[redacted]

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

UNITED STATES INTERNATINAL TRADE COMMISSION

WASHINGTON, DC

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In the Matter of :

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CERTAIN PHOTODYNAMIC :

THERAPY SYSTEMS, : Investigation Number

COMPONENTS THEREOF, : 337-TA-1411

AND PHARMACEUTICAL :

PRODUCTS USED IN :

COMBINATION WITH THE :

SAME :

- - - - - - - - - - - - - x

[redacted]

Deposition of MARK CAROTA

Conducted at Wolf, Greenfield & Sacks

Thursday, December 5, 2024

10:35 a.m. EST

Job No.: 563515

Pages: 1 - 137

Reported By: Karen Klerekoper, CSR-4250, RPR

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

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

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

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

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

Q What do you mean by that?

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

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

A Yes, I'm sure he did.

Q Do you recall which features?

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

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

Q So how did you solve the uniformity problem?

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

Q And who came up with the solutions?

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

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

A It didn't make any sense to me.

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

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

Q In designing the product --

A Yes.

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

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

Q And then if we look --

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

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

A Yes.

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

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

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

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

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

Do you see that?

A Yeah.

Q Do you know how one would photodynamically

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

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

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

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

Have you seen this before?

A No. What page do you want me on?

Q Just the first page for now.

A Okay.

Q And this is titled Photodynamic Stimulation Device and Methods?

Do you see that?

A Um-hmm.

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

MS. CHEN: Objection, lacks foundation and

Q So, if you read those -- have you read those two paragraphs?
A No. Did you want me to?
Q Yeah, if you can.
A Okay.
(Pause in the proceedings.)
A Okay.
Q And then if I can just get you to look at what's figure 1, which is like the second page of the patent.
A Okay. This one right here, the first one?
Q You can do that or the next one. They are both pretty much the same --
A Okay.
Q -- at least in terms of the question I'm going to ask you about.
So, you would agree that -- that Exhibit 11 discloses a device with five panels, right?
A Okay. So you're on this one right here, right?
Q Yes.
A Is this where you are at? So "this" being

11?

Q Yes.

A Looks like it.

Q And those panels are connected by hinges?

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

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

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

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

A Yep.

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

Do you see that?

A Yes.

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

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

Do you see that?

A Yeah.

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

A Not necessarily.

Q Why not?

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

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

Q At the treatment surface?

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

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

Q You can probably put that down for now.

So, changing subjects a little bit.

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

A I would say yes.

Q Okay. So, when were those?

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

Q And who were those presentations given to?

A The salesforce.

Q Were those employees of SUN?

A Yes.

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

A Outside of SUN?

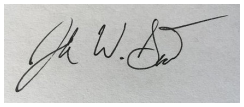
Q That involved people who weren't SUN employees.

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

CERTIFICATE OF NOTARY PUBLIC

I, John Gugarty, Notary Public, do hereby certify that the aforementioned witness was sworn before me at the aforemention 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.



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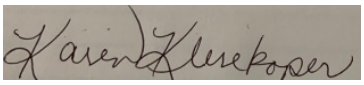
John Gugarty, Notary Public
for the State of Massachusetts

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.



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Karen Klerekoper