to strike the last
6 question and answer.

7 JUDGE MOORE: All right. Give me just one
8 moment.

9 I'm going to overrule the objection. The
10 question was simply about packaged unit. I understand where
11 the objection is coming from.

12 You say you're going to move on, but the Court is
13 quite aware, he's not here to testify about economic issues
14 or -- at all. So continue.

15 MR. SHAW: Thank you, Your Honor.

16 MR. LARIVÉE: Thank you.

17 BY MR. SHAW:

18 Q. So can we pull up JX-105C, please. Actually,
19 sorry, can you take that down, Jeff.

20 So we've heard a lot in this trial so far,
21 Doctor, about how Biofrontera recommends using the RhodoLED
22 XL at a distance of 4.3 to 5.9 inches from the treatment
23 surface, right?

24 A. If you say so.

25 Q. Well, you've been here for at least some of the

1 trial?

2 A. For some of it. I --

3 Q. The RhodoLED XL works at a distance of 4.3 inches
4 from the treatment surface, doesn't it?

5 A. By "works," you mean what?

6 Q. There's nothing preventing a healthcare provider
7 from operating the RhodoLED XL to treat a patient at 4.3
8 inches from the treatment surface, right?

9 A. That's correct.

10 Q. Not only that, but the RhodoLED XL provides a
11 dose of light sufficient for photodynamic therapy with
12 Ameluz at 4.3 inches from the treatment surface, right?

13 A. So the label for Ameluz gives a range that has a
14 midpoint and two margins, an upper and a lower bound.
15 Presumably, that is because that's the intended range at
16 which to get the fluence that's intended. So 4.3 is the
17 lower bound of that range. That's what's told to me in the
18 manual and on the label. I assume that it works as proposed
19 at that distance.

20 Q. So you don't know whether the RhodoLED XL will
21 provide a dose of light sufficient for photodynamic therapy
22 with Ameluz at 4.3 inches from the treatment surface; is
23 that right?

24 A. Well, I just said that I assume. I mean, I
25 haven't measured it personally, so I just go by what I read

1 in the manual. And if it tells me that there's a range
2 that's recommended and it has a lower and an upper bound, I
3 as a healthcare practitioner assume that that's the fluence.
4 Within that range, I'm going to get the fluence that's
5 necessary to do the job.

6 They say it's 37, a fluence of 37. I assume that
7 there is some variability around that, but that within 4.3
8 to 5. -- where are we --

9 Q. 5.9.

10 A. -- that that's going to be within the range of
11 tolerance for providing therapeutic effect.

12 Q. Now, "treatment surface" in this context is a
13 little bit of a term of art. Do you agree with that?

14 A. A term of what?

15 Q. A term of art.

16 A. Art?

17 Q. So "treatment surface" is -- it means the surface
18 that you're treating that has AK lesions or some other
19 lesion on it, right?

20 A. It means the treatment that -- the surface that
21 you're treating. I can't speak to exactly what lesion we're
22 treating on it, but I think it's self-explanatory. You have
23 a device. You're not treating an empty room. You're
24 treating a patient who has a treatment surface.

25 Q. Agreed, Doctor. And so the face is a common

1 treatment surface in dermatological practice, right?

2 A. Yes.

3 Q. And you agree that the front of a patient's face
4 is not planar, right?

5 A. Yes.

6 Q. And dermatologists in general know that the front
7 of a patient's face is not planar, right?

8 A. I think everybody knows that.

9 Q. The side of a patient's face isn't planar either,
10 is it, Doctor?

11 A. It's not.

12 Q. And chest, shoulder, those aren't planar either,
13 right?

14 A. Well, you know, the back gets closer to being
15 planar. The chest gets close to being planar. But the face
16 is obviously contoured.

17 Q. And you know that the variance in distance
18 between the tip of the nose and the forehead is generally in
19 the realm of 1 to 2 inches, don't you?

20 A. I don't know that per se. I've seen some
21 discussion about this, but I don't remember the exact number
22 that was given or the source that was given for that. So I
23 don't really know offhand the average size of the human nose
24 and its distance, you know, relative to the forehead.

25 Q. Okay. But you know that there's a variance in

1 average size -- or in -- strike that. Let me ask it again.

2 You know that the size of human noses vary,
3 right?

4 A. Of course.

5 Q. And dermatologists in general know that the size
6 of human noses vary, don't they?

7 A. Everybody knows it.

8 Q. And you also know as a dermatologist that
9 patients often shift or move around during treatment, don't
10 you?

11 A. That's true.

12 Q. And in general dermatologists know that?

13 A. Yes, they do.

14 Q. And similar companies designing PDT devices are
15 generally aware that the front of a patient's face is not
16 planar, aren't they?

17 A. I can't speak to what a company knows.

18 Q. That's because you've never designed a medical
19 device, have you?

20 A. I think we've established that.

21 Q. So, Doctor, just yes or no. Have you ever
22 designed a medical device?

23 A. No, I have not.

24 Q. Okay. And so when a dermatologist like yourself
25 positions a patient for PDT treatment, you don't use a ruler

1 to measure whether the treatment surface is the exact
2 recommended distance from the PDT device, do you?

3 A. No, I don't.

4 Q. You just eyeball it, right?

5 A. Pretty much.

6 Q. All right. Can we please -- hold on.

7 MR. SHAW: Your Honor, can I confer with counsel
8 for a second, please?

9 JUDGE MOORE: Yes.

10 MR. SHAW: Thank you.

11 JUDGE MOORE: Off the record.

12 (Discussion off the record.)

13 MR. SHAW: So, Your Honor, we need to go on the
14 Biofrontera confidential record for a second, please.

15 JUDGE MOORE: All right. Let's stay off the
16 record for a moment for the courtroom to clear.

17 (Discussion off the record.)

18 (Whereupon, the hearing proceeded in confidential
19 session.)

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

2 JUDGE MOORE: Please be seated.

3 All right. Back on the record.

4 MS. CHEN: Your Honor, I have an update regarding
5 Mr. Lundahl. He should be released from the hospital today.
6 However, he is going to go and check in with his doctor in
7 Boston, so we don't anticipate he will be able to testify.
8 For that reason, we will move to withdraw his rebuttal
9 witness statement.

10 We -- I just informed Biofrontera, and they are
11 considering whether to oppose or not. So we haven't
12 bottomed out on that yet.

13 JUDGE MOORE: Okay.

14 MS. OKUN: Yes, Your Honor. If we could get back
15 to you after the lunch break, would that be appropriate?

16 JUDGE MOORE: Yes.

17 MS. OKUN: Thank you.

18 MS. CHEN: Thank you, Your Honor.

19 JUDGE MOORE: All right. We hope the best for
20 him.

21 MR. SHAW: May I proceed, Your Honor? Just a few
22 recross questions.

23 JUDGE MOORE: Yes.

24 MR. SHAW: Thank you very much.

25 RECROSS-EXAMINATION

1 BY MR. SHAW:

2 Q. Thanks for coming back, Doctor. So you have
3 treated patients with multiple AK lesions on --

4 THE REPORTER: I'm so sorry. When you get away
5 from the microphone, I hear nothing.

6 MR. SHAW: Apologies.

7 BY MR. SHAW:

8 Q. You have treated patients with multiple AK
9 lesions on disparate areas of their face. True?

10 A. True.

11 Q. And you were just talking about how the amount of
12 Ameluz in one tube covers 60 square centimeters. Right?

13 A. It is 20 square centimeters in one tube, per the
14 label.

15 Q. There's nothing that requires you to put all 20
16 square centimeters on a continuous area on a patient's face,
17 right?

18 A. No, there's not.

19 MR. SHAW: Nothing further, Your Honor.

20 JUDGE MOORE: All right. Any redirect?

21 MR. LARIVÉE: Nothing further.

22 JUDGE MOORE: All right. So we appreciate your
23 testifying. And with that, you are released.

24 THE WITNESS: Thank you.

25 (The witness stood down.)

1 JUDGE MOORE: And we will go briefly off the
2 record to bring the next witness.

3 (Discussion off the record.)

4 JUDGE MOORE: Back on the record.

5 We can introduce the witness, and I will get her
6 sworn in.

7 MS. PETERSON: Good morning, Your Honor. Lauren
8 Peterson for Biofrontera. We would like to call our next
9 witness, Ms. Julia Rowe.

10 JUDGE MOORE: Raise your right hand.
11 Whereupon--

12 JULIA ROWE,
13 having been first duly sworn/affirmed, was examined and
14 testified as follows:

15

16 THE WITNESS: I do.

17 JUDGE MOORE: All right. Thank you.

18 DIRECT EXAMINATION

19 BY MS. PETERSON:

20 Q. Good morning.

21 A. Good morning.

22 Q. Could you please introduce yourself for the
23 record.

24 A. Yes. My name is Julia Rowe, and I am a vice
25 president at Charles River Associates.

1 Q. Mr. Ortega, could you please put RX-1418 up on
2 the screen.

3 Ms. Rowe, do you recognize this document?

4 A. I do.

5 Q. And is this your current CV?

6 A. It is, yes.

7 Q. And is this CV accurate?

8 A. Yes.

9 Q. Okay. Could you please describe your educational
10 background.

11 A. Sure. I have a Bachelor's in business
12 administration from the University of Michigan and a
13 Master's of accountancy from DePaul University. Since
14 graduating with my Master's, I have obtained a CPA and I am
15 also now a CLP.

16 Q. And, Ms. Rowe, could you please describe your
17 professional experience.

18 A. Yes. I have worked at CRA and another consulting
19 firm for about 15 years. My specialty or area of expertise
20 is in intellectual property valuation and related financial
21 and economic issues.

22 Q. Okay.

23 MS. PETERSON: Your Honor, Biofrontera would like
24 to offer Ms. Rowe as an expert in financial and economic
25 issues.

1 MR. SHAW: No objection, Your Honor.

2 JUDGE MOORE: All right. She is admitted for
3 that purpose.

4 MS. PETERSON: Mr. Ortega, could you please put
5 RX-8 on the screen, please.

6 BY MS. PETERSON:

7 Q. Ms. Rowe, do you recognize RX-8, which is on the
8 screen and also in the binder in front of you?

9 A. I do.

10 Q. Is this your direct testimony in this
11 investigation?

12 A. Yes.

13 Q. Okay. Mr. Ortega, if you could please turn to
14 page 14.

15 Ms. Rowe, do you recognize the signature on this
16 page?

17 A. Yes, I do.

18 Q. And does RX-8 reflect your testimony in this
19 investigation?

20 A. It does.

21 Q. Does RX-8 contain your own answers to questions
22 from counsel?

23 A. Yes.

24 Q. Are these answers true and correct to the best of
25 your understanding?

1 A. Yes.

2 Q. Are there any corrections to your testimony you
3 would like to make?

4 A. No.

5 Q. Mr. Ortega, if you could please put RX-10 up on
6 the screen.

7 Ms. Rowe, do you recognize RX-10?

8 A. I do.

9 Q. And you understand that -- if you -- Mr. Ortega,
10 if you could scroll through this -- that this statement has
11 been redacted in light of the recent ruling by the ALJ on
12 domestic industry?

13 A. That's my understanding.

14 Q. Okay. So, Ms. Rowe, is RX-10 your direct
15 testimony in this investigation?

16 A. Yes, it is.

17 Q. And, Mr. Ortega, if you could please turn to page
18 21.

19 And, Ms. Rowe, do you recognize the signature on
20 this page?

21 A. Yes, that's my signature.

22 Q. Does RX-10 also contain your answers to questions
23 from counsel?

24 A. Yes.

25 Q. And are those answers true and correct to the

1 best of your knowledge and understanding?

2 A. Yes.

3 Q. Are there any corrections to your testimony you
4 would like to make?

5 A. No.

6 Q. Okay. Next, could we please have RDX-19.

7 Ms. Rowe, do you recognize RDX-19?

8 A. Yes.

9 Q. And what is RDX-19?

10 A. These are some demonstratives that I prepared
11 along with my initial witness statement, which was marked
12 RX-8.

13 Q. Okay.

14 MS. PETERSON: Your Honor, we move to admit RX-8
15 and RX-10 into evidence.

16 MR. SHAW: No objection, Your Honor.

17 JUDGE MOORE: All right. They are admitted.

18 (Respondents Exhibit Numbers RX-0008 and RX-0010
19 were received into evidence.)

20 MS. PETERSON: Thank you, Your Honor. I pass the
21 witness.

22 MR. SHAW: Your Honor, Sun Pharma has no
23 cross-examination for this witness.

24 JUDGE MOORE: All right. Well, a short day for
25 you. Well, thanks for showing up, and you are released.

1 THE WITNESS: Thank you, Your Honor.

2 (The witness stood down.)

3 JUDGE MOORE: And we will go --

4 MS. OKUN: Your Honor, just in light of being a
5 little surprised that we're not doing that witness, can we
6 have just a couple minutes to switch around and get counsel
7 ready?

8 JUDGE MOORE: Certainly.

9 MS. OKUN: Thank you.

10 JUDGE MOORE: We will go off the record. Let me
11 know when you're ready.

12 (Discussion off the record.)

13 JUDGE MOORE: Back on the public record.

14 MR. LANDMON: Thank you, Your Honor. Chad
15 Landmon, again. Biofrontera calls to the stand again
16 Dr. Robert Grove.

17 JUDGE MOORE: All right. We will get you sworn
18 in.
19 Whereupon--

20 ROBERT GROVE,
21 having been first duly sworn/affirmed, was examined and
22 testified as follows:

23

24 THE WITNESS: I do.

25 JUDGE MOORE: Okay.

1 DIRECT EXAMINATION

2 BY MR. LANDMON:

3 Q. Good morning, Dr. Grove. Can you please
4 reintroduce yourself to the Court.

5 A. Yes. My name is Robert Grove.

6 Q. And, Dr. Grove, in front of you, you should have
7 a copy of RX-006C.

8 Do you see that?

9 A. Yes, I believe that's what's in front of me here.

10 Q. Is this your initial written witness statement?

11 A. Yes, it is.

12 Q. And if we turn to page 86.

13 A. 86. It's on the screen. Yes.

14 Q. Actually, sorry, page 85.

15 Is that your signature?

16 A. Yes, it is.

17 Q. Does this statement contain your answers to
18 questions from counsel in this investigation?

19 A. Yes, it does.

20 Q. Are the answers in your initial witness statement
21 accurate and truthful?

22 A. Yes, they are.

23 Q. Would you like to make any corrections to your
24 initial witness statement?

25 A. No, I would not.

1 Q. And if we can now turn to the next page, page 86.

2 Is this the list of exhibits referenced in your
3 witness statement?

4 A. Yes, it is.

5 Q. Did you also prepare a set of demonstratives to
6 assist with your testimony?

7 A. Yes.

8 Q. If we could bring up RDX-0017C.

9 Is this the set of demonstratives that you
10 prepared in relation to your initial witness statement?

11 A. Yes, it is.

12 MR. LANDMON: Your Honor, Biofrontera would like
13 to move Dr. Grove's initial witness statement into evidence.

14 MR. GANGULY: No objection.

15 JUDGE MOORE: All right. Why don't we just get
16 the number.

17 MR. LANDMON: I'm sorry, Your Honor, it is
18 RX-006C.

19 JUDGE MOORE: All right. It is admitted.

20 (Respondents Exhibit Number RX-006C was received
21 into evidence.)

22 MR. LANDMON: Thank you, Your Honor. We pass the
23 witness.

24 JUDGE MOORE: All right.

25 MR. GANGULY: May I proceed, Your Honor?

1 JUDGE MOORE: Yes.

2 MR. GANGULY: Tuhin Ganguly for Complainant, Sun
3 Pharma.

4 CROSS-EXAMINATION

5 BY MR. GANGULY:

6 Q. Nice to see you again, Dr. Grove.

7 A. It's nice to see you again as well.

8 Q. Dr. Grove, two of the prior art references you're
9 relying on in your obviousness analysis are the Lundahl
10 patent and the Larsen application, right?

11 A. Yes, that's right.

12 And if you could stay in front of the microphone,
13 it would be easier for me to hear.

14 Q. Yep.

15 A. Yes, that's correct.

16 Q. Is this better?

17 A. Yeah, that is better.

18 Q. Now, in your opinion, the combination of Lundahl
19 with Larsen renders at least the independent claims of the
20 asserted patents obvious, right?

21 A. Yes. Virtually all of the claims of the asserted
22 patents are disclosed by information in the combination of
23 the Lundahl and Larsen references.

24 Q. Okay. And so in your analysis, you start with
25 Lundahl, and then you combine elements from Larsen to come

1 to your conclusion that the claims are obvious. You agree
2 with that statement, yes?

3 A. It's -- yes, it's fair to say Lundahl is our
4 primary reference, but it's the combination that provides
5 the prior art that discloses what's in those two patents.

6 Q. Right. And so I understand that, so if you could
7 just answer my question yes or no.

8 A. Yeah.

9 Q. In your analysis, you start with Lundahl and then
10 combine elements from Larsen to come to your conclusion that
11 the claims are obvious. Do you agree with that statement?

12 A. Yes.

13 Q. All right. Lundahl discloses a single-panel
14 fixed U-shaped device, right?

15 A. That's correct.

16 Q. Okay. Larsen, on the other hand, discloses an
17 illuminator with five applicators that you consider to be
18 panels. True?

19 A. That's also correct.

20 Q. And in your opinion, a POSA would have been
21 motivated to break Lundahl up into five panels to meet
22 Larsen's five-panel disclosure. True?

23 A. A POSA would be motivated to provide some
24 adjustability to Lundahl's fixed U shape.

25 MR. GANGULY: So I'm going to move to strike that

1 answer. It was a yes-or-no question, Your Honor. And I can
2 ask again.

3 JUDGE MOORE: Yes, granted.

4 BY MR. GANGULY:

5 Q. Okay. So, Dr. Grove, in your opinion a POSA
6 would have been motivated to break Lundahl up into five
7 panels to meet Larsen's five-panel disclosure. Do you agree
8 with that statement?

9 A. Yes.

10 Q. Okay. All right. So, Dr. Grove, you recall I
11 took your deposition in this case, right?

12 A. Yes.

13 Q. Okay. And during that deposition, I showed you a
14 copy of the Lundahl patent, and you can see that it is
15 marked as Exhibit 12, which is from your deposition. Do you
16 recall that?

17 A. I do.

18 Q. Okay. Now, what I have on the screen is Figure
19 4A from the exhibit, the Lundahl exhibit that was used in
20 your deposition. And this Exhibit 4A has some annotations
21 on it.

22 Do you see that?

23 A. I do.

24 Q. And is that your signature next to those
25 annotations? Or initials?

1 A. Yes.

2 Q. Okay. And do you recall that during your
3 deposition, I asked you to indicate on Figure 4A how you
4 would break Lundahl into five panels. Do you recall that?

5 A. I do.

6 Q. Okay. And in response to that, you annotated
7 Figure 4A as we see here, correct?

8 A. I did.

9 Q. Okay. Now, since it's a little hard to see, I'm
10 going to annotate this. Okay.

11 So what I've done here is, since it was a little
12 hard to see from the annotation, I have labeled generally
13 what the five panels are that you annotated.

14 Do you see that?

15 A. I do.

16 Q. And do you agree that that's how -- those are the
17 five panels that were depicting when I asked you to annotate
18 Figure 4A?

19 A. Yes.

20 Q. Okay. Now, as we can see in Figure 4A, there are
21 also two cathodes for the tubes down at the bottom. Do you
22 see that?

23 A. I do.

24 Q. Okay. And as we can see, in the annotations, you
25 don't include the ends of Lundahl where the cathodes are

1 located in your five panels that I asked you to annotate
2 when I asked you to show me how you would break Lundahl up
3 into five panels. True?

4 A. True.

5 Q. Okay. And for the record, I'm going to mark this
6 as CDX-1001.

7 All right. Dr. Grove, some of the claims of the
8 asserted patents also require that the panels of the
9 illuminator are connected by nested hinges or hinge
10 structures on inner side surfaces of adjacent panels, right?

11 A. Yes.

12 Q. Right. And we had some discussion about that
13 yesterday. Do you recall that?

14 A. I do.

15 Q. Okay. Now, we can agree that Lundahl does not
16 disclose hinges, correct?

17 A. That's correct.

18 Q. Instead, in your combination of Lundahl and
19 Larsen, you're relying on Larsen's disclosure that his five
20 applicators are connected by hinges. True?

21 A. Correct.

22 Q. Okay. So, Mr. Sayres, can we please bring up
23 Larsen at RX-0099.2. All right.

24 And can we zoom in to Figure 1, the -- yep, in
25 the middle. Okay. Great.

1 All right. Dr. Grove, I know we don't agree on
2 the location of the hinges in Figure 1 in Larsen, but we can
3 agree that in Figure 1 of Larsen, you can't actually see
4 what Larsen's hinges look like, right?

5 A. That's correct.

6 Q. Okay. And in the Larsen specification, Larsen
7 doesn't provide a description of the physical structure of
8 the hinges. Fair?

9 A. Fair.

10 Q. And Larsen doesn't disclose whether the hinges --
11 whether his hinges have flanges that stick out from the
12 barrel, like in the RhodoLED XL. True?

13 A. That's true, yeah.

14 Q. And Larsen doesn't disclose whether its hinges
15 have flanges that are integrated into the barrel, like in
16 the BLU-U 4170E, right?

17 A. I wouldn't agree that the flanges are integrated
18 into the barrel of the 4170E, but -- but your general
19 statement is correct, that Larsen does not describe in any
20 detail the hinges that would be between the panels.

21 Q. Now, can we please, Mr. Sayres, bring up
22 Dr. Grove's witness statement at RX-006C.45, and
23 specifically Question 208.

24 And so can we have -- can you call out Question
25 208. And I believe the rest of the answer is probably on

1 the next page. Okay. That's good. Thank you.

2 Dr. Grove, on the screen in front of you is
3 Question and Answer 208 from your witness statement. And
4 beginning at Question 208, you provide testimony about the
5 claim limitation that you identify as "higher intensity
6 proximate second edges limitation."

7 Do you see that?

8 A. Yes.

9 Q. All right. Now, in the table in your Answer 208,
10 you provide the language of what you call the "higher
11 intensity proximate second shorter edges limitation." Fair?

12 A. I'm sorry, could you repeat that?

13 Q. Yeah. So in your answer, there's a table. Do
14 you see that?

15 A. Yes.

16 Q. And so in that table, you provide language of
17 what you're referring to as the "higher intensity proximate
18 second shorter edges limitation." You're providing the
19 language for that limitation, right?

