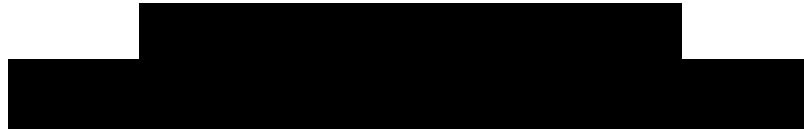




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Transcript of Mark Carota

Date: December 5, 2024

Case: Certain Photodynamic Therapy Systems & Pharmaceutical Products (337-TA-1411)

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WORLDWIDE COURT REPORTING & LITIGATION TECHNOLOGY

IPR2025-00287

Biofrontera Inc. et al v. Sun Pharmaceutical Industries, Inc.

Sun Pharmaceutical's Exhibit 2052

EX2052, Page 1

1 UNITED STATES INTERNATIONAL TRADE COMMISSION
2 WASHINGTON, DC
3 - - - - - x
4 In the Matter of :
5 :
6 CERTAIN PHOTODYNAMIC :
7 THERAPY SYSTEMS, : Investigation Number
8 COMPONENTS THEREOF, : 337-TA-1411
9 AND PHARMACEUTICAL :
10 PRODUCTS USED IN :
11 COMBINATION WITH THE :
12 SAME :
13 - - - - - x
14 [REDACTED]
15 [REDACTED]
16 Deposition of MARK CAROTA
17 Conducted at Wolf, Greenfield & Sacks
18 Thursday, December 5, 2024
19 10:35 a.m. EST
20 Job No.: 563515
21 Pages: 1 - 137
22 Reported By: Karen Klerekoper, CSR-4250, RPR

1 Deposition of MARK CAROTA, conducted at the
2 offices of:

3
4 Wolf, Greenfield & Sacks
5 600 Atlantic Avenue
6 Boston, MA 02210
7 617.646.8000

8
9
10
11 Pursuant to Subpoena, before John Gugarty,
12 Notary Public for the State of Massachusetts; and
13 Karen Klerekoper, Court Reporter, CSR-4250, RPR.

1 A P P E A R A N C E S

2 ON BEHALF OF SUN PHARMA:

3 BETTY CHEN, ESQUIRE

4 DESMARAIS

5 101 California Street, Suite 3070

6 San Francisco, California 94111

7 415.573.1905

8 ON BEHALF OF BIOFRONTERA:

9 CHAD A. LANDMON, ESQUIRE

10 TREVOR WAGNER, ESQUIRE

11 POL SINELLI

12 Franklin Tower

13 1401 I Street NW

14 Washington, DC 20005

15 202.783.3300

16 ON BEHALF OF THE WITNESS:

17 J. MARK DICKISON, ESQUIRE

18 LAWSON & WEITZEN

19 88 Black Falcon Avenue, Suite 345

20 Boston, Massachusetts 02210

21 617.439.4990

22

1 Q Do you know whose idea it was to obtain
2 patents on this?

3 A I'm not positive, no. I believe it was
4 Scott because he was in charge of intellectual
5 property at the company.

6 Q Do you recall any conversations you had
7 with him about obtaining patents on this?

8 A I don't recall specifics, but I know I
9 discussed it with him, more in general terms for
10 me.

11 Q What do you mean by that?

12 A Well, in general terms of applying for the
13 patents and so forth, and, you know, again, that
14 wasn't our main goal of what we were trying to
15 achieve, but it was certainly, as Scott reviewed
16 some of the technical documents in draft form that
17 were being developed, his job, I believe, was to
18 review some of those documents to determine if
19 there were patentable features within that device.

20 Q Did he ever tell you what he thought were
21 patentable features of the device?

22 A Yes, I'm sure he did.

1 Q Do you recall which features?

2 A I don't specifically. I know that
3 uniformity was a big one because that was --
4 that's the more difficult. It was one of the more
5 difficult challenges that we had.

6 It was also challenges in just achieving
7 the wavelength with LEDs because they weren't
8 readily available at the target that we wanted.

9 Q So how did you solve the uniformity
10 problem?

11 A A multitude of ways. It was done -- and
12 this is just my recollection -- through sizing,
13 spacing, electronic feedback, and the actual
14 mechanical design.

15 Q And who came up with the solutions?

16 A Oh, it was -- you know, to tell you who
17 came up with the final solution, I can't tell you
18 for sure, but I know it was derived by us because
19 we were really the only ones that -- we really
20 controlled the spec and how to judge it.

21 Q Did Continuum or Odic provide any of the
22 ideas that went into the solution?

1 A It didn't make any sense to me.

2 Q It was a long-winded question. Sorry
3 about that.

4 A That's okay. I'll try to give you an
5 answer.

6 Q In designing the product --

7 A Yes.

8 Q -- was it the general consensus that you
9 wanted to create an indentation on an inner side
10 surface of the panel to accommodate the hinge?

11 A I would have to dig into the drawings to
12 tell you that. Okay? But it's reasonable to
13 assume that.

14 Q And then if we look --

15 A The most difficult way to get uniformity
16 is at the hinges so, that's where the challenges
17 are. Where some of the challenges are. I
18 shouldn't say "everything," but that's one of
19 them.

20 Q And is that difficulty because of the gap
21 between the lights at the place where there is a
22 hinge?

1 A Yes.

2 Q So, is the idea that you want to get the
3 lights as close together as you can?

4 A Not necessarily. It's a combination of
5 density, power, angle, diffuser, the LED itself.
6 There is a lot a -- there is no simple, you know,
7 oh, just do this indentation. You suddenly
8 happens (as said). It doesn't work like that.

