UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION AND EDWARDS LIFESCIENCES LLC,

Petitioners,

v. CASE NO. IPR2021-01527
IPR2021-01584
Aortic Innovations LLC, IPR2021-00034
IPR2021-00193
Patent Owner. Patent 10,792,172

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REMOTE ZOOM VIDEOCONFERENCE DEPOSITION OF EXPERT

NIGEL P. BULLER, M.D.

VOLUME 1

Washington, D.C.

June 16, 2022

7:40 a.m. - 2:07 p.m.

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DEPOSITION OF NIGEL P. BULLER, M.D.

June 16, 2022

THE REPORTER: Hello. My name is Marceline Noble, a California certified shorthand reporter, and this deposition is being held via videoconferencing equipment.

The witness and the court reporter are not in the same room.

The witness will be sworn in remotely.

NIGEL P. BULLER, M.D.,

having been first duly sworn, testifies as follows:

THE REPORTER: Thank you.

MR. LOWENSTEIN: Madam Court Reporter, may I begin?

THE REPORTER: Yes.

EXAMINATION

BY MR. LOWENSTEIN:

Q. Good morning, Dr. Buller. How are you?

A. Good morning. I'm well.

Q. I trust your travel to D.C. was well?

A. Yes.

Q. And this is not your first deposition, is it?
A. It's not.
Q. How many times have you been deposed?
A. I think a large number. More than 50.
Q. That sounds terrible.
When was your last deposition?
A. Well --
Q. Roughly, I don't need to know precisely.
A. Three years ago. I haven't traveled or done a deposition in the last -- at least two and a half years since COVID began.
This is my first time in the States in the last two and a half years.
Q. I trust it will be just like riding a bicycle and it will come back to you very quickly. Let's try not to speak over one another and that will allow for a more clear transcript.
What -- can I use the term "TAVR"? Do you know what that term refers to?
A. Sorry. What term?
Q. TAVR?
A. No, I don't know the term.
Q. You've never heard the term "TAVR"?
A. Oh. Yeah, I'm sorry. I think it's your accent.
As in T-A-V-R. As in the technology we're

talking about.

Q. I wish to clarify that.

On this point, you have the accent, sir. But fair enough.

Okay. Now, when was the first TAVR delivered endovascularly, to your understanding?

This phrase will probably come up -- endovascularly? Now, just -- Madam Court Reporter, I'm going to use the phrase "TAVR" a lot, the word "TAVR" a lot. That's capital T-A-V-R. Okay.

So why don't I ask the question again, Dr. Buller.

Dr. Buller, to your understanding, when was the first TAVR delivered endovascularly?

A. I might clarify. Are you talking about clinically in a patient or are you talking about in an animal?

Q. In a patient.

A. 2002 by Alain Cribier and friends.

THE REPORTER: (Clarification.)

MR. LOWENSTEIN: A-l-a-i-n, C-r-i-b-i-e-r, and friends.

Q. And was Dr. Cribier with an organization called PVT?

A. He was one of the founders of PVT. But this was

being done as a clinical procedure in the city of Rouen.

THE REPORTER: (Clarification.)

MR. LOWENSTEIN: I think, Madam Court Reporter, could it be possible for during breaks, because I can't have a colloquy --

(Off record discussion.)

BY MR. LOWENSTEIN:

Q. Dr. Buller, I believe she's asking you how to spell Rouen.

A. Just in France. If we could just change it to in France, that will satisfy everybody. I will try and --

Q. Very good. I can't spell that.

Okay. So what was PVT's business?

A. The name PVT stands for Percutaneous Valve Technologies, and it was exactly that. They were a company that was founded by four individuals, one of which was Alain Cribier, to develop percutaneous valve technology.

Q. And was -- were TAVRs seen as a revolutionary device in that time frame, 2002?

A. Yes. I don't know the term's even used, that TAVR. That came about later, I believe.

But I mean the concept of delivering a heart valve by vascular (sic) means, not by conventional surgery, was revolutionary, yes, for the majority of

people.

Perhaps not to Alain Cribier, but to the majority of the medical community it was revolutionary.

Q. And you sometimes see the acronym TAVI.

Have you seen that, sir?

A. Yes. I have.

Q. And do you understand TAVI and TAVR to be more or less interchangeable?

A. Yes.

Q. Okay. And did Edwards acquire PVT?

A. Yes. I believe they did. I can't remember the year, but after -- after the first implants developed by Cribier, then there came a time when Edwards acquired PVT.

Q. I believe that acquisition occurred in late 2003 or early 2004. Is that consistent with your understanding?

A. I'll -- I'll take your word for it. I don't have the dates off the tip of my --

Q. And what was the acquisition price, to your recollection?

A. No, I don't (sic).

Q. And do you have any understanding as to whether Edwards considered it to be a good acquisition or not?

A. I have no -- I have no knowledge of the internal

thinking of the acquisition and I don't -- I just can't answer that question.

I don't know.

Q. Now, did -- was Edwards seen as an industry leader in valve technology prior to that acquisition?

A. I believe so.

Q. And Edwards was, prior to that acquisition, developing intellectual property of its own relating to TAVRs; is that correct?

A. I believe that is the case, but I have no internal knowledge of -- of Edwards and what they were doing in that field at that time.

Q. Do you have any understanding of why Edwards saw fit to acquire PVT?

A. No, because that would be known to Edwards. I just have no internal knowledge. I was not part of Edwards and, therefore, that would be something I wouldn't know.

Q. You've represented Edwards in many litigations, is that fair to say?

A. Yes.

Q. And have you had an opportunity to speak to people at Edwards?

A. I've spoken to many people at Edwards over many years, yes.

Q. Do you have an understanding whether PVT was ahead of Edwards at the time of the acquisition in terms of developing TAVRs?

MR. SUMMERS: Objection. Vague.

THE WITNESS: I don't really know. I can answer that.

I mean, I would guess because they acquired them or wanted them, but in some sense is they must have been or it could have been for its intellectual property or know-how.

I don't have an internal knowledge of Edwards as to what their decision making was, but I think it's fair to suppose that there were clearly things they wanted. But exactly what those things were, I don't know.

MR. LOWENSTEIN: Mr. Summers, that objection was improper. You can object to the form. But you are not allowed to object as vague.

So, do you understand?

MR. SUMMERS: Okay. So we're going to have --

MR. LOWENSTEIN: I'm just suggesting a question. You can object to form under the rules. I can show you the rules if you like. You can't object as vague.

MR. SUMMERS: Yes. That's fine. Okay.

BY MR. LOWENSTEIN:

Q. Now, SAPIEN, you're familiar with the SAPIEN device?

A. Yes.

Q. And the SAPIEN device was released in Europe in 200- -- it got a CE mark in Europe in 2007; is that correct?

A. I believe that's true.

Q. And the SAPIEN was delivered via 22 Fr. or 24 Fr. delivery system; is that correct?

A. Yes. Or transapically.

Q. Can you describe transapically for implanting a TAVR?

A. It's a transapical procedure where a small incision is made in the chest between the ribs to expose the apex of the heart.

The apex of the heart is penetrated so you have access into the left ventricle and you could use that route going through the apex of the heart rather than the ventricle to replace the aortic valve.

Q. And a transapical procedure, that's a surgery; correct?

A. Yes. It's often combined with an interventional cardiologist I think I said.

Q. Is a transapical procedure considered to be an open-heart surgery?

A. No. It's different from open-heart surgery. Conventional aortic valve replacement by open-heart surgery would be open the chest, splitting the sternum, opening the whole chest, putting the patient on bypass, replacing -- removing the diseased valve and replacing it with a surgical replacement valve.

That would be conventional open-heart surgery.

But mostly normal in 2002 when Alain Cribier first did a TAVR procedure.

Q. Now, the -- going back to transapical. That requires a surgery; correct?

A. Yes.

Q. An interventional cardiologist who is not a surgeon cannot perform a transapical procedure; correct?

A. Well, they may be able to. There are people that are sort of skilled -- qualified, but it requires an incision in the chest and then the procedure to be put in.

But I wouldn't like to say that no interventional cardiologist was --

Q. I think you may have misheard my question. Let me ask it again.

An interventional cardiologist who is not a

surgeon cannot perform a transapical procedure; is that correct?

A. I think that's correct.

Q. Now, I'll ask the equal, the transfemoral implantation of a TAVR is less invasive than a transapical procedure; is that correct?

A. Yes.

Q. And why is that?

A. Because it is done remotely, you're not opening the chest at all. It's done at the top of the leg via the femoral artery and sometimes that can be done with a tiny incision and a needle puncture of the artery.

Q. How deep is -- were the devices, the access point? How deep in the body is that?

A. Well, an incision is made in the skin, a small incision, then a needle is put through and down. It depends very much on the patient's build and how much tissue they have, but a couple of centimeters down to the -- the femoral artery.

Q. And an interventional cardiologist is able to perform that procedure?

A. Oh, yes.

Q. You don't need to be a surgeon, in other words?

A. No.

Q. Can you perform a transfemoral procedure with

local anesthesia?

A. Yes.

Q. You don't need general anesthesia, in other words?

A. You don't. On occasions you will because of a particular circumstance, but you don't have to do a transfemoral procedure.

Q. Do you agree that 24 Fr. is the widest diameter for the surgeon via the transfemoral artery?

A. It's not necessary, but that's a -- that's a good average for the largest of people. There will be the sort of opposite of a very large person that's larger, the 24 Fr. equates to 8 millimeters, and that's sort of upper limit or towards the upper limit of the size of the femoral artery.

Q. And, in fact, it was desirable to reduce the French size, the delivery system even via the transfemoral route; is that correct?

A. It was certainly desirable. I mean interventional cardiologists were very used to doing procedures from the femoral artery and therefore it was desirable to make the procedure so that it could be done from the femoral artery and, therefore, it was nice to get things down to a sort of size that could be images through the femoral artery, at least in a significant

proportion of patients.

Q. Now, do you agree that the first SAPIEN introduced in 2007 in Europe and I believe 2011 in the United States, if memory serves, do you agree that that was a landmark milestone?

A. I'm not exactly sure what you're asking. I wouldn't call the approval as being a landmark.

The actual device and the work done and the data was certainly a very big landmark.

The approval, I think, was sort of a natural part of that and came about in 2007 in Europe and certainly an achievement for the company, but I think it was expected that it would be approved because the data was looking very good.

Q. I said "landmark milestone."

Would you agree that the approval of the SAPIEN for transfemoral only in 2011 was an important milestone?

A. Yes.

Q. Why was it an important milestone?

A. Because then physicians had access to it without having to be part of the clinical trials and clinical program. It meant that it was now on the market to be used so physicians who wanted to -- to start implanting these devices to treat their patients were then able to

embark on training and get their hands on the device and treat their patients.

Q. Now, in -- I apologize. I think I've already asked this, but just to confirm, the SAPIEN was approved out of 22 Fr. or 24 Fr. delivery diameter; is that correct?

A. From memory, I think that's right. I need to see the approval to be sure. I don't know whether it was specified those sizes, but when it was approved it was being used as one or two, 24 Fr, but I can't remember the actual approval.

Q. And we can all agree that to go from French to millimeters, you just divide the French number by three; is that correct?

A. Yes. So 24 Fr. is 8 millimeters.

Q. But it was still desirable to reduce the French size even further via the transfemoral route; is that correct?

A. Yes. I mean within limits. There's a generalization "the smaller, the better." It makes the procedure easier, applicable to a larger number of people because not everybody's femoral artery is 8 millimeters. Small people and people with disease will have smaller arteries and, therefore, as a general statement the smaller you can make these devices, all

other things being equal, the better.

Q. And are you familiar with the SAPIEN XT device?

A. Yes.

MR. LOWENSTEIN: And for the court reporter's benefit, that's SAPIEN as we used before and the next word is capital X, capital T.

THE REPORTER: Thank you.

BY MR. LOWENSTEIN:

Q. Now, the principal improvement in the SAPIEN XT as compared to the SAPIEN was at a narrower crimp profile; is that correct?

A. One of the improvements, yes.

Q. You don't think that was the most significant one?

A. I'm not saying it's the most significant one, but it was one of the improvements.

Q. They also changed the metal used in the frames to a cobalt chromium; is that correct?

A. Yeah, that was part of how they got to smaller with cobalt chromium could be thinner struts and still have similar strength and, therefore, they were able to make the struts by changing the metal to cobalt chromium.

Q. And the reason Edwards switched to cobalt chromium was in order to reduce the size of the metal

frame; is that correct?

A. That's my understanding.

Q. And that change allowed the SAPIEN XT to be delivered transfemorally at a 16 or 18 Fr. diameter; is that correct?

A. Yes. At a smaller diameter than the preceding SAPIEN, yes.

Q. Now, can we agree -- going back to the SAPIEN -- the SAPIEN did not have any outer cloth; correct?

A. The SAPIEN did not have any outer cloth; correct.

Q. And we've used different terms. We've seen outer cloth, outer cuff, outer skirt.

The SAPIEN did not have any of those, is that fair to say?

A. That's fair.

Q. And the SAPIEN XT did not have an outer cloth, correct?

A. That's correct.

Q. The SAPIEN XT did not have -- and now I'll list the same things -- an outer cloth, an outer skirt, a fabric cuff or anything else on the outside of the frame; is that correct?

A. No. You can't say that. It had a -- I'm agreeing with what you said in terms of cloth and skirt and those things, but it obviously had sutures to the

extent to the outside of the frame. If you look at it, you can see lots of sutures coming around the back.

And there were sutures on the outside as indeed there were on SAPIEN, but there was no cloth.

Q. That's a perfectly fair clarification. Let me just reask the appropriate question so I can get a clean answer, although I think I understand what you're saying.

So the question is, we can agree that the SAPIEN XT did not have an outer cloth or a fabric cuff or skirt; correct?

A. Correct.

Q. Now, the first approved Edwards SAPIEN device that had an outer skirt was the SAPIEN 3; is that correct?

A. I think that's correct.

Q. And that approval came in 2015. Am I remembering correctly?

A. I'll take your word for it. I don't have the date in front of me. I don't have it in the front of my mind, but that sounds about right.

Q. And the outer skirt for the SAPIEN 3 was intended to address perivalvular leakage; is that correct?

A. Yes.

Q. Now, for everyone's sanity, can I use the acronym

"PVL" to refer to perivalvular leakage?

A. That's fine.

Q. Okay. It was known --

When was it first known that an outer seal could address perivalvular leakage?

MR. SUMMERS: Objection. Form.

MR. LOWENSTEIN: I'll ask a new question.

Q. When was it known that an outer seal could address PVL in the context of TAVRs?

MR. SUMMERS: Objection. Form.

THE WITNESS: Very early on.

There were teachings from Cribier -- who we talked about previously, the same man Cribier -- of using outer covering on stents to -- to address PVL. There were many teachings. I think conceptually the idea that something on the outside would be useful was known from early on in the '90s.

BY MR. LOWENSTEIN:

Q. So it was known in the '90s that an outer seal would address PVL, but Edwards did not introduce to the public a device with an outer seal used for TAVRs until the SAPIEN 3; is that correct?

A. A commercial, I -- I'm just not sure what you mean by "introduced to the public." These devices obviously are sold to the medical profession to be

licensed. They didn't introduce a commercial device with a covering on the outside until the SAPIEN 3.

Q. Can we agree that PVL is a matter of life and -- excuse me.

New question. Can we agree that PVL is a matter of life and death?

A. It can be. It's not always. I mean, there are degrees of PVL which are trivial and not -- I mean PVL, the larger it is, the more important it is, and we learned more about it as time went on. It wasn't known it was going to be as important as it was very early on in the development of TAVR.

Q. Can we agree that a narrow crimp profile can be a matter of life and death?

A. Can be. Again, that's taking -- it isn't always.

Some people have relatively large arteries, the reason to get into. Some people have disease and it tends to be very difficult if you're treating through very diseased, narrow arteries.