20 A. Providing the limitation for the "higher
21 intensity proximate second edges," correct.

22 Q. Okay. Right. For example, in the third row, the
23 language you provide is, "The light sources are arranged
24 such that a higher intensity of light is emitted proximate
25 the second edges compared to the intensity of light emitted

1 not proximate the second edges."

2 Do you see that?

3 A. I do.

4 Q. Okay. Now, it's your opinion that Lundahl
5 discloses this limitation, right?

6 A. Lundahl discloses light sources that are arranged
7 with a higher intensity near the forehead and chin of a
8 patient.

9 Q. Okay. So you agree that it is your opinion that
10 Lundahl discloses this limitation. Fair?

11 A. In a general sense, yes.

12 Q. Okay. So let's bring up Claim 1 of the '512
13 patent, which is JX-0001. And can we highlight the fourth
14 element, beginning with "wherein." Okay.

15 Now, we saw you had included some language in
16 your table about the higher intensity limitation, as you're
17 referring to it. But when we look at Claim 1, the full
18 fourth element reads, "wherein each of the at least five
19 panels has two first edges and two second edges shorter than
20 the two first edges, and the light sources are arranged such
21 that a higher intensity of light is emitted proximate the
22 second edges compared to the intensity of light emitted not
23 proximate the second edges."

24 Did I read that correctly?

25 A. You did.

1 Q. Okay. Now, that fourth element requires that --
2 requires five panels that each emit a higher intensity of
3 light close to the shorter edges of the panel. We can agree
4 on that, right?

5 A. That's what it says.

6 Q. But Lundahl does not have five panels, right?

7 A. That is correct.

8 Q. Okay. And since Lundahl doesn't have five
9 panels, Lundahl doesn't disclose the full element as it is
10 written in Claim 1. We agree to that, right?

11 A. I agree.

12 Q. Okay. Now, if a POSA designed a lamp with a --
13 with rectangular panels that were right near the four edges,
14 such that each had equal intensity around the four edges, it
15 would not meet the claim limitation. Do you agree?

16 A. Yes, I think that's a fair statement.

17 Q. Okay.

18 All right. Mr. Sayres, can we please bring up
19 RDX-0017C.100. All right.

20 Now, Dr. Grove, on this slide, as noted in the
21 title, you're illustrating the combination of Lundahl and
22 Larsen, right?

23 A. Yes, that's correct.

24 Q. Okay. Now, in the bottom right of this slide,
25 you illustrate the combined device of Lundahl and Larsen.

1 True?

2 A. It's an illustration of how one would -- a POSA
3 would combine the teachings of Lundahl with the teachings of
4 Larsen, correct.

5 Q. Right. And as we see in your parenthetical --
6 you created this slide, right?

7 A. Yes.

8 Q. And then in the parenthetical in the bottom
9 right, you say, "Modified to illustrate combined device."
10 Right? That's what you say?

11 A. That is what I said, yes.

12 Q. And so we can agree that what you're showing in
13 the bottom right is the combined device of Lundahl and
14 Larsen, per your parenthetical? We can agree on that,
15 right?

16 A. Modified to illustrate the combined device,
17 that's correct.

18 Q. Okay. All right. In the combined device shown
19 here at the bottom right of RDX-17.100, the yellow circles,
20 those represent LEDs, right?

21 A. That's the intent, correct.

22 Q. Okay. And you had mentioned "modified" in your
23 label of this. And so in -- the modification is referring
24 to the -- I think the background of that combined device is
25 what is disclosed in Larsen, right?

1 A. It's modified to illustrate the combination of
2 Lundahl's illuminator with Larsen's LED panel device,
3 correct.

4 Q. Now, if we can zoom back out a little bit,
5 Mr. Sayres.

6 On the left of the slide, you show Lundahl's
7 device, right?

8 A. That's correct, as it would be used, yes.

9 Q. And here, you're showing Figures 1 and Figures 2
10 from the Lundahl reference. True?

11 A. Yes.

12 Q. And then you've highlighted -- you've highlighted
13 in yellow those are fluorescent tubes that are disclosed in
14 the Lundahl reference. True?

15 A. Yeah. This is in Figure 2. It's actually a
16 cross-section through the middle of the U, but it is showing
17 essentially one-half of the arc of the fluorescent tubes,
18 yes.

19 Q. Okay. And the yellow, the yellow highlighting
20 that you've applied, that's indicating the fluorescent tubes
21 that are disclosed in Lundahl, right?

22 A. Yes. It's clearly -- or more clearly shown,
23 perhaps, in the Figure 1. But, yes, the yellow that you see
24 in this drawing is the -- intended to be the fluorescent
25 tube -- tubes of Lundahl.

1 Q. Okay. And can we zoom back out again,
2 Mr. Sayres?

3 And so the LEDs shown on the combined device on
4 the right, those are coming from the Larsen reference,
5 right?

6 A. The LEDs are a key component of the Larsen
7 reference.

8 Q. And, Mr. Sayres, can we bring up Figure 2 from
9 the Larsen reference, which is RX-0099.2. And can we zoom
10 in on the -- yeah, those. Thank you.

11 Now, as we can see from Figure 2 of Larsen, the
12 LEDs in Larsen are placed in regular row arrangements that
13 are equidistant from each other. Do you agree with that?

14 A. Yes, I do.

15 Q. Can we go back to slide 100 from RDX-17, please.

16 And in the combined device shown on the right,
17 the LED rows are not equidistant from each other. We can
18 see that, right?

19 A. That's correct.

20 Q. Okay. Instead, they have been arranged in
21 accordance with Figure 2 from Lundahl, which is shown on the
22 left. True?

23 A. Yes. It's a representation of incorporating
24 Lundahl's teachings into the Larsen's LED panels, correct.

25 Q. Okay. So you're using Lundahl's spacing and

1 light distribution of light -- of the light sources and then
2 dividing Lundahl's one-panel device into five panels. Do
3 you agree with that statement?

4 A. We're using the approximate spacing of Lundahl,
5 correct.

6 MR. GANGULY: Your Honor, I am going to move to
7 strike that answer. It was yes or no. I can ask it again.

8 JUDGE MOORE: Granted.

9 BY MR. GANGULY:

10 Q. Okay. All right.

11 A. Could you repeat -- do you want to repeat the
12 question?

13 Q. I will. I will.

14 A. Okay.

15 Q. So you're using Lundahl's spacing and light
16 distribution of the light sources and then dividing
17 Lundahl's one-panel device into five panels. Do you agree
18 with that statement?

19 A. Generally, yes.

20 Q. All right. Mr. Sayres, can we please bring up
21 RDX-0017C.49. All right.

22 Now, I have -- we have slide 49 from your slide
23 deck on the screen. You see that?

24 A. Yes.

25 Q. All right. And here, again, you're

1 illustrating -- you illustrate your combined device with the
2 heading "Higher Intensity Proximate Second Edges
3 Limitation - Larsen Plus Lundahl."

4 Do you see that?

5 A. I do.

6 Q. All right. Now, in your invalidity analysis of
7 this claim limitation, you compare your combined device of
8 Lundahl and Larsen to the accused RhodoLED XL. True?

9 A. To the -- yes, I believe so.

10 Q. Okay.

11 A. We --

12 Q. Yes.

13 A. -- mention both, yes.

14 Q. Okay. And to see that actually, we can go to the
15 next slide, which is slide 50.

16 A. Yes.

17 Q. Right?

18 And here on slide 50, you -- which is also titled
19 "Higher Intensity Proximate Second Edges Limitation -
20 Lundahl Plus Larsen."

21 Do you see that?

22 A. Yeah, this is the exact slide I think you were
23 referring to.

24 Q. Right. And on the left, what we have is one of
25 the panels from your combination of Lundahl and Larsen.

1 That's what's shown on the left, right?

2 A. Correct.

3 Q. And then on the right side of the slide, we have
4 one of the panels from the RhodoLED XL, which is the accused
5 product in this case. Correct?

6 A. That's correct.

7 Q. Right. And you're comparing the -- one of the
8 panels from your combination to one of the panels from the
9 RhodoLED XL. Fair?

10 A. That's fair.

11 Q. And that's a part of your invalidity analysis.
12 True?

13 A. Yeah, I believe so.

14 Q. Mr. Sayres, can we please bring up Claim 1 of the
15 '512 patent again, which is at JX-001.18.

16 Can we highlight the second element, please.

17 Thank you.

18 Okay. Dr. Grove, the second element of Claim 1
19 of the '512 patent reads, "light sources disposed on
20 surfaces of the at least five panels, the illuminator being
21 configured to uniformly illuminate a treatment surface of
22 the patient via the light sources."

23 Do you see that?

24 A. I do.

25 Q. We can agree that in addition to the five panels

1 connected by nested hinges or hinge structures, the claims
2 that you say are obvious in view of the combination of
3 Lundahl and Larsen also require the illuminator to uniformly
4 illuminate a treatment surface, right?

5 A. Yes.

6 Q. Okay. And as we can see from the claim language,
7 the light sources being used to uniformly illuminate a
8 treatment surface are disposed on the at least five panels
9 of the illuminator, right?

10 A. That's correct.

11 Q. Okay. Now, Lundahl doesn't disclose five panels,
12 correct?

13 A. That is correct.

14 Q. And so for the first part of this element, which
15 is "light sources disposed on surfaces of the five panels,"
16 your opinion is that Larsen discloses that portion of the
17 element. True?

18 A. The combination discloses all of these elements.

19 Q. Right. And so in the combination, for the
20 portion of the element that says "light sources disposed on
21 surfaces of the at least five panels," for that limitation,
22 you're relying on the Larsen reference. Fair?

23 A. Yes. The Larsen reference has panels.

24 Q. Okay. You don't rely on Lundahl for the portion
25 of this element that says "light sources disposed on at

1 least five panels." True?

2 A. That's a fair statement.

3 Q. Yeah. Now, the second part of the limitation
4 talks about uniformly illuminating a treatment surface.

5 Do you see that?

6 A. I do.

7 Q. Okay. Now, in this investigation, "uniformly" --
8 "uniformly illuminate a treatment surface" and "uniformly
9 illuminating a treatment surface" have been construed to
10 mean "irradiating light over the active emitting area such
11 that the measured irradiance at a treatment surface is at
12 least within 60 percent of the measured maximum."

13 You're aware of that, right?

14 A. Yes. I believe that's in the asserted patents
15 and also in Lundahl.

16 Q. Okay. Now, you just mentioned Lundahl, but
17 Larsen doesn't disclose how to achieve uniformity meeting
18 the requirements of 60 percent of the measured maximum at
19 all points. You agree with that statement?

20 A. Yes, I do.

21 Q. Okay. That teaching is coming from Lundahl,
22 right?

23 A. Yes.

24 Q. Okay. And you're specifically relying on the
25 60 percent measurement in Lundahl for uniformity between two

1 and four inches. You agree with that statement?

2 A. Yes.

3 Q. All right. Dr. Grove, it's your opinion that it
4 is well-known that the field of optics and illumination is
5 complex, and in some cases requires extensive measurement
6 and experimentation, right?

7 A. In the broadest sense, correct.

8 Q. Yeah. And it's further your opinion that the
9 amount of experimentation and testing necessary to achieve a
10 specific design goal increases where the treatment surface
11 is not flat, right?

12 A. It's more difficult to uniformly illuminate a
13 surface which is not flat.

14 Q. Right. And that human -- we can agree that a
15 person's face is not flat, right?

16 A. Absolutely.

17 Q. All right. And so you also agree that in the
18 field of optics and illumination, the challenges of
19 achieving a specific design goal are further compounded by
20 the fact that the shape of an illuminator doesn't
21 necessarily follow the contours of a face or other treatment
22 area. We agree on that?

23 A. Must be taken into account, yes.

24 Q. Okay. So let's talk about how Lundahl achieves
25 his disclosed uniformity measurement.

1 Can we please turn to Lundahl, which is RX-0065,
2 Mr. Sayres, and specifically to the overview at RX-0065.20.

3 All right. So -- thank you.

4 Now, as we can see in the overview, Lundahl uses
5 seven U-shaped fluorescent tubes, correct?

6 A. Yes.

7 Q. Okay. And if we turn to column 6, lines 39
8 through 42, we can see that Lundahl states that "The U shape
9 provides the desired irradiance and irradiance uniformity
10 for scalp and facial irradiation, and thus ensures that the
11 proper visible light dosage is applied to all target areas
12 during PDT."

13 Did I read that correctly?

14 A. Yes, you did.

15 Q. Okay. And Lundahl discloses -- Lundahl discloses
16 that an aluminum reflector located behind the tubes
17 increases both the output irradiance and the uniformity of
18 the output distribution, right?

19 A. For a fluorescent illuminator, that's correct.

20 Q. And if we turn to Figure 5B on page RX-0065.7,
21 here we see a drawing of Lundahl's reflector. Do you agree?

22 A. Yes, I do.

23 Q. Okay. And so as we can see, in Lundahl the
24 reflector has about nine segments, right?

25 A. I believe it is nine, correct.

1 Q. Yeah. And there are particular angles and
2 distances given for each of those segments. True?

3 A. That is correct.

4 Q. And Lundahl provides measurements for those
5 segments to the thousandth of an inch, right?

6 A. That is also correct.

7 Q. Now, the tubes in Lundahl are covered by a
8 polycarbonate shield which directs cooling air flow. True?

9 A. That shield is between the tubes and the patient,
10 correct.

11 Q. So let me try it again. The tubes in Lundahl are
12 covered by a polycarbonate shield which directs cooling air
13 flow. Do you agree with that statement?

14 A. Yes.

15 Q. Okay. And Lundahl teaches that different
16 portions of the tubes are cooled to different amounts to
17 improve uniformity. Do you agree with that statement?

18 A. I do.

19 Q. Okay. Lundahl also teaches using a light sensor
20 that monitors outputs from the U-shaped tubes to provide a
21 signal for adjusting the output from the tubes. You agree
22 with that, right?

23 A. I do.

24 Q. So in addition to those things, Lundahl also
25 teaches that the number of tubes and spacing between the

1 tubes was chosen to achieve desired uniformity and power
2 output. Do you agree with that?

3 A. Yes. A key part of his patent.

4 Q. Okay. That it teaches that, in addition to the
5 other things that we talked about? We can agree with that,
6 right?

7 A. Yes.

8 Q. Okay. Now, with respect to uniform illumination,
9 you testified that to meet the requirement for a reasonable
10 expectation of success, a POSA must have reasonably expected
11 that modifying Lundahl's device with Larsen's panels and
12 LEDs would provide the required irradiance of at least
13 60 percent of the measured maximum over the entire treatment
14 surface.

15 You testified to that, right?

16 A. I did.

17 Q. Okay. And, Mr. Sayres, can we please bring up
18 Question and Answer 321 of Dr. Grove's opening witness
19 statement, which can be found at RX-0006C.72.

20 Okay. I think it's -- can we scroll down a
21 little bit? Page 72, yeah. So let's call out the last
22 paragraph in Answer 321, which begins with "In view of this
23 understanding."

24 All right. And in this last paragraph of your
25 Answer 321 in your witness statement, you state, "The device

1 resulting from the combination" -- I'm sorry. "The device
2 resulting from combining the teachings of Lundahl and
3 Larsen, which I have illustrated in RDX-0017C.100, has
4 effectively the same light arrangement and pattern as Figure
5 2 of Lundahl. Because of this, a POSA would at least
6 reasonably expect that this resulting device would provide
7 an irradiance of at least 60 percent of the measured maximum
8 over the entire treatment surface, as required by the
9 asserted claims."

10 Did I read that correctly?

11 A. A POSA would absolutely reasonably expect that.

12 Q. Okay. So -- but you submitted an opening expert
13 report in this case, didn't you, Dr. Grove?

14 A. Yes, I believe so, yes.

15 Q. Mr. Sayres, can we bring up Dr. Grove's opening
16 report at paragraph 186. And can we highlight the last
17 sentence.

18 In your opening expert report, though, what you
19 said was, "I have considered these factors, and it is my
20 opinion that a POSA would be required to perform undue
21 experimentation to make and use an illuminator that provides
22 uniform illumination over the full scope of the claims."

23 You said that in your opening expert report,
24 right?

25 A. In a different context, I did, yes.

1 Q. Now, as we talked about, Lundahl discloses many
2 features to achieve uniformity, including its cooling
3 system, the aluminum reflector, and the spacing of the
4 U-shaped tubes and the light sensor, right?

5 A. He did.

6 Q. Okay. And in your combined device of Lundahl and
7 Larsen, you're not using Lundahl's U-shaped fluorescent
8 tubes. Can we agree on that?

9 A. I'm sorry. The last part of that was we're not
10 using --

11 Q. Sorry. I will repeat my question.

12 A. Okay.

13 Q. In your combined device of Lundahl and Larsen,
14 you are not using Lundahl's U-shaped fluorescent tubes,
15 right?

16 A. That is absolutely correct.

17 Q. Okay. And yes or no, Dr. Grove, in your
18 combination of Lundahl and Larsen, are you using Lundahl's
19 reflector?

20 A. No, we are not.

21 Q. Okay. Again, Dr. Grove, yes or no, are you using
22 Lundahl's cooling system in your combination?

23 A. We are not.

24 Q. Okay. Dr. Sayres -- I'm sorry. Mr. Sayres, can
25 we bring up the Lundahl reference at column 4, lines 12

1 through 15 at -- sorry, 12 through 18 at RX-0065.19.

2 In this paragraph -- so, Dr. Grove, we just
3 talked about a few of the things from Lundahl that you're
4 not including in your combination. Do you recall that
5 testimony?

6 A. Yes, absolutely.

7 Q. Okay. And Lundahl's -- but Lundahl's
8 specification states, "The present invention differs from
9 conventional light sources because of the biological
10 requirements imposed on a PDT light source. A much higher
11 degree of precision and integration is required of the
12 components of the present invention. Output spectrum,
13 irradiance, and irradiance uniformity all must be controlled
14 to assure that the properties of the device are suitable to
15 deliver light to the target lesions and drive the
16 photodynamic reaction."

17 That's what Lundahl disclosed to the world.

18 Do you see that?

19 A. I do.

20 Q. Okay. All right. Dr. Grove, why don't we switch
21 gears for a little bit. One of the prior art references you
22 rely on is Hente, right?

23 A. That's correct.

24 Q. Okay. And in your view, a POSITA would have been
25 motivated to combine Hente with Lundahl and Larsen. True?

1 A. Yes.

2 Q. The asserted patents in this investigation relate
3 to an adjustable illuminator that provides a uniform
4 distribution of light that is suitable for photodynamic
5 therapy and diagnosis, right?

6 A. Those are the claims, yes, in the asserted
7 patents, yeah.

8 Q. Yeah.

9 And can we bring up JX-001.4 at column 2, at
10 lines 50 through 53. And that is the '512 patent.

11 Okay. And beginning at line 50, the
12 specification of the '512 patent says, "Therefore, it is an
13 object of some embodiments of the present invention to
14 reduce or eliminate dead spaces and provide for a more
15 uniform light distribution in an adjustable illuminator
16 designed for PDT or PD of a variety of target areas."

17 Do you see that?

18 A. I do.

19 Q. Okay. Now, you agree that Hente does not ever
20 mention photodynamic therapy or diagnosis, right?

21 A. That's correct.

22 Q. Okay. And Hente doesn't mention eliminating
23 optical dead spaces, right?

24 A. He does not mention that, correct.

25 Q. Okay. And Hente does not discuss the uniformity

1 of light distribution in the same context as Lundahl. We
2 can agree on that?

3 A. We can.

4 Q. Okay. Can we please bring up RDX-0017C.16,
5 Mr. Sayres.

6 Now, Dr. Grove, I have on the screen slide 16
7 from your slide deck. And as we can see from the title,
8 this is some figures from the Hente reference. Right?

9 A. That's correct.

10 Q. All right. Now, as we can see from your slide,
11 Hente discloses an illuminator with four separate
12 light-emitting sections. Fair?

13 A. Fair.

14 Q. All right. Those sections are connected by a
15 connection means, which is shown by the circle labeled 50.
16 You can see that on the --

17 A. 5-0, correct.

18 Q. 5-0. Right?

19 A. Yes.

20 Q. Mr. Sayres, can we please bring up Q/A 163 from
21 Dr. Grove's opening witness statement. And can we scroll
22 down a little bit, please. All right. To the image. All
23 right. Perfect. Thank you.

24 Now, in your witness statement at Question and
25 Answer 163, you include a picture of Figure 2 from the Hente

1 reference. That's what we're seeing here; is that right?

2 A. That's correct.

3 Q. Okay. And in the figure, you have labeled circle
4 50 as "connection means."

5 Do you see that?

6 A. I do.

7 Q. Okay. As we can see, Figure 2 of Hente shows
8 three circles at the corners of the four light-emitting
9 sections. Correct?

10 A. Yes.

11 Q. Okay. Each of those circles represents a
12 connection means 50. Can we agree on that?

13 A. That's my understanding, correct.

14 Q. Okay. And as Hente explains, connection means 50
15 might be a hinge, a stamping, a cutting, or a foil, right?
16 It could be any one of those four things?

17 A. Yes.

18 Q. All right. And, Dr. Grove, we can agree that
19 some hinges have flanges that extend from the barrel, like
20 in the RhodoLED XL. We have talked about that, right?

21 A. That's absolutely correct.

22 Q. Right. And some hinges don't have flanges that
23 extend, like in the BLU-U 4170E. True?

24 A. No, the 4170E has flanges. They are just short
25 and flat-ended and stubby, but those are flanges.

1 Q. Okay. So we can agree that some hinges have
2 short, flat, stubby hinge flanges, fair?

3 A. They all have some means of connecting to
4 adjacent panels. That's absolutely correct.

5 Q. Okay. And we can agree that Hente does not
6 describe what its hinges actually look like, right?

7 A. That is also correct.

8 Q. And Hente does not describe whether its hinges
9 have flanges that extend or whether they are kind of short,
10 stubby flanges. True?

11 A. Yeah, Hente does not disclose hinges in any
12 detail.

13 Q. Okay. And now, Dr. Grove, it is also your
14 opinion that Hente renders obvious the limitation "at least
15 one panel includes a recess configured to receive a flange
16 of one of the nested hinges." Right?

17 A. A POSA would assume that, yes. Would understand
18 that from the drawing.

19 Q. Okay. So let's bring that drawing up.
20 Mr. Sayres, can we bring up RDX-0017C.85. Okay.

21 Now, Dr. Grove, this is your slide 85. And on
22 this slide we have a zoomed-in view of Figure 2 from Hente,
23 correct?