9 Q So, what was the purpose of having the
10 indentation to put the hinge in?

11 A I don't -- I can't tell you specifically,
12 but it was probably to aid in the hinge achieving
13 a mechanical gap that was acceptable from a
14 uniformity standpoint.

15 Q And if we look back to claim 1 that we
16 were talking about earlier, you see at the
17 beginning of the claim, it talks about a system
18 for photodynamically diagnosing or treating a
19 patient.

20 Do you see that?

21 A Yeah.

22 Q Do you know how one would photodynamically

1 you know, the stated goal was to have something
2 that could be a direct replacement without need
3 for clinical trials, if we could.

4 Q I'm going to hand you what's marked as
5 Exhibit 11.

6 (Marked for identification Exhibit 11,
7 U.S. patent application publication/Larson.)

8 Q If you want to turn to the second page,
9 you will see that this is a U.S. patent
10 application publication. The inventor is Larson.

11 Have you seen this before?

12 A No. What page do you want me on?

13 Q Just the first page for now.

14 A Okay.

15 Q And this is titled Photodynamic
16 Stimulation Device and Methods?

17 Do you see that?

18 A Um-hmm.

19 Q And if you look at the abstract, the first
20 sentence there, it's talking about photodynamic
21 therapy, right?

22 MS. CHEN: Objection, lacks foundation and

1 Q So, if you read those -- have you read
2 those two paragraphs?

3 A No. Did you want me to?

4 Q Yeah, if you can.

5 A Okay.

6 (Pause in the proceedings.)

7 A Okay.

8 Q And then if I can just get you to look at
9 what's figure 1, which is like the second page of
10 the patent.

11 A Okay. This one right here, the first one?

12 Q You can do that or the next one. They are
13 both pretty much the same --

14 A Okay.

15 Q -- at least in terms of the question I'm
16 going to ask you about.

17 So, you would agree that -- that Exhibit
18 11 discloses a device with five panels, right?

19 A Okay. So you're on this one right here,
20 right?

21 Q Yes.

22 A Is this where you are at? So "this" being

1 11?

2 Q Yes.

3 A Looks like it.

4 Q And those panels are connected by hinges?

5 A I can't really tell by this drawing, but I
6 would imagine they are.

7 Q So maybe we can turn to paragraph number
8 72; it's on page 152531.

9 A I'm sorry. Which one was that again?

10 Q Sure. So at the bottom, it's 152531, and
11 it's paragraph 72.

12 A Yep.

13 Q And that first sentence, it says: For the
14 treatment of large tissue areas according to
15 figure 1, several applicators are flexibly
16 connected to each other through hinges.

17 Do you see that?

18 A Yes.

19 Q And if you read all of paragraph 72, it
20 ends by saying that the panels can be positioned
21 so that the radiated surface -- sorry -- the
22 adjusted scan length and frequency gives the

1 radiated surface a total radiation of the
2 necessary wavelength without leaving any
3 un-radiated gaps.

4 Do you see that?

5 A Yeah.

6 Q So that's providing a uniformity of light,
7 right?

8 A Not necessarily.

9 Q Why not?

10 A It's saying it has un-radiated -- it says
11 that there weren't any gaps in the radiation. It
12 doesn't say it's uniform.

13 So the gaps in the radiation at the gap
14 lines, they could have barely anything. And in
15 the center of those panels, there could be, you
16 know, ten times that amount. I don't know.
17 Uniformity means uniformity of the skin.

18 Q At the treatment surface?

19 A Yeah. You are getting it from the light,
20 but it needs to be 2 to 4 inches on the skin. So
21 you need to be sure that you're irradiating that
22 properly, you know? And you get there by making

1 sure you have some uniformity in a lot of testing,
2 and so forth, you know, at the light source.

3 Q You can probably put that down for now.

4 So, changing subjects a little bit.

5 Did you participate in any -- any
6 presentations outside of the company about the new
7 design?

8 A I would say yes.

9 Q Okay. So, when were those?

10 A God, a couple of times, the salesforce,
11 sales meetings, just more to bring them up in
12 general of what we were doing.

13 Q And who were those presentations given to?

14 A The salesforce.

15 Q Were those employees of SUN?

16 A Yes.

17 Q Okay. Were you involved in any
18 presentations outside of SUN?

19 A Outside of SUN?

20 Q That involved people who weren't SUN
21 employees.

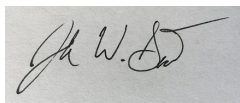
22 A The only thing I can think of is, if I had

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CERTIFICATE OF NOTARY PUBLIC

I, John Gugarty, Notary Public,
do hereby certify that the aforementioned witness
was sworn before me at the aforementioned location,
and that I am neither counsel for, related to, nor
employed by any of the parties to this case and
have no interest, financial or otherwise, in its
outcome.

IN WITNESS WHEREOF, I have hereunto set
my hand and affixed my notarial seal this 5th day,
of December, 2024.

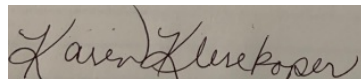


John Gugarty, Notary Public
for the State of Massachusetts

CERTIFICAT OF SHORTHAND REPORTER

I, Karen Klerekoper, the Court Reporter
before whom the foregoing proceedings were taken,
do hereby certify that the foregoing transcript is
a true and correct record of the proceedings; that
said proceedings were taken by me stenographically
and thereafter reduced to typewriting under my
supervision; that review was requested; and that I
am neither counsel for, related to, nor employed
by any of the parties to this case and have no
interest, financial or otherwise, in its outcome.

IN WITNESS WHEREOF, I have hereunto set my hand
and affixed my notarial seal this 12th day of
December 2024.



Karen Klerekoper