THE REPORTER: (Clarification.)

MR. SUMMERS: Narrow arteries.

Let's let the witness testify.

BY MR. LOWENSTEIN:

Q. Please. Go ahead, sir.

A. That was correct.

Q. Did you finish your answer?

A. Yes.

Q. You agree that certain patients are unable to get an AVR (sic) implanted through an open-heart surgery; correct?

A. There is a group of patients that just are not suitable to even consider for open-heart surgery, that is correct.

Q. And is it fair to say that there's a group of patients for whom a transapical implantation of a TAVR would be inappropriate?

A. Yes. As -- I mean, you can -- it's worth saying that there are individual patients that you can come up with almost everything. There is no medical treatment I know of that is suitable for everybody. So it is, of course, the case that there are always individuals for one reason or another, they are not suitable for any treatment that you care to mention.

Q. Now, Edwards said in its press release in November 2nd, 2011, in connection with the SAPIEN being approved for transfemoral delivery, it said "This" -- "this" being the SAPIEN, I'm quoting.

Quote, "This is the first U.S. commercial approval for a transcatheter device enabling aortic valve replacement without the need for open-heart

surgery," closed quote.

Is that a true statement? Or was that a true statement?

A. I don't recall the document as I'm sitting here and you're reading from it. I mean, I think you're reading it correctly and everything, then yes, I take that to be that's what it said.

Q. I'm not asking whether that's what it said. I'm asking whether it's true?

A. It sounds like a reasonable statement, but I haven't seen the document. If you can share the document and I can have a minute to think about it. But you reading it to me like that, it sounds certainly a reasonable thing for Edwards to have said.

Q. Let me ask you this. If Edwards Lifesciences says something to the public in a press release, do you have any reason to believe it's not true?

A. Well, I would look at anything and as you're asking me to do, but now I've got no reason -- I don't believe they would -- would deliberately lie or confuse people when they're putting out a press statement.

I think they would be very careful to make sure what they were saying was reasonable and accurate.

Q. You have exhibits.

Do you have Exhibit 1032 available to you?

A. I don't think I do. I have a limited number of exhibits in my file. But I will have a look. I don't think I have a full set of exhibits here.

Q. My colleague, Mr. Hsieh, can share with us and perhaps you can share your screen.

MR. HSIEH: Share my screen or send it to him?

MR. LOWENSTEIN: Do both.

MR. HSIEH: You should receive that exhibit over chat.

BY MR. LOWENSTEIN:

Q. Dr. Buller, do you see in the chat function?

A. I do. But I don't know how to get it.

MR. SUMMERS: See Exhibit 1032.

THE WITNESS: I do. But how do I --

MR. SUMMERS: Double click on it.

It opens this box.

By MR. LOWENSTEIN:

Q. I think you meant to say it --

A. I could save it now.

Okay. I've got it in front of me. But I've lost you. What I'll try to do is move it to my other screen if I can.

MR. LOWENSTEIN: Can you go to the first paragraph.

Q. Okay. So we're looking at Exhibit 10232 on a share screen.

A. Yes.

Q. You have the document in front of you as well.

MR. SUMMERS: Maybe I can stop you for a second because the witness has opened his copy and he's not looking at the share screen right now.

I think you want him to look at the share screen; correct?

MR. LOWENSTEIN: Provided that's okay with you guys. We've sent you a copy so you can confirm, but if it's okay with you, I suggest we all look at the share screen.

MR. SUMMERS: Okay. Let's close that.

THE WITNESS: I've lost the --

BY MR. LOWENSTEIN:

Q. Dr. Buller, are you able to see the share screen?

A. Yes. I think I may have just got it.

Yes. Yes.

Q. Very good.

Why don't you just start reading the first paragraph and let me know when you're done.

A. To myself?

Q. Yes. Please. You don't need to read it out loud. Read it to yourself.

A. Yes, I've read it.

Q. We can see that the press release is a November 2nd, 2011, announcement that Edwards has received approval from the FDA for the transfemoral delivery of the Edwards SAPIEN transcatheter; is that correct?

A. Yes.

Q. And we see in the last sentence of the first paragraph, it reads, quote, "This is the first U.S. commercial approval for a transcatheter device enabling aortic valve replacement without the need for open-heart surgery," closed quote.

Do you see that?

A. Yes.

Q. Do you believe that sentence is true?

A. Yes.

Q. And let's go to the third paragraph. This is a quote from Michael A. Mussallem, M-u-s-s-a-l-l-e-m, Edwards' chairman and CEO. And he says, quote, "This day marks an important milestone for inoperable patients (sic) that have long been awaiting a therapeutic solution for the often debilitating symptoms associated with severe aortic stenosis," closed quote.

Do you see that statement, sir?

Do you believe that reason to be true?

A. I have no reason to doubt.

MR. SUMMERS: You misread that. It was "American patients" and you said "patients." I just want the record clear.

MR. LOWENSTEIN: All right. My apologies.

Q. Did Edwards ever seek approval from the FDA to deliver any SAPIEN device via the common iliac?

A. I don't know.

Q. Did Edwards ever seek approval anywhere in the world to deliver any SAPIEN device via the common iliac?

A. I don't know.

Q. Can we agree that any endovascular procedure via the common iliac would be a far more invasive procedure than via the transfemoral?

A. No. It's the most -- it is more invasive, absolutely. It's through an artery which is further up towards the heart but way less invasive. So if a patient couldn't have a device via the femoral artery but could have one via the common iliac artery and thereby would avoid conventional open-heart surgery, it would be well worthwhile.

Q. Okay. You may have misheard my question because I wasn't asking for a comparison of the common -- you pronounced it iliac. I was (sic) asking for a comparison between a common iliac open-heart surgery. I

was asking about a comparison between common iliac and femoral bridge.

So let me ask the question again having clarified.

You agree that endovascular implanting a TAVR via the common iliac would be a far more invasive procedure than via the femoral artery; is that correct?

A. I wouldn't use the "far more." It would be more invasive, yes. But it would, as I've said, it would be much less than open-heart surgery.

Q. How deep of an incision would need to be made to access the common iliac artery?

A. A couple of inches.

Q. Are you sure about that?

A. Yeah.

Q. It couldn't possibly be 10 centimeters though, could it?

A. Well, you can make an incision, but it could be 10 centimeters, that would be four inches, roughly speaking, but it would be a couple of inches incision to access the common iliac artery.

Q. Have you ever implanted any stent where you obtained access via common iliac?

A. Stent, yes. Stent graft, yes.

Q. What kind of stent?

A. A -- an aortic stent graft.
Q. And you entered through the common iliac?
A. Yes, a surgeon. I mean was doing the procedure as the surgeon. I didn't do the entry and I also used larger interventional devices which were run in by the common iliac artery.
Q. What type of procedure was that?
A. To put in a device early predecessor of the hemopump, which is a vascular support. It's not a permanent device like a stent or a graft or a TAVR. It's a device that goes in to help pump blood around the body.
Q. When did you do that?
A. Back in the late '80s.
Q. How many times did you implant a stent via the common iliac?
A. Only a few. Only a handful.
Q. And what were the circumstances suggesting that would be appropriate?
A. A larger device wouldn't fit through the femoral artery in patients being treated, so it needed to go into a far larger access artery.
Q. And I think you said this in your last answer, but I just want to make sure it's clear, you agree that you wouldn't be a surgeon to access the common iliac; is

that correct?

A. Ideally, yes. And if you're going to connect a conduit to the common iliac, then yes, you would want a vascular surgeon to do that part of the procedure.

Q. Are you familiar with the Kainuma reference?

A. It rings a bell, but you'd have to show me. I can't bring it to my mind's eye. I think I remember the name.

MR. LOWENSTEIN: Ed, can you usher (sic) -- kind enough both as before --

MR. HSIEH: In the chat?

MR. LOWENSTEIN: Yes. So this is exhibit --

THE WITNESS: Sorry. I didn't mean to speak over you. That's the iliac artery, common iliac artery access article I relied on. Is that the one you're talking about?

BY MR. LOWENSTEIN:

Q. Yes. It's Exhibit 1043.

A. I don't have it in front of me. If you would share it.

Q. Yes. Mr. Hsieh just shared it via the chat, but he's also going to share the screen as well if you would -- so -- if it's okay with you, you're welcome to note --

A. Shared on screen worked very well last time.

Q. Very well. Okay. Let's go to page 3. Okay. Let's go to paragraph starting under "General Anesthesia."

And I'm going to ask you a question about the third sentence, but if you want to read it, then I'll ask the question. Just let me know when you're done.

A. Okay. I've read down to the third sentence.

Q. Okay. And so you agree that a 22 Fr. arterial sheath was used in Kainuma to a -- a -- can we go back to page 3, please.

A. (Witness complies.)

Q. Okay. So we're -- again, we're looking at the paragraph starting under "General Anesthesia." I'm asking about the third sentence starting "Because of the relatively narrow external iliac arteries..."

A. Yes.

Q. We see that a 22 Fr. arterial sheath was used for this procedure; is that correct?

A. That's what it says, yes.

Q. And that's approximately seven and a third millimeters?

A. Yes.

Q. Is there any suggestion in Kainuma that a larger French size would be appropriate?

A. I assume reading it required what they're

doing -- what they were trying to do in Japan, that they -- they needed a 22 Fr. and that's what they used, a 22 Fr. But --

Q. I understand that. But my question is, is there any suggestion in Kainuma that a larger French size would be appropriate?

A. Not -- not that I have seen. Not that I could see on the page you're showing me.

Q. I'm asking about the entire reference.

A. Not that I remember.

Q. I want to go to page 4 now.

And let's look at the paragraph starting with "We consider." Let's look at that first paragraph. "We consider trans" -- quote.

I'm reading from page 4, Kainuma, quote, "We consider transfemoral access as the technique of choice because it is less invasive than the transapical approach, which necessitates surgical thoracotomy."

Do you see that, sir?

A. Yes.

Q. So Kainuma considers transfemoral access to be the technique of first choice; is that fair to say?

A. Technique of choice because it's less invasive than transapical approach.

Q. And that's a reasonable medical opinion; is that

correct?

A. Entirely.

Q. Now, let's look at the last incomplete sentence in that column. You see it says, quote, "To accomplish transfemoral TAVI using a 22 Fr. arterial sheath, adequate peripheral vessels are required on one side at the level of the common femoral artery and above, without significant untreated aneurysmal disease or excessive calcification."

Do you see that, sir?

A. Yes.

Q. So is it fair to say that the same sheath, same 22 Fr. sheath is identified for access both via the femoral artery and the common iliac artery?

A. Yes. It's the 22 Fr. sheath is required to deliver the valve they want to deliver. That's what determines the size.

Q. I'm not sure you quite answered my question.

A. I apologize.

Q. Let me -- let me ask it again.

In Kainuma, the same 22 Fr. arterial sheath is recommended for both transfemoral route and the common iliac route; is that fair to say?

A. No, I wouldn't say "recommended." It's the size sheath they needed to deliver the size valve they were

delivering.

Q. Let me ask a less opinionated question.

You would agree that in Kainuma, the very same 22 Fr. arterial sheath is identified for use in both the common iliac route and the femoral route; is that fair to say?

A. Yes. It's what they required.

Q. Do you believe prior to the SAPIEN device, there was a long-term need in the industry for a -- I asked prior to the SAPIEN device, was there a long-felt need in the industry for an aortic valve replacement that would not require open-heart surgery?

And I believe the answer was yes?

A. Correct.

Q. Why was that?

A. Because we didn't have such a device. And because we were all aware of patients that would benefit from the device. We had a population of patients who just weren't thin enough or had other medical conditions that prevented them from undergoing conventional open-heart surgery and, therefore, we felt a real need to have a device that could be used in a less invasive procedure for a TAVR procedure.

Q. Can an inner frame be a graft covering?

A. I couldn't hear that. Sorry. You went away from

the microphone and I didn't hear the question.

Q. Let me reask. Can an inner frame be a graft covering?

A. That is a position that you have taken in prosecution and, therefore, I have used that position in my analysis of prior art. I don't have an opinion on whether it can.

I do have an opinion on that's what you have said constitutes in a frame and, therefore, I've used it in my analysis of the prior art.

Q. So I think what you said is you have no opinion one way or the other on whether an inner frame can be a graft covering; is that correct?

A. I haven't had to go to that full process. I have been aware of the file history that you and AI took the position that in a frame can be a graft covering and therefore I have used that position in my analysis.

Q. So in your expert opinion, you can't state whether it is more likely than not that an inner frame can be a graft covering; is that correct?

A. I haven't considered that question.

Q. You haven't considered the question one way or the other whether it is more likely than not that an inner frame can be a graft covering, correct?

A. Correct. I haven't considered the question

because I am aware that's the position AI took and therefore have used the position that AI took for my analysis.

Q. But you don't have any opinion on whether AI's -- I think you meant Aortic Innovations, correct?

A. Yes.

Q. You don't have any opinion, one way or the other, on whether AI's position that an inner frame can be a graft covering is correct; is that right?

A. I haven't needed to. So I haven't considered that at any great length. What I know because it's a fact is that AI have taken that position and therefore I've used that position in my analysis.

Q. You're aware of that certain claims at issue in this proceeding require, for instance, that an inner frame is a graft covering; correct?

A. Yes. And that's the position that AI have taken, that an inner frame can be a graft covering.

Q. And you can't say one way or the other whether any reference that you see has an inner frame that is a graft covering; correct?

A. Well, it -- it's a question of definition. AI has taken the position that the inner frame can be a graft covering. And if you take that position that AI have taken, then an inner frame can be a graft covering,

and I've used it for my analysis.

Q. I'm not asking about AI's position. I'm asking about your expert opinion. In your expert opinion, you cannot say one way or the other whether any of the references you've ever seen in your entire life discloses an inner frame is a graft covering; correct?

MR. SUMMERS: Objection. Form.

THE WITNESS: I think I've answered the question you're asking. I've used the position that AI have taken to do my analysis; therefore, I have taken that position and applied it in looking at the prior art.

I have not considered independently because I felt that the need to as to whether that is a position that other people would take in other situations.

I have dealt with the task at hand in this IPR of considering whether the prior art -- prior art teaches what AI are claiming.

BY MR. LOWENSTEIN:

Q. I'm not asking at all about AI's position. I'm just asking about your personal expert opinion.

In your personal expert opinion, do you believe that an inner frame can be a graft covering?

MR. SUMMERS: Objection. Form.

THE WITNESS: I haven't got an opinion on

that. I haven't considered that question.
BY MR. LOWENSTEIN:
Q. Did anyone tell you not to consider that question?
A. No.
Q. You made a personal decision not to consider whether an inner frame can be a graft covering?
A. No. I haven't -- I haven't -- I haven't needed to. I think we're -- we're at cross purposes.
What I have done is an analysis using the positions that AI have taken and that I have applied, and it's in my four declarations, which you have.
I have not considered outside of that whether this is a position that anyone else, including myself, would take.
Q. You just don't know? You just don't know whether an inner frame can be a graft covering?
A. I haven't considered it.
Q. I'm asking you to consider it right now. Please consider right now and tell me whether an inner frame can be a graft covering?
A. You would need to show me an example. You would need to show me what you're talking about.
Q. How about Alain Cribier?
A. What do you -- what with Cribier?

Q. Is Cribier's inner frame a graft covering?

MR. SUMMERS: Objection. Form.

THE WITNESS: Cribier's inner frame -- I really don't understand your question.

I don't know what inner frame Cribier you're talking about.

If you could show me what you're talking about is -- I've relied on several different Cribier things, a medical article, patents of Cribier and when you're saying as a question Cribier's inner frame, I am just not sure what you are talking about and what question you're asking me.