24 A. Yes.

25 Q. Okay. And in this zoomed-in view, we see the

1 junction from Hente's Figure 2 between the light-emitting
2 section 30 on the left and 20 on the right. That's what
3 we're looking at?

4 A. Yes, that's correct.

5 Q. All right. Now, if we zoom in a little bit,
6 Mr. Sayres, to the junction -- yeah, right there, perfect.

7 And as we can see on this slide, Dr. Grove, you
8 have added two dotted blue lines in Figure 2 of Hente that
9 you labeled "indentation in a surface." Right?

10 A. That's correct.

11 Q. Right. But you know, Dr. Grove, Hente's
12 specification does not disclose an indentation between
13 panels 20 and 30. You agree with that, right?

14 A. I do.

15 Q. Okay. And Hente's specification does not
16 explicitly disclose a recess between panels 20 and 30.
17 That's true also, isn't it?

18 A. That is also true.

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

20 JUDGE MOORE: All right.

21 MR. LANDMON: Good afternoon, Your Honor. I was
22 wondering if it was morning or afternoon. Chad Landmon
23 again. May I proceed?

24 JUDGE MOORE: Yes.

25 MR. LANDMON: Thank you.

1 If we could have up on the screen RDX-17C.16.

2 REDIRECT EXAMINATION

3 BY MR. LANDMON:

4 Q. Dr. Grove, you might remember -- and I'm not sure
5 I needed to put the slide up, as I'm thinking about it. But
6 you just were testifying about Hente. Do you remember
7 getting asked about that?

8 A. Yes, I do.

9 Q. Are you relying on Hente for teachings related to
10 PDT?

11 A. Nothing related to PDT, no.

12 Q. All right. If I can next have you bring up on
13 the screen CX-1324C.

14 Dr. Grove, do you remember being asked some
15 questions about your opening expert report?

16 A. I do.

17 Q. And do you recall -- and if I can ask you to turn
18 to page 71 of the expert report.

19 At paragraph 186, do you recall being asked --
20 there we go.

21 A. Yes.

22 Q. And do you recall giving a response which -- I
23 don't want to put words in your mouth, but I think you said
24 it dealt with undue experimentation in a different context.
25 Do you recall that?

1 A. I did say that, yes.

2 Q. And if we can turn to paragraph 192 of your
3 opening report, which is on page 74 marked at the bottom.

4 So in paragraph 192, if you see, you've got a
5 paragraph there and then there is a number 1 that says, "Can
6 provide uniform illumination to the extremities and torso."
7 Were your comments in your expert report regarding undue
8 experimentation relating to uniform illumination of the
9 extremities and torso?

10 A. I'm sorry, could you please repeat that question?

11 Q. Sure. So you were asked some questions about
12 whether your statements in the prior paragraph we were
13 looking at relating to undue experimentation --

14 A. Yes.

15 Q. -- and you responded back and said yes, that's
16 what it says in a different context.

17 A. That's correct.

18 Q. And I'm trying to understand, is the context you
19 were addressing them relating to uniform illumination
20 relating to the extremities and torso?

21 A. That's exactly correct.

22 MR. LANDMON: Counsel, can I request your CDX?

23 BY MR. LANDMON:

24 Q. Dr. Grove, do you recall being asked about what's
25 been marked CDX-1001?

1 A. Yes, I do.

2 Q. And do you recall being asked questions about you
3 not including the cathodes at the two far ends of Figure 4A
4 of Lundahl?

5 A. Yes.

6 Q. And what I mean by that is when you annotated
7 this to include the five panels -- when you annotated this
8 to include the five panels, I believe you explained -- let
9 me know if I'm wrong -- that you didn't include the cathodes
10 on the two far ends?

11 A. I did not, that's correct.

12 Q. Can you explain for us why you didn't include the
13 cathodes?

14 A. Yes, because the -- Lundahl discloses or
15 describes these fluorescent tubes have a dark region very
16 close to the cathodes, which obviously does not provide the
17 same illumination as most of the tube. And so that portion
18 of the fluorescent tubes would certainly not be incorporated
19 into a combined device.

20 Q. And you can probably take that down now, or tell
21 me how to take it down. Thank you.

22 And if I can ask you now to pull up RX-0099. And
23 if we can move over to Figure 1. If you could pull up the
24 image in the center. Perfect. Thank you.

25 Dr. Grove, do you recall getting asked about this

1 figure during your cross-examination?

2 A. Yes, I do.

3 Q. Okay. How many options are there for where to
4 place hinges in the device disclosed there?

5 MR. GANGULY: Objection, Your Honor, outside the
6 scope of the cross. I just asked if you could see the
7 hinges. This is testimony regarding what -- the various
8 places that the hinges can be located, which is a very
9 different issue that's going on between the parties.

10 MR. LANDMON: Your Honor, he was asked whether
11 you could see hinges. He was then asked about the --
12 whether the hinges were disclosed in Larsen. And I think it
13 is relevant for him to explain where a POSA -- looking at
14 this image, how a POSA would interpret that, where the
15 hinges are and where they could be.

16 MR. GANGULY: My questions were simply can you
17 see the hinges and does it describe what the hinges look
18 like. It was nothing about where the hinges are.

19 JUDGE MOORE: I'm going to overrule the
20 objection. Go ahead.

21 MR. LANDMON: Thank you, Your Honor.

22 BY MR. LANDMON:

23 Q. Do you need the question read back? Dr. Grove?

24 A. Yes. Sorry.

25 Q. Or I will say it. So looking at Figure 1 of

1 Larsen, how many options are there for where to place the
2 hinges?

3 A. Your question is how many options are there to
4 connect adjacent panels?

5 Q. Correct. With the figure disclosed in Larsen.

6 A. Yeah, in general, there are three locations to
7 connect adjacent panels.

8 Q. And what's --

9 JUDGE MOORE: We have an objection.

10 MR. GANGULY: Objection, Your Honor. Your Honor,
11 this is clearly outside the scope. This is about connecting
12 adjacent panels, which is -- which was not within the scope
13 of my cross-examination. So I would move to have the last
14 answer stricken.

15 MR. LANDMON: I believe it is just the same
16 objection that you just ruled on, Your Honor. It is the
17 same exact question I just asked.

18 JUDGE MOORE: All right. You know, there were
19 questions about this figure, are the hinges there. I
20 believe it opened the door. I am overruling the objection.

21 THE WITNESS: Could you repeat the question
22 again?

23 BY MR. LANDMON:

24 Q. So you actually answered the first question.

25 The second question I had --

1 A. Okay.

2 Q. -- what's the most common option for connecting
3 panels with hinges?

4 A. The most common option is to put what are called
5 butt hinges between the two panels.

6 Q. Would a POSA have known that prior to 2015?

7 A. Absolutely. It's generations of hinges.
8 Generations of people have used those hinges.

9 Q. Okay. Dr. Grove, changing topics a little bit,
10 do you recall you had testified that Lundahl -- or you were
11 asked questions about your testimony of Lundahl disclosing
12 the proximate light limitation. Do you recall that
13 testimony?

14 A. I do.

15 Q. Is your opinion that the proximate light
16 limitation is disclosed solely by Lundahl or by the
17 combined -- or that this limitation is taught by the
18 combined device of Lundahl and Larsen?

19 A. Are you asking is the proximate light limitation
20 disclosed strictly by Lundahl?

21 Q. Yes, or is it your opinion that it's disclosed
22 and taught by a combination of Lundahl and Larsen.

23 A. Well, Lundahl discloses having higher intensity
24 near the forehead and chin of the patient, which is directly
25 relevant to the proximate light limitation. And it's

1 implemented in the combined device using the panels, LED
2 panels described in Larsen.

3 Q. So, Dr. Grove, you were asked a few questions
4 about some of the disclosures in Lundahl. And I want to
5 walk through a couple of your -- the items you were asked
6 about.

7 Do you recall being asked about reflectors?

8 A. Yes, I do.

9 Q. Okay. Are reflectors like those taught in
10 Lundahl needed for LEDs?

11 A. No. The LEDs put out light in basically one
12 direction, whereas fluorescent tubes put out light 360
13 degrees around the circumference of the tube.

14 Q. And would a POSA have understood that prior to
15 2015?

16 A. Oh, absolutely. The light sources that are
17 producing light in all directions, if you're trying to
18 illuminate a surface, you don't want to waste the light
19 going away from your subject. And so light sources have had
20 reflectors for, probably, as many years as there are light
21 sources. But if you have a light source that's directional,
22 as LEDs are, then there's no need for a reflector.

23 Q. And do you recall being asked about a
24 polycarbonate shield?

25 A. Yes, I do.

1 Q. Are polycarbonate shields like those disclosed in
2 Lundahl needed for LEDs?

3 A. No, they are not needed.

4 Q. And why?

5 A. There's always a risk that fluorescent tubes
6 could break or, even worse, explode. And since the device
7 disclosed in the asserted patents is to be used two to four
8 inches from the patient's face, obviously an exploding
9 fluorescent tube would be a major problem.

10 So for illuminators that contain fluorescent
11 tubes, a -- it's an absolute safety requirement to have a
12 clear polycarbonate shield to protect the patient during
13 treatment.

14 Q. And would a POSA have understood that prior to
15 2015?

16 A. Absolutely.

17 Q. I believe you were also asked about certain
18 cooling systems that were disclosed. Do you recall that?
19 That are disclosed in Lundahl. Do you recall that?

20 A. I do.

21 Q. And is the cooling system disclosed in Lundahl
22 needed for LEDs?

23 A. The cooling system disclosed in Lundahl is
24 definitely not needed. It is described in detail as to how
25 to cool the fluorescent tube appropriately. And since the

1 combined device does not have fluorescent tubes, the cooling
2 system described by Lundahl is definitely not needed in the
3 combined device.

4 Q. And would a POSA have understood that prior to
5 2015?

6 A. Absolutely.

7 MR. LANDMON: No further questions, Your Honor.

8 JUDGE MOORE: All right.

9 RECROSS-EXAMINATION

10 BY MR. GANGULY:

11 Q. Dr. Grove, you were just testifying about how the
12 cooling system from Lundahl is not needed in the combined
13 device. Do you recall that testimony?

14 A. Lundahl's -- yes, that's right, Lundahl's cooling
15 system is not required in the combined device.

16 Q. But you know, don't you, sir, that an LED's
17 output efficiency decreases as the temperature increases.
18 You know that, right?

19 A. I do know that.

20 MR. GANGULY: Nothing further, Your Honor.

21 JUDGE MOORE: All right.

22 MR. LANDMON: No further questions, Your Honor.

23 JUDGE MOORE: Okay. All right.

24 So I believe now you are done testifying. We
25 appreciate you doing so. And with that, you are released.

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

2 JUDGE MOORE: All right.

3 (The witness stood down.)

4 JUDGE MOORE: We're at 12:29. So it is time for
5 the lunch break. And we will return at 1:30.

6 (Whereupon, at 12:29 p.m., a lunch recess was
7 taken.)

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1 A F T E R N O O N S E S S I O N

2 (1:30 p.m.)

3 JUDGE MOORE: Please be seated.

4 All right. Back on the record.

5 MR. LARIVEE: Your Honor, may proceed?

6 JUDGE MOORE: Yes.

7 MR. LARIVEE: Brian Larivee for the Biofrontera
8 Respondents again. Biofrontera calls Dr. Michael Ehrenreich
9 as its next witness.

10 JUDGE MOORE: All right. We'll get you sworn in
11 again.
12 Whereupon--

13 MICHAEL EHRENREICH,
14 having been first duly sworn/affirmed, was examined and
15 testified as follows:

16 THE WITNESS: I do.

17 JUDGE MOORE: Okay.

18 DIRECT EXAMINATION

19 BY MR. LARIVEE:

20 Q. Good afternoon, Dr. Ehrenreich.

21 Can you please state your name again on the
22 record.

23 A. Michael Ehrenreich.

24 Q. And, Dr. Ehrenreich, you should have a copy of
25 RX-7C next to you in the witness box, in that binder.

1 A. Not yet, I don't. Okay, I do now.

2 Q. Okay. In that binder, could you open it up and
3 see what you see on the front page -- or in the binder?

4 A. Yes. I see my initial witness statement.

5 Q. And could you please turn to page 79.

6 A. Yes.

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

9 A. Yes, it does.

10 Q. Are the answers in your witness statement
11 accurate and truthful?

12 A. Yes, they are.

13 Q. Would you like to make any corrections to your
14 initial witness statement?

15 A. My understanding is that a change was made to
16 Answer 191 already, but it's not in the one that I have in
17 front of me.

18 Q. Okay. We will get up on the screen the
19 agreed-upon corrected version that you signed on July 1.

20 In the meantime, can you look at the binder in
21 front of you and see what the date is on the last page of
22 the witness statement?

23 A. The signature page, you mean?

24 Q. Um-hum.

25 A. The date is May 10th, 2025.

1 Q. It's May?

2 A. May 10th.

3 Q. All right. We will --

4 A. I now have one in front of me dated July 1, which
5 I recall signing yesterday.

6 Q. And so can we be sure that this is RX-7C, your
7 corrected witness statement of July 1, 2025?

8 A. I'm just going to flip to that one correction and
9 make sure that it's all done correctly. Yes, this is the
10 corrected version.

11 Q. And on page 79, do you see your signature?

12 A. I do.

13 Q. And does this witness statement contain your
14 answers to questions from counsel in this investigation?

15 A. Yes, it does.

16 Q. Are the answers in your witness statement
17 accurate and truthful?

18 A. To the best of my knowledge.

19 Q. Would you like to make any other corrections to
20 your witness statement at this time?

21 A. No, nothing at this time.

22 MR. LARIVÉE: Your Honor, Biofrontera would like
23 to move Dr. Ehrenreich's rebuttal witness statement, RX-7C,
24 into evidence.

25 MR. HABBAZ: No objection, Your Honor.

1 JUDGE MOORE: All right. It's admitted.

2 (Respondents Exhibit Number RX-007C was received
3 into evidence.)

4 BY MR. LARIVEE:

5 Q. And, sir --

6 MR. LARIVEE: I'm sorry, Your Honor.

7 BY MR. LARIVEE:

8 Q. Sir, your binder should also contain RDX-18C.

9 A. Yes.

10 Q. All right. Just want to make sure you have that.

11 MR. LARIVEE: We pass the witness.

12 JUDGE MOORE: All right. And I meant to do this
13 before when we came back from break, so we're going to just
14 handle some procedural things, and then we'll get to cross.

15 The devices that are in the courtroom, they --
16 are they physical exhibits? Will they be marked as physical
17 exhibits?

18 MS. CHEN: Yes, they are physical exhibits.

19 JUDGE MOORE: Okay. Both the same?

20 MR. LARIVEE: Yes, we agree.

21 JUDGE MOORE: Okay. Because I think the Court is
22 getting some e-mail or something that they would be picked
23 up by the parties. But physical exhibits are part of the
24 record, and they would stay here with the ITC through the ID
25 and then also through the Commission so that the Commission

1 would have access to them, if they wish.

2 So I'm not sure if there's some confusion, but I
3 just wanted to let the parties know that that would be the
4 procedure.

5 MS. CHEN: Understood. That's not a problem.

6 JUDGE MOORE: All right. Oh, and I lost the
7 other. Oh, the parties this morning had not yet sent the
8 list of agreed-upon exhibits. Has that been sent?

9 MS. CHEN: Yes, it has.

10 JUDGE MOORE: Okay. All right. And so those
11 exhibits that were sent in the e-mail, we just discussed,
12 are entered into the record.

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

15 MS. CHEN: And while we're on housekeeping
16 matters, I have the exhibit number of the rebuttal witness
17 statement for Mr. Lundahl that we would move to withdraw.
18 My understanding is that's unopposed.

19 JUDGE MOORE: Okay.

20 MS. CHEN: And that is CX-15.

21 JUDGE MOORE: All right. And the motion is
22 granted.

23 MS. CHEN: Thank you.

24 MR. LARIVÉE: Without objection.

25 JUDGE MOORE: Yes, without objection, it's

1 granted.

2 All right. So that's all I have, unless there's
3 any other housekeeping.

4 All right. When you're ready.

5 MR. HABBAZ: Your Honor, may I proceed?

6 JUDGE MOORE: Yes.

7 MR. HABBAZ: Raymond Habbaz for Sun Pharma.

8 CROSS-EXAMINATION

9 BY MR. HABBAZ:

10 Q. Good to see you again, Dr. Ehrenreich.

11 A. Hello.

12 Q. It's your testimony that the asserted claims are
13 invalid for lack of written description and lack of
14 enablement, right?

15 A. Correct.

16 Q. It's your opinion that undue experimentation
17 would be required to use the claimed illuminator for
18 photodynamic diagnosis of a patient, right?

19 A. Correct.

20 Q. Do you recall that when I asked you at your
21 deposition if you had ever performed a photodynamic
22 diagnosis before, you answered, no, you had not ever
23 photodynamically diagnosed a patient.

24 Do you recall that testimony?

25 A. I recall something to that effect. If you could

1 pull it up, I could confirm if you like.

2 Q. So we won't pull it up. You have a binder in
3 front of you.

4 A. Yeah.

5 Q. If you can turn to, I believe, CX-1330C. It
6 should be your deposition testimony. Do you see that?

7 A. Okay. Yes, I'm here.

8 Q. Okay. And if you could turn to page 205. Let's
9 not show it yet. Sorry.

10 Are you on page 205, sir?

11 A. Yes, I'm there.

12 Q. Thank you. And line 22, if you could read lines
13 22 to 24 to yourself.

14 A. Yes, I'm reading that.

15 Q. And if you could turn to page 211 of your
16 deposition testimony as well.

17 A. Yes.

18 Q. If you could read from line 3 on page 211 until
19 page 212, line 3. And let me know when you're done, sir.

20 A. If you just give me a moment.

21 MR. LARIVÉE: Could we have those lines again?

22 MR. HABBAZ: Sure. It's page 205, line 22 to 24;
23 page 211, line 3, until 212, line 3.

24 THE WITNESS: Okay, I've reviewed it.

25 BY MR. HABBAZ:

1 Q. Does that refresh your recollection as to whether
2 you testified at your deposition that you had never
3 performed a photodynamic diagnosis on a patient?

4 A. It does. And I said I think in the first
5 instance, to the best of my recollection. And that is still
6 mostly correct. Well, something came to my mind, but, yes,
7 that is what I -- what is on the deposition is what I said
8 then.

9 Q. Right.

10 A. That is of course true.

11 Q. And you testified that, no, you had never
12 photodynamically diagnosed a patient. True?

13 A. Well, it says here I've never performed
14 photodynamic diagnosis --

15 Q. Sir, I'm not --

16 A. I don't believe I have. I'm just confirming. I
17 don't believe I have.

18 Q. Well, again, I'm going to --

19 A. I'm sorry. Clarify the question.

20 Q. Just listen to my question and --

21 A. I'm listening.

22 Q. Thank you. Appreciate it.

23 Doctor, you testified, no -- let me read it this
24 way. You testified --

25 MR. LARIVÉE: Your Honor, objection to improper

1 impeachment. I don't think he has disagreed with
2 Mr. Habbaz's line of questioning here.

3 JUDGE MOORE: All right. We have kind of a messy
4 record here and a little bit of back and forth. So I'll
5 overrule the objection, and we'll see where we go.

6 BY MR. HABBAZ:

7 Q. And I'm not trying to impeach you, Doctor. I'm
8 just trying to get your testimony straight.

9 You testified that you had never photodynamically
10 diagnosed a patient. That's your testimony, right?

11 A. Sorry, could you refer me to the second page
12 again that you asked me to look at, page what?

13 Q. 211.

14 A. 211. Right.

15 So, I mean, the record is what the record is, but
16 the first -- I mean, I can't answer yes because you did not
17 phrase what I said. You paraphrased what I said. So I
18 said: I don't believe I have. And then when I reflected
19 back on this later on in the same document, I stated I was
20 able to tell you without referencing an article that no, I
21 hadn't. So this reflects back on "I don't believe I have."
22 So I -- if you just phrase the question to match the
23 document, I can give you a yes or a no.

24 Q. I'll try this one more time, Doctor.

25 You testified the following: "When you asked me

1 if I had ever photodynamically diagnosed a patient, I was
2 able to tell you without referencing an article that no, I
3 hadn't because I had an understanding of what that question
4 meant."

5 You gave that testimony, right, Doctor?

6 A. Yes, it's right here.

7 Q. Thank you. Now, let's look at Question 23 in
8 your witness statement.

9 A. Are you going to pull it up or am I just looking
10 for it?

11 Q. In the opening witness statement. Do you see
12 Question 23, Doctor?

13 A. Yes.

14 Q. In Question 23, you testified that you have used
15 "photodynamic techniques to treat and diagnose patients."

16 That's your testimony now, right, Doctor?
17 Doctor, those are the words in your answers to questions,
18 yes?

19 A. I'm reading. Those are my words, yes. They're
20 on the page.

21 Q. You have never used a pharmaceutical agent to
22 diagnose skin cancers or other skin conditions. True?

23 A. That's correct.

24 Q. In your witness statement, you provide an
25 overview of photodynamic therapy. True?

1 A. You'd have to point me to it, but I'm sure I had.

2 Q. Sure. Let's look at Question 20.

3 A. Yes.

4 Q. And you were asked what is photodynamic therapy?
5 Do you see that?

6 A. I do.

7 Q. And here in Answer 20, you give an overview of
8 photodynamic therapy. Do you agree?

9 A. I see it, yes.

10 Q. And if we could pull up CDX-1100.3.

11 Now, Doctor, this slide is labeled on the right
12 Photodynamic Treatment. Do you see that?

13 A. I do.

14 Q. And there are steps with letters A, B, C, D, and
15 E. Do you see those?

16 A. I do.

17 Q. In photodynamic treatment at step A, a
18 sensitizer, such as ALA, is applied to a lesion. Right?

19 A. That's what the slide says, yes.

20 Q. And you know that to be true generally about how
21 photodynamic treatment works, right, Doctor?

22 A. Yes. That's among the first steps, yes.

23 Q. Next as shown at B, the ALA will diffuse and
24 accumulate in abnormal cells such as tumor and dysplastic
25 cells, right?

1 A. Ideally. It can also diffuse into things like
2 seborrheic keratoses, psoriasis, you know, so cells that
3 are, you know, other than the background skin that have a
4 higher metabolic rate. So whatever we mean by abnormal.