BY MR. LOWENSTEIN:

Q. We're going to look at Cribier.

A. Thank you. Which Cribier?

Q. We'll pull it up. Exhibit --

MR. HSIEH: 1012.

MR. LOWENSTEIN: We're going to look at Exhibit 1012.

THE WITNESS: Which may have --

BY MR. LOWENSTEIN:

Q. We're going to pull up a share screen. So maybe we could look at that. You're welcome to reference the hard copy as well, of course. And I also shared it in the chat so the court reporter has it as well.

So do you agree that we're looking at Exhibit 1012 and this is something you're familiar with I assume?

A. This isn't -- yeah. This is -- in Cribier's publication, it shows a picture of the Edwards SAPIEN THV and the picture you have in front of me on the share screen is the Edwards SAPIEN THV.

Q. Okay. And do you believe you see an inner frame in this image? Just so -- let me clarify so there's no ambiguity what we're referring to.

We're looking at page 2 of Exhibit 1012. And the page at the bottom is 348. And we're looking at an image of the Edwards SAPIEN THV.

Do you agree with all that?

A. Yes. That's what I've got in front of me on the share screen.

Q. Very good.

Do you see an inner frame in this picture?

A. Using AI's position, the answer is yes.

Q. Do you see a graft covering in this picture?

A. I see a -- a skirt inside the stent, it's sewn on the inside of the stent, which AI's position would mean that it is an inner frame.

Q. I -- I want to clarify. I asked whether you see a graft covering in this picture?

A. Yes. As a fabric cloth inside the frame, which is sewn to the inside of the frame with multiple sutures that I can see.

Q. And leaving aside whatever Aortic Innovations has said, in your personal expert opinion, you cannot tell me one way or the other whether we can see an inner frame in this picture from Exhibit 1012; is that correct?

A. One has to define the terms. As I said -- I think I said repeatedly and very clearly, using AI's position, it is an inner frame. I do not think before knowing AI's position that I would have characterized the cloth inside the frame as an inner frame.

Q. So your understanding of there being an inner frame -- the possibility of there being an inner frame in this picture from Exhibit 1012 that we're looking at is entirely dependent upon AI's position; is that correct?

A. Yes. AI have taken the position, as I believe patentees are able to do, and that position informs me as to what I can look for in the prior art.

This is one of my pieces of prior art. AI have taken the position, I can look at this and say, therefore, this is an inner frame using the position that AI has taken.

Q. But-for AI's position, do you believe that Cribier does not disclose an inner frame; correct?

A. Using AI's position --

Q. I said but-for. But-for. But-for AI's position, it's your opinion that there is --

A. I'm sorry. I'm speaking over you. I apologize.

Have you finished your question?

Q. Let me reask it again.

I want you to understand that the question's framed -- it comes in the first two words that I'm going to use.

But-for Aortic Innovation's position, your expert opinion is that there is no inner frame in the picture of the SAPIEN that we see in Exhibit 1012; correct?

A. I would not have used the term "inner frame" to describe the cloth inside the SAPIEN stent before knowing AI's position.

Q. Okay. Very good. We've been going about an hour. Why don't we take a short break.

Five minutes, let's say, or 10 minutes if you prefer. And then let's get back on.

I'll remind everyone that you're not allowed to speak to Mr. Summers or anyone else at Knobbe of the deposition during the break.

(Off record from 8:39 till 8:56.)

BY MR. LOWENSTEIN:

Q. Dr. Buller, do you recall we were speaking earlier about a cut necessary for access via the common iliac?

A. Yes.

Q. And you said a two inch cut may be used.

Were you referring to the length of the incision?

A. I think I said a couple of inches from memory. I don't have a transcript or anything, but I thought I said a couple of inches. And you said it could be 10 centimeters and I said, yeah, it could be four inches.

Q. Are you referring to the depth of the cut or the length of the cut?

A. Length of the cut.

Q. How deep would the cut need to be?

A. Well, like I was saying, the femoral artery, you have to go down very much depend on the build of the patient. You've got to go --

Q. I'm sorry. I think you may have said the femoral artery. Just to be clear, I'm asking about the common --

A. Sorry. I misspoke. The common iliac. It depends on the build of the patient, you would have to go a couple of inches down as well as an incision a couple of inches across.

Q. You believe you only have to go a couple of inches down to reach the common iliac?

A. As I've said, it depends on the build of the patient and exactly how much of the patient there is and how much adipose tissue, et cetera, you will have to go a few inches down and a few inches across.

Q. Could it be 10 centimeters deep?

A. It could be, yeah.

Q. And the common iliac lies at the back of the pelvis; is that correct?

A. Yes. The common iliac divides into the internal iliac and the external iliac -- the common iliac divides into the internal iliac and the external iliac and you can access it without opening the peritoneal cavity.

Q. The incision that is used to access the common iliac for a TAVR procedure as you envision it, would that type of incision be used for any other surgeries?

A. Yes.

Q. What type of surgeries?

A. Well, for one I said stent graphs for use in the aorta and -- and what I was talking about were large developmental devices, the hemopump, but it may be used for other procedures.

I told you what I have been involved with it and use of. As I'm sure you are aware, I have not done a

TAVR device so I've never used a TAVR device. I've never put a TAVR device in a patient via any route.

Q. You would consider a kidney transplant surgery to be a major surgery?

A. Kidney transplant, yes.

Q. And are you aware that the same incision to access the common iliac would also be used for kidney transplant?

A. It may be, yes. I don't know that that's the only one that can be used for a kidney transplant. I'm afraid I'm not that familiar with kidney transplants.

It's outside my field.

Q. Is there any kidney transplant surgery that's not a major surgery?

A. No. I would regard transplant surgery and kidney transplant surgery as major surgery.

Q. And leaving aside the removal of a kidney, just the incision itself entails a major surgery; is that fair to say?

A. No. I wouldn't say the incision, the cutting of skin and tissues is major surgery. But removing someone's kidney and putting in another kidney, that's major surgery. You're taking one thing out and putting another thing in. It's a major procedure.

MR. LOWENSTEIN: Ed, can you share -- we're

going to share one of Dr. Brecker's declarations.

This is Exhibit 2002 and I believe the one we're going to use is from --

MR. HSIEH: This is from 00034.

MR. LOWENSTEIN: Okay. We're going to share the one from IPR 2022-00034.

Q. And I believe Mr. Hsieh has shared the document. And I'm going to -- we're going to go to paragraph 57, which is on page 36 of the document.

A. I have got a share document. I'm afraid nothing's changed at my end.

MR. HSIEH: Give me one second.

BY MR. LOWENSTEIN:

Q. He just needs a second. He has shared the file. But he's going to share the screen.

MR. HSIEH: What page again?

MR. LOWENSTEIN: It's page 36.

Q. Okay. So let's go to the third sentence.

First of all, are you familiar with Dr. Stephen Brecker?

A. Yes. I know Dr. Stephen Brecker.

Q. Do you agree that Dr. Brecker is an experienced interventional cardiologist with a ton of experience implementing TAVRs?

A. Yes. I wouldn't use the term "a ton of." He's

an interventional cardiologist, I know, I met him and yes, he certainly has a very significant experience with TAVRs.

Q. He's implanted over a thousand TAVRs; is that your understanding?

A. I have no personal knowledge of that, but I've read his reports where I think he says that and I'm perfectly willing to accept that as the truth.

Q. Okay. Now, I'm going to read a series of statements that we're going to see on the screen. I'm basically just going to ask if you think Dr. Brecker's statements are accurate.

So let's look at the first one.

Quote, "The principal benefit of an endovascular delivery, e.g., via the transfemoral approach is that it is a noninvasive approach wherein a purely percutaneous method may be used and the patient may be discharged from the hospital in a matter of days."

Do you see that?

A. I do.

Q. Is that statement fair?

A. It's fair.

Q. And next sentence, "Transfemoral delivery rapidly became the overwhelmingly dominant approach, and has remained so ever since," closed quote.

Do you see that, sir?

A. I do.

Q. Is that a true statement?

A. That's still talking about TAVR, is it? Yes.

Q. It is.

A. I'm just saying that it is locked into because we do use other radial arteries for other procedures, but not for TAVR. So I think I said we do use other procedures, such as a radial artery approach, but not for TAVR.

Q. So this statement as respect to TAVRs that I just read is correct?

A. I'm just saying that it is locked into TAVRs, but yes, it's perfectly fair if it's locked into TAVRs.

Q. Okay. Let's look at the next sentence.

Quote, "An 'endovascular' -- And "endovascular" itself is in quotes -- "delivery via the common iliac, by contrast, is far more invasive, involves major vascular surgery, is associated with numerous complications and has been used very rarely."

Do you agree with that?

A. No. I don't agree with that. I don't think major vascular surgery.

Q. May I just -- I don't know if this will change your answer at all. Let's take that sentence and let's

assume it's in the context of TAVRs.

Do you believe the statement I just read to you is correct in the context of TAVRs?

A. No. I wouldn't classify it as major vascular surgery.

Q. Why not?

A. Because it's not major vascular surgery. It's, on the scale of things, relatively minor vascular surgery. It is vascular surgery, I'm not disputing that.

I'm saying it really shouldn't be classed as major vascular surgery and is associated with numerous complications. I mean all procedures can be associated with numerous complications.

Q. Okay. So you disagree that it is major vascular surgery.

Do you agree with his statement that it's far more invasive?

A. It's more invasive. Again, I think it's rather emotive to say "far more." It is more invasive, we've already been through this earlier this morning. It is more invasive. I wouldn't classify it as major vascular surgery. All procedures can be associated with complications.

Q. I know you've been retired for some time. But

let's imagine we have an elderly patient and we're saying -- talking about elderly patients and you're telling her you can have a transfemoral approach -- let's say there's an internist there who is working under you and you see -- let's assume this young fellow tells the patient we could do the transfemoral approach or we can go to the common iliac, but that will be a major vascular surgery.

Would you correct the internist and tell the patient, no, it's not a major vascular surgery at all?

A. I'd correct him every way around. If you can do a procedure through the common femoral artery, it is less invasive, then you would obviously do it, if it was possible in this hypothetical patient you're talking about.

But if it's not possible, then you've got to talk about how you could do the procedure. It would only go to the internal iliac artery if it was not possible to do it from the femoral artery.

You're -- you're moving up to a larger artery and a more invasive procedure, both of which I have said and, therefore, you wouldn't do it as an alternative.

You will do the more invasive procedure when you can't do the less invasive procedure.

Q. I want to -- I want to -- I think we've walked

straight from my question. Let's make sure my question is squarely in your mind.

We're talking about a situation where you're in the room and you have a -- a resident, thank you. You have a resident that we refer to in the United States and the resident is counseling the patient, you're observing this consultation.

And the resident is talking about various possible routes. And the resident is comparing the transfemoral route versus the common iliac route. And the resident advises this elderly patient that the common iliac route is a major vascular surgery.

You would step him in and you would correct the resident; is that correct?

A. I've got to understand the context that's being talked here, because it's not making a lot of sense to me.

What I'm saying is that access -- if it is required by the internal -- by the common iliac artery is not in my mind major vascular surgery.

Q. You were correct -- you would correct the resident and you would say that, I'm sorry, that's just not true. The common iliac is not a major vascular surgery, not at all. That's what you would say?

A. No. Because in front of a patient, this is a

rather silly hypothetical, if -- if I may say. Because -- I'd want to understand why and what is actually being said to the patient so the patient can have the best advice.

If either routes are possible, via the femoral or via the internal iliac, you would always go by the femoral. It's less invasive and a simpler procedure.

It would only be if you couldn't go because of disease or the size of the patient, or the size of the device you are wishing to use on the patient that you would go to the common iliac artery; and, therefore, you're not presenting it to a patient you could do one or you could do the other.

Q. Fair enough. You would always use the transfemoral approach.

Let's change the hypothetical.

Let's say, for whatever reason with this given patient, the transfemoral approach is not available. The resident says to the elderly patient, ordinarily we would use transfemoral approach because it's minimally invasive and you'll be -- released within a couple -- under local anesthesia and you'll be released after a couple of days.

But in your circumstance, that option is not available. We think you should go via the common iliac,

but that involves major vascular surgery.

Do you believe the resident will have spoken incorrectly to the patient by using the phrase "major vascular surgery" to characterize an approach via the common iliac; is that correct?

A. Yes. I personally -- I would not use the term "major vascular surgery" to just access via the common iliac artery.

Q. So you wouldn't want to embarrass the resident in front of the patient, that's understandable.

When you get out of the room, you would ask the resident what on earth are you saying? Why on earth would you call trivial as the common iliac version a major vascular surgery? Where did you go to medical school? That's what you would say?

A. No. You're putting, frankly, rather unfair and ridiculous words into my mouth. That is not what I would say.

If you want me to answer questions, then ask the question. But I would not say it's trivial, which is the word you just used.

I've said it is more invasive than the femoral, but I wouldn't regard it as major vascular surgery. I certainly wouldn't regard it as trivial. These procedures on patients aren't trivial and you just said

I would tell the person off and tell him that it's trivial.

That is not what I said and it's not a correct characterization of anything that I've said.

Q. My apologies, I thought you were finished speaking. I didn't mean to speak over you.

But you wouldn't take the resident out of the room and you would say why did you characterize the common iliac approach as a major vascular surgery, that's what you would ask?

A. I would certainly talk to him about why he's saying it's major -- I would want to understand what his understanding is and what is going on, because he may know something about the patient I don't know and he was aware of something I wasn't aware of.

But all other things being equal, I wouldn't regard accessing the patient's common iliac artery as major vascular surgery.

Q. If the resident said to the patient the transfemoral -- the femoral (sic) route is unavailable to us for whatever reason and we can go via the common iliac, but it's far more invasive, would that be prudent advice to the patient?

A. Well, I'm not sure I said "advice to the patient." If you can't go with the femoral, if you've

got to say if we do this procedure at all, we have to go from somewhere, and the alternatives, and you have to talk to the patient about what the alternatives are. And going from the iliac, the common iliac would be less than open-heart surgery, would be less than transapical if it was otherwise a possible approach, if that individual patient's anatomy would allow you to perform the procedure via the common iliac artery.

Q. I'm not sure why you're referring to transapical and open-heart surgery because that wasn't part of the scenario. Let's make sure we focus upon the scenario we're talking about.

So the resident says the transfemoral -- the femoral is unavailable, so we can consider going via the common iliac, but it is, quote, "far more invasive."

Would that be a correct statement or not?

A. Yes. As I've said, and I think I've said repeatedly more invasive, I wouldn't use the word "far" again. I think you're deliberately using -- it is more invasive, but it's not possible to go from the femoral artery for whatever reason, then you've got to talk to the patient about where you can go from.

Q. Now, the resident says to the patient the common iliac route is associated with numerous complications, is that true?

A. All routes are associated with numerous complications. It's not -- if you say accessing your body, your vascular system is associated with numerous complications, that is true.

Q. I'm just asking about one specific route. So the resident says the common iliac route is associated with numerous complications.

That's a true statement; correct?

A. Yes. All -- all access routes are associated with numerous complications. You're not telling the patient that there is a route that has no complications. So we're going for a route that is -- has got numerous complications. Accessing the vascular system has complications for any access site.

Q. So I just want to make sure something is clear in my mind, Dr. Buller. And this is my chance to ask you questions. Only chance I'm going to get.

And I'm trying to phrase my questions as precisely as possible.

I'm not asking about -- I'm just asking you about one specific route. I'm just using this as a for instance. But you understand that you're required to answer the specific questions that I ask.

Do you understand that?

A. I do.

Q. Okay. And so if you answer a question that I didn't ask, you can understand how would that interfere with my examination.

Is that fair?

A. I think so.

Q. Okay. So I'm just going to ask you to please answer the specific questions that I ask and if the question is unclear, you can let me know.

Is that fair to say?

A. Yes.

Q. Okay. Let's proceed under that understanding.

The internist -- I'm sorry, the resident, excuse me, we have terms -- the resident says to the patient, you know, using -- delivering a TAVR via the common iliac, that's used very rarely.

Is that a true statement?

A. Yes.

Q. Now, let's go back to Dr. Brecker's declaration, paragraph 57.

Quote, "It has never" -- and he's referring to common iliac, of course, the common iliac route -- "has never been used in the overwhelming majority of implanting hospitals"; true?

A. I just don't know that. Dr. Brecker may have more knowledge than me. But I don't know whether that

is true or not true.

Q. Do you have any basis upon which to believe it's not true?

A. No. As I said, he may well know more than I do, but I don't know that's true.

Q. Fair enough.

Next sentence, quote -- of Dr. Brecker's paragraph 57. Quote, "To reach the common iliac artery, a surgeon would need to utilize a large incision typically used for renal," parenthesis, "(kidney) transplant surgery," closed quote.

True statement?

A. No. I don't think that that is a true statement.

Q. What is your -- why do you believe that is not a true statement?

A. Because I think it can be done through a smaller incision if it's used for a renal kidney transplant.

Q. And what is your basis for that?

A. I've been involved in these procedures, as I've told you.

Q. Back in the '80s?

A. Yes. First in the '80s, the late '80s.

Q. So over 30 years ago?

A. Yes. That's just when the time -- late '80s was -- that's years ago.

Q. Next sentence. "The vessels lie deep in the retroperitoneal space," closed quote.

Is that true?

A. Yes. That's what I was talking about. It lies behind the peritoneum. So it is at the retroperitoneal space.

Q. It lies deep in the retroperitoneal space, correct?

A. The retroperitoneal space is a space. It doesn't lie six feet deep in that space. I'm not sure what is meant there. It lies in the retroperitoneal space. That is a space.

Q. The next sentence, "There is a need" -- quote, "There is a need for surgical dissection through the anatomical layers of the anterior abdominal wall, including multiple layers of abdominal muscles."

True?

A. Yes.

Q. "Arterial control by means of vascular clamps is required."

True?

A. Yes.

Q. Quote, "In many cases because of the difficulties of access, vascular surgeons prefer anastomosing" -- let me read it again.

Quote, "In many cases because of the difficulties of access, vascular surgeons prefer anastomosing a graft onto the common iliac vessel as it can be easier to access and close a graft than the native common iliac artery itself."

Is that true?

A. Yes. That's what I spoke about earlier. I mean he can make the procedure very much simpler from the point of view of an interventional cardiologist to be entering the artery by an interposed graft.

Q. And such a graft could be made from Dacron; is that correct?

A. Correct.

Q. And Dacron is a form of PET; is that correct?

A. Correct. I believe it's a Dupont trademark for PT fibers.

Q. For the court reporter benefit, we may use the term PET, that's capital P-E-T.

Let's go back to Brecker's paragraph 57 -- excuse me, Dr. Brecker's paragraph 57.

He says, quote, "Make no mistake, this is major vascular surgery and requires an experienced vascular surgical team to undertake it safely," closed quote.

Now I think I know you disagree with the first clause of that sentence because we had a lengthy

discussion about it.

So I'm just asking you about the second phrase in the second sentence, which is essentially that a TAVR procedure via the common iliac, quote, "requires an experienced vascular surgical team to undertake it safely," closed quote.

Is that true?

A. Well, I would hope so. I mean, can you imagine letting an unexperienced vascular team -- I mean, of course, any procedure requires experience. It's just saying any more you want the person to have experience.

Q. I'm not suggesting the question is controversial.

A. You need an experienced vascular surgical team to do vascular surgery. It's a wise precaution.

Q. Fair enough.

Next sentence. I'll read into it for context.

A TAVR procedure via the common iliac, quote, "carries with it major risks of vascular injury, dissection, vessel rupture, infection, bleeding, renal failure and a requirement for postoperative intensive care."

True?

A. I would take out the word "major." But it carries risks of vascular injury, infection, vessel rupture, bleeding, renal failure and a whole lot of

other things. You could add, but I would take out "major."

This is a procedure done by an experienced surgeon that could be done without great risk. And with all of these risks being entirely reasonable the procedure that you want to take.

Q. Let's go to the next sentence.

Quote, "Compared to a femoral surgical cutdown, iliac artery cutdown is associated with greater blood loss (2.6-fold greater blood loss)."

Let's break this up.

True?

A. I don't know. I don't know where it comes from. I mean that's a very precise figure.

Q. "82 percent longer procedure time."

True?

A. I don't know.

Q. "1.5 days additional hospital stay."

True?

A. I don't know.

Q. "And 1.8-fold higher rate of perioperative complications."

True?

A. It may be from this one article, but -- Dr. Brecker is quoting from, I wouldn't generalize it as

being a statement of fact.

Q. I may just need one moment. But it should not take more than a minute or so.

Okay. We're going to look at Exhibit 1044, which is one of your exhibits. It's called Criado.

And Mr. Hsieh is in the process of sharing it. And we'll bring it up momentarily.

Criado for the court reporter's benefit is C-r-i-a-d-o, and that's the last name of the author.

THE REPORTER: Thank you.

BY MR. LOWENSTEIN:

Q. Okay. Dr. Buller, you have Exhibit 1044 in front of you?

A. I do.

Q. And I assume this document is familiar to you?

A. Yes.

Q. Okay. Now, you see in the "Techniques," a few sentences in, it says, "A 10 millimeter Dacron graft is the best conduit because it provides enough luminal space for introduction of all delivery systems."

Do you see that sentence, sir?

A. Yes.

Q. So we're talking about Dacron graft that is used in the context of a common iliac procedure; is that correct?

A. Yes. I believe so.
Q. And what is the function of the Dacron graft?
A. To allow you to pass devices through it into the common iliac artery.
Q. So because the diameter of the Dacron graft is 10 millimeters, is it fair to say that whatever's passing through the graft would be less than 10 millimeters?
A. Or very tight. I don't know with this particular graft, because it doesn't state here the type. That dimension could be internal or external. I just don't know.
Q. I think -- I just want to clarify.
The 10 millimeter graft diameter can be an external diameter of the graft or an internal diameter of the graft, and you're not sure?
A. It could be. And if it is an internal diameter, you could therefore put a 10 millimeter device through it.
Q. Now, when Edwards using a French size, like 24 Fr. Ascendra, 18 Fr., is that an interior diameter or an exterior diameter?
A. It -- it varies and it's quite complicated what these things actually mean because technology's changed and you need to look device by device to see what's actually being meant and what size is actually there.

There's a lot of confusion the size is of devices and what they are internal or external, whether they expand or contract.

So you need to know the specific one.

All I'm saying here is I just don't know in the sentence whether the 10 millimeter is an internal or external graft.

Q. Okay. Let's go down a little bit and we'll see on the right column on the first page of Criado.

Do you know him?

A. I've met him.

Q. Okay. Very good.

So let's look at the right column and we'll see that it's referring to the March 2005 approval of the first endograft -- the Gore-tek device.

Do you see that, sir?

THE REPORTER: (Clarification.)

MR. LOWENSTEIN: Do you see it says tek and it says W.L. Gore?

Q. What is the crimp diameter of the Gore-tek device?

A. I don't know. As I sit here, I don't know. You could look it up.

Q. It's 27 Fr.

Do you have any reason to believe that's wrong?

A. I have no reason to believe it's wrong -- did you say 27?

Q. I believe so.

A. If that's what you're telling me, I accept that.

Q. The -- it refers to thoracic endovascular aortic repair, which is the acronym -- the acronym for which is capital T-E-V-A-R.

Do you see that?

A. Yes.

Q. And you agree that this is distinct -- TEVAR is distinct from a TAVR procedure; correct?

A. Yes. This is the sort of procedure I was talking about earlier of putting stent grafts into the aorta. This is one particular type of stent graft in one particular time frame.

Q. Now, I want to go to the left-hand column.

Do you see it refers to greater than 22 Fr. -- greater than or equal to 22 Fr. as a quote, "large-bore sheathe or catheter size."

Do you see that?

A. Yes.

Q. Do you think it's fair to characterize 22 Fr. or greater as a large-bore sheath or catheter size?

A. It may well be, because they're saying greater than, so they're not putting upper limits on it.

They're saying that is an equal to or greater than.

They're putting a lower limit of 22 Fr., but they're saying anything bigger than that.

Q. Well, that's not quite right, is it? Because what it actually says -- another way to read this is 22 Fr. is considered a large-bore sheath or catheter size; correct?

A. I think that's compatible. What I just said they're saying is they started with 22 Fr., if you go larger, they would classify large sheathes.

Q. I think we're on the same page. I just want to make sure there's no ambiguity.

It is fair to say that a sheath size 22 Fr. is a large-bore sheath; correct?

A. I'll say in this context, in this paper, that's exactly what they're saying.

Q. Do you think that's crazy?

A. No. That's what they're saying.

Q. Do you -- do you -- is it a reasonable statement?

A. It's an entirely reasonable statement, but you're reading numbers and things coming in context of when they're said and what's being said.

Q. Okay. Let's go to the second page of Criado I think you said. In Figure 1 it says 10 centimeter Dacron graft.

I think we can agree that is a typo. Is that right?

A. I think that's fair. I think it means millimeter.

Q. I want to look at the incision in Figure 2.

Do you see that, sir?

A. I do.

Q. And, in fact, there are two incisions; is that correct?

A. I'm sorry? I think there are two.

Q. Maybe you wouldn't refer to it. There's a puncture and an incision.

Is that fair to say?

A. I'm not sure what you're -- what you're actually referring to. I can see the incision, which is still open, which is in the upper part of the exposed skin. I can see what almost looks like a healed incision below it. It may just be a stretch mark in the same place, and then further down I see the Dacron graft.

Q. Yes. Yes.

And would you -- obviously that's inserted through a hole in -- that's made. Would you refer to that as an incision or something else?

A. What they refer to it as is a stab incision.

Q. Which you see in Figure 2, it says stab incision.

MR. SUMMERS: I appreciate you're trying to help but when it comes to repeating, let's have Dr. Buller restate his testimony.

MR. LOWENSTEIN: I'm not misstating it.

Q. If I ever misquote you, please let me know. I'm not trying to.

But getting back to the -- Figure 2, are you able to estimate the length of the incision that we see?

A. Which? The stab one?

Q. No. The larger incision.

A. Well, the graft we know is of the order of 10 millimeters. We don't know whether it's inside or outside. So you've got to measure that. All I would say, it's 5 -- 5 -- 50 millimeters, perhaps 60 millimeters long. I don't have calipers or anything. It looks to me as though it's of the order of 60 millimeters or perhaps a bit more.

Q. 60 millimeters is 6 centimeters?

A. Yes.

Q. Let's go to the next page, which is the third page of the PDF, but the page number on the document is 349.

And you'll see there's a first bullet that says, "A 10-millimeter-diameter Dacron graft is the best conduit because it provides enough luminal space for

introduction of all delivery systems (even the largest size)."

Do you see that?

A. I do.

Q. Do you believe that's correct?

A. I can't -- they're talking here, as you fairly realize about these -- we're not talking about TAVER. We're talking about the aortic endografts. And they're saying it's for the larger size, I take that to be true, but I don't know what the larger size are, so I can't -- I can't of my own knowledge sitting here say that's what they say.

But I don't know that that's true.

Q. Fair enough.

Which you can see on the -- if you look at the first page of the document or first endograft, just for the court reporter. Do you see --

A. In the title.

Q. Yes. Thoracic -- in the title.

You can take that down. Give me a moment.

A. You know I can't hear you.

Q. I'm talking to my colleague.

A. Okay.

Q. Just give me a moment. We're going to output (sic) another document.

Okay. So we just uploaded another document.

I don't believe this one has been previously marked as an exhibit. Perhaps I'm not remembering, but the title of the document is --

Are you able to share it?

MR. HSIEH: Yes. Give me one second.

BY MR. LOWENSTEIN:

Q. Okay. The title of the document is, quote, "Recent Advances in Transcatheter Aortic Valve Implantation: Novel Devices and Potential Shortcomings," closed quote.

A. I do. I have the title page up in front of me.

Q. Very good.

And the lead author is J. Blumenstein or "Stein" perhaps.

Okay. So let's go to the "Introduction" and we see he says -- as I think we discussed earlier, the first man implantation of a TAVI was by Cribier in 2002, and then continuing on.

So let's look at the sentence starting with "As such." It says, "As such in 2011, more than 20 percent of patients with isolated aortic valve replacement were treated by a TAVI procedure in Germany," closed quote.

Does that sound right to you?

A. That's what it says.

Q. I mean does that sound reasonable to you?

A. It was done by surgery. It doesn't sound unreasonable, but I don't have any knowledge of German procedures in 2011. These are German authors writing a paper from Germany.

I would bow to their knowledge. It doesn't sound in any sense unreasonable patients set down by surgery.

Q. Okay. Let's go down a little bit. You see it says, quote -- quote --

A. Sorry, do I see that?

Q. I was referring to my colleague. We're going to highlight it.

So we're going down. We're still in the first -- left-hand column of we'll call it the Blumenstein paper for shorthand. And we see it says, quote, "After initial enthusiasm, some major concerns of the TAVI technology became obvious in larger cohort trials. Especially the incidence of paravalvular leakage, stroke and access-related complications could be identified as important factors regarding the post-procedural outcome," closed quotes.

Do you see that?

A. I do.

Q. Is that a fair statement at the time?

A. At the time this was published -- this isn't

prior art, is it?

This is published in 2013. So I haven't seen this before or taken notice of it because it's not prior to the priority dates of the patents. But what it's saying doesn't sound unreasonable or out of kilter with the things that were being told, but I think we recognized that paravalvular leak or PVL and vascular complications were reported well before 2013.

Q. Now, the next sentence is, quote, "Driven by these concerns, the main interest of new or 2nd generation devices would be the avoidance of paravalvular leakage, the reduction of sheath diameter and the repositionability of the valve prostheses."

Do you see that?

A. I do.

Q. Is that a fair statement?

A. It's their view. It's their view. It wouldn't be everybody's view.

Q. Do you disagree with it?

A. I'm saying it wouldn't be everybody's view.

Q. Is it consistent with your understanding?

A. No. Some people didn't think that.

A repositionability is a feature that some devices have, but some devices today, some of them are not repositional at all, and there's still a significant

presence on the market, and we're talking today in 2022.

So it is their view. I don't doubt it was their view.

But it wouldn't be everybody's view that was working in the field.

Q. I'm asking about your view. So this is obviously written in 2013 as you properly observed.

And is it your understanding, that, quote, "main interest of new or 2nd generation devices would be the avoidance of paravalvular leakage, the reduction of sheath diameter and the repositionability of the valve prostheses"?

A. And what is your question?

Q. Whether that's your understanding of the concerns at the time?

A. People at the time had those concerns. And clearly these are them, because they'd written it. But it wouldn't be everybody's concern.

Q. I understand. I'm asking for your understanding of what you thought the principal issues were in 2013.

A. Well, I didn't do these procedures. So it wouldn't -- I'm really not sure what you're actually asking me.

What I am saying is this is a fair statement. I'm sure it's characterizing their views. But it

wouldn't be everybody's view at the time. And this is 2013, which is after the prior art dates of the patents.

Q. So by "these procedures," you mean TAVR procedures?

A. Yes.

Q. So you did not perform TAVR procedures in 2013?

A. I've never -- as I've said already, I've never performed a TAVR procedure and, therefore, this really applies to the feelings of people who are performing the procedures and what they saw as the priorities. And they're listing three priorities, one of which I'm saying wouldn't have been everybody's because repositionability is -- is not everyone's concern.