5 Q. Yes.

6 A. You know, it has a broad range. It's not a
7 medical term exactly.

8 Q. Understood. So they at least accumulate in tumor
9 and dysplastic cells, you agree?

10 A. Some of them. Not all of them. We know it
11 doesn't accumulate in all tumor cells.

12 Q. That wasn't my question.

13 A. Okay. Some tumor cells, if that's the question,
14 yes.

15 Q. Well, it's your testimony that within the skin,
16 once applied, ALA diffuses and accumulates in tumor and
17 dysplastic cells. Right, Doctor?

18 A. Again, you'd have to point me to the exact
19 language but, again, my intention was never to imply it to
20 all tumor and all dysplastic cells. It might diffuse into
21 it; it might not. But we know from the literature that not
22 all of them will fluoresce with photodynamic diagnosis. I
23 can't say categorically every abnormal cell, every tumor,
24 every dysplastic lesion. It's some subset of that. I
25 didn't mean for it to be exhaustive of every tumor and every

1 cell. And that's clear.

2 MR. HABBAZ: And I move to strike everything
3 after "yes," and we can pull up CX- -- sorry. I'll move to
4 strike and leave it there for a second.

5 MR. LARIVÉE: I don't think that that's a proper
6 objection. We haven't seen what his testimony is. The
7 doctor asked to see where in the -- where to look and had
8 offered an answer to the question on a scientific issue.

9 JUDGE MOORE: Well, it was -- you know, as has
10 been the practice, and you've seen, if a question is a
11 yes/no question, then -- on cross, you should be able to
12 give a yes or no answer. "Right, Doctor," is a yes-or-no
13 question.

14 I don't believe there was actually a "yes"
15 anywhere in the answer. So you may want to reask the
16 question, but the objection is overruled. Or -- yeah, go
17 ahead.

18 MR. HABBAZ: Sorry, is the testimony stricken,
19 Your Honor?

20 JUDGE MOORE: Yeah, that's exactly -- that's why
21 I paused. It's actually a motion to strike, which is
22 granted, not an objection overruled. Thanks. Thank you.

23 MR. HABBAZ: Thank you, Your Honor.

24 BY MR. HABBAZ:

25 Q. Doctor, it's your testimony that within the skin,

1 once applied, ALA diffuses and accumulates in tumors and
2 dysplastic cells. Yes or no, sir? Doctor?

3 A. You'll have to pull that up for me so I can
4 confirm the language that you're asking me to confirm.

5 Q. Okay. If we could pull up CX-1323C.

6 And, Doctor, this is your expert report in this
7 investigation. Correct?

8 A. Yes.

9 Q. This is your opening expert report, right,
10 Doctor?

11 A. Seems to be, yes.

12 Q. And if we can go to paragraph 33.

13 And in the first sentence of paragraph 33, you
14 wrote in your report, "Within the skin, once applied, ALA
15 diffuses and accumulates in tumors and dysplastic cells."
16 Those are the words you wrote in your report, right, Doctor?

17 A. That's what's there, yes.

18 Q. If we can go back to our slide.

19 As shown at step C, the ALA within the cells is
20 converted into a photosensitizer. Here that's PpIX. Right,
21 Doctor?

22 A. That's what's shown.

23 Q. As shown at D, a light is used to illuminate the
24 affected area with a specific wavelength of light. That's
25 what's shown, right, Doctor?

1 A. It says light. I don't see a specific wavelength
2 indicated.

3 Q. Well, we're demonstrating here the principles of
4 photodynamic treatment. And you know that one of the
5 principles of photodynamic treatment is that after, say,
6 PpIX is accumulated in a cell, light of a specific
7 wavelength is illuminated on the surface of the skin, right,
8 Doctor?

9 A. Are you asking me something about this
10 illustration or are you telling me what photodynamic therapy
11 is? Is there a question there somewhere?

12 Q. The question is -- was as worded. In the
13 principles of photodynamic treatment, you agree that a light
14 is used to illuminate the affected area with a specific
15 wavelength of light. True?

16 A. Is that the language I used? I mean, generally,
17 I'm not disputing it. I just don't know what you're getting
18 at. I don't dispute that light is used at a specific
19 wavelength. That's all correct. But I'm not -- I just --
20 if you ask me to --

21 Q. Thank you, Doctor.

22 A. -- use specific words, I need to see the specific
23 words.

24 Q. If you can answer my questions as worded, I would
25 appreciate that. Thank you.

1 Now, Doctor, you're familiar with an absorption
2 spectrum, right? That concept is familiar to you?

3 A. Yes.

4 Q. You testified that you as an expert could find
5 the absorption spectrum for a photosensitizing agent,
6 correct?

7 A. And if I did, you will have to refer me back to
8 it to refer -- refresh my memory.

9 Q. You don't have a recollection as to testifying
10 that you as an expert could find the absorption spectra for
11 a photosensitizing agent? Is that your testimony?

12 A. There's a lot of testimony here, so if you want
13 me to confirm a specific phrasing -- I don't like that
14 you're paraphrasing, I don't know the context -- I'm happy
15 to confirm all of this for you, just put it in front of me.

16 Q. My question is --

17 A. I don't want to testify from memory. I want to
18 be accurate. We have a big record. We wrote things down.
19 Please don't ask me to paraphrase from memory when it's
20 unnecessary.

21 Q. Doctor, my question was: Do you recall
22 testifying? If the answer is you don't --

23 A. So the answer is no, I don't specifically recall
24 it.

25 Q. Thank you. Let's pull up page 29 of your

1 deposition, line 2.

2 You testified -- "Question: Would it be easy as
3 an expert to find the absorption spectra for a
4 photosensitizing agent?

5 "Answer: I could probably find an article."

6 Were you asked that question and did you give
7 that answer?

8 A. Yes, it's in the transcript. There it is.

9 Q. Specifically, for PpIX, in your opening report,
10 you state that PpIX generally absorbs light over 400 to 700
11 nanometers. True, Doctor?

12 A. It sounds correct. Again, I -- I'm not going to
13 force you to keep showing me things if it sounds like, you
14 know, something that's accurate. But, yes, it absorbs in
15 the 400- to 700-nanometer range. This is known.

16 Q. You stated that PpIX generally absorbs light over
17 400 to 700 nanometers in wavelength with maximal absorption
18 at 410, 630, and 690 nanometers wavelength. True?

19 A. That I'll have to refresh myself on.

20 Q. Okay. Let's pull up CX-1323C. In your opening
21 report in paragraph 33, you stated in the third sentence,
22 "PpIX absorbs light in the 400 to 700 nanometer wavelength
23 with maximal absorption at 410, 630, and 690 nanometers
24 wavelengths."

25 That's what's stated in your report, right,

1 Doctor?

2 A. Yes, and this is a direct quote from a journal
3 article. So I'm citing it here.

4 Q. Doctor, the words I read are stated in your
5 report. True?

6 A. It's in my report as a citation. It's in
7 quotations.

8 Q. Again, Doctor, these are yes/no questions as to
9 what is in the report.

10 You agree --

11 A. It is in the report, I do not deny that, in
12 quotation marks.

13 Q. You agree that if a dermatologist is using an
14 agent that's known to absorb light at a particular
15 wavelength, that dermatologist can use an illuminator that
16 emits light at a wavelength generally near the peak to
17 excite the agent. True?

18 A. Let me rephrase to make sure I understand it. So
19 a dermatologist, knowing that there's an absorption peak,
20 can use a light more or less around that absorption peak for
21 excitation of the agent? Am I correct in paraphrasing you?

22 Q. I used the word "illuminator."

23 A. Illuminator?

24 Q. So I can ask it again.

25 A. Okay. But I'm more or less on track, right?

1 Q. Yes, you are.

2 A. Okay. Go ahead, then.

3 Q. You agree that if a dermatologist is using an
4 agent known to absorb light at a particular wavelength, that
5 dermatologist can use an illuminator that emits light at a
6 wavelength generally near the peak to excite the agent.
7 True?

8 A. True.

9 Q. If we could bring up our slide. And again, going
10 through the steps of photodynamic treatment at step E when
11 PpIX is exposed to the light at various wavelengths, it
12 creates reactive oxygen species that kills the treated cells
13 through a cytotoxic reaction. Right, Doctor?

14 A. That's what this slide is showing, yes.

15 Q. And that's how a photodynamic treatment works
16 generally. True?

17 A. Generally, I would note that a reactive oxygen
18 species requires oxygen in the tissue.

19 Q. But that's a general step in photodynamic
20 treatment. You agree, right, Doctor?

21 A. Yes, with the necessary background scenario that
22 there's oxygen.

23 Q. With oxygen?

24 A. It's a given.

25 Q. Thank you. The technique used today for

1 photodynamic treatment had been known for decades, correct?

2 A. Yes.

3 Q. Undue experimentation is not required to practice
4 the photodynamic treatment aspects of the claims. That's
5 your opinion. Right, Doctor?

6 A. I have not made an argument that that was
7 required. I didn't really offer an opinion on that.

8 Q. Let's pull up Question 209 in your witness
9 statement. And you were asked: "Question: You said that
10 undue experimentation would have been required for the
11 photodynamic diagnosis aspect of the asserted claims. Does
12 that mean undue experimentation would not be required to
13 practice the photodynamic treatment aspect of the asserted
14 claims?

15 "Answer: Yes, that is my opinion."

16 You were asked that question and gave -- and
17 provided that answer in your testimony, right, Doctor?

18 A. Thank you for refreshing my memory. I did say
19 that.

20 Q. Now, let's turn to CDX-1100.4.

21 This slide is labeled on the left Photodynamic
22 Diagnosis. Do you see that?

23 A. I do.

24 Q. As you testified, photodynamic diagnosis was
25 generally known as of the priority date of the asserted

1 patents. True?

2 A. In specific instances, true.

3 Q. My question was a little bit different.

4 Photodynamic diagnosis was generally known as of the
5 priority date of the asserted patents. True?

6 A. Yes.

7 Q. Looking at CDX-1100.4, step A for photodynamic
8 diagnosis includes applying the photosensitizing agent to
9 the skin such as ALA. True?

10 A. True.

11 Q. At steps B and C, again, the sensitizer such as
12 ALA will accumulate in abnormal cells and get converted to
13 PpIX. True?

14 A. That's true.

15 Q. At step D, the lesion is exposed to light, again,
16 with a wavelength of light within the absorption spectra of
17 a photosensitizer, such as PpIX. True?

18 A. Correct.

19 Q. At step E, PpIX will fluoresce with a bright red
20 color. True?

21 A. That's correct. And it's detected by something.

22 Q. And --

23 A. That's the last step there.

24 Q. Yes. And there's detection. Thank you, Doctor.

25 A. Right, with either the human eye or a camera or

1 something like that.

2 Q. Once you apply a photosensitizer and illuminate
3 the treated area with a particular range of wavelengths of
4 light, the skin will emit fluorescence. True?

5 A. I'm sorry, can you repeat?

6 Q. Sure. Once you apply the photosensitizer and
7 illuminate the treated area with a particular range of
8 wavelengths of light, the skin will emit fluorescence.
9 True?

10 A. I don't think I can answer that as true or false
11 without further characterization.

12 Q. You agree that the photosensitizer fluoresces
13 most clearly when exposed to particular wavelengths of light
14 and the treated skin emits fluorescence at a particular
15 wavelength. True?

16 A. A particular wavelength, yes, true.

17 Q. We can take that down. Thank you.

18 You're familiar with a Wood's lamp. True?

19 A. I am.

20 Q. To diagnose a typical skin condition using a
21 Wood's lamp, you would first turn the Wood's lamp on.
22 Right?

23 A. First turn the Wood's lamp on?

24 Q. Yes.

25 A. I'm not going to fight you on that one.

1 Q. The answer is yes, Doctor?

2 A. Yes.

3 Q. You would then illuminate the area you are
4 looking to diagnose. True?

5 A. True.

6 Q. And then you would use your eyes to visually see
7 if the tissue was responding. True?

8 A. If it was auto-fluorescing, is that what you mean
9 by "responding"?

10 Q. Well, Doctor, you agree that the last step in
11 using a Wood's lamp to diagnose a typical skin condition is
12 that you would use your eyes to visually see if the tissue
13 was responding. True?

14 A. I'm just clarifying that "responding" means
15 auto-fluorescing. Is that -- what do we mean by
16 "responding"? That's not a -- that's not a distinct term.
17 So the Wood's lamp does something very specific. It causes
18 autofluorescence. By "autofluorescence," we mean something
19 endogenous in the skin that fluoresces --

20 Q. Okay.

21 A. -- not an externally applied thing. So that's
22 not a medical term. I just need something specific.

23 MR. HABBAZ: I'm going to move, again, to strike
24 the answer.

25 THE WITNESS: Ask it again.

1 JUDGE MOORE: All right. Motion granted.

2 BY MR. HABBAZ:

3 Q. And I think let's pull up page 199 of your
4 deposition, line 15 to 23.

5 Were you asked the following questions at your
6 deposition?

7 "Question: Can you describe your process for
8 using a Wood's lamp to diagnose a typical skin condition?

9 "Answer: Yes. You would take the Wood's lamp,
10 you would turn it on, you would irradiate, illuminate the
11 area you're looking to diagnose something, then you would
12 use your eyes to visually see if the tissue was responding."

13 You were asked that question and you gave that
14 answer at your deposition, right, Doctor?

15 A. Yes. And, again, by "responding" I mean
16 auto-fluorescing. That's all I was clarifying.

17 Q. Again, I move to strike everything after "yes."

18 A. Okay, yes, it's in my deposition. I'm not
19 disputing that.

20 JUDGE MOORE: Granted.

21 BY MR. HABBAZ:

22 Q. Doctor, you agree it was known in the art at the
23 time of the asserted patents that there were illuminators
24 that could be used for both photodynamic therapy and
25 diagnosis. True?

1 A. Illuminators that could be used for both
2 photodynamic diagnosis and phototherapy?

3 Q. Oh, I can ask the question again.

4 A. Yes, please.

5 Q. You agree it was known in the art at the time of
6 the asserted patents that there were illuminators that could
7 be used for both photodynamic therapy and diagnosis. True?

8 A. If I said that, you'll have to point me to it
9 again. It doesn't come readily to mind.

10 Q. I'm not asking -- my question wasn't you have
11 previously testified. I'm just asking: Do you agree? And
12 then we can go to the testimony. Can I ask the question
13 again?

14 A. Yes. In answer to that, I don't -- nothing comes
15 -- I don't agree because I can't think of an instance of it.
16 But if I said something different, then I'll review it.

17 Q. Okay. So one of the references you relied on in
18 your direct testimony is the Lundahl '071 patent, right?

19 A. I believe so.

20 Q. And you know that the asserted patents
21 incorporate the Lundahl patent by reference, right?

22 A. Right.

23 Q. And if we could pull up the '512 patent, if we
24 could go to column 1, line -- starting at 49 until around
25 60. Thank you.

1 Doctor, the '512 patent at column 1, line 49,
2 incorporates by reference U.S. Patent Number 6,223,071 in
3 its entirety for "the techniques, methods, compositions, and
4 devices related to PDT and PD."

5 You see that, right, Doctor?

6 A. I do see that.

7 Q. Let's pull up your slide RDX-18C.24. Sorry,
8 RDX-18C, if we have it. Thanks.

9 Doctor, the -- and this is your slide, right,
10 Doctor?

11 A. I believe so, yes.

12 Q. The title of the Lundahl patent says that it is
13 an illuminator for photodynamic therapy and diagnosis,
14 right?

15 A. That's the title, yes.

16 Q. And if we could turn to your slide 35, and these
17 are excerpts from the Lundahl patent on your slide 35,
18 right, Doctor?

19 A. Correct.

20 Q. We see here on the left that Lundahl discloses:
21 "The present invention is directed to a photodynamic therapy
22 using an illuminator that provides a uniform distribution of
23 light. In particular, the present invention is directed to
24 an apparatus and method for photodynamic treatment (PDT) or
25 diagnosis (PD) of actinic keratosis of the scalp or facial

1 areas of a patient."

2 Do you see that, Doctor?

3 A. I do.

4 Q. "The present invention is also directed to an
5 apparatus and method for PDT and PD of other indications
6 (e.g., acne) and other areas of the patient (e.g., arms,
7 legs, et cetera)."

8 Do you see that, Doctor?

9 A. I do.

10 Q. And there you're quoting from Lundahl at column
11 1, lines 9 to 17, right, Doctor?

12 A. Yes.

13 Q. Now, turning to your slide 26, and if we can zoom
14 in on the center portion on the top.

15 You show here from Lundahl that Lundahl discloses
16 it is an object of the present invention, therefore, to
17 provide an improved illuminator for PDT and/or PD. Right,
18 Doctor?

19 A. I see that, yes.

20 Q. And, finally, if we could go to the Lundahl
21 reference itself and take a look at claim 1. That's at
22 column 16, line 10.

23 Doctor, the illuminator claimed in Lundahl is "an
24 illuminator for photodynamically diagnosing or treating a
25 contoured surface."

1 Do you see that, Doctor?

2 A. I do.

3 Q. Okay. We can put that down.

4 And let's turn to your slide 68. So that's
5 RDX-18C.68.

6 And this is your slide, right, Doctor?

7 A. It is.

8 Q. On your slide 68, you're summarizing your opinion
9 that there are 6,000 permutations for the experimentation
10 required to practice the asserted claims. True?

11 A. It says 6,000 permutations.

12 Q. And this reflects your testimony that there are
13 6,000 permutations required to practice the asserted claims.
14 True?

15 A. It's not meant to be a precise number. It's
16 meant to be by way of order of magnitude illustration.
17 Nobody is saying it's exactly 6,000.

18 Q. I understand. But what you're illustrating on
19 your slide and in your testimony is these 6,000 permutations
20 and how you arrived at that number. That's true --

21 A. Yes.

22 Q. -- correct?

23 A. Yes, that's what's on the slide.

24 Q. Starting at the top left, you have 100
25 dermatological diseases and conditions, right?

1 A. Yes.

2 Q. And then you state on your slide that a POSA --
3 that's a person having ordinary skill in the art, right,
4 Doctor?

5 A. Right.

6 Q. You state that a POSA would experiment with
7 wavelengths of light from 400 to 700 nanometers at
8 10-nanometer intervals, right?

9 A. Yes.

10 Q. And then you end up with 3,000 permutations on
11 the top portion of your slide, right?

12 A. Correct.

13 Q. And if I understand your math, what you're doing
14 is saying that there's wavelengths of light from 400 to 700
15 nanometers, and if you take 10-nanometer intervals, that
16 means you are testing at 30 different intervals.

17 Did I do the math correctly?

18 A. That seems about right, yes.

19 Q. And then it's those 30 intervals, at 10
20 nanometers each, times the 100 dermatological diseases and
21 conditions that gets you to your 3,000 permutations. True?

22 A. Correct.

23 Q. Doctor, you testified earlier that an expert
24 could find an article with the absorption spectra for a
25 photosensitizing agent. Right?

1 A. I testified and I think it said I could probably
2 find one, or words to that effect. "Probably" was
3 definitely in there.

4 Q. Well, you have an ALA on your slide here on the
5 bottom. Do you see that, ALA?

6 A. I do see that.

7 Q. As we said earlier, ALA is a precursor to PpIX,
8 right?

9 A. That's right.

10 Q. And the absorption spectra for PpIX is known and
11 published in the art, right?

12 A. It is.

13 Q. And now looking at the bottom part of your slide,
14 you get to 6,000 permutations at the end, right?

15 A. Right.

16 Q. And the way you go from 3,000 permutations to
17 6,000 permutations is you're multiplying it by two, right?

18 A. Right.

19 Q. And the reason for that is you have two branches,
20 with ALA or with what's marked here as MAL or methyl ALA,
21 right?

22 A. Correct.

23 Q. And what you're saying is you would need to run
24 your 3,000 permutations twice, once for ALA, once for methyl
25 ALA, true?

1 A. Right, and it's all by way of illustration that
2 there are multiple sensitizers. It's not meant to be an
3 exhaustive list.

4 Q. But going off the example you're providing --

5 A. Yeah, it's --

6 Q. Going off the example you're providing --

7 A. It's two branches, correct.

8 Q. You agree, Doctor, that you would need to run all
9 3,000 experiments on the top row, including experimenting
10 with wavelengths at intervals, twice, once for ALA and once
11 for methyl ALA, right?

12 A. That's what the slide shows.

13 Q. And this is your slide, right, Doctor?

14 A. It is.

15 Q. And as you said earlier, ALA will be converted to
16 PpIX, right?

17 A. That's correct.

18 Q. And you know that methyl ALA is also converted to
19 PpIX, right, Doctor?

20 A. That is true.

21 Q. We can take down the slide. Thank you.

22 Consulting the state of the prior art is one
23 factor in the enablement analysis. True?

24 A. Yes.

25 Q. As part of your analysis in your opening expert

1 report on enablement, you searched for research articles
2 regarding photodynamic diagnosis. Right, Doctor?

3 A. I did.

4 Q. Any article that you found describing
5 photodynamic diagnosis was included in your report. Right?

6 A. Not necessarily. Ones that I might have deemed
7 relevant. I'm not saying I -- everything that came up that
8 I glanced at that was an abstract. Some articles were
9 brought to my attention. So it's not meant to be an
10 exhaustive list of everything I might have looked at.

11 Q. You agree, don't you, Doctor, that if you found
12 an article describing photodynamic diagnosis, you would have
13 put it in your report if you found it? That's your
14 testimony, right, Doctor?

15 A. Again, it would have to be -- depends what it
16 said. How relevant I felt it was. If it was not redundant
17 with other, you know, ideas of photodynamic diagnosis. I
18 don't think that every single article ever written that ever
19 mentions it would be necessarily included. So we'd have to
20 be specific about what report you're talking about, which
21 article.

22 MR. HABBAZ: Well, I move to strike the
23 testimony.

24 JUDGE MOORE: Granted.

25 BY MR. HABBAZ:

1 Q. And let's pull up your deposition at page 213,
2 line 3. And you were asked the question: "If you found an
3 article describing photodynamic diagnosis, you would have
4 put it in your report; is that fair?

5 "Answer: Not necessarily. If I found an article
6 describing photodynamic diagnosis, would I have put it in my
7 report? Yes, I would have, if I found it."

8 You were asked that question and you gave that
9 answer, right, Doctor?

10 A. I did. If you could read the next question and
11 answer, though.

12 Q. Well, Doctor, the question was I asked you that
13 question and you gave that answer? True?

14 A. It's true, but it's out of context.

15 MR. HABBAZ: Your Honor, I move to strike
16 everything after "it's true."

17 JUDGE MOORE: Granted.

18 BY MR. HABBAZ:

19 Q. Can you turn to -- in your binder, to CX-108.
20 We'll also have it up on the screen.

21 A. CX-108. Hang on. Can I just work off the
22 screen, do you think, or do I need to look it up here?

23 Q. Whatever you're comfortable with, Doctor, is
24 fine.

25 A. I think I'll try off the screen for now.

1 Q. This is Exhibit 8 to your deposition. Do you see
2 that?

3 A. Yes.

4 Q. The title of this article is Photodynamic
5 Diagnosis and Therapy in Dermatology, correct?

6 A. Yes.

7 Q. You did not include this article in your opening
8 report in this case. True?

9 A. I don't believe I did.

10 Q. And at the time of your deposition, you had never
11 seen this article. True?

12 A. I -- not that I recalled.

13 Q. You did not review this article before you
14 disclosed your opinions about enablement and written
15 description. True?

16 A. In the deposition you're saying?

17 Q. I'll ask it again. Sorry.

18 A. Yeah.

19 Q. You did not review this article before you first
20 disclosed your opinions about written enablement and --
21 sorry. Let me try that again.

22 You did not review this article before you first
23 disclosed your opinions about enablement and written
24 description in your opening expert report. True?

25 A. I think that's correct.

1 Q. And if we could turn to CX-109.

2 This is Exhibit 7 to your deposition. Do you see
3 that?

4 A. I do.

5 Q. This article was published in JAAD, J-A-A-D --
6 sorry, this article was published in JAAD, J-A-A-D. Do you
7 see that?

8 A. I do.

9 Q. And that's the Journal of the American Academy of
10 Dermatology, right?

11 A. Correct.

12 Q. And it was published in the year 2000, right?

13 A. Yes.

14 Q. And do you see in the abstract it states -- if we
15 could -- starting with the -- sorry. If we could scroll up,
16 about five lines in, do you see the word "Moreover"?

17 A. "Moreover," yes.

18 Q. And it reads: "Moreover, the fluorescence of
19 photosensitizing compounds is also utilized as a helpful
20 diagnostic tool for the detection of neoplastic tissue."

21 Do you see that, Doctor?

22 A. I do.

23 Q. At the time of your deposition, you had not
24 reviewed this article. True?

25 A. Not to my recollection.

1 Q. You did not review this article before you first
2 disclosed your opinions about enablement and written
3 description. True?

4 A. Correct, not to my recollection.

5 Q. And, Doctor, you have never published any
6 research articles related to photodynamic therapy. True?

7 A. True.

8 Q. Okay. If we could pull up your slide RDX-18.25.
9 I want to talk about your opinions regarding
10 whether one of skill in the art would be motivated to modify
11 the BLU-U lamp. Is that okay?

12 A. Sure.

13 Q. Okay. Now, it's your opinion that a person of
14 skill in the art would be motivated to modify the BLU-U lamp
15 as that lamp is disclosed in the Lundahl reference. Right,
16 Doctor?

17 A. Yes, and as I use it in my office.

18 Q. Yes. And so on this slide here, you're showing
19 Figures 1 and Figures 2 of Lundahl, right?

20 A. Yes.

21 Q. As you describe it, Lundahl discloses a PDT lamp
22 with a fixed U shape, right?

23 A. A PDT lamp with a fixed U shape? That's what
24 seems to be here, yes. You're asking if Lundahl discloses
25 that?

1 Q. It's your opinion that Lundahl discloses what you
2 have called a PDT lamp with a fixed U shape, right?

3 A. That sounds about right.

4 Q. It's your testimony that the fixed U shape of the
5 BLU-U can make PDT difficult, depending on the physical
6 shape of each individual patient, right?

7 A. Correct.

8 Q. You also say that it can be difficult to treat
9 PDT on some areas of the body such as the arms, right?

10 A. Correct.

11 Q. It's your testimony that Lundahl was designed for
12 treating heads; it was not designed for treating other body
13 parts of a patient's body. True?

14 A. That's my understanding, yes.

15 Q. And if we could turn to Lundahl, RX-65. And if
16 we turn to page 18, and if we look at column 1, line 9, what
17 we reviewed earlier.

18 And column 1, line 9, of RX-65 reads: "The
19 present invention is directed to photodynamic therapy using
20 an illuminator that provides a uniform distribution of
21 visible light. In particular, the present invention is
22 directed to an apparatus and method for photodynamic
23 treatment (PDT) or diagnosis (PD) of actinic keratosis of
24 the scalp or facial areas of the patient."

25 That's what it says, right?

1 A. Yes.

2 Q. We agree Lundahl discloses using its illuminator
3 to treat the scalp and the face, right?

4 A. Well, it says the field of the invention includes
5 the scalp or the facial areas of the patient. That's what
6 it says.

7 Q. Well, specifically, it's the present invention is
8 directed for the treatment of the scalp and the face, right?

9 A. That's what it says.

10 Q. Lundahl continues at line 14. "The present
11 invention is also directed to an apparatus and method for
12 PDT and PD of other indications (e.g., acne) and other areas
13 of the patient (e.g., arms, legs, et cetera)."

14 Do you see that?

15 A. I do.

16 Q. Now, in your analysis, you treat the Lundahl
17 patent and the BLU-U 4170 device as slightly
18 interchangeable. Is that fair to say?

19 A. I think that the BLU-U device is probably a
20 subset of what might be disclosed in the Lundahl patent,
21 so --

22 Q. Understood.

23 A. -- there's other stuff in there, but the BLU -- I
24 think that the BLU-U device is clearly a physical
25 representative of one -- one version of it.

1 Q. Fair to say if it's disclosed in the BLU-U
2 device, it's disclosed in Lundahl, right?

3 A. Yes, I think that's true.

4 Q. You know that the on-label indications for the
5 BLU-U 4170 device include treating the upper extremities,
6 right, Doctor?

7 A. I'd have to check the label. It doesn't come
8 readily to mind.

9 Q. Let's pull up CX-106, page -- well, let's look at
10 page 1 first.

11 And that's the operating manual for BLU-U 4170D,
12 right, Doctor?

13 A. Yes.

14 Q. And this is the device you're relying upon in
15 your opinions about the motivation to combine, right?
16 Sorry, let me -- I misspoke. Let me rephrase my question.

17 This is the device you're relying upon for your
18 motivations to modify, right?

19 A. It looks similar to the device I have in my
20 office, yes.

21 Q. And this is -- right. You're relying on the
22 BLU-U 4170D device in your opinions today, right, Doctor?

23 A. I understand they have letters after them. I
24 think I have something called 4170D, is what I've been told.
25 But, again, from what I could see looking at this picture,

1 it seems to be what I have.

2 Q. Understood. And if we could turn to page 4 and
3 look at the top portion of the page at CX-106.4 under
4 indications for use, it states that the BLU-U is indicated
5 for the treatment of minimally to moderately thick actinic
6 keratoses of the face, scalp, or upper extremities, right,
7 Doctor?

8 A. I do see that.

9 Q. Upper extremities, that includes the arms, right,
10 Doctor?

11 A. I think -- yes.

12 Q. Now, let's talk about your practice using the
13 BLU-U device. In your practice, for about 90 percent of
14 your AK treatment procedures, you're treating AKs on the
15 face or on the scalp, right?

16 A. That sounds about right.

17 Q. The arms and the hands are approximately the
18 remaining 10 percent of your AK procedures, right?

19 A. Right, with a smattering of backs and chests, but
20 mostly when I'm off the face or the head, it's going to be
21 the arms.

22 Q. And I just need a clear record, so I'll ask my
23 question again. I think the answer was yes.

24 Arms and hands are proximally the remaining
25 10 percent of your AK procedures, right, Doctor?

1 A. Approximately, yes.

2 Q. With the BLU-U when you are treating arms and
3 hands, you resort to using pillows and instrument stands in
4 order to fit arms or hands into the treatment area, right?

5 A. Yes.

6 Q. In your words, these are jerry-rigged or
7 jury-rigged approaches that you resort to when treating the
8 arms because the BLU-U 4170 is a fixed, single panel device,
9 right?

10 A. Correct.

11 Q. And we can show Question 159 in your witness
12 statement.

13 And you state that a dermatologist would be
14 motivated to modify lamps like the BLU-U 4170 to be more
15 flexible and adjustable, right?

16 A. Right.

17 Q. What you're saying, Doctor, if I understand
18 correctly, is that a dermatologist would be motivated to
19 modify the BLU-U 4170 because of the problems that you've
20 articulated that they would encounter when treating
21 patients, right?

22 A. The problems that I articulated in treating
23 patients. Can you be -- I mean, just point me to something
24 specific. Obviously, I've identified problems and I would
25 have been motivated to make those changes, but I don't know

1 if you're asking me about something specific.

2 Q. No, so the problems we reviewed earlier were
3 treating patients of different -- let me pull it up --
4 specifically, the problems you identified that are your
5 motivation to modify the BLU-U is treating patients of
6 different sizes and treating different areas of the body,
7 right?

8 A. Right, different sizes and different areas.
9 Correct. Not just arms. I mean, it's other things that
10 I've discussed.

11 Q. And your solution that you articulate here in
12 your answer is that there's a motivation to modify the fixed
13 U shape to be more flexible and adaptable to each patient's
14 physiology, right?

15 A. The last sentence there? Yes, that's what's
16 there.

17 Q. You think a dermatologist would be motivated to
18 modify the lamp to be more flexible, more adjustable, right?

19 A. That's what I wrote here, more flexible and
20 adaptable.

21 Q. You've been using the BLU-U 4170 device for about
22 17 years. Fair?

23 A. With a brief hiatus when I didn't own one when I
24 started my practice, yes.

25 Q. After all of your years of using the original

1 BLU-U 4170 device, you've never tried to modify or improve
2 the BLU-U device, right?

3 A. Right.

4 Q. You've never told Sun Pharma about any ideas
5 you've had about modifying the device, right?

6 A. No, I did not.

7 Q. As a dermatologist, you agree that it's important
8 that a PDT device delivers uniform light to a treatment
9 surface, right?

10 A. PD, photodynamic diagnosis, you're saying? Or
11 did you say PD or PDT?

12 Q. PDT.

13 A. Sorry. I thought you said PD there.

14 Q. I can rephrase the question.

15 A. Okay. Please.

16 Q. As a dermatologist, it is important that a PDT
17 device delivers uniform light to a treatment surface, right?

18 A. Yes, I agree.

19 Q. You agree that when you're making these proposed
20 modifications to the BLU-U device, you still need to
21 maintain uniformity for PDT treatment, right?

22 A. Yes.

23 Q. Even if you were modifying the device to have a
24 larger treatment area, you would still need to maintain
25 uniformity as part of the considerations when you're making

1 these panels adjustable, right?

2 A. Yes.

3 Q. And as we talked about earlier, these aren't
4 actual modifications that you've done to any specific
5 medical device, right?

6 A. No, I have made no modifications myself.

7 Q. You've never designed or modified the design of
8 any medical device. True?

9 A. Correct.

10 Q. And in terms of your own use of the BLU-U 4170
11 device, you're still using the BLU-U 4170 to treat arms and
12 hands in your practice, right?

13 A. Yes, I do.

14 Q. You have no plans to stop using the older BLU-U
15 device to treat arms and hands, right?

16 A. Not at the moment.

17 Q. In treating the arms, you can use something
18 that's called a Mayo stand with the old BLU-U device, right?

19 A. A Mayo stand is just a stand that many doctors
20 have in their offices.

21 Q. It's an example of an approach that you've called
22 a jerry-rigged device that's necessary for treating the arms
23 with the old device. Right?

24 A. It's one instance, one component of that
25 jury-rigging, or whatever we'll call it, of figuring out how

1 to position people.

2 Q. The answer is yes, Doctor?

3 A. That sometimes I use a Mayo stand for that? Yes.

4 Q. Now, if we could pull up your slide 20, RDX-18C,
5 slide 20. Sorry, RDX. I'm sorry. Thank you, Mr. Sayres.

6 So if I'm following your modifications correctly,
7 we would take your modifications to the old 4170 device and
8 we would upgrade it to have adjustable panels, right?

9 A. Not necessarily.

10 MR. LARIVÉE: Objection, outside the scope.

11 MR. HABBAZ: Your Honor, we're discussing his
12 motivations to modify and his proposals to make the device
13 more flexible and adjustable.

14 MR. LARIVÉE: He doesn't -- he doesn't talk about
15 adjusting the device.

16 MR. HABBAZ: What was that?

17 JUDGE MOORE: So I think the suggestion is that
18 he doesn't talk about modifying the device in his testimony.
19 Do you have a response to that?

20 MR. HABBAZ: Yes. It's the testimony we've been
21 describing about his motivations to modify lamps to be more
22 flexible. I can pull up the witness statement, if you'd
23 like, Your Honor.

24 MR. LARIVÉE: Your Honor, we'll withdraw the
25 objection.

1 JUDGE MOORE: Okay. All right. Overruled, then.

2 BY MR. HABBAZ:

3 Q. Should I reask my question?

4 A. Yes, please.

5 Q. Following your modifications -- well, your
6 proposal is that you'd be motivated to modify the old 4170
7 device to be more flexible and adjustable, right?

8 A. Yes.

9 Q. And what's motivating you is to upgrade this
10 device we see on the screen, the 4170, to better treat arms
11 and hands. That's one of your motivations we talked about,
12 right?

13 A. Not just arms and hands.

14 Q. That's one of the motivations we talked about,
15 right, Doctor?

16 A. Arms and hands, yes.

17 Q. You agree that even if the panels were
18 adjustable, you would still need to figure out how to rest
19 the patient's arms and hands somewhere during a PDT
20 treatment, right?

21 A. They would still need to be rested somewhere,
22 yes.

23 Q. And you're aware of the new BLU-U 4170E device,
24 right?

25 A. I am.

1 Q. The new BLU-U 4170E device, just like the old
2 lamp, is approved to treat the upper extremities, right?

3 A. I'd have to see its approval.

4 Q. So if we could pull up JX-91C. Just to the first
5 page, please.

6 And this is the operating manual for the BLU-U
7 4170E device, right, Doctor?

8 A. That's what it says it is.

9 Q. And if we can turn to page 4, we see in the
10 indications for use that the BLU-U 4170E device, just like
11 the old device, is approved to treat the upper extremities,
12 right?

13 A. I see that.

14 Q. And as we can see in the courtroom, the new BLU-U
15 4170E device has five adjustable panels, right?

16 A. I have not had the opportunity to examine such a
17 device.

18 MR. HABBAZ: Your Honor, can the witness approach
19 the device very briefly?

20 JUDGE MOORE: Yes, if you think it would be
21 useful, certainly.

22 MR. HABBAZ: It's just to answer the one
23 question.

24 JUDGE MOORE: Certainly.

25 THE WITNESS: I will go back as I can see from

1 here. I can see that it is five panels.

2 BY MR. HABBAZ:

3 Q. The five panels are adjustable, right, Doctor?

4 A. I have not had the opportunity to use this
5 device.

6 Q. Okay. You don't know one way or the other if the
7 new 4170E device has adjustable panels; is that your
8 testimony?

9 A. I believe --

10 Q. It's just a yes/no.

11 A. I have heard it to have that, but I have not used
12 it personally, so I really have no firsthand knowledge of
13 it. It's not on the market. It has not been sold. I just
14 don't know for sure.

15 MR. HABBAZ: And, again, I'm going to move to
16 strike.

17 JUDGE MOORE: Granted.

18 BY MR. HABBAZ:

19 Q. Doctor, a dermatologist using the new BLU-U 4170E
20 device will still use a stand like a Mayo stand to position
21 a patient's hands for treatment, right?

22 A. As far as I can tell.

23 Q. Let's pull up CX-1351.

24 And before we play it, for the record, CX-1351,
25 already in the record, is a video that's found on the Sun

1 Pharma website for the BLU you 4170E device. And if we
2 could play it from minute 1, 17 seconds, until minute 1, 46
3 seconds.

4 (Video played.)

5 (Discussion off the record.)

6 JUDGE MOORE: We'll let it play. It will not be
7 transcribed.

8 MR. HABBAZ: And if we could restart to minute 1
9 and 17 seconds.

10 MR. LARIVÉE: We're going to just object for now
11 as beyond the scope. I don't think this is cited in his
12 expert report.

13 MR. HABBAZ: I can respond, Your Honor, if you
14 wish.

15 JUDGE MOORE: Go ahead.

16 MR. HABBAZ: And so the motivation to modify
17 opinion is in Dr. Ehrenreich's report, specifically about
18 the modifications required in order to alleviate the need to
19 use things like a stand to treat the arms. What this video
20 is showing is that with that modification of adjustable
21 panels, they're going to use the same stand. So it directly
22 contradicts and in response to his opinion.

23 JUDGE MOORE: All right. Overruled. Go ahead.

24 BY MR. HABBAZ:

25 Q. And if we could play from -- do you have it?

1 Thank you.

2 (Video played.)

3 BY MR. HABBAZ:

4 Q. AND if we could pull up CDX-1100.1.

5 And these are excerpts and screenshots from
6 CX-1351. Do you see that, Doctor?

7 A. That these are screenshots from it? Yes.

8 Q. And we can see here on the slide, that the BLU-U
9 4170E has five adjustable panels, right?

10 A. I see that.

11 Q. The BLU-U 4170E can be used to treat the face,
12 the scalp, and upper extremities, right?

13 A. I see that.

14 Q. That includes treating the hands and arms, right?

15 A. And upper extremities would include hands and
16 arms, yes.

17 Q. And as you heard on the video, the dermatologist
18 stated that when treating the upper extremities, "I use a
19 Mayo stand to make sure the patient is comfortable." Right?

20 A. Was she a dermatologist? I don't know who that
21 was.

22 Q. Well, we can replay the video. I wanted to save
23 some time. But in the beginning, she identifies herself as
24 a dermatologist, but I'll --

25 A. I'll grant that she was a dermatologist. I'm

1 just saying I don't know who she is. I don't know that
2 she's not --

3 Q. Thank you, Doctor.

4 A. -- a doctor. I have no idea.

5 Q. You agree that a Mayo stand is shown in the video
6 with the 4170E device being used to treat the upper
7 extremities, right?

8 A. Yes, there's a Mayo stand being used.

9 Q. Now, let's move on from arms and hands and talk
10 about using the BLU-U 4170 to treat other body parts.

11 A. Okay.

12 Q. Now, we saw the label for the 4170 device, right?

13 A. Yes.

14 Q. And it's for treating the face, the scalp, and
15 upper extremities, right?

16 A. Correct.

17 Q. Using the device to treat AKs on the chest would
18 be off-label use, right?

19 A. Correct.

20 Q. Using the device to treat AKs on the back would
21 be off-label use, right?

22 A. That's correct.

23 Q. Now, you've testified that the BLU-U has been
24 used to treat various areas of the body for decades, right?

25 A. Yes.

1 Q. And you mentioned this earlier, you do use the
2 BLU-U to treat patients' chests, but it's on the rare
3 occasion, right, Doctor?

4 A. Right. It's uncommon compared to the other uses.

5 Q. It's quite rare, right, Doctor?

6 A. I don't know what "quite rare" means, but it's --
7 I think the numbers we gave before are that about 90 percent
8 on the face and head, about 10-ish percent on the face and
9 arms, and a smattering of other uses is about right.

10 Q. And the other uses, that would include chest and
11 back?

12 A. Chest and back, et cetera, shoulders.

13 Q. Thank you. Now, switching to talking about the
14 size of the patient, it's your testimony that the size of
15 someone's body parts has never prevented you from doing a
16 PDT treatment. True?

17 A. True.

18 Q. And if we could pull up CDX-1100.2. You see here
19 on the screen, Doctor, the Lundahl Figure 1, which we've
20 also -- you've been using as a stand-in for the 4170 device,
21 right?

22 A. Right.

23 Q. And there's a patient near the device whose chest
24 is too big for the device. Do you see that?

25 A. When facing face -on, I can see that, yes.

1 Q. You testified in your deposition, that you cannot
2 recall ever facing this sort of problem of trying to do a
3 PDT device treatment but failing because of the size of a
4 patient, right?

5 A. Well, in my deposition, I told an anecdote about
6 a medical assistant who tried to do just this. She tried to
7 put the patient in front-wise. So that happened, but it
8 was, you know -- you know, a one-off kind of thing.

9 Q. And, again, the question was slightly
10 different --

11 A. Yeah.

12 Q. -- that in your history doing PDT treatments, you
13 had never not done a treatment on someone because of the
14 size of their body parts, right?

15 A. Not that I can recall, but I would have selected
16 only patients that would have fit. Meaning, if I had a very
17 large man, I would have known that it wasn't even a
18 possibility.

19 Q. Again --

20 A. I never tried to fit somebody in and it didn't
21 fit at that moment.

22 MR. HABBAZ: Again, I'm going to move to strike.

23 JUDGE MOORE: Granted.

24 BY MR. HABBAZ:

25 Q. Again, you were asked at your deposition have you

1 ever not done a PDT treatment on someone because of the size
2 of their body parts, and you answered not that you could
3 recall, right, Doctor?

4 A. That's my deposition, yes.

5 Q. And you never tried to fit someone into the
6 device and they didn't fit, right?

7 A. Correct.

8 Q. And as we discussed earlier, almost all of your
9 AK cases are for the face, the scalp, hands, or arms, right?

10 A. Correct.

11 MR. HABBAZ: I pass the witness.

12 Thank you, Doctor.

13 REDIRECT EXAMINATION

14 BY MR. LARIVEE:

15 Q. Dr. Ehrenreich, Brian Larivee for Biofrontera.

16 I'm going to pick up with a couple of questions
17 about your opinions on why a POSA would have been modified
18 -- would have been motivated to modify the prior fixed art
19 U-shaped device.

20 Now, you were asked about whether certain body
21 parts could fit inside the BLU-U 4170D. Do you remember
22 that?

23 A. Yes.

24 Q. And can you describe any challenges that you have
25 had yourself or at your practice to position a patient's

1 hand or arm inside the BLU-U?

2 A. Yes. So I think that focusing on the Mayo stand
3 is a little bit misleading. It's just part of the apparatus
4 that you need because, as has been asked and admitted to,
5 uniformity of light is really the key feature.

6 And even if you rest it on the Mayo stand, it
7 needs to rest somewhere, you still need to -- in the fixed
8 U-shaped device, you're going to need to rotate that arm,
9 let's say, towards the light source, so you're going to get
10 uniform illumination. And I thought looking at the new
11 device, the image that was shown from the video showing the
12 treatment on the arms was a great example of how flexible
13 the new device is because you're able to get that right down
14 onto the arms when it's sitting on the Mayo stand. You
15 can't do that, really, with the fixed device. So that was a
16 great example of an improvement in terms of being able to
17 position it.

18 So that's one example is that arms -- it's not
19 just resting on the Mayo stand. It's positioning it so that
20 it gets uniform illumination.

21 Secondly, though chest and backs are rare, and
22 I've never gotten to a point, I don't think, where I had
23 somebody that I couldn't fit into the device, it's certainly
24 something that's in my mind if I think about, well, what are
25 my options for a patient. If I have a very large patient, I

1 know that I can't think about PDT on the chest or the back
2 if that was something that I wanted to do.

3 So it's an obvious limitation of the device.
4 It's not a big opening, and given -- you know, I can't say
5 the average size of people in America, but, you know, we're
6 a somewhat obese nation. And, you know, certainly a lot of
7 people, if you did want to treat the chest or the back, it
8 would not be amenable to that.

9 Finally, even just on its basic use, right, its
10 most basic use, which is face and scalp, you know, you can
11 imagine that, you know, there could be somebody with a very
12 small face. The device I understand was designed from the
13 fifth percentile of the female scalp, head, to the 95th
14 percentile of the male head, but that still leaves people on
15 either end that it wasn't designed for.

16 You can imagine, you know, some very thin old
17 lady, perhaps, who, you put them in and their cheeks are
18 going to be further than the recommended 2 to 4 inches from
19 the device, and maybe do a treatment and you don't get the
20 result you expect and you don't know why. Is it because it
21 was too far? What else might have gone wrong? But,
22 certainly, there's a lot of, you know, situations where you
23 might look at it and say, you know, boy, that could be
24 better if it were more flexible somehow.

25 Q. Is positioning the patient relative to the

1 illumination surface important for uniformity?

2 A. Yes.

3 Q. And have you ever treated a patient with a BLU-U
4 that needed additional follow-up treatments?

5 A. Yes. It's not uncommon that you treat someone
6 and, you know, several months later you treat them again.
7 It's hard to say in that instance, you know, did you not get
8 all of it -- did not all of them respond the first time or
9 only some of them? Didn't get new ones? But it's not
10 uncommon, people that need PDT, if you're treating it, like,
11 for field treatment because they have a lot AKs, that
12 they'll get multiple treatments.

13 And, again, you don't always know if maybe they
14 didn't respond well to the first one or, you know, why
15 you're in that situation.

16 Q. Is it possible that the patients need to be
17 treated multiple times because of the uniformity of light
18 that is delivered?

19 A. It's possible. It's just really hard to say. If
20 someone, you know, is not positioned correctly and doesn't
21 get the correct uniformity, then certainly it's possible
22 that that's a reason why they wouldn't get a brisk response
23 to the treatment.

24 Q. Sir, you remember the part of your cross-exam
25 where you were asked a lot about whether, in relation to

1 your written description and enablement opinions, Lundahl,
2 the patent, disclosed a device that was capable of both
3 photodynamic diagnosis and photodynamic therapy. Do you
4 remember that line of questioning?

5 A. Yes, I do.

6 Q. And were you asked to develop an opinion on
7 whether Lundahl itself enabled photodynamic diagnosis?

8 A. No.

9 Q. And just because the Lundahl prior art reference
10 states that it can be used for photodynamic diagnosis, does
11 that make it true?

12 A. No. In fact, you know, I consider it an
13 impossibility to use the BLU-U light in my office for any
14 form of photodynamic diagnosis. It's a physical
15 impossibility if you put somebody's head, for example, into
16 the BLU-U device and then illuminate or irradiate their face
17 with this, and you're trying to detect some kind of
18 fluorescent signal, so, firstly, where are you standing to
19 get that signal? Between the patient somehow and the 2
20 inches to 4 inches to the light source? Have you put a
21 camera in there? This is just clearly not a device that can
22 ever be used under any circumstances, in my opinion, for
23 photodynamic diagnosis.

24 Let alone the fact that it's designed to
25 irradiate for 16 minutes, 40 seconds, right, and that is not

1 at all the time frame that anybody would ever think to do
2 photodynamic diagnosis, which is done in short intervals of
3 time. So it is just very clear that this is in no way or
4 form, no matter what somebody might have wrote in the claim,
5 in a patent or described it in a patent, this is not
6 something that anybody would ever think to use for
7 photodynamic diagnosis. THE REPORTER: I just want to
8 clarify, is it 16 or 60? 16 minutes?

9 THE WITNESS: 16 minutes 40 seconds.

10 THE REPORTER: 1-6?

11 THE WITNESS: 1-6.

12 THE REPORTER: Thank you.

13 MR. LARIVÉE: Mr. Habbaz, can I have a copy of
14 the cross-demonstratives that you used, 1100.3 and 1100.4,
15 please.

16 BY MR. LARIVÉE:

17 Q. Dr. Ehrenreich, do you recall being asked about
18 this demonstrative, CDX-1100.3?

19 A. I do.

20 Q. And, sir, step A relates to photosensitizer,
21 correct?

22 A. Correct.

23 Q. Does this demonstrative tell you anything about
24 how long the photosensitizer would be left to incubate on
25 the skin?

1 A. I don't see anything on this slide that says
2 anything about that.

3 Q. Does this demonstrative say anything about the
4 wavelength of light that would be used?

5 A. It just says light.

6 Q. Does this demonstrative tell you anything about
7 the fluence of light that should be applied?

8 A. No.

9 Q. Does this slide tell you anything about the
10 length of time the exposure should occur?

11 A. No.

12 Q. Sir, you were asked about this demonstrative as
13 well, RDX-1100.4.

14 A. Yes.

15 Q. Right? And does this -- this is -- does this
16 demonstrative tell us anything about the length of
17 incubation time that ALA should have after it's applied?

18 A. No.

19 Q. Does it tell you anything about the wavelength of
20 light to be used?

21 A. No.

22 Q. Does it tell you anything at all about the length
23 of time that the skin needs to be exposed in order to do
24 photodynamic diagnosis?

25 A. No.

1 Q. Does it tell you anything about the fluence that
2 needs to be done to do photodynamic diagnosis?

3 A. No.

4 Q. Sir, you have seen something like this image
5 before, correct?

6 A. It was just shown to me during my
7 cross-examination.

8 Q. Well, could we have RDX-21, please, cover page.

9 MR. HABBAZ: Your Honor, before it's shown on the
10 screen, I'm going to object. There's no foundation for this
11 one.

12 MR. LARIVÉE: Your Honor, we're going to a
13 demonstrative slide that is a copy of the slide that Sun
14 Pharma has used on redirect and was part of the opening
15 statement in this case.

16 MR. HABBAZ: Your Honor, that slide has not been
17 used on redirect with Sun Pharma. And, again, if he can lay
18 a foundation for being present during the opening and seeing
19 this slide, he can ask that, but that hasn't been done yet.

20 JUDGE MOORE: Okay. Sort of a Catch 22. You
21 asked that the slide not come up, but it's not possible to
22 lay a foundation without the slide coming up. So I
23 understand the situation we're in. Certainly, his seeing
24 the slide now doesn't create a foundation for questions, but
25 we will see where we go with the foundation questions.

1 MR. HABBAZ: Thank you, Your Honor.

2 BY MR. LARIVEE:

3 Q. Dr. Ehrenreich, I'd like to ask you whether you
4 were in the courtroom for opening statements on Monday
5 morning, but I know the answer. Could you tell us where you
6 were on Monday morning?

7 A. Unfortunately, when I got here on Monday morning,
8 I was denied entry because my New Jersey driver's license
9 was not a REAL ID. And despite my best efforts, I could not
10 get access to the building. As a result, I spent my day
11 going back and forth to New Jersey to get my passport.

12 Q. And, sir, you remember that you were served a set
13 of demonstratives by Sun Pharma in this case?

14 A. Yes.

15 Q. Right? And with respect to CDX-1100.4, this
16 image is nothing that you made yourself, right?

17 A. No, I certainly didn't make that.

18 Q. And if that image is in your demonstratives, it's
19 because it came from Sun Pharma, right?

20 A. Right.

21 MR. LARIVEE: And can we see that image? I think
22 I've laid the foundation now so that we could -- we could
23 see that image.

24 JUDGE MOORE: Okay. You can make a statement if
25 you want.

1 MR. HABBAZ: Your Honor, I continue my objection.
2 I think the foundation has been laid that he saw the slide I
3 used during cross-examination. Then there's a reference to
4 some unknown demonstrative. It hasn't been identified. And
5 there has been no foundation laid. It's obviously not in
6 his witness statement. And so if there can be foundation --
7 we just need more of a record of foundation for it. There
8 should be more foundation for the record, Your Honor.

9 JUDGE MOORE: All right. Do you have a response?

10 MR. LARIVÉE: I'm just wondering whether I can
11 show Mr. Habbaz the slide that I was intending to share.

12 JUDGE MOORE: Yes. If that would be helpful,
13 yes.

14 MR. HABBAZ: Can I approach, Your Honor?

15 JUDGE MOORE: Yes.

16 MR. HABBAZ: Thank you.

17 MR. LARIVÉE: We're going to build another
18 foundation, Your Honor.

19 JUDGE MOORE: All right.

20 BY MR. LARIVÉE:

21 Q. Dr. Ehrenreich, you offered an opinion on
22 enablement and written description in this case, correct?

23 A. I did.

24 Q. And then you sat for a deposition, right?

25 A. Yes.

1 Q. And you understand that Dr. Shmuylovich also
2 offered a written opinion in this case, right?

3 A. Yes.

4 Q. And then he sat for deposition?

5 A. Yes.

6 Q. And then Dr. Shmuylovich offered a new -- or a
7 written direct testimony or written rebuttal testimony to
8 your opinion in this case. Do you recall that?

9 A. Yes.

10 Q. And what was new in the Shmuylovich witness
11 statement that you identified that was not present in his
12 report before his deposition?

13 MR. HABBAZ: Your Honor, objection, leading.
14 Counsel is testifying. And, again, I don't know where this
15 is going in terms of the foundation.

16 JUDGE MOORE: Overruled. I think that's just a
17 question.

18 Go ahead.

19 THE WITNESS: Well, let me reflect. Obviously,
20 it was a big document. I'm trying to figure out what was in
21 it and what was not.

22 But, you know, I believe that there was an
23 introduction at some point by Dr. Shmuylovich about the
24 discussion of photodynamic diagnosis and stating an opinion
25 to the effect that the only difference between photodynamic

1 therapy and photodynamic diagnosis was that photodynamic
2 diagnosis used, I think he said, millisecond exposures and
3 photodynamic therapy used, obviously, you know, many minute
4 exposures.

5 I don't know if that's the only thing that was
6 new in there, but that did strike me as something that was
7 newly introduced at that time. I don't know -- I'm not
8 really sure, you know, if that's relevant to this or not.

9 BY MR. LARIVEE:

10 Q. And was there a demonstrative with respect to the
11 millisecond exposure?

12 A. I believe that there was. There was a slide that
13 showed, I believe, a comparison of photodynamic therapy and
14 photodynamic diagnosis, kind of a split-screen slide,
15 similar to the one I was looking at here, and I think that,
16 if I recollect, that that might have been a demonstrative
17 that had that on it. But I'd have to see it to, you know,
18 fully refresh my memory of it.

19 MR. HABBAZ: Your Honor, I object. I now
20 understand this is an attempt to get this witness to discuss
21 our witness' rebuttal demonstratives that have not yet been
22 offered. Dr. Shmuylovich has not yet testified in the
23 rebuttal case. And counsel is attempting to ask his own
24 expert to preempt that examination and comment on
25 Dr. Shmuylovich's slides.

1 MR. LARIVÉE: Well, Your Honor, preemption
2 wouldn't have been necessary if the opinions had been
3 disclosed in Dr. Shmuylovich's expert report. And we have
4 laid a foundation that it was not in the expert report, and
5 we think that this is Dr. Ehrenreich's one chance to testify
6 on the new opinion that's offered.

7 JUDGE MOORE: All right. So this is a
8 procedural. So the procedure to handle a situation like
9 this would have been some kind of motion to strike, not an
10 attempt to preempt. So given that I don't know of any
11 motion to strike on the record, it would be untimely to ask
12 for one now.

13 So the objection is sustained.

14 MR. HABBAZ: Thank you, Your Honor.

15 MR. LARIVÉE: No further questions at this time.

16 RE CROSS-EXAMINATION

17 BY MR. HABBAZ:

18 Q. Dr. Ehrenreich --

19 A. Yes.

20 Q. On redirect, you testified about the difference
21 between using the new BLU-U 4170E device and the old BLU-U
22 4170 device to treat the hands. Right?

23 A. I testified regarding the photo that was shown
24 from the video. I've never used the new device.

25 Q. You -- Doctor, you gave testimony about the

1 differences between using those two devices in order to
2 treat hands. True?

3 A. I don't think that's what I did.

4 Q. You've never used the BLU-U 4170E device before.
5 True?

6 A. True.

7 Q. Any testimony you may have given about using the
8 device, the 4107E device, to treat hands, you were assuming
9 that based on your watching of the video and looking at the
10 device in the courtroom, right?

11 A. Correct.

12 Q. Okay. And if we could pull up CX-1355.

13 And this is a video for the BLU-U 4170 device.

14 Do you see that, Doctor?

15 A. This is a video?

16 Q. Well, we'll start the video in a second.

17 A. Okay.

18 Q. I want to just get you on the same page. It's a
19 video of the -- it's the start of a video of the 4170
20 device, right, Doctor?

21 A. I'm about to see that, yes.

22 Q. And do you recognize --

23 MR. LARIVÉE: Is this a -- objection. This is
24 outside the scope of the redirect.

25 MR. HABBAZ: Your Honor, the witness was asked

1 questions to contrast his experiences between using the old
2 device and the Mayo stand and a hypothetical modification to
3 that device. And this is a video that directly goes to the
4 experiences using that old device that he testified about.

5 MR. LARIVEE: And this is -- I didn't ask him any
6 questions about the video. I mean, if Sun Pharma wants to
7 have an advertisement session in the middle of court, that's
8 interesting, but it's not -- it wasn't the scope of my
9 redirect questions to Dr. Ehrenreich.

10 This is entirely new cross-examination on an
11 exhibit that is nowhere in his report.

12 JUDGE MOORE: All right. We had testimony about
13 a video. We had testimony about modifications and the
14 difference between the old device and the new device. This
15 is in evidence. I'm going to allow this video.

16 MR. HABBAZ: Thank you, Your Honor.

17 BY MR. HABBAZ:

18 Q. And, Dr. Ehrenreich, do you recognize the BLU-U
19 4170 device on the screen?

20 A. It seems to be, yes.

21 Q. And do you see on my side, it's on the right side
22 of the screen, the patient's arms are being placed through
23 the device. Do you see that?

24 A. I do see that.

25 Q. And there's a stand that the patient's arms are

1 on, right?

2 A. I do see that.

3 Q. And if we could play the video at around minute
4 3.

5 (Video played.)

6 MR. HABBAZ: Thank you.

7 BY MR. HABBAZ:

8 Q. And if we could pull up on the left side of the
9 screen the screenshot we had up earlier from CX-1351 at 142.
10 I believe it was CDX-1100.1.

11 And, again, Doctor, on the left side of the
12 screen is the BLU-U 4170E device with adjustable panels
13 being placed around a patient's hands, right?

14 A. Right.

15 Q. And on the right side of the screen, from
16 CX-1355, is a screenshot showing placing the old BLU-U 4170
17 device around the patient's hands, right?

18 A. Yes.

19 MR. HABBAZ: No further questions.

20 REDIRECT EXAMINATION

21 BY MR. LARIVÉE:

22 Q. Dr. Ehrenreich, you were just shown a video,
23 right?

24 A. Yes.

25 Q. And you were just pointed to the first video you

1 were shown and those were CX-1351 and 1355, right?

2 A. Yes.

3 Q. Do you know who made those videos?

4 A. I don't know for certain. I'd assume they were
5 made by Sun.

6 Q. Do you know when those videos were made?

7 A. I have no idea.

8 Q. Do you know whether those videos -- do you know
9 what is in the rest of those videos?

10 A. No.

11 Q. Do you know whether those videos were made for
12 this litigation?

13 A. I don't know.

14 MR. LARIVEE: No questions.

15 MR. HABBAZ: No further questions, Your Honor.

16 JUDGE MOORE: All right. We are at 3 -- well,
17 first of all, you are released. We appreciate you
18 testifying.

19 THE WITNESS: Thank you, Your Honor.

20 JUDGE MOORE: You may get up.

21 (The witness stood down.)

22 JUDGE MOORE: We're at 3:05. So it's time for
23 our afternoon break. We will return at 3:20.

24 (A recess was taken at 3:05 p.m., after which the
25 proceedings resumed at 3:20 p.m.)

1 JUDGE MOORE: Please be seated.

2 MR. SHAW: Thank you, Your Honor. Sun Pharma
3 recalls Dr. Leonid Shmuylovich.

4 JUDGE MOORE: All right.

5 MR. SHAW: May I proceed, Your Honor? Oh, I'm
6 sorry.

7 JUDGE MOORE: Let's get him sworn in. Yes.

8 Raise your right hand.

9 Whereupon--

10 LEONID SHMUYLOVICH,
11 having been first duly sworn/affirmed, was examined and
12 testified as follows:

13

14 THE WITNESS: Yes.

15 JUDGE MOORE: All right. Thank you.

16 When you're ready.

17 MR. SHAW: Thank you, Your Honor. Sorry for
18 jumping the gun on you.

19 JUDGE MOORE: No problem.

20 DIRECT EXAMINATION

21 BY MR. SHAW:

22 Q. Welcome back, Doctor.

23 A. Thank you.

24 THE REPORTER: I'm sorry. Your microphone is
25 off, Doctor.

1 THE WITNESS: Sorry about that.

2 BY MR. SHAW:

3 Q. You should have a binder there in front of you.

4 A. Yes.

5 Q. Can you turn to CX-13C. It should be the first
6 document in the binder.

7 A. Yes.

8 Q. And it's titled Rebuttal Witness Statement of
9 Leonid Shmuylovich, Ph.D., M.D. Do you recognize that
10 document?

11 A. Yes, I do.

12 Q. What is it?

13 A. This is the rebuttal witness statement that I
14 wrote with the aid of counsel.

15 Q. And if you look briefly at Question and Answer
16 Number 12, can you please summarize the opinions you reached
17 in your rebuttal witness statement briefly?

18 A. Sure. In responding to some of the arguments
19 laid out by -- in the record, first, the question -- I come
20 to the conclusion that the asserted claims of the patent are
21 enabled. Second, that they do have sufficient written
22 description.

23 I disagree with Dr. Ehrenreich's assertion that a
24 POSITA would be motivated to modify the old BLU-U device in
25 a manner that's consistent with what's been done with the

1 new BLU-U device.

2 And I also offer, in a shorter section at the
3 end, the question of obviousness from a -- a term that I
4 learned from you guys, objective evidence of it, related to
5 the connection between how the device succeeded because of
6 the features in the patent.

7 Q. Now, can you please turn to CX-13C.64, please.
8 It should be the last page.

9 A. The last page of this?

10 Q. Yeah. Sorry.

11 A. Okay. Thank you. Got it.

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

13 A. Yes.

14 Q. Is that your signature?

15 A. It is.

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

18 A. It does.

19 Q. Now, can you please turn to page CX-13C.2.

20 A. Yes.

21 Q. And are these the exhibits that you discussed in
22 your rebuttal witness statement?

23 A. They are.

24 Q. Now, Doctor, did you prepare any demonstratives
25 to help illustrate your rebuttal testimony?

1 A. I did.

2 Q. You should have in your binder a tab marked
3 CDX-16C.

4 A. Yes. I see it on the screen. I am looking for
5 it here.

6 Q. It's all right, Doctor. Do you see the
7 demonstrative --

8 A. I see it on the screen, I'm sorry, yeah.

9 Q. That's okay.

10 A. Oh, it's right here. I'm so sorry. It's a
11 separate binder.

12 Q. Great.

13 MR. SHAW: So, Your Honor, we move to admit
14 CX-13C, the rebuttal witness statement of Dr. Leonid
15 Shmuylovich.

16 MR. LARIVÉE: Without objection.

17 JUDGE MOORE: All right. It is admitted.

18 (Complainant Exhibit Number CX-13C was received
19 into evidence.)

20 MR. SHAW: And we also move to admit as
21 demonstrative CDX-16C, in the same manner that we have been
22 doing throughout the trial.

23 JUDGE MOORE: Right. They will be handled as
24 other demonstratives.

25 MR. SHAW: Thank you, Your Honor. I pass the

1 witness.

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

3 JUDGE MOORE: Yes.

4 CROSS-EXAMINATION

5 BY MR. LARIVEE:

6 Q. Good afternoon, Dr. Shmuylovich.

7 Brian Larivee on behalf of the Biofrontera
8 Respondents. Nice to see you again.

9 A. Same here. Nice to see you.

10 Q. Sir, you have offered opinions on obviousness in
11 your rebuttal report, correct?

12 A. Yes.

13 Q. And you understand that the obviousness inquiry
14 takes place at the time of the invention, correct?

15 A. Yes.

16 Q. And that the obviousness inquiry takes place from
17 the perspective of a person of ordinary skill in the art,
18 correct?

19 A. Yes.

20 Q. The priority date of these patents is October
21 2015, correct?

22 A. Yes.

23 Q. And in October 2015, sir, you were an intern
24 physician in pediatrics, correct?

25 A. That's right.

1 Q. And the opinions you are offering with respect to
2 obviousness relate to the use of Lundahl in the BLU-U,
3 correct?

4 A. That's right.

5 Q. And you first gained experience in photodynamic
6 therapy as a resident physician in dermatology, right?

7 A. Not exactly.

8 Q. It was a yes-or-no question.

9 A. I am having trouble answering yes or no.

10 Q. When was the first time you conducted a
11 photodynamic illumination session?

12 A. As a resident, yes.

13 Q. And your assignment on obviousness was to respond
14 to Dr. Ehrenreich's opinions, right?

15 A. Yeah.

16 Q. And you put the materials you relied on in your
17 witness statement on page 2 and 3, right?

18 A. Yes, yes, those exhibits, yes.

19 Q. Mr. Ortega, could we have CX-13C at pages 2 and
20 3.

21 Sir, you have been in court this week, right?

22 A. I have.

23 Q. And you understand that Biofrontera's position is
24 that the combination of Lundahl with another reference
25 called Larsen renders the claim obvious, right?

1 A. I have heard that argument, yes.

2 Q. And nowhere on your list here is Larsen, right?

3 A. I don't see Larsen on this list.

4 Q. So one of the main references on obviousness is
5 simply not a part of your opinion, correct?

6 A. I wouldn't put it that way.

7 Q. That was a yes-or-no question.

8 A. I'm having trouble answering yes or no.

9 Q. Okay. You put all of the materials you relied on
10 in this list?

11 A. I did.

12 Q. You're not aware of any errors in your witness
13 statement, are you?

14 A. That's correct.

15 Q. So Larsen is not here, right?

16 A. Larsen is not listed in these exhibits, that's
17 correct.

18 Q. Now, you do rely on a declaration of Dr. Heather
19 Roberts, right?

20 A. Yes. I know that I -- there's a section there
21 about -- so the answer is yes.

22 Q. And Dr. Roberts testified that as of the priority
23 date of the invention, she had actually used the BLU-U 4170,
24 right?

25 A. Right.

1 Q. But Dr. Roberts is not here testifying today,
2 correct?

3 A. That's right.

4 Q. She is not the subject of a cross-examination?

5 A. No.

6 Q. And your witness statement refers to her as "an
7 expert witness," right?

8 A. I think I called her that, yeah.

9 Q. But your testimony says nothing about speaking to
10 her in this investigation, right?

11 A. That's true.

12 Q. And all your testimony about Dr. Roberts is on
13 one page of your opinion, correct?

14 A. In my rebuttal witness statement, that is true.

15 Q. And let's -- and nowhere in your witness
16 statement did you compare Dr. Roberts with the
17 qualifications of a person of ordinary skill that --
18 according to the definition adopted by Judge Moore, right?

19 A. That's right.

20 Q. And is it also true, sir, that you offered an
21 opinion on commercial success in this case?

22 A. I wouldn't put it that way. It's kind of an
23 incomplete characterization.

24 Q. It was a yes-or-no question.

25 A. Forgive me, it's my confusion about the legal

1 standard. I have learned this term "nexus." And I'm not
2 sure if by answering a question I'm going to say something
3 that's legally incorrect. So I apologize. I am having
4 trouble answering the question as a yes or no.

5 Q. Sure. Let's see if we can refresh your
6 recollection.

7 Could we have -- Abe, could we have CX-13C.4.

8 Is there a heading in your report called
9 Commercial Success?

10 A. Yes.

11 Q. And you answered questions about commercial
12 success?

13 A. In the context of this nexus between the
14 patent -- the things in the patent and the commercial
15 success, which I understand is this legal term called
16 "nexus," yes.

17 Q. You offered an opinion on commercial success,
18 right?

19 A. As I said, in the context of nexus, yes.

20 MR. LARIVÉE: Move to strike everything other
21 than "yes."

22 JUDGE MOORE: Granted.

23 BY MR. LARIVÉE:

24 Q. You're not an accountant, are you,
25 Dr. Shmuylovich?

1 A. No.

2 Q. And you're not an economist, Dr. Shmuylovich?

3 A. Nope.

4 Q. You don't own a dermatology practice, correct?

5 A. I do not.

6 Q. You didn't conduct any market research into the

7 purchasing habits of dermatologists, did you?

8 A. No.

9 Q. Sir, you also offered an opinion on industry

10 praise, right?

11 A. Yes.

12 Q. And let's look at your demonstrative on that.

13 Abe, could we have CDX-16C, page 53.

14 Sir, is this the demonstrative that you included

15 in your -- with your testimony today?

16 A. Yes, it is.

17 Q. And this demonstrative quotes two exhibits,

18 right?

19 A. It does.

20 Q. It quotes CX-1249, correct?

21 A. Right.

22 Q. And it quotes CX-1225, right?

23 A. Yep.

24 Q. Did you actually read those two documents,

25 Dr. Shmuylovich?

1 A. Yes.

2 Q. And the quote in the upper right is from a press
3 release from Biofrontera, correct?

4 A. Right.

5 Q. And you understand that that press release was
6 authored by Biofrontera itself, right?

7 A. Right.

8 Q. And you also highlight an article from
9 Dermatology Times in the bottom right.

10 Do you see that?

11 A. Yes.

12 Q. And that quotes David Cleaver of Cleaver
13 Dermatology, right?

14 A. Um-hum.

15 Q. So when you read the press release, you realized
16 that the quote in the Dermatology Times article was the
17 exact same quote in the press release, right?

18 A. They certainly are similar, yeah.

19 Q. Well, let's have a look.

20 Could we see, Abe, side-by-side CX-1225 at 3.
21 And scroll down to the next page.

22 There's the Cleaver Dermatology people, correct?

23 A. Yeah. I actually know him. I have met him at a
24 conference.

25 Q. Great.

1 A. Yeah.

2 Q. Give him my regards.

3 Could you please scroll down to the next page.

4 And, Dr. Shmuylovich, could you compare the quote
5 from the Dermatology Times article to the quote on the press
6 release on the right? Read them quietly to yourself.

7 You agree that the Dermatology Times article is
8 simply quoting the press release, right?

9 A. Yes.

10 Q. Sir, I want to switch gears for a moment. You
11 offered opinions in this case on written description and
12 enablement, correct?

13 A. Yes.

14 Q. And you prepared some demonstratives to go with
15 that, right?

16 A. Yes, I did.

17 Q. Could we please see 16C, page 8.

18 And, sir, do you see your -- do you see the slide
19 in front of you?

20 A. Yes.

21 Q. And did you prepare this slide?

22 A. Yes.

23 Q. And in the upper third of the slide, you would
24 agree with me the difference you're highlighting here is the
25 time between photodynamic diagnosis and photodynamic

1 therapy, right?

2 A. The time scale, yeah.

3 Q. And for photodynamic diagnosis, or PD, you're
4 saying it's about a millisecond exposure to light, right?

5 A. This says it's on the order of milliseconds.

6 Q. On the order of milliseconds, right?

7 A. That's what the tilde means.

8 Q. Yes. And for photodynamic therapy, you're
9 telling us the exposure is about 10 or 20 minutes, right?

10 A. Yeah.

11 Q. In fact, it's your testimony that the main
12 difference between PDT and PDT -- and PD is the length of
13 time that the treatment area is illuminated and the effect
14 that the light has on the agent, right?

15 A. Sorry, can you repeat that? It was a little bit
16 muddled at the beginning.

17 Q. Sure. In fact, it's your testimony in your
18 witness statement that the main difference between PDT and
19 PD is the length of time that the treatment area is
20 illuminated and the effect that the light has on the agent,
21 right?

22 A. Yeah.

23 Q. Now, you offered an opinion on written
24 description in your rebuttal witness statement, right?

25 A. Yes, I did.

1 Q. And that opinion on written description begins at
2 Question and Answer 179 and runs through Question and Answer
3 194, right? Page 48 of your witness statement.

4 A. That's right, the Section 5, Written Description.

5 Q. And you put all of your opinions about written
6 description in that section of your testimony, right?

7 A. All the ones that I was asked about.

8 Q. And you understand that a patent's specification
9 must include a written description that clearly demonstrates
10 to a POSITA that the inventors were in possession of the
11 claimed invention when the application was filed, right?

12 A. Yes.

13 Q. And you understand that the written description
14 requirement can be met through any combination of content in
15 the application, including text, structures, figures,
16 diagrams, formulas, and claims, right?

17 A. Correct.

18 Q. And so in your Written Description rebuttal
19 section, you have cited all the text, structures, figures,
20 diagrams, formulas, and claims that you're relying on for
21 your opinion, right?

22 A. I answered the questions that were asked of me.

23 Q. That was a yes-or-no question.

24 A. So I'm not sure about the term "all" that you
25 have there. I answered the questions that were asked of me.

1 I'm sorry if I can't answer it better.

2 MR. LARIVEE: Move to strike.

3 JUDGE MOORE: Granted.

4 BY MR. LARIVEE:

5 Q. Let me ask again.

6 So in your Written Description rebuttal section,
7 you cited to all the text, structures, figures, diagrams,
8 formulas, and claims that you're relying on for your
9 opinion, right?

10 A. For my opinion in response to the questions.

11 Q. Sir, you would agree with me that there is
12 absolutely no reference to milliseconds in any portions of
13 the specification that you have cited in your written
14 description testimony, is there?

15 A. I don't recall the term "milliseconds" in the
16 patent specification. I would have to look closely at it,
17 but I don't recall it.

18 Q. Well, give me a moment.

19 There's no reference to a "nearly instantaneous
20 process" in any portions of the specification that you have
21 cited in your written description testimony, is there?

22 A. I wouldn't put it that way.

23 Q. It was a yes-or-no question.

24 A. The term "nearly instantaneous," I do not recall
25 in the -- in the statement, so the answer is yes for that.

1 Q. All right. Well, to be fair, let's look at some
2 of your demonstratives.

3 Here's -- could we see CDX-16C.43.

4 And this is part of your -- this is a
5 demonstrative related to your written description opinion,
6 right?

7 A. Yes.

8 Q. And there's -- we don't see any reference to
9 milliseconds here, do we?

10 A. You're right.

11 Q. And let's look at CDX-16C.45.

12 Sir, there is no reference to milliseconds here,
13 right?

14 A. Hold on a second. Let me look.

15 Where it says "chemical or biological changes" --

16 Q. I didn't ask whether it said "chemical or
17 biological changes." I asked whether there was a reference
18 to milliseconds. Can you try and answer that question?

19 A. Sorry. Milliseconds are a unit of time. Are you
20 asking me if there's any sort of time-based indication here?
21 Anything that's a rate? No.

22 Q. I'm asking you whether there's a reference to
23 milliseconds here.

24 A. I do not see the term "milliseconds" on this
25 page.

1 Q. Do you see the words "near instantaneous process"
2 here?

3 A. No.

4 Q. Let's look at CDX-16C.46.

5 You would agree there's no reference to
6 milliseconds on CDX-46 [sic], correct?

7 A. Yeah, first prescribed period, second prescribed
8 period, but no milliseconds, you're right.

9 Q. And there is no reference to a nearly
10 instantaneous process here?

11 A. As I said, period is described. That's a unit of
12 time. It doesn't describe specifically how long that time
13 is, you are right.

14 MR. LARIVÉE: Move to strike as non-responsive.

15 JUDGE MOORE: I think -- I can't assume here.
16 You want to strike everything but the "you are right"?

17 MR. LARIVÉE: Yes. Yes, Your Honor.

18 JUDGE MOORE: All right. Granted.

19 MR. LARIVÉE: Mr. Ortega, could we please have
20 CDX-16C at 47.

21 BY MR. LARIVÉE:

22 Q. Sir, this is another demonstrative related to
23 your written description opinion, right?

24 A. Yes, it is.

25 Q. And so there's no reference to milliseconds

1 anywhere in the part of the specification you quote, right?

2 A. That is correct.

3 Q. And there's no reference to a nearly
4 instantaneous process, right?

5 A. That is correct.

6 Q. Now, let's finish with CDX-16C.44.

7 Sir, there is no reference to milliseconds or
8 instantaneous process here, right?

9 A. That's correct.

10 Q. Now, on the slide -- on the right side of the
11 slide, you show us two excerpts of -- from column 9,
12 correct?

13 A. That's right.

14 Q. But Answer 189 of your testimony on written
15 description, you cite column 9, lines 1 through 48. Do you
16 recall that?

17 A. The exact lines that I cited, I trust you that
18 that's what I wrote, but I do not recall the exact lines
19 that I cited on that page.

20 Q. Well, let's see. You agree with me that you have
21 relied on this example in column 9 for the proposition that
22 the invention thus provides a method for photodynamically
23 diagnosing or treating a contoured surface of a patient?

24 A. Yes.

25 Q. Okay. Let's -- Mr. Ortega, could I please have

1 JX-1C. And let's focus on column 9, please.

2 Okay, sir. So I am directing your attention to
3 the paragraph that I just read that begins, "Column 9, line
4 44."

5 Do you see that paragraph that I just read on the
6 record?

7 A. Yes.

8 Q. And above it, you would agree that there are
9 references to time, right?

10 A. Sure.

11 Q. And those references go from line 35 down to line
12 42, right?

13 A. Yes.

14 Q. And you would agree that in certain embodiments,
15 the illuminator is configured to irradiate the patient's
16 skin with low-intensity blue light for about one hour to
17 about three hours, and irradiate the patient's skin with
18 high-intensity -- with the high-intensity red light for
19 about 20 minutes to about 30 or 40 minutes.

20 Do you see that?

21 A. I do.

22 Q. And so there's no example in column 9 about
23 milliseconds, right?

24 A. That's true.

25 Q. And there's no reference in column 9 to any sort

1 of nearly instantaneous process, right?

2 A. That's right.

3 Q. Dr. Shmuylovich, you also offered an opinion on
4 enablement, right?

5 A. I did.

6 Q. And one of the -- you included analysis to the
7 Wands factors there, right?

8 A. Yes, I did.

9 Q. And one of those Wands factors is the amount of
10 direction provided by the patents and existence of working
11 examples, right?

12 A. Right.

13 Q. And we have just discussed what the specification
14 teaches about photodynamic diagnosis, right?

15 A. Not exactly.

16 Q. Well, we have just discussed all the parts of the
17 patent that you cite for support on written description,
18 right?

19 A. There are some terms that I describe in my
20 witness statement that you didn't include that support the
21 specification for photodynamic diagnosis, so I am having
22 trouble answering with a yes or a no.

23 Q. So you understand, sir, that you offered opinions
24 on written description, right?

25 A. Yes, I did.

1 Q. And the written description is about the support
2 in the specification for the invention, right?

3 A. That's right.

4 Q. And we just looked at all your demonstratives,
5 right?

6 A. We did.

7 Q. And there wasn't any demonstratives related to
8 written description that discussed time in the order of
9 milliseconds, right?

10 A. That's right.

11 Q. And there wasn't anything in there that discussed
12 time in terms of a nearly instantaneous process, right?

13 A. Right.

14 Q. And you would agree, Dr. Shmuylovich, that the
15 portions of the specification that you rely on are only
16 related to visible light, right?

17 A. Yeah. The patent describes light from 400 to 700
18 nanometers. And that's what many would consider visible
19 light.

20 Q. And you have put some of that in your
21 demonstratives, right?

22 A. Absolutely.

23 Q. And so if we look at CDX-16C, page 15, this tells
24 us that the invention relates generally to an adjustable
25 illuminator that provides a uniform distribution of visible

1 light, right?

2 A. That's right.

3 Q. And if we look at CDX-16C, page 17, on the left
4 part of the slide we see the same part I just read on
5 visible light, right?

6 A. Absolutely.

7 Q. And on the right side, there are more references
8 to visible light, right?

9 A. Yep.

10 Q. And there's no references to ultraviolet light,
11 right?

12 A. So this patent --

13 Q. That was a yes-or-no question.

14 A. I'm sorry. I was thinking out loud. I
15 apologize.

16 In the specification, they describe visible
17 light, you are right.

18 Q. And you would agree with me that the visible
19 spectrum is typically defined as wavelengths ranging from
20 400 nanometers to 700 nanometers in wavelength, right?

21 A. Yes.

22 Q. And, in fact, it's your testimony that a POSITA
23 would recognize that the claims are directed to photodynamic
24 diagnosis and treatment of skin conditions using light
25 within the visible spectrum, typically defined as

1 wavelengths ranging from approximately 400 nanometers to 700
2 nanometers, right?

3 A. Absolutely. I said it then and I will say it
4 now, totally agree.

5 Q. And the wavelength peak of a Wood's lamp is 365
6 nanometers, right?

7 A. The peak? Yes.

8 Q. Sir, you have cited several papers in connection
9 with your analysis of Wands, the state of the prior art,
10 right?

11 A. Yes.

12 Q. Let's look at CDX-16C.28, right? This is one of
13 the papers you relied on?

14 A. Yes, Fritsch, from 1998.

15 Q. And Fritsch, which is CX-342, uses a Wood's lamp
16 for a photodynamic diagnosis, right?

17 A. Almost.

18 Q. It was a yes-or-no question.

19 A. I am having trouble answering in light of the
20 prior question you asked me. Because as you can see, their
21 wavelength range is 370 to 405, not 365. So it highlights a
22 challenge in the literature around exactly what wavelengths
23 are used.

24 Q. I wasn't -- I asked you a question -- my question
25 to you, sir, was: Fritsch, which is CX-342, uses a Wood's

1 lamp for photodynamic diagnosis, right?

2 A. They call it a Wood's lamp, yes.

3 Q. And you also relied on a paper called Bologna,
4 right?

5 A. Bologna is a textbook. We call it the bible of
6 dermatology.

7 Q. Okay. And that was produced as CX-1084, right?

8 A. I believe so. I don't remember the exact number,
9 but I'm sure you're going to show it in a second.

10 Q. Well, let's look at Question and Answer 130. We
11 will make sure we get the cross-reference right. CX-13C,
12 page 36, Q/A 130.

13 A. Yep. That's right.

14 Q. And Bologna uses a Wood's lamp, right?

15 A. Um-hum.

16 Q. Let's look at CDX-16C, page 31.

17 A. Yep, Redondo.

18 Q. And Redondo, which is CX-1076, that uses a Wood's
19 lamp, right?

20 A. That's right.

21 Q. Now, is it your testimony that filters could be
22 used for visual detection of fluorescence?

23 A. Yes.

24 Q. But you would agree with me there's nothing in
25 the patent specification about filters for visual detection

1 of fluorescence, right?

2 A. Right.

3 Q. So, sir, even though the patents are directed to
4 diagnosis using visible light, all of the papers we just
5 discussed are relying on papers -- are relying on Wood's
6 lamps, right?

7 A. Yes.

8 Q. And the peak of illumination of a Wood's lamp is
9 at -- outside of the visible range, right?

10 A. As we saw, it depends. But typically, yes.

11 MR. LARIVÉE: I am going to move to strike that
12 answer.

13 MR. SHAW: Your Honor --

14 JUDGE MOORE: Yeah.

15 MR. SHAW: -- the witness is clearly indicating
16 it is not a yes-or-no question that can simply be answered
17 yes or no, which is part of what we've talked about. Like,
18 he's saying, "I can't answer that yes or no." So I don't
19 know what there is to strike. It's not a yes-or-no
20 question.

21 JUDGE MOORE: All right.

22 MR. LARIVÉE: I think the question was about the
23 peak.

24 JUDGE MOORE: Yes. Yeah. I am going to overrule
25 the objection, grant the motion to strike.

1 As we have said --

2 THE WITNESS: I apologize.

3 JUDGE MOORE: -- and I think the witness has
4 handled this well -- if you think that you can't answer yes
5 or no, let him know that you can't answer yes or no. I
6 think we're doing fine with that.

7 So go ahead.

8 BY MR. LARIVÉE:

9 Q. Sir, you will agree that one of the Wands factors
10 that you offered testimony on is the level of skill in the
11 art?

12 A. Yes.

13 Q. And you are offering it from the perspective of
14 someone who has been qualified as an expert under Judge
15 Moore's definition of a POSA, right?

16 A. That's right.

17 Q. Now, sir, you submitted an expert report in this
18 case, right?

19 A. I did.

20 Q. And that is RX-17C, right?

21 A. That's the rebuttal expert report, yes.

22 Q. And is that your signature on the front page?

23 A. Yes, it is.

24 Q. And in your expert report, you offered an opinion
25 on enablement and written description, right?

1 A. I think I do, yeah.

2 Q. And you offered the same opinion, that in your
3 view as one of -- as an expert in this case, that the claims
4 were enabled, right?

5 A. Right.

6 Q. And the specification provided adequate written
7 description, right?

8 A. Right.

9 Q. Now, when you wrote this expert report, you told
10 us that the report accurately reflects a summary of your
11 validity opinions and analysis in this investigation, right?

12 A. At the time, yeah.

13 Q. And you stated that if called to testify, you
14 would have the same opinions and analysis, right?

15 A. I think there was -- okay, sorry. I'm not sure I
16 can answer that with a yes or no.

17 Q. Well, let's -- it was a yes-or-no question.

18 A. I think there's a qualifying statement, so I am
19 not sure I can answer that with a yes or no.

20 Q. Let's see paragraph 5.

21 A. Right.

22 Q. Can we highlight the first sentence.

23 JUDGE MOORE: All right. I don't think we have a
24 pending question.

25 BY MR. LARIVÉE:

1 Q. And so my question was: You told us that the
2 report accurately reflects a summary of your validity
3 opinions and analysis in this -- pardon me.

4 This tells us that you stated that if called to
5 testify, you would have the same opinions and analysis,
6 right?

7 A. Of this investigation to date, yes.

8 Q. Now, if we can go back to CDX-16C.8.

9 We spoke about this a minute ago, right? And
10 this is -- this reflects that -- the photodynamic diagnosis
11 time of millisecond exposures, right?

12 A. That's right.

13 Q. And here, you're telling us that the main
14 difference between photodynamic diagnosis and photodynamic
15 therapy is the exposure time, right?

16 A. The mechanism by which they work, the main
17 difference is exposure time, yes.

18 Q. Now, Dr. Shmuylovich, you would agree that your
19 expert report in this case doesn't say anything about
20 milliseconds, right?

21 A. I don't recall using that term in my expert
22 report. I believe you're right.

23 Q. And your expert report also doesn't reference an
24 instant or nearly instantaneous exposure with respect to
25 photodynamic diagnosis, does it?

1 A. Correct.

2 Q. Now, in your witness statement, it's your
3 testimony that the main difference between PDT and PD is the
4 length of time that the treatment area is illuminated and
5 the effect that the light has on an agent, right?

6 A. Um-hum. Yes.

7 Q. And it's also your opinion that one of skill in
8 the art would have known that these claims were enabled,
9 right?

10 A. Yes, absolutely.

11 Q. Now, you, yourself, in your expert report didn't
12 talk at all about the main difference between PDT and PDT --
13 and PD being the length of time that the treatment area is
14 illuminated and the effect that the light has on the agent,
15 right? Strike that. Let me try and ask a better question.

16 Sir, you're an expert witness in this case?

17 A. That's right.

18 Q. And you were deposed -- you submitted your
19 rebuttal expert report.

20 Could we see page RX-17C, the cover.

21 You submitted your expert report in February,
22 right?

23 A. That's right.

24 MR. SHAW: Objection, Your Honor. The expert
25 reports are not in evidence. And I don't -- it seems like

1 counsel is trying to impeach Dr. Shmuylovich somehow, but he
2 hasn't asked the question. And he can't just put the expert
3 report up on the screen -- it's not in evidence -- and then
4 read portions of the expert report into the record.

5 MR. LARIVÉE: This isn't for impeachment. This
6 goes to the Wands factors.

7 JUDGE MOORE: All right. But we can't take
8 testimony from his expert report into the Wands factors. He
9 has to testify. This isn't -- this isn't in the record for
10 that purpose.

11 MR. LARIVÉE: Right.

12 BY MR. LARIVÉE:

13 Q. I guess my last question for you,
14 Dr. Shmuylovich, is that if this, as you say in your witness
15 statement, was easy for -- enabled for a person of ordinary
16 skill in the art, why were you unable at the time you issued
17 an expert report in February to speak about what is now the
18 main difference between PD and PDT?

19 A. Oh, sure. It's because I'm responding to -- I
20 realize that there was confusion on the side of
21 Dr. Ehrenreich about what is the mechanism of PD and PDT and
22 how they differ. It seems like there's a big difference
23 that Biofrontera is trying to claim about how these
24 mechanisms work.

25 And that is something that is so clear in the

1 literature for someone with my background, I didn't realize
2 it needed explaining. So to make that point clearer, I put
3 it into the report in response to the questions about what
4 is the difference between these things.

5 It's kind of central to my argument.

6 Q. Right. But as we discussed, there's nothing in
7 the asserted patents about millisecond exposure with respect
8 to the opinions you had offered on written description,
9 right?

10 A. It's just background. Everyone knows this.

11 MR. LARIVÉE: Move to strike as non-responsive.

12 JUDGE MOORE: Granted.

13 MR. LARIVÉE: No further questions at this time.

14 JUDGE MOORE: All right.

15 When you're ready.

16 MR. SHAW: Thank you, Your Honor.

17 REDIRECT EXAMINATION

18 BY MR. SHAW:

19 Q. Doctor, I want to pick up on that last question
20 you were just asked. So you said the fact that PDT requires
21 exposure on the order of milliseconds is just background,
22 right?

23 A. Yeah.

24 Q. Can you describe what you mean, please?

25 A. Absolutely. It's my understanding that when you

1 have a patent that you write, there is a certain amount of
2 information that people of ordinary skill know, and you
3 don't have to reteach every single aspect of kind of basic
4 science, basic principles.

5 When you are doing -- when you have a
6 photosensitizer light like PpIX, once you excite it into an
7 excited state, at the same time you generate these reactive
8 oxygen species, which is like a poison to the cell, and you
9 generate light. Both of those things are happening.

10 Now, if you just look, you -- at the light,
11 that's diagnosis. And the amount of time you need to do
12 that is very short. There are people who literally study it
13 at the nanosecond level. I mean, milliseconds is, you
14 know -- or microsecond level. So milliseconds is just to
15 indicate this is a short time span.

16 Now, some cells start to accumulate this toxin,
17 but they don't die instantly. They take time to accumulate.
18 That's why it's a longer time scale. But the process is the
19 exact same process. It's a high -- it's a chemical change.
20 And that's why I was -- when the specification -- when they
21 say "chemical change," that's kind of part of the idea of it
22 being instantaneous. Chemical changes can be very quick.
23 You go from a high-energy state to a low-energy state.

24 So, to me, I never would have imagined that that
25 was a point of question in forming my opinions, to try to

1 explain why I think that a person of ordinary skill would
2 understand that this device inherently is able to do
3 photodynamic diagnosis. Because, literally, you have to
4 turn it on, it generates blue light, and you see the
5 fluorescence.

6 Q. Now, Doctor, you were asked some questions on
7 cross in the context of your written description opinions
8 about whether there's a reference to milliseconds in the
9 patent. Do you recall that?

10 A. Right.

11 Q. And you were also asked whether there is a
12 reference to nearly instantaneous in the patent. Do you
13 recall that?

14 A. Right.

15 Q. Can we pull up the '512 patent, please, at column
16 9. And if we can zoom in on lines 15 through 31.

17 A. Yes.

18 Q. Now, Doctor, in lines 15 through 31, it talks
19 about a prescribed period. Do you see that?

20 A. I do.

21 Q. Would a person of ordinary skill at the time of
22 this patent have understood what was the prescribed period
23 for photodynamic diagnosis?

24 A. Absolutely. And --

25 MR. LARIVÉE: Objection, outside the scope.

1 MR. SHAW: Outside the --

2 JUDGE MOORE: Okay. They're conferring here.

3 Give me a little more information on the
4 objection.

5 MR. LARIVÉE: We -- the questions were about
6 whether millisecond exposure was listed in the
7 specification. And all of the examples here in column 9 are
8 on the orders of hours and minutes. And so if we're going
9 to -- if where counsel is going with this is something that
10 is far afield of that, it seems outside the scope.

11 JUDGE MOORE: Okay. I'm going to overrule the
12 objection. We're talking about a time period. We looked at
13 the specification and we talked about time periods.
14 Overruled.

15 MR. SHAW: Your Honor, can I check the realtime,
16 just to get the question that I was on?

17 JUDGE MOORE: Sure.

18 MR. SHAW: Thank you so much.

19 BY MR. SHAW:

20 Q. All right. So, Doctor, I had just asked you:
21 Would a person of ordinary skill in the art at the time of
22 this patent have understood what was the prescribed period
23 for photodynamic diagnosis?

24 A. Yeah. I mean, this is why -- and I apologize,
25 because it is my first time doing this. This is why I

1 struggled answering the question initially.

2 Q. So, Doctor, then what would have been the
3 prescribed period in the mind of a person of ordinary skill
4 in the art in 2015 for photodynamic diagnosis?

5 A. Again, you just know that it's a short time
6 period. And, you know, the hours and stuff, that's for
7 treatment. For diagnosis, it's a short time period,
8 milliseconds. That's all you need.

9 Q. Now, separately, if we can go down to lines 35
10 through 42 in column 9 of the '512 patent.

11 You see that section, Doctor, that starts "In
12 certain embodiments"?

13 A. Yes.

14 Q. Can you just tell us what's being described in
15 that section?

16 A. Yeah. This is a really cool idea. They're
17 basically saying that you can use blue light for a short
18 period of time, to illuminate the skin, and then after that,
19 use high-intensity red light.

20 And the idea here is that low-level blue light
21 will inactivate just the top layer of skin. Because what
22 you have to remember is blue light is very shallow in its
23 depth of penetration, because the melanin and other stuff
24 absorbs it really strongly. And the red light penetrates
25 deeper.

1 So if you get PpIX delivered and it's in all
2 layers of your skin, right, then if you want to deliver it
3 deep, the stuff at the top, it blocks -- it absorbs light.
4 You can't use it.

5 So the strategy to kill the cells that are deep
6 is to make the PpIX on top effectively inactivated. And you
7 do that by shining low-intensity blue light. And they talk
8 about that a little bit higher up in the specification, the
9 photobleaching idea. So it kind of points out, if you take
10 a long time and you photobleach the top layer, all of a
11 sudden the bottom layer becomes amenable to treatment.

12 It's a very clever idea. I haven't seen it done
13 in the real world, but it's a beautiful idea.

14 Q. Now, Doctor, switching gears a little bit, you
15 mentioned a second ago in the context of the time for PDD
16 that PDD and PDT have a similar mechanism.

17 A. That's right.

18 Q. Did you make a slide to illustrate that?

19 A. I did.

20 Q. And do you recall being asked about that slide
21 during your redirect -- or your cross-examination?

22 A. Yes.

23 MR. SHAW: Would Mr. Yoon like a copy? I am
24 happy to approach.

25 JUDGE MOORE: Yes, go ahead. Thank you.

1 MR. SHAW: Thank you.

2 Actually, Your Honor, may I have a brief recess?
3 We've got the wrong slide here. I apologize.

4 JUDGE MOORE: All right. We will go briefly off
5 the record.

6 (Discussion off the record.)

7 JUDGE MOORE: Back on the record. Go ahead.

8 BY MR. SHAW:

9 Q. So, Doctor, is this the slide that you were
10 referencing a second ago?

11 A. It is.

12 Q. And this is CDX-16C.8?

13 A. That's right.

14 Q. Now, Doctor, before we get into that slide, you
15 mentioned a moment ago Dr. Ehrenreich's opinion about
16 whether the asserted patents enable PDT. Can you just
17 remind me of what that is?

18 A. Yeah. It's my understanding that there's no
19 argument that the asserted patents do enable PDT.

20 Q. And how, if at all, does that affect your opinion
21 as to whether the asserted patents enable PDD?

22 A. Yeah, I mean, I guess because, as you see, they
23 are so related, all the concerns around why PDD is not
24 enabled seemingly are evaporated in their analysis of why
25 PDT is enabled. Like, do you need to do undue

1 experimentation? Well, you don't need it for PDT, so why
2 would you need it for PDD? Do you need to search for 3,000
3 or 6,000 different combinations? You don't have to do that
4 for PDT, so why would you have to do that for PDD?

5 Like, at every single part of the analysis, if
6 you accept that the written description is sufficient for
7 PDT, that it's sufficient for PDD. You don't need to find
8 100 different diagnoses. You know which ones to have. It
9 just doesn't make sense.

10 JUDGE MOORE: All right. I think in some of the
11 questions and whatever, we have been talking about PDD. Is
12 that --

13 MR. SHAW: Do you want me to clarify?

14 JUDGE MOORE: Yes.

15 MR. SHAW: Of course, Your Honor.

16 JUDGE MOORE: Just because --

17 MR. SHAW: I think I used a different term than
18 some other folks might. I apologize.

19 BY MR. SHAW:

20 Q. Dr. Shmuylovich, how do PD and PDD relate to each
21 other as terms?

22 A. I'm sorry. PD is photodiagnosis. PDD is
23 photodynamic diagnosis. It is the same thing. If there is
24 only D's, it's the diagnosis. If there is a T, then it's
25 therapy. So I apologize for using those terms. I'm sorry

1 about that.

2 JUDGE MOORE: It's fine.

3 BY MR. SHAW:

4 Q. So, Doctor, briefly, I want to just look at this
5 slide that you were asked about on cross. So in this slide,
6 where does the process for PD and PDT start?

7 A. It starts with a patient that you apply the
8 precursor to. And in this case, we're saying that could be
9 ALA.

10 Q. And, now, what happens after you apply the
11 precursor such as ALA to the patient in PD and PDT?

12 A. Well, over some time that precursor will be
13 absorbed. It will get into the cells, and it will
14 metabolize into PpIX. And it just so happens that when
15 cells are hyperproliferative, such as neoplastic cells, that
16 process is more efficient.

17 And that's kind of the trick. That's why you get
18 more PpIX in the cancerous cells than the background cells.
19 All of them have it, but you just get more in the neoplastic
20 cells.

21 So that's that second step.

22 Q. What happens next in PD and PDT?

23 A. So next, you apply light. And, you know, here,
24 the reason that I said "light" generally and not a specific
25 wavelength of light is I'm trying to give a general overview

1 of the mechanism.

2 Depending on which fluorophore you have, you know
3 which wavelength you need. Like with PpIX, we know that the
4 peak is at 405, and then there are some smaller bands, you
5 know, in the green and the red. But if you had another
6 fluorophore, it is pretty simple to either look up the
7 fluorescence peaks or just measure them.

8 And so that's why we put "light" here as a
9 general and not a specific. Deliver light. That energy
10 gets absorbed by the photosensitizer. The photosensitizer,
11 you can think about it getting, like, charged up into a
12 charged state. And then slowly -- and so then what you will
13 have is light coming out. That's the fluorescence. You
14 will have some reactive oxygen species coming out. That's
15 the poison.

16 And over time what happens is you run out of
17 juice. You run out of energy. You have energized -- as you
18 do this process, these photosensitizers get used up. That
19 is called photobleaching. So you run out of energy.

20 Q. Now, Doctor, from the excited state up here in
21 green at the top of your slide 8, you have got two arrows
22 labeled Relaxation. Why is that?

23 A. Right, because when you are an excited
24 photosensitizer, there's different things that can happen.
25 You can relax energy down back to the ground state and

1 result in fluorescence, or you can relax and generate
2 reactive oxygen species.

3 And, like, the details of that is a quantum
4 mechanics phenomenon. It's known, but it was too
5 complicated to put into this diagram.

6 Q. Now, Doctor, is there just one PpIX molecule in
7 the excited state there?

8 A. In this diagram, I only drew one.

9 Q. But in the real world?

10 A. In the real world, there's like millions.

11 Q. And so are you able to obtain fluorescence and
12 reactive oxygen species at the same time?

13 A. Absolutely. Like in physics we would think of
14 this as like an ensemble. This is one example, but imagine
15 there's a whole population of them. Some of them fluoresce;
16 some of them turn into ROS. And in that process you use up
17 the activated PpIX, and it undergoes a chemical breaking,
18 just like Dr. Foguet said. And eventually you run out of
19 active photosensitizer that can be activated.

20 Q. And how is the fluorescence used in this process?

21 A. The fluorescence, you can visualize it. So the
22 fluorescence -- and the specification says this. You can
23 locate the -- locate the neoplastic tissue. They use the
24 word "locate." You can see it. Sometimes by eye, depending
25 on the fluorophore; sometimes with a camera.

1 Q. Now, that brings us to sort of a side point,
2 Doctor, but you were asked about filters on
3 cross-examination. Do you recall that?

4 A. Yes.

5 Q. Do you need a filter to visually detect all
6 fluorescence?

7 A. No.

8 Q. Can you give an example?

9 A. Absolutely. All -- many of the examples that
10 Mr. Larivee pointed out in the literature that I showed.
11 The whole point of me showing that was you can visually see
12 it. It's a pink glow, even with a blue illumination.

13 Q. Now, back to your diagram in CDX-16C.8, Doctor.
14 This right relaxation arrow says "Reactive oxygen species."
15 What's happening there?

16 A. The reactive oxygen species? Yeah, so that's the
17 photosensitizers that are -- some of that excited state goes
18 back down to its ground state and, in the process, generates
19 these reactive oxygen species. As Dr. Ehrenreich said, you
20 have to have oxygen there. That's true. And then that
21 reactive oxygen species is like a toxin that goes into the
22 cell and destroys it.

23 Q. Doctor, were you the first one who recognized
24 this relationship between the procedure and mechanism for PD
25 and PDT?

1 A. I wish I was, but no.

2 Q. Are you aware of someone else who recognized it
3 before you?

4 A. Yes.

5 Q. Who?

6 A. Fritsch, the paper that I referenced, 1998.

7 Q. Now, Doctor, you recall you were also asked about
8 the Kulka reference on cross-examination, right?

9 You know what, Doctor, it's all right. We will
10 move on.

11 Now, Doctor, you were also asked a little bit
12 about Wood's lamp on cross, right?

13 A. Yes.

14 Q. What does a typical Wood's lamp look like?

15 A. It's a handheld device -- I have a picture of one
16 of them. It's a handheld device that has a magnifying glass
17 on the front. And if you -- that you're looking at. And
18 then if you looked on the other side, there would be two
19 little fluorescent bulbs.

20 Q. Now, what is the -- what wavelengths of light
21 does a typical Wood's lamp emit?

22 A. It's a very broad source. People always say it
23 is 365. And usually that is the center wavelength, but it
24 ranges from like 320 up into the visible, beyond 400.

25 Q. Now, have you seen any concrete examples that

1 speak to a Wood's lamp that emits light above 400 nanometers
2 in the visible spectrum?

3 A. Yes.

4 Q. So I am going to put on the document camera here
5 CDX-16C.28, which refers to the Fritsch reference, CX-0342.

6 Do you see that, Doctor?

7 A. I do.

8 Q. And you've got some excerpts here from the
9 Fritsch reference on this slide. Do you recall that?

10 A. Yes.

11 Q. In the top right part of this slide, you've got
12 some red underlining in that excerpt. What are you showing
13 with the red underlining?

14 A. Just reiterating what has been known at least
15 since 1998, which is that -- in this case, Your Honor, this
16 is the PDD terminology -- that if you have fluorescence of
17 porphyrins that are accumulating within tumor tissue, that
18 fluorescence is used to detect tumor tissue.

19 Q. In the bottom right portion of slide 28, what are
20 you showing in that excerpt?

21 A. There is a couple of steps that they describe in
22 there. One is applying the ALA. That's how you are able to
23 get enough -- that's how you are able to deliver that PpIX
24 accumulation into the tumor.

25 And then after waiting some time, it accumulates.

1 And then you shine -- in this case they say a Wood's light,
2 which they say is from 370 to 405 nanometers, extending into
3 the visible, in the blue, and that generates red
4 fluorescence.

5 Q. Now, on cross-examination, Doctor, one of the
6 things you said about Fritsch -- you were asked to confirm
7 that it's a Wood's light, and you said they called it that.

8 Do you recall that?

9 A. That's right.

10 Q. Why did you say that?

11 A. Again, I apologize for sounding defensive there.
12 It's just that sometimes in literature you see "Wood's
13 lamp," sometimes you see "Wood's light." And the exact
14 wavelengths are not exactly told to you all the time. So I
15 have seen, you know, Wood's lamps that -- where they don't
16 specify the wavelength at all, and so you kind of say, okay,
17 well, it's probably 365. But it is also well-known that
18 it's a broad peak.

19 And so it's just hard to know exactly what exact
20 wavelength you're dealing with when you see that term in the
21 literature.

22 MR. SHAW: Your Honor, can I have one minute to
23 confer with my co-counsel, please?

24 JUDGE MOORE: Sure.

25 MR. SHAW: Thank you very much.

1 All right. Apologies, Your Honor. Thank you. I
2 have nothing further for now.

3 JUDGE MOORE: All right.

4 MR. LARIVEE: Your Honor, I have two, maybe three
5 questions.

6 JUDGE MOORE: All right.

7 RECROSS-EXAMINATION

8 BY MR. LARIVEE:

9 Q. Dr. Shmuylovich, when you were speaking to
10 Mr. Shaw, you testified to the effect that the device is
11 inherently able to do photodynamic diagnosis because,
12 literally, you have to turn it on. Right? That was -- that
13 was about what you said?

14 A. That was about what I said, yeah.

15 Q. And it's also been your testimony that the
16 photodynamic diagnosis is done by exposing the area treated
17 with ALA for a matter of milliseconds, right?

18 A. It can be done that way, yeah.

19 Q. And so you would agree with me that it's not
20 simply a matter of turning the illuminator on, it's also a
21 matter of turning the illuminator off a matter of
22 milliseconds later, right?

23 A. No.

24 MR. LARIVEE: No further questions.

25 REDIRECT EXAMINATION

1 BY MR. SHAW:

2 Q. Doctor, why isn't it just a matter of turning the
3 illuminator off after a few milliseconds?

4 A. Okay, sorry. This is just -- let me clear up the
5 confusion here.

6 If the question is how long does it take for
7 fluorescence to develop, to be emitted, it's a matter of
8 milliseconds. But how long does it take to take a picture
9 or to look with your eyes? You can push the button and
10 look, and then you can turn it off when you're done. Or you
11 can push the button and take a picture and then turn it off
12 when you're done.

13 There is no, like, oh, my goodness, if I don't
14 cut it off within a millisecond, suddenly something bad will
15 happen. That's just not correct. So no, you don't have to
16 turn it off within a millisecond.

17 Q. So you are saying fluorescence appears within a
18 matter of milliseconds and then continues on?

19 A. And continues on. And as long as you are able to
20 do photodynamic therapy, you are seeing some fluorescence.
21 It fades over time, as everyone knows. That's the process
22 of photobleaching. But that takes a long time relative to
23 the treatment times. That's why treatment times are so
24 long. If you could treat someone within, like, a
25 millisecond, okay, great, but that's not what it is.

1 So fluorescence happens quickly. It persists.
2 It is on all the time. And it fades, just like your battery
3 in your phone fades over time. But that doesn't mean that
4 you have to turn it on for a millisecond and turn it off
5 right away. That's not how this works.

6 MR. SHAW: Nothing further, Your Honor.

7 JUDGE MOORE: All right.

8 MR. LARIVÉE: Nothing further, Your Honor.

9 JUDGE MOORE: All right. Someone was rising.
10 No? Okay.

11 We are at 4:31. So as is the normal course, the
12 parties should meet and confer about exhibits. If we have
13 any objections, we will deal with them in the morning. And
14 are there any other housekeeping issues? Starting with
15 Complainant.

16 MR. SHAW: Nothing from the Complainant, Your
17 Honor.

18 JUDGE MOORE: All right.

19 MR. LARIVÉE: Nothing from Respondents, Your
20 Honor.

21 JUDGE MOORE: All right. Okay. With that, we
22 are adjourned for the day.

23 And I didn't release you. You are released.

24 THE WITNESS: Thank you so much.

25 (The witness stood down.)

1 (Whereupon, at 4:32 p.m., the hearing recessed,
2 to reconvene at 9:00 a.m. on Thursday, July 3, 2025.)
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1	C O N T E N T S				
2					
3	WITNESS	DIRECT	CROSS	REDIRECT	RECROSS
4	MICHAEL EHRENREICH	489	510	537	548
5	JULIA ROWE	550			
6	MICHAEL EHRENREICH	597	602	650	662
7				665	
8	ROBERT GROVE	556	558	587	595
9	LEONID SHMUYLOVICH	667	671	697	712
10				712	
11					
12	AFTERNOON SESSION: 597				
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14	CONFIDENTIAL SESSIONS				
15	530 - 547				
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1	E X H I B I T S	
2	EXHIBIT NO:	RECEIVED
3	COMPLAINANTS	
4	CX-13C	670
5		
6	RESPONDENTS	
7	RX-0011C	510
8	RX-0008 and RX-0010	554
9	RX-006C	557
10	RX-007C	600
11		
12	EXHIBIT LISTS SUBMITTED FOR ADMISSION:	
13	CX-0012C	
14	CX-0016C	
15	CX-1307	
16	RX-0002C	
17	RX-0003C	
18	RX-0004C	
19	RX-0009C	
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1 CERTIFICATE OF REPORTER

2 TITLE: Certain Photodynamic Therapy Systems, Components
3 Thereof

4 INVESTIGATION NO: 337-TA-1411

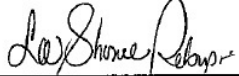
5 HEARING DATE: July 2, 2025

6 LOCATION: Courtroom B

7 NATURE OF HEARING: Evidentiary Hearing

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10 Date: July 2, 2025

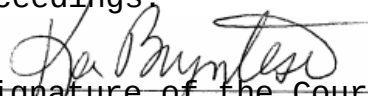
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