Q. But I'm asking about what your personal opinion as an expert as to the main concerns to persons of ordinary skill in 2013 in connection with second-generation TAVR devices.

And my question is, is it your opinion that in 2013 the main interest of new or second-generation devices would include the avoidance of PVL and the reduction of sheath diameter?

A. All of these things were concerns of people in the field in 2013 and this is an entirely reading sentence written by this group in Germany.

Q. Now, as you've said, you've never implanted a

TAVR; is that correct?

A. That's correct.

Q. Were you closely following the literature relating to TAVRs in 2012?

A. Yes.

Q. Why?

A. Because I had a -- an interest in the development. I was -- I knew very well and I was a friend of Alain Cribier. I was interested in the beginning and I was interested in the continued development of it. It's very important for treating patients.

Q. When did you first come to know Cribier, Alain Cribier?

A. Alain Cribier, I first met him and got to know him well in the early '90s.

Q. What was the context?

A. We were both on meetings together. We were on panels together. We served on advisory boards of medical device companies together and, therefore, I knew him and his interest in developing it.

I talked to him about it at a sort of time that he was doing research on it about his research and, therefore, I knew Alain Cribier and was fired in part by his enthusiasm for the fact that it would come to

fruition.

Q. I don't mean to be insulting, but is he still among us?

A. Yes.

Q. Are you still in contact with him?

A. I haven't seen him for a couple of years. But I saw him last a couple of years ago and had a chat with him that things had come a long way.

Q. And is he -- I can't recall, is he based in the U.S. or is he elsewhere?

A. No. In France.

Q. Now, let's go back to the Blumenstein article. Let's go to the right-hand column on the first page.

Okay. Do you see what this paragraph says is -- refers to the SAPIEN valve, which is the first valve commercially available in Europe for transient called transfemoral as well as in the U.S. for transfemoral only. I think we discussed that, but that's consistent with your understanding?

A. Yes.

Q. And it says, "Over the years, some modifications led to the development of the most recent valve."

And I think we discussed that as well. Is that your understanding?

A. The most recent development by Edwards.

Q. And the SAPIEN XT, it says is a new generation of SAPIEN, and is already CE-mark approved and commercially available in Europe.

Is that consistent with your understanding at the time?

A. By 2013, yes, it was.

Q. And it says the SAPIEN XT can be used for both transfemoral -- just so we're clear, I'm not quoting, I'm paraphrasing. I'm basically walking through this first paragraph paraphrasing what we see.

So I'm now -- I'm on the sentence, "The valve can be used for both transfemoral and transapical, or TF and TA." Let me reask the question, Dr. Buller.

Is it consistent with your understanding that SAPIEN XT can be used for both transfemoral and transapical at this time?

A. Yes.

Q. The next sentence says, quote, "Compared to prior generations, a cobalt-chromium frame permits thinner struts without loss of structural integrity and it provides sufficient radial force," closed quote.

That's consistent with your understanding?

A. Yes.

Q. And thinner struts -- quote, let me start over. "Thinner struts and a more open design allow for a lower

crimped profile and allow a smaller sheath diameter, while maintaining the valve's radial stiffness"; is that correct?

A. Yes. That's consistent with what I know about it and, in fact, we even spoke about it earlier today, the thinner struts from using cobalt-chromium.

Q. Your recollection is correct. We did talk about this.

Let's go under Figure 2. It says, quote, "For the transfemoral access, the Novaflex + and the eSheath are used. The concept of these systems is the loading of the valve inside the descending aorta, which allows a reduction of the sheath diameter to 16 Fr., which is one of the major concerns regarding vascular-related complications," closed quotes.

Do you see that?

A. Yes.

Q. So this article refers to the major concerns were -- regarding vascular-related complications.

Do you take that to mean large -- larger crimp size of previous generations?

A. Sir, I'm not exactly sure what words you're asking me about.

Do I take what to be what?

Q. Do you see the last clause or phrase of what I

read to you? It says "which is one of the major concerns regarding vascular-related complications"?

A. Yes.

Q. And what I believe the authors are referring to is the larger French size of the prior generation's sheaths. And I'm curious to know whether that is consistent with your understanding?

A. Yes. I think that's consistent.

Q. And so the shift from the SAPIEN to the SAPIEN XT allowed practitioners to go from a 22 Fr. to 24 Fr. for the SAPIEN to 16 Fr. or 18 Fr. in the SAPIEN XT?

A. That's what they're saying here, yes.

Q. And that's consistent with your understanding?

A. Yes. That -- that is consistent with the fact that they were developing smaller devices and they were reducing the size that's required to go into the femoral artery where it's an important factor in the likelihood of vascular complications from the method of accessing the femoral artery.

Q. Now, if we look at Figure 3, you'll see there's the 18 Fr. device and the 16 Fr.

A. Yes.

Q. Do you understand from this figure that 18 Fr. and 16 Fr. refer to the interior diameter?

A. That's what they're showing, that's what I take

these lines -- lines to be, the internal diameter.

I mean, I'm sure you already understand that the eSheath is a sheath that can get bigger. It expands. It's -- and therefore that's its size when it's not expanded.

Q. Now, if you wanted to determine the exterior diameter of these sheaths, how would you do that?

A. You would measure it.

What do you mean how would you do it?

I mean --

Q. I guess I'm asking, do you have a -- a rough approximation of the difference in diameter between an interior diameter and an exterior diameter for any given delivery system?

A. No. It depends only on the maker and the design and whether there's reinforcement and stopping kinking it matters how it affects the wall --

THE REPORTER: (Clarification.)

THE WITNESS: And kink resistance I think I said. But the easiest way to find out the external diameter would be to ring the manufacturer and ask them or failing that, to take up a micrometer and measure it.

BY MR. LOWENSTEIN:

Q. I don't know. I feel like they might take your call more readily than mine. But who knows.

A. Well, they try and speak to physicians, that's correct.

Q. Okay. Let's go to page 5 in the PDF. Page 278 of the Blumenstein paper, of course. We're in what they refer to as page 278. Let's go to the second paragraph starting with "As mentioned."

So it says, "As mentioned" -- quote, "As mentioned above, new or so-called 'second generation' devices provide different solutions regarding these issues. However, additional leak sealing techniques, which are usually placed on the outer stent part might enlarge the size of the devices. In this context the diameter of the introducer sheath is a major limitation, especially for transfemoral devices."

Do you see that?

A. I do.

Q. Is that statement true?

A. It's not an unreasonable statement that's being made in this article. It's not prior art. It's not something I considered in my analysis because it wasn't published until 2013. But it's an entirely reasonable statement for these authors to make.

But I haven't specifically.

Q. Now we've been going about an hour, maybe a little more than an hour. Perhaps we should take

another 10-minute break, if that works for everyone.

A. Sure.

MR. SUMMERS: Okay. Just want to mention we're here in DC. It's 1 o'clock.

MR. SUMMERS: Would you want to have lunch now?

MR. LOWENSTEIN: We may have to have two lunch breaks then. We're happy to accommodate that.

THE WITNESS: I'm not hungry, so I don't mind doing another hour. What time are you in California?

BY MR. LOWENSTEIN:

Q. If you can all hold out -- I mean we're only going five hours today.

We can go off the record, Court Reporter.

(Off record from 9:59 till 10:13.)

MR. LOWENSTEIN: We can go back on the record.

Q. So we're going to share -- or I guess we have already shared, Walther, I'll just pronounce it Walther for purposes of my ease.

A. That's fine.

Q. And I believe that you have it marked as Exhibit 1007.

Ed, would you share.

I trust you're very familiar with this document?

A. Yes, I'm familiar with it.

Q. Just for accuracy I'll state, do you know Walther?

A. No.

Q. So let's look at the title, "Transcatheter valve-in-valve implantation: In vitro hydrodynamic performance of the SAPIEN + cloth transcatheter heart valve and Capentier-Edwards Perimount valves."

What does it mean by "valve-in-valve implantation"? Or what is meant by "valve-in-valve implantation"?

A. Putting one valve inside another valve.

Q. Were you done with your answer?

A. Yes. Valve-in-valve.

Q. We're talking about a situation where a previously implanted valve has failed and you're implanting a second valve to act as a replacement valve for the replacement valve (sic), in other words; is that fair to say?

A. It's fair to say as generalization in patients what you said, but this isn't talking about an implanted valve. This is an in vitro experiment. So neither of the valves are implanted and so your characterization isn't right for this particular paper.

Q. I -- I'm reminded there's some issue with this document where it doesn't allow you to highlight particular sentences, so I think we have a different version --

MR. HSIEH: Yes. I can do the other version.

MR. LOWENSTEIN: So bear with us while he's uploading that.

Q. I think you disagreed with my characterization of valve-in-valve in the context of this paper. Why is --

Why was my characterization wrong in the context of this paper?

A. Because this is an in vitro experiment. It's not an implanted valve, because it's done in a sort of a prospect (sic) box on the bench if you're with me.

Q. Of course. Now I understand.

So in vitro, I think, as you've just said, that means out of the body, of course?

A. Yes.

Q. And hydrodynamic, does that refer to water as opposed to blood?

A. Correct.

Q. Now, if we look at "Methods," just as part of the abstract. You see it says, "Edwards SAPIEN + cloth." So essentially what Walther has done, he's taken the

SAPIEN, the one from 2007 I think it was, at least in Europe, and he's added a cloth to the SAPIEN.

Is that your understanding?

A. Yes. This is -- my understanding is this is an Edwards commercial type SAPIEN valve that has an outer cloth added.

Q. And you see it says "Model 9000MIS"?

A. Yes.

Q. What does that refer to?

A. I don't know. It's presumably the actual sort of part number. The devices have particular part numbers. So that will be traceable by Edwards, I would guess.

Q. Now, so because this is valve-in-valve, the cloth that is added is -- when it's expanded is in contact with the valve, the replacement valve that's already there, correct?

A. Yes. The outer valve, the -- the -- what there is there's a Carpentier-Edwards Perimount valve is a well-known surgical replacement valve that was being used widely at the time of this publication. And the experiment I think is saying how good a fit and sealing they can achieve with the cloth-covered SAPIEN put inside the Capentier-Edwards Perimount valve.

Q. So just to clean up, I think you basically said this, but let me just confirm we're on the same page.

The cloth from Walther's valve when expanded will be in contact with the Carpentier-Edwards Perimount valve in the bench; is that correct?

A. Yes.

Q. And if we were to make the leap that this were -- any of this were ever to be in the human body, even in the human body, Walters is not envisioning its outer cloth that contacts the patient's native leaflets?

MR. SUMMERS: Objection.

THE WITNESS: No. It's contacting the leaflets of the Carpentier-Edwards Perimount valve. It's being put into a valve which is the Carpentier-Edwards Perimount valve, so it's contacting the leaflets of that valve.

BY MR. LOWENSTEIN:

Q. Not the patient?

A. There isn't a patient.

Q. I know. If we make the leaf -- go ahead, please.

A. There is no patient. There is no native valve. This is an in vitro bench topic experiment where you're using a Carpentier-Edwards Perimount valve and you're putting this modified SAPIEN valve inside it.

Q. Of course. Of course. We all understand that.

A. Good.

Q. What I'm talking about is obviously what this is

testing is the intro test that may or may not relate to in vivo situation where you've got a Carpentier-Edwards Perimount valve that is implanted in a human body that is fit. And so what this test is looking at is let's imagine we put Walther's valve inside the Carpentier-Edwards Perimount valve and we expand it. And if we imagine that any of this was in the human body, even then the Walther cloth would contact the leaflets of the Carpentier-Edwards Perimount valve, not the leaflets of the patient; correct?

A. Yes. But I think it has much wider implications, if this were where you could imagine that it would be potentially used for -- for preventing leak inside a native valve. The experiment they're doing is inside a Carpentier-Edwards Perimount valve, but Carpentier-Edwards Perimount valve was built very much to mimic a native valve.

Q. And you'll agree that the cloth that Walther asked SAPIEN is then to address PVL, is that fair to say?

A. Yes.

Q. And the --

A. That's its primary purpose.

Q. I'm sorry, I didn't mean to cut you off.

And the PVL that Walther is looking to address is

the leakage between its cloth and the Carpentier-Edwards Perimount valve; is that correct?

A. Yes.

Q. It's not trying to address PVL between the outer cloth and the native leaflet; correct?

A. As I've already said, there are no native leaflets, so they can't assess leakage between the native leaflets because there aren't any.

Q. That's not the intention. It's intended to address --

A. It's an experiment to see how well it seals against the valve and the valve they're using for experiments -- experiment is the Carpentier-Edwards Perimount, but it has implications which goes beyond using it just in a Carpentier-Edwards Perimount.

Q. Does Walther say that?

A. No. I'm saying that.

Q. Well, Walther does not say that, correct?

A. I think that's true.

Q. Okay. Let's go to page 2 of Walther -- sorry, page 2 of the PDF, which is page 1121 of the document and let's look at -- let's look at Figure 1. It looks like at the top image in Figure 1.

Why don't we zoom in on that. So we are looking at, as I said, the top image of Figure 1.

And would you call this a side-view or how would you characterize this?

A. Side-view is fine.

Q. And we see the Walther outer cloth surrounding SAPIEN valve; is that correct?

A. Yes.

Q. And the Walther cloth is made of PET; is that correct?

A. Walther says it's made of PET and it says that's polyethylene terephthalate. T-e-r-e-p-h-t-h-a-l-a-t-e.

Q. Okay. Okay. All right.

What is the -- if I took a cross-section of that cloth, laid it flat on a table, how thick would it be?

A. I can't give you an exact dimension, but you can get a rough idea of its thickness looking at the picture because you know some of the dimensions of the -- of the valve.

Q. So what's your best estimate of the width of the cloth that Walther uses?

A. It looks in that photograph to be a couple of millimeters.

Q. Your estimate is that's a couple of millimeters?

A. Yes.

Q. Based upon a side-view?

A. Based on the side-view.

Q. How can you tell from the side-view how thick the cloth is?

A. Because you're looking at how much it comes out further than the device. You can see the diameter of the device at the top where you can see the underlying frame. You're not in the room so --

You can see the SAPIEN valve. You can see the frame diameter.

Q. So --

A. And you can see how much further the cloth comes out.

Q. So it's -- oh, I see. So you're looking -- you see where Mr. Hsieh has put the mouse --

A. Yes. Where the little hand is. I've got a little hand. You can see he's got little hands are going up and down the struts and then that is the edge of the frame. And now he's got the hand on the extra sort of extrusion, if you're with me, of the cloth from the frame and it looks to me that's a couple of millimeters in thickness.

Q. Okay. So if I were looking at the diameter, that would add 4 millimeters to the overall diameter of the valve plus the cloth in the expanded state; is that fair to say?

A. Yeah. I'm taking this picture to be -- it's just

sitting there in the room with the cloth having been put on the SAPIEN valve, and they've taken a photograph of it.

So actually you're right, there's no compression. It doesn't look like it's got any forces acting on it other than it's sitting there in that photograph.

So it looks to me that cloth, that's the order of a couple of millimeters, which you might be saying on each side. So that two plus two would add 4 millimeters to the total diameter.

This is eyeball. I'm not trying to say that I can accurately do it. Looks like a couple of millimeters either side. So fully expanded it would add 4 millimeters to the -- to the size of the device.

Q. Now, the -- I believe your testimony was it has a fibrous finish.

Is that correct?

A. Yeah. I think you can see it in the photos. It's got a textured finish and you can see fibers sticking out, particular two sides where you've got them against the darker background.

Q. What is a fibrous finish?

I guess I'm focused on the word "finish."

A. The word -- finish just means the -- the cloth is there, the finished cloth.

Q. Why do you call it a fibrous finish? It seems like, for example, if I put a finish of oil on my car or something like that, it's something I've added.

Is that something you had in mind or something else?

A. Sorry. Not at all. It's just is you can see the fibers. If you get the impression the whole thing is a -- is a massive fiber, you see from the front of it, it looks like a fibrous cloth.

Q. I'm sorry. Go ahead.

A. It -- it's not been, you know, sort of embedded in something or buried in plastic or, you know, the fibers are bare, visible, and in places protruding.

Q. How did the fibers attach to the frame?

A. How do --

Q. The fibers attach to the frame?

A. The cloth. The fibers are part of the cloth. And the cloth is being -- I think it says it's being stitched onto the perimeter of the device.

So the cloth is held on by stitching. The fibers are just part of the cloth.

Q. And is the cloth woven?

A. It doesn't say. I don't believe it says.

Q. Do you know?

A. I don't know, because it doesn't say. And I

don't know extra knowledge of publication, but looking at it, it looks to me to be that it's probably a knitted cloth. But I don't know. But I'm just giving my best sort of educated guess.

Q. What's the difference between knitted and woven?

A. Well, woven is -- it's an over and under, over and under. The whole cloth is over and under.

Knitted is like you see your -- your mother or people with knitting. So the thing is done in loops, a whole series of loops. Knitted fabrics are a series of interconnected loops, whereas, woven is over, under, over, under.

Q. But you'll agree that Walther never refers to its cloth as knitted; correct?

A. Correct. He doesn't refer to -- as I sit here, I mean, without going through -- I don't think he says how it is formed. He says it's PET cloth, but he doesn't say it was woven.

Your original question to me is was it woven? Does it look like it's woven?

To me, it looks as though it may be a knitted cloth. He doesn't say.

Q. Do you -- is it fair to say that from the image we're looking at -- again, we're looking at the top image in Figure 1 of Walther -- that the fibers are

opaque such that you cannot see the frame behind the fibers; is that fair to say?

A. The mass of fibers that the cloth is made from is opaque. You can see the individual fibers. They talk about the mass of fibers from which the cloth is made.

Q. And is it fair to say that you cannot see the metal frame on the proximal end of Walther?

A. Which do you mean? Which -- just to be clear to what you mean, by proximal? You mean the top or bottom?

You can see the frame at the top --

Q. I mean the bottom.

A. I can't -- I can't clearly see the frame. I don't know if I can see a couple -- I can't clearly see the frame on top.

Q. Okay. Ed, let's go to Figure 2.

A. By Figure 2, you mean the one they label as Figure 2, not the second one of Figure 1?

Q. Correct. Although we're having a sidebar here. Just give me a second.

A. Okay.

Q. Okay. So -- sorry for that. We're -- we're now still in Walther and we're looking at Figure 2, and we're looking at the -- you'll see there are three photos in Figure 2, and I'm going to ask you about the one that's the top row on the left.

Do you see that?

A. You've got it on my screen in front of me. That's good.

Q. And do you agree -- why don't you tell me, what do we see here?

A. What do we see? We're seeing the rubber ring, the red, orangy color is the ring in which the -- the Carpentier-Edwards Perimount is being fixed. And within the Carpentier-Edwards Perimount is deployed the -- the cloth covered SAPIEN inside it.

Q. Now --

A. Looking at the bottom.

Q. Yes.

And do you agree from the perspective of the patent that this side is referred to as the proximal end?

A. Your patent -- yes, this is referred to as proximal.

Q. Do you see the metal frame in the image that we're looking at, Figure 2, the top two to the left?

A. I can't see anything that I definitely can say is metal frame. It's not a very good image. It's not a very high quality image. I can't see anything that I can say is the frame in this particular -- one of the three pictures. I can see the frame in the other two

pictures.

Q. So if we go to the image to the right in the same top row, you can see the apices -- I guess the patent called them the distal apices of the frame?

A. Yes. And I can see a bit more of it. I can see struts. I can certainly see the apices, which is brighter because they have the light reflected on them, but you can also see the struts extending to the left and right, or up and down from each of the apices.

You can see the structure of the top of the SAPIEN frame, which is not surprising to look this way, because the outer cloth doesn't come all the way up to the top of the -- of the device. And it's clearly sitting, you know, fairly proud in the Carpentier-Edwards valve.

Q. Okay. Let's go down to -- same page, 2, methods. Same page.

(Off record discussion.)

BY MR. LOWENSTEIN:

Q. Okay. Okay. So you see the third sentence, it says, "The SAPIEN valves were deployed inside various CEP valves (see Figures 2 and 3) via the 33 Fr. Ascendra system."

Do you see that?

A. Yes.

Q. And is there any indication in Walther that any other delivery system is used?

A. None. I mean, the 33 Fr. Ascendra system is the -- was a standard commercially available system used for transapicals, and I think they're just using what was available to them. So they're using what is an Edwards commercial system, a 33 Fr. Ascendra system.

Q. So you agree that this is a transapical procedure? Obviously we're talking in vitro.

Like I said, fair to say that you would use the 33 Fr. system for transapical at the time but you wouldn't use it for transfemoral?

A. No. No. No. This is -- this is -- the 33 Fr. Ascendra system was a system that was used in transapical procedure. This is not a transapical procedure.

They're using the Ascendra 33 Fr. system as the delivery means in this -- in this experiment.

Q. Of course. Of course.

A. But they would use it because that's what was used to deliver the -- the SAPIEN valve.

Q. If you were going transapical?

A. Yeah. In a clinical procedure, you would use it. So what it tells you is that they were able to deliver a SAPIEN valve, plus the cloth cover via the standard

equipment that was used at that point in time for some procedures at that point in time.

Q. Okay. I'd like to go to the last -- I'm sorry, page 7 of the PDF. Page 1126 of Walther. And -- and there's this exchange between Dr. Maisano and Dr. Walther.

A. Yes.

Q. And Dr. Maisano says, "Thomas, you have not shown us" -- I'm sorry -- "you have shown us a valve which is not available on the market, the SAPIEN with cloth. There are obviously two questions I have regarding this design. One is how much the cloth increases the delivery system size, and, number 2, how much the cloth decreases the effective orifice area of the transcatheter valve?"

First of all, do you see that?

A. I do. I see it.

Q. And then Dr. Walther responds, "Important questions. I am not sure whether it changes the effective orifice area that much and I am pretty sure that you just squeeze it in. You have four atmospheres and really it is just filling little gaps there. We have used that valve in the initial TRAVERSE study, in about 10 patients and we thought that this would be helpful to seal off against paravalvular leak."

A. So he's been using it in a study called TRAVERSE -- capital T-R-A-V-E-R-S-E -- in about 10 patients.

Q. And do you know if this is a transapical procedure?

A. I -- I don't know anything that's not there and I've not gone along and followed it up because I don't believe it falls in the prior -- our time frame. This was prior art. This was published in 2011.

In fact, this conversation is in September of 2010. This is at a meeting where they presented the data and he's giving them more information there saying it's been used in about 10 patients in the TRAVERSE study.

But I don't know more than is written there.

Q. Okay. So the next paragraph of his, Dr. Walther's answer, he says, quote, "The question of when it will be available, I am not so certain. I hope it will come pretty soon. I think it will be an advantage, at least for the transapical approach, where tight crimping is not an issue," closed quote.

Why is tight crimping not an issue in transapical approach?

A. I don't quite honestly know what he means, because you've got potentially the transapical approach,

you can be using the 33 Fr. Ascendra as he did for this in vitro experiment, and that leaves you a lot of work (sic) and, therefore, it's not an issue.

You don't have to crimp it down so tightly because you've got the 11 millimeters and dividing 33 by 3 to come up with 11, you've got potentially a lot of room there.

Q. Now, is the 33 Fr. Ascendra system, is the 33 Fr. the interior diameter or the exterior diameter?

A. I don't know.

Q. If it's the interior diameter, would you have any reason to believe that the exterior diameter would not add 4 Fr.?

A. I -- I just don't know. I don't know, I haven't used, as I've already said several times, the Ascendra delivery system. I just have no idea of the -- whether the dimension is internal or external or indeed if it was internal, what extra dimension that would be of the thickness of the system.

Q. Okay. Give me a moment.

Dr. Buller, you're familiar with the SAPIEN 3, of course?

A. Yes.

Q. And SAPIEN 3 had an outer skirt; is that correct?

A. Yes.

Q. And the SAPIEN -- sorry. That is not my dog.

The SAPIEN 3 is the first Edwards TAVR that had the outer skirt or cloth or cuff; is that correct?

A. No. Because this one we just looked at has cloth. It's the first commercially approved one.

Q. That's what I meant to ask. Can I reask a better question?

A. Yes.

Q. Is it fair to say that SAPIEN 3 is the first commercially-released Edwards TAVR device that has any sort of outer sealing external to the frame?

A. To the best of my knowledge, that's true.

Q. And am I correct that the SAPIEN 3 was approved in 2015, at least by the FDA?

A. Yes. I think we went through this earlier. I think that's right. But the same caveats I said, I don't know offhand that I've got the date in my mind, but that sounds reasonable, if that's what you're telling me.

Q. Can we agree that the outer skirt in SAPIEN 3 is thinner than Walther's cloth?

A. No. It depends. Walther's cloth looks to me as if it's very compressible. It looks like it can be squashed down. The photos that we've looked at is not squashed. It just appears to be sitting in air to be

photographed and I have no idea what it's being squashed down to. It may be well (sic). It may well have been the case that it could be squashed down, something of the same sort of size or thinner than the outer skirt on SAPIEN 3.

Q. I heard of a lot it may, it may, it may, it may. You don't know, do you?

A. That's what I'm saying, it may.

Q. But it may not; correct?

A. It may not. But you asked me whether it was thicker and I'm answering you so that you understand that I can't say that it is thicker because it may be able to be compressed to a dimension which is either not dissimilar or even thinner than the outer cloth on the SAPIEN 3.

Q. In the SAPIEN 3, in the expanded state, if we look at where the skirt is stitched to the frame, how thick would a cross-section of that skirt be at that point?

A. I -- I don't know. SAPIEN 3 is not prior art and, therefore, I haven't studied it for this case or this deposition.

I do not know. I don't have to mind the dimension of the cloth of SAPIEN 3 dimension part of it.

Q. Are you familiar with a phenomenon called

bunching?

A. Yes.

Q. And are you aware that if you have an outer cloth when you crimp it, the cloth can bunch?

A. Well, it might. It depends on the characteristics of the cloth. If the cloth is compressible and squashable, it might not bunch because it may be able to be compressed lengthwise as well as thickness-wise.

Q. Do you know whether Walther's device when crimped will bunch?

A. No. There isn't a picture. I haven't the information in Walther, nor does it give a picture. But my guess is if there were any bunching at all, it would be minimal because it would be designed as a squashy cloth.

Q. You said that was a guess?

A. Yes. That's my -- my educated guess. And it is related to, as you understand, that the second author of Walther is one of the inventors on what is referred to in this case I think is Spenser 2, and this is a real-world experiment or the concept which was taught in the Spenser 2 patent, and that's why it's got one of the inventors as an author in Walther.

Q. You're saying that Walther is a real-world

implementation of Spenser 2.

You agree that Walther is a real-world embodiment of Spenser 2's Figure 22 embodiment; correct?

A. Yes. I think that's a fair -- that's a fair characterization. It is using a concept towards Spenser 2 and it doesn't surprise me that one of the inventors on Spenser 2 is an author in Walther.

Q. And by "concept," you're referring to SAPIEN with an outer cloth; correct?

A. To Walther, yes, SAPIEN with an outer cloth.

Q. And are you aware of any instance of a SAPIEN with an outer cloth being implanted transfemorally?

A. No.

Q. Are you aware of any instance of a SAPIEN with an outer cloth being delivered via the common iliac?

A. No.

Q. So in the history of the world, you're not aware of any instance with an outer cloth, like the one we see in Spenser 2, Figure 22, like the one we see in Walther, ever being implanted transfemorally; is that correct?

A. I've answered I'm not aware of it.

Q. And you're not aware of any instance in the history of the world of an outer cloth, like the one we see in Walther, like the one depicted in Figure 22 of Spenser 2, ever being implanted in any person in the

history of the world via the common iliac; is that correct?

A. Can I just clarify on what you're --

Q. You've got to answer my question.

A. No. I've got to clarify your question to answer it.

That's fair, isn't it?

Q. We'll see.

A. Are we dealing up to the prior art date or are you coming up with history of the world?

Q. I mean up to the present.

A. You mean up to the present?

Q. Yes.

A. Do you have, therefore -- I mean, is a cloth SAPIEN ultra -- SAPIEN 3 ultra has a cloth on the outside, which has been implanted by the femoral artery, because if it's the history of the world that it's coming up to today, I'm aware that SAPIEN 3 ultra has been used.

So I'm just trying to clarify what your question actually is. If --

Q. So we see in Walther a delivery via a 33 Fr. Ascendra system; is that correct?

A. Yes.

Q. And because Spenser 2, Figure 22 is the

embodiment of Walther, is it fair to assume that 33 Fr. Ascendra would be used for that procedure as well?

A. I'm sorry? Ask that question again.

Q. Because Spenser 2, Figure 22, is embodiment -- or Walther's embodiment of Figure 22 --

A. Yes.

Q. -- is it fair to say that we can reasonably deduce that Figure 22 embodiment would also be implanted via 33 Fr. Ascendra system?

A. No.

Q. Why not?

A. Well, because you have a whole lot of variables that you can change at Walther. Figure 22 is taught it can be put on any valve and it's specifically taught it can be put on a percutaneous valve.

Q. That's not true.

A. I thought it did. Then you corrected me.

Q. Show me where it says that. Let's look at Spenser 2.

A. Let's look at Spenser 2.

Can you stick it up on the screen for me?

Q. Yes. But you'll agree that the -- before we do that, you'll agree like that the -- let's go before the SAPIEN 3 ultra.

You're not aware of any cloth like the one we see

in Walther, like the one we see in Spenser 2, Figure 22, ever being implanted in a TAVR via the common iliac; is that fair to say?

A. I haven't looked, but I'm not aware.

I'm aware of devices that are not dissimilar to the SAPIEN 3 ultra being implanted by the femoral.

Q. Say it again? I didn't hear you.

A. Can the court reporter read it back. I don't want to paraphrase it.

Q. Fair enough.

(Record read.)

BY MR. LOWENSTEIN:

Q. Do you have in mind it's the SAPIEN 3?

A. I was talking about SAPIEN 3 ultra, because it's got a more textured fabric on the outside, which is tightly applied to the frame. The SAPIEN 3 is another one that has baggy materials, they're slightly different from the teaching in Figure 22 of Spenser 2.

Q. You agree that in Walther and Figure 22, Spenser 2, the cloth goes much higher up on the outer frame; is that fair to say?

MR. SUMMERS: Object to the form of the question.

THE WITNESS: Higher than what?

///

BY MR. LOWENSTEIN:

Q. Levi. Like the jeans.

A. No. Levi teaches the cloth can go to any level you want.

Q. You believe that Levi teaches that the cloth can go to any level that you want.

A. Yes.

Q. So you think --

A. It both teaches it in the specification and in the claims. It can go from a first location to a second location without limitation.

Q. So you believe that the embodiments you rely upon in Levi, the cloth -- the skirt can go anywhere you want; is that correct?

A. No. You're -- you're really distorting what I've said.

What I have said is that Levi teaches that the cloth can go from a lower point of the inflow that you can choose up to any point you want, a second position, and that is both taught and claimed in Levi.

Levi then has embodiments, which are particular examples, and it has embodiments that show that the outer fabric going to two different levels.

Q. And the embodiments you relied upon in Levi, those embodiments in the expanded state, the skirt is

intended to lie below the annulus, correct?

A. No. No. That's nonsense.

Q. Nonsense?

A. Yeah. Of course it isn't intended to lie below the annular (sic). One embodiment it comes up towards the top of the valve; in the other embodiment, it covers the whole of the first row of cells.

Q. I believe my question was framed in terms of the embodiments you relied on.

A. They are the two embodiments. That the two embodiments or single embodiment -- depends how you look at it -- it has different heights, outer cloth on it. One goes up one cell and the other goes up one and a half cells to cover the second row.

Q. So what are the two embodiments you relied on in Levi?

A. They're not necessarily two. Hang on. You asked me -- I've got Spenser. You asked me to show you something in Spenser 2 and then you dropped it and never let me show it to you.

Q. Too much time on TV. You're reminding me of my attention span, so I moved to a different line of inquiry.

A. You don't want me to show you in Spenser 2 where it teaches --

Q. No. Let's stay on Levi for a second. I want to know what the two embodiments are that you relied on?

A. They're not necessarily two embodiments. They're different versions of the same embodiment. And they are -- I have a copy of Levi here, so -- Levi. The ones that we've talked about in my declaration are the 42, Figure 42 and Figure 43 show two different heights of the outer skirt.

Q. So you agree that because they're different heights of the outer skirt, those two heights can't exist in the same valve at the same time; correct? It's one or the other?

A. Well, you could theoretically have a different height on one side than the other. But I can't think of any reason why you would choose to do that. But you could. But I -- I -- I have taken it to be that this is a representation of it all the way around circumference.

Q. But you agree that it -- okay. So you'll agree that any sense of a person (sic) would stitch the outer skirt at the same level around the entirety of the valve; correct?

A. No. What I'm -- what I've just said, I have said I've taken the figures to be representative that it's going around like that, but you could easily envision that the entire one side than the other side, that's not

a difficult thing to envision.

Q. So you believe that Levi has in mind is we're going to have -- we're going to go up to the second row on one side and another row on the other side?

A. No. I'm saying that's a possibility. I have no idea what was in his mind at the time. I'm saying it just is a possibility that you could have a different height skirt on one side than the other side.

Q. So you believe there's one iteration of Levi's valve that has the outer skirt attached to the first row of the outer frame, the embodiment of the outer frame; is that fair to say?

A. Yeah, Figure 43 appears to show valve has an outer skirt attached at the top, so at the distal using the proximal distal, as we've been defining them earlier, at the distal end of the first cells.

Q. You said distal end, but I believe in the lexicon or -- of the patent you mean proximal, correct?

A. Yes. So it's distal. Because they're at the top, all right, at the top is an easier word to use. So the top of the first cell.

Q. I'm sorry, maybe we're -- please say it again. The top row of the --

A. In Figure 43, the figure shows the outer skirt attached at the top of the first row of cells.

Q. First row of cells, starting from the proximal end; correct?

A. Starting from the bottom of the device as we're looking at this from the proximal end.

Q. All right. And you believe Figure 42 shows a different valve or the same valve, I guess, but in that figure, the skirt is attached to the second row of cells; is that correct?

A. Yes. It's got a variation. It's got the skirt going to a higher position than in Figure 43. So it goes up to what you could call the top of the second row of cells counting up from the bottom.

Q. Let's go to -- let me ask you this.

Aside from Figure 42, are you aware of any other disclosure in Levi that shows the outer skirt attached to the second row of cells in the outer frame from the bottom?

A. Yes. There's disclosure that features that you can connect it where you want. You can connect it as high or as low as you wish.

Q. Is there any other figure that depicts --

A. There's no other figure that I am aware of. There is -- there is teaching. But you can connect the skirt where you wish and, therefore, you can have it going up as far as you wish it, and that is I think in

column 3 and it is also claimed in the claims.

Q. Now, in -- you'll agree that you did not rely on Levi claims in your obviousness grounds; is that fair to say?

A. It is fair to say.

I didn't know this was really an issue until later when I read the Brecker reports and things. I didn't know there was going to be so much dispute about Figure 42, 43.

They clearly show what I'm talking about, but there seems to be dispute as to whether this actually shows what I think it shows.

Q. Let's go to Figure 1.

A. Figure 1.

Q. You agree that Figure 1, the skirt is attached to the bottom row of cells; is that fair to say?

A. Yeah.

Q. And the same is true in Figure 2?

A. Yes. Figure 2 is, again, a multiplied embodiment, has a different number of cells going around. Figure 1 is different than Figure 2 in a different way.

If you look at the number of cells going around, there are three large cells going around each commissure.

Q. I believe it's c-o-m-m-i-s-s-u-r-e, but I am not 100 percent sure.

A. That's correct.

Q. So you believe Figure 2 is a different embodiment than Figure 1?

A. I wouldn't call it a different embodiment. I think within an embodiment you're allowed to have a difference of variations within the embodiment.

What I can say is that Figures 1, 2 and 3 aren't the same. You can clearly count the number of box cells between the commissures, it's easier in 3, perhaps. There's 1, 2, 3, 4 or as in Figure 2, there's only 1, 2, 3. So Levi is allowing the variations.

Q. Okay.

A. Dimensions.

Are you with me.

Q. I am.

The question I want to ask you, you agree that in each of the Figures 1, 2 and 3 the outer skirt is only attached to the bottom row of cells?

A. Correct.

Q. Now, let's look at Figure 18.

A. Figure 18.

Q. Is Figure 18 consistent with the outer skirt being attached to the bottom row of cells?

A. I think 18 seems to be different again. Figure 18 appears to be different again, because if you go down, you can see the commissure window with the -- commissure window with the commissures inside it. And if you go down, you can see a straight line coming down from the commissure window, there's two whole cells before you get to the outer skirt. That is different from Figures 1 and 2 and 3.

Q. But my question is in Figure 18, is that fairly consistent with the outer skirt being stitched to the bottom row of cells in the outer frame?

A. No.

Q. Not consistent with that?

A. It doesn't appear to be, unless the frame has an extra row of cells. I can't tell on this figure what it's corresponding or what it isn't, because it appears to be different. There appear to be more cells in this device.

Q. You think Figure 18 is different than Figure 17?

A. No. I'm not saying it's different from Figure 17. I'm saying different from Figures 1, 2 and 3.

Q. Okay. Let's look at Figure 17 and then look at Figure 18.

A. Okay.

Q. I'll ask again, do you believe Figure 18 is consistent with the outer skirt being attached to the bottom row of cells in the outer frame?

A. If -- if you take it from Figure 17, it appears to come up close to the bottom row of cells.

Q. It doesn't go to the second row of cells, clearly; correct?

A. No. It doesn't go to the second row of cells. It comes up close to the first row of cells, but there appears to be an increased number of rows of cells, at least on Figure 18, which is being rotated.

Figure 17, I cannot even see the commissure window, so the two don't correlate with each other.

Q. Fair enough. That's a fair point.

A. Do you see what I mean? I'm not sure they're the same.

Q. Let's look at Figure 56.

A. Figure 56.

Q. Is this consistent with the outer skirt being attached to the bottom row of cells of the outer frame?

A. Figure 56 looks very similar to Figure 18. I haven't compared them side by side, but I'm just trying to do it for you.

It may be attached just below the top of the bottom row of cells. You can see a little bit of what I

take may be the bottom row of cells poking out on top of the outer skirt.

Q. Say that again?

A. The skirt attachment appears to be a little below the top of the bottom row of cells.

Q. It's definitely not attaching to the second row of cells from the bottom; correct?

A. Assuming they're the same dimensions going up, no, it isn't.

Q. Can you see any figure in Levi, aside from Figure 42, that depicts the outer skirt being attached to the second row of cells?

A. No. Figure 42 is the only figure that shows that, but there is text that supports it.

Q. Let's go to column 2 of Levi.

A. Yes.

Q. Before -- before we go to column 2, let me ask you a question. Looking at all of the figures in Levi, do we see any outer -- image of the outer skirt in Levi that resembles the outer skirt in Walther?

MR. SUMMERS: Object to the form of the question.

THE WITNESS: It really depends what you mean "resembles."

Is it the same as Walther?

No, but there is an outer skirt that for the same reason, i.e., sealing, an improving sealing, and in that there are similarities. But there is no picture, which is the same as the photographs in Walther.

BY MR. LOWENSTEIN:

Q. You agree that Walther appears to have a thicker -- that the outer cloth in Walther appears to be thicker than the outer skirt of Levi; is that fair to say?

A. No. As we talked about, Walther, I would expect, squashed down and I don't know whether the squash-down dimension would be great (sic) or less or the same as in Levi.

Q. Okay. I'm just talking about an expanded state. Can we agree that the outer cloth in Walther is thicker than the outer skirt of Levi?

A. In the uncompressed state, the cloth in Walther appears to be thicker than the -- than the diagrams or teachings in -- in Levi.

Q. Can we agree that the outer cloth in Walther covers more of the height of the outer frame relative to Levi?

A. No. No. Because one of the figures in Levi say the skirt coming up to a higher level and the teaching of Levi comes in coming up to whatever level you wish it

to come to.

Q. You're referring to Figure 42?

A. I'm referring to Figure 42 and the teaching of the parties that teaches the skirt come up to second level and it's not constrained as to what that level can be.

Q. Can you somehow show a side-by-side comparison of Walther's Figure 1 and Levi's Figure 42?

MR. HSIEH: I can attempt to do so.

BY MR. LOWENSTEIN:

Q. Okay. Dr. Buller, can you see a side by side showing Walther's Figure 1 compared to Levi's Figure 42?

A. Yes.

Q. So let's just be clear, we can agree that the -- we can agree that we're looking at the expanded state of both Levi and Walther in the comparative exhibits; correct?

A. Yes.

Q. And you agree that the outer skirt in this -- in these images is thinner in Levi relative to Walther's outer cloth; is that fair to say?

A. I wouldn't dimensional, the patent drawings, I couldn't say that.

Q. So just to be clear, when 42 is the only thing that shows -- the only thing in Levi that goes to the

second row of cells from the bottom, that is gospel, but everything else in Levi's figure shows we just can't accept, right?

A. No, I wouldn't tell you from Figure 42 what the dimensions of the outer skirt are, the thickness. It's a patent drawing and I wouldn't use it to get a dimension.

Q. Why should we rely upon Figure 42, which is the only figure in the entire patent that seems to show it to the second row of cells? Why is that --

A. Because that's not the thickness. You asked -- unless I mis- -- completely misunderstood your question, you asked me about thickness and I'm saying from the patent drawing 42, I can see it's going up to the -- the top of the second row of cells, that's not dimensioning the thickness of the fabric, that's just seeing where it's attached.

Q. So you believe -- I just want to make sure I understand. You believe that the globing (sic) laser cut PET that is used in Levi might be thicker than the outer cloth in Walther?

A. No. I'm saying it's not limited, and therefore I wouldn't dimension from the patent drawing. Your question is asking me whether Figure 42 shows that it's thinner, and I'm saying I wouldn't obtain that dimension

from a patent drawing such as Figure 42 in Levi.

Q. You believe that Levi wants a thick cloth?

A. No. I think Levi would not want a thick cloth. Levi is designed so that it can pouch out and pouch up and therefore parts of it will become probably radially thicker than Walther because it is designed such that it is larger than the frame and, therefore, bits can stick out. And I think you see that in the figures, that it's shown bulging out and therefore the thickness of it in the radial direction can become very much larger than Walther.

Q. Let's pretend that the judges on the tribunal are here right now watching your testimony. Let's pretend that.

You're going to testify under oath that the outer skirt in Levi might be as thick as the outer cloth in Walther in the extended state? That's your testimony?

MR. SUMMERS: I'm going to object to the form of that question. We are --

MR. LOWENSTEIN: Do not interrupt my deposition.

Q. Answer the question, please.

MR. SUMMERS: Judges aren't here. But go ahead.

THE WITNESS: I think perhaps I've explained

it badly or perhaps you didn't understand my explanation.

But what I'm saying is Levi is designed so that there is excess material on the outside and that is designed so that it can form pouches sticking out from the frame.

And those pouches sticking out in the radial direction can end up being thicker than the outer fabric on Walther.

BY MR. LOWENSTEIN:

Q. Okay. Let's put that to the side.

Let's say I cut off the outer skirt on Levi and I laid it on my desk, and I cut off the outer skirt in Walther and I laid it right next to it and I took a ruler -- laid it flat, I took a ruler and I measured which would be thicker.

Would you agree that Walther's cloth would be thicker?

A. Uncompressed, yes. And I've said that I think several times.

MR. SUMMERS: Wait. Let him finish his answer.

THE WITNESS: Walther can be compressed down and made thinner and Levi can be puckered up and made thicker.

BY MR. LOWENSTEIN:

Q. I know we haven't paid you over half a million dollars. But we can all see -- we can all see with our plain eyes Walther's outer -- excuse me, Mr. Summers, you need to stop interrupting my deposition.

MR. SUMMERS: Quit asking questions.

BY MR. LOWENSTEIN:

Q. We can all see -- we can all see that Walther's outer cloth is plainly much thicker in the uncompressed, expanded state relative to Levi's outer skirt?

A. No. Levi is designed to pucker up, to fold, to crease, and therefore you end up with material or you could end up with layer on top of layer deliberately on the outside.

Q. I did not ask you about compressed state. I asked you about the uncompressed, expanded state. We can all see what is plainly in front of all of us.

MR. SUMMERS: Please let the witness finish his answer.

MR. LOWENSTEIN: Excuse me. Mr. Summers, you need to be quiet.

MR. SUMMERS: Stop interrupting.

MR. LOWENSTEIN: I need you to stop speaking.

MR. SUMMERS: Stop interrupting the witness.

MR. LOWENSTEIN: I need you to stop speaking right now.

MR. SUMMERS: You heard me.

Go ahead.

BY MR. LOWENSTEIN:

Q. We can all see with our bare eyes in comparing the expanded valve -- the expanded valve, not the compressed valve -- in Walther versus Levi, we can all plainly see that the outer cloth in Walther is much thicker than Levi's outer skirt, can we not?

A. No.

Q. We can't see that?

A. No. It's a patent drawing. You're -- you're reading stuff into it that I think is entirely inappropriate.

Levi is designed that when it's expanded it can have areas where the cloth can double up, fold over. This is talking about expanded. I'm not talking about the compressed device. And therefore in those areas, the cloth may become thicker than Walther's outer cloth.

I have said this several times.

Q. Let's break for lunch.

Back in an hour.

THE WITNESS: I'll do less if you want.

MR. LOWENSTEIN: Let's go off the record.

(Lunch recess from 11:23 till 12:27.)
MR. LOWENSTEIN: Is everyone ready?
MR. SUMMERS: Yes.
THE REPORTER: Yes. Thank you.
MR. LOWENSTEIN: Let's go back on the record then.

Q. So we're going to share Levi again, okay.

Let's go to column 2. And you can see we're in the -- you can share the whole column. Just show the full screen.

Okay. You see there's a section called "Background"?

A. Yes.

Q. Okay. I'd like to look at the last paragraph in the section called "Background." It starts at the beginning of column 2.

A. Yes.

Q. So it says, quote, "An important design parameter of transcatheter heart valve is the diameter of the folded or crimped profile. The diameter of the crimped profile is important because it directly influences the physician's ability to advance the transcatheter heart valve through the femoral artery or vein. More particularly, a smaller profile allows for treatment of a wider population of patients, with enhanced safety."

Do you see that?

A. Yes.

Q. This tells you that Levi is concerned with narrowing the crimp profile such that a -- the catheter can be transmitted transfemorally; is that fair to say?

A. Yes. That's one of the things he said there.

Q. In fact, does Levi have any relationship to SAPIEN 3?

A. I'm not exactly sure what you're asking. I think SAPIEN 3 is an embodiment of Levi, but there's no sub-relationship. Levi and his colleagues are the inventors that led to the commercial embodiment called SAPIEN 3.

Q. Okay. I want to go to -- now, we see a "Summary."

And is it fair to say that's a summary of the invention?

A. That's what I understand the section to be, the summary is a summary of the vention (sic) invented concept.

Q. Is it fair to say that the problem Levi is trying to address is problem of a crimp profile, getting a narrower crimp profile, is that at least an aspect of the problem that Levi is trying to address?

A. Yes. It's an aspect of the problem he's trying

to address. Obviously he wants it to be a good valve or reliable valve, but all other things being equal, he wants it to be a smaller a crimp profile as is possible.

Q. Is there any indication of Levi that he wants his valve to be transmitted through any route aside from transfemoral?

A. I can't remember. At I -- obviously, by the time of Levi, the various possibilities we're naming including transapical and therefore I can't actually answer that.

His main focus is on getting it smaller so you can do a higher proportion of patients from the femoral that he acknowledges by virtue of that statement, that some you can't do and therefore he would be interested potentially in others routes, but the ones that you can't do. Some people's -- some arteries are complete blocked and you can't go through them and therefore you've got to go through other routes.

Q. Okay. I'd like to go to other -- I think it's 22 -- 21. 22, rather. Starting "The outer diameter." I'm going to read it.

It says, quote, "The outer diameter of the inflow end portion of the frame is smaller than the outer diameter of the outflow end portion of the frame," closed quote.

Do you see that?

A. Yes.

Q. And then he says, "The reduced" -- quote, "The reduced diameter of the inflow end can be due to a reduced amount of materials positioned within the inflow end portion of the frame. The reduced diameter at the inflow end portion can make room for an outer skirt positioned around the inflow end portion."

Have I read that correctly, more or less?

A. Yes.

Q. Now, can I understand from this that what Levi is doing is it's creating a valve that has a narrower portion at the inflow end or as Aortic's patent sometime refers to it as the proximal end, and that narrowed diameter facilitates the addition of an outer skirt; is that fair to say?

A. Yes. That's one of the things. I don't know -- yes. It allows room for the additional width without adversely affecting the crimp profile as much as if you didn't have that tapering.

Q. So the notion is that Levi wants the outer skirt to be attached to the narrower portion, not the non-narrowed portion; is that correct?

A. Yes. But one of his ideas of teaching is that you can narrow the frame over a section and that can in

turn allow room for a skirt.

Q. And if you attached a skirt on the non-narrowed portion of the frame, that would sort of defeat the purpose of the narrowing in the first place; is that fair to say?

A. Well, I don't know that it would defeat the purpose. You -- you might want to attach only parts of it on the higher part and, therefore, it wouldn't take up as much room.

Levi's skirt that we've looked at, you'll remember, at the top isn't complete. It sort of has cutouts and those cutout parts will have material removed which reduces the bulk of material at the top end of the skirt in the figures we've already looked at.

MR. LOWENSTEIN: Could we go to Figure 1, Ed. Pull up Figure 1.

Q. Okay. And we already talked about this, but I just want to understand you.

We agreed before, I think, that in Figure 1 at least, the outer skirt is attached to top of the bottom row of cells in the outer frame; is that fair to say?

A. Yes.

Q. And we can see that there are two more substantially similar rows of cells just above it; is that fair to say?

A. Yes. They're not the same as each other. It's not a uniform structure, but that, I think, is fair to say substantially, they're not vastly different.

Q. And if you look, there's a top row of -- a top row of cells, which is materially different in shape compared to the first three cells, and that's the -- the row of cells that has the commissures?

A. Yes. Has these great big cells on the top row, and then there's the somewhat smaller commissure windows, which is to say, they are also cells that they're opening, they are the actual leaflet material comes through to create the commissure.

Q. Now, let's say that I attached the outer skirt at the top of the third row of cells, would that extend into the wider portion of the frame when crimped?

A. Well, it depends how much the wider row extends up. I mean, I think, yes, it likely would. But you can see the point that I'm making that because of the scalloped profile of the outer skirt, there is a lot less material in the outer skirt from the upper part there than the lower part.

Are you with me?

And therefore -- therefore if you attach that upper part, you're taking up less room than if you turn the thing upside down and had a take of continuity of

the excess fabric going around.

So it depends on all the dimensions as to how far your tapering goes and how much material is in the skirt and how big the unit is cut out from.

Q. Is it fair to say that Levi's solution is essentially you have a frame that, as we discussed, has a wider portion and narrower portion when crimped?

We can agree to that?

A. He has many different concepts, but one of the concepts is he has a narrower frame at the proximal end, proximal distal way, yes.

Q. And you attach the outer skirt to the -- towards the proximal end of the frame where it's narrower; correct?

A. You can. You can -- as I've already said, you can attach the skirt as high or as low as you wish. That's covered in the teaching.

Q. But the passage we just looked at suggests that you attach the outer skirt at the narrower portion because that allows you to get a narrower crimp profile, which I think we pretty much agreed is one of the objectives; is that fair to say?

A. That's one possibility. You don't have to necessarily practice all of his teaching all at once. But yes, that's one of the teachings that you attach the

skirt in the zone that you can make narrower, but I don't think it's in any sense limited to that.

Q. Now, you mentioned there being excess material at the bottom of the outer skirt; is that fair to say?

A. Yeah. There's excess material all the way around in that the skirt is loose. As you can see, I'm looking at Figure 1. If you look at where the 18 is sort of pointing to, the whole skirt is bulging out. I think you can see that. There's excess material. I -- the -- the total circumference of the material is greater than the circumference of the underlying frame.

Q. Now, the -- what that allows you to do, that excess material when crimped, it gives Levi's frame room to elongate; is that correct?

A. That's -- that's the excess bagginess top to bottom it gives us, but I'm talking about the circumferential, which is different. So the circumferential -- I mean, there's two bagginesses (sic) if you like, two excess material. One is top to bottom, which allows it to elongate without the skirt limiting the -- the -- the movement of the frame.

And the other one is -- is the circumferential, which allows it to bulge out to a degree like 18. It couldn't bulge out like the zone shown in 18 unless there was also excessive material around the

circumference.

Q. So I think you said there were two things. And one of them is the excess material allows you to elongate a frame. That's one of the things that you said; is that fair to say?

A. (No audible response.)

Q. I think you're nodding. Could you say yes if that's your view?

A. I said yes to your question. One of the things it allows is the frame to elongate.

Q. Okay. If you said it, I'm sorry, I saw you nod. I didn't hear. Fair enough.

Now, if I removed that excess material from the bottom, that would interfere with the device's ability to elongate when crimped; is that fair to say?

A. Not necessarily. I mean if it was completely noncompliant material, but Levi also teaches that you could use stretchy material that would allow it.

So again, it depends on various characteristics that are being told that you could put together in one place. If the material was stretchy, then the frame could still elongate, it would just stretch the covering.

If the covering is not stretchy, then you need the excess material, the bagginess to allow it to

elongate, and I think Levi covers both of those possibilities.

Q. If laser-woven cut PET is the skirt that you're using --

A. I'm sorry?

Q. If you're using a laser-cut woven PET, that's the material from which your outer skirt is compressed --

A. It's one of the materials. It doesn't get limited to one of the materials used in the embodiments.

Q. I'm sorry. I don't think I finished my question.

My question was, if you're using a laser-cut woven PET as the outer skirt and you remove the excess material, because you attached the outer skirt higher up on the frame, that would tend to inhibit the frame's ability to elongate when crimped; is that fair to say?

A. It might, but not necessarily. It depends if the material itself elongate or the fibers can reorientate to elongate, like is taught on the inside of the frame.

Q. But I specified material, which was laser-cut woven PET in that.

A. Yeah. But it's on the inside, too. If you orientate the fibers to be at 45 degrees and you have the weave loose enough, then there's room for the fibers to reorientate and the cuff becomes longer to allow the movements of the frame.

Q. You believe this teaching is in Levi?

A. The teaching is that that's how they have the inner skirt relatively tight to the frame and yet it's still allowed to elongate to allow the frame to be crimped.

Q. You believe this teaching is made as to the outer skirt?

A. No, not specifically. I'm saying you could. You're asking me if you had laser-cut PET, would you have to have the bagginess, and I'm saying not necessarily.

Q. So I just want to make sure we're speaking the same language.

You agree with me that Levi does not teach with respect to the outer skirt that the frame would still be able to elongate if you remove the excess material while crimped?

A. Yes. I think -- I think Levi teaches that if you have stretchy fabric, then things can elongate. I'm saying it's perfectly possible within Levi's teaching to have fabric that can stretch from the outside of the frame.

Q. And let's look at column 8, starting at line 54.

A. Column 8.

Q. Ed's going to get there momentarily if you prefer

to wait. It's up to you.

Okay. Could you highlight starting with, "When the valve is deployed" in the paragraph.

Okay. So I'm going to leave what Levi says in column 8, lines 54 to 59. It says, quote, "When the valve is deployed, the frame" -- I'll just start rereading, if that's okay.

So again, I'm reading from Levi lines 54 to line 60. Column 8 if I did not specify.

And it reads, quote, "When the valve is deployed, the frame can expand to the cylindrical shape shown in Figure 4. In one example, the frame of a 26-millimeter valve, when crimped, had a diameter D1 of 14 Fr. at the outflow end of the valve and a diameter D2 of 12 Fr. at the inflow end of the valve," closed quote.

I think this is not fairly noncontroversial, but this teaching is in accord with the other passage we looked at where you have a narrower portion of the valve when crimped and a wider portion of the valve; is that fair to say?

A. Yes, I don't know that looking at the passage but yes, that's exactly what it is. There is a two French difference.

Q. I'd like to -- sorry. Were you -- were you saying something?

A. Me?
Q. Yes.
A. There is a two French difference from the top to the bottom, both being 14 Fr. down to 12 Fr.
Q. I'm sorry. I thought I interrupted you. Fair enough.
Okay. Let's go to column 9, I believe it is. Yes. Let's go to lines -- I'm going to ask you to read to yourself the paragraph that Ed is highlighting, starting in column 9, line 36 to line 44, and let me know when you're done, please.
A. Yes, I've read -- I've read that.
Q. Okay. So this is paragraph is about known fabric skirts; is that correct?
A. It's known fabric skirts, yes.
Q. Okay. And what Levi says is, "Unfortunately, a fabric skirt, which has -- which inherently has limited elasticity, cannot elongate along with the frame and therefore tends to deform the struts of the frame and prevent uniform crimping."
Do you see that?
A. I do. And this is talking about the internal skirt now. This section is about the internal skirt, not about the outer skirt. This is about skirt 16, which is the internal skirt.

It says at the paragraph above, if you go to the beginning of the paragraph that's on my screen above the highlighted one, it says, "skirt 16 can be secured to the inside of frame 12."

Q. Fair enough.

Let's -- you agree now that Levi teaches that a fabric skirt cannot elongate with the frame; is that true?

A. He's saying the known fabric skirts that are orientated the way he says -- I mean exactly what he says when they come, but he goes on then to say, "By reorientating the fibers" -- exactly what I was saying to you a few minutes ago -- if you reorientate the fibers to be at 45 degrees, then it can stretch in the longitudinal direction and allow the frame to expand. That's exactly what happened with the internal skirt, which is attached to the frame.

All of this is about the internal skirt.

Q. What you just said is -- is false, isn't it?

A. I'm sorry?

Q. What you just said is false, isn't it?

A. Is false?

Q. Yes.

A. I'm under oath and I'm telling absolutely the truth.

Q. Let's look. Let's look. Because you're talking about the paragraph starting at line 52, aren't you?

A. I wasn't talking specifically about that. I was telling you my opinion from -- from my head.

Q. Now, you see the first line of that paragraph says, "Referring to Figure 16B, in contrast to known fabric skirts" --

He does say that, doesn't he?

A. Yes.

Q. So he's not talking about known fabric skirts anymore, is he?

A. No. He's talking about in contrast, you can do it the way that you make it so it can move and allow the frame to stretch. This is prior art. This is what he's teaching.

Q. I just asked a yes-or-no question. A yes-or-no question is he's not talking about known fabric skirts; correct?

A. No. He is saying known fabric skirts, then he's going on to highlight this.

Q. Okay. And -- so he's not talking about known fabric skirts anymore; correct?

It's a yes-or-no question.

A. What he's saying is in contrast to known fabric skirts.

Q. I think the answer to my question is yes, is it not? In contrast to known fabric skirts, therefore he's not talking about known fabric skirts anymore, correct?

A. That's what his opinion is. That's what he's saying.

Q. Okay. Very good. Because I think the answer is yes. And because -- because -- because a known fabric skirt in here -- in here has limited elasticity, correct?

A. Yes. Known as of the date of the writing of this, but this is the prior art. So what is known --

Q. I'm just asking -- I'm just asking what Levi says. Levi says as to known fabric skirts --

A. By the date. By the priority date, both are known. By the priority dates of the AI patents --

Q. So let's be clear. The priority -- this was filed in 2011; is that correct?

Levi was filed in 2011?

A. It was filed May -- I've got on the front of this particular one, May the 17th, that was publication date.

When was it filed?

July 15th, 2011?

Q. But you agree that Walther -- Walther's was a known fabric skirt at the time of Levi; correct?

A. Yes.

Q. And you agree that Spenser 2, Figure 22, the compressible material, that was a known fabric skirt or compressible material I think they called it well before Levi; correct? That was 2014.

A. I'm not sure whether there's a question pending but if there is, I've missed it. We're talking --

Q. Let me ask the question then.

A. We're talking about --

Q. Let me ask the question. You said there was no question. Let me ask the question.

You agree that Spenser 2, Figure 22, the compressible material therein from 2004 was a known fabric skirt by 2011 when Levi was written; was it not?

MR. SUMMERS: Object to the form of the question.

THE WITNESS: It was none.

BY MR. LOWENSTEIN:

Q. And such fabric skirts that were known, Levi tells us inherently, inherently have limited elasticity; correct?

A. None.

MR. SUMMERS: Object to the form of the question.

THE WITNESS: Completely wrong. You misunderstand.

BY MR. LOWENSTEIN:

Q. Levi does not say that a fabric skirt which inherently has limited elasticity?

A. Yes. But Levi's not talking about the whole collection of known fabric skirts. Knitted fabrics have great stretchability. There are all sorts of fabrics.

Levi is talking about a woven fabric with a specific orientation of the fibers and he's saying the characteristics of that. He's not saying every fabric skirt. His known fabric skirts are not -- he's saying that this fabric skirt with woven fibers was known.

Q. That's not quite true either, is it? Let's look at what he says. Let's look at what he says.

MR. SUMMERS: Counsel, please let the witness finish his answer.

MR. LOWENSTEIN: Mr. Summers, I've heard quite enough from you.

Q. Let's look back at what he says. "Known fabric skirts comprise" -- that means include -- "a weave of warped and weft fibers." He's not talking about the subcategory of known fabric skirts, is he?

A. Yes. He's talking about ones with weft and woven fibers.

Q. You've been an expert witness long enough to know what the word "comprise" means in patents, don't you?

A. Including.
Q. Yes. Yes. It means including.
And so what this says effectively in patent is known fabric skirts include a weave of warped and weft fibers; correct?
A. Yes. Known fabric skirts do, but there are other known fabric skirts that don't.
Q. That's not what Levi says, however; correct?
A. That's the use of English that is there. He's not pretending to be characterizing every known fabric skirt. Those skirts were known that were stretchy. I've used one.
Q. We're just talking about what Levi teaches.
A. What Levi teaches is correct. He's talking about known fabric skirts include a weave of warp and weft. He's not saying he's in any sense characterizing all known fabric skirts.
You are misreading it.
Q. We can put to the side --
A. I'm sorry. I couldn't hear you.
Q. We can put to the side argument, but I want to ask you about the word "inherent," because that's another patentees sort of term, isn't it?
"Inherently" means necessarily, doesn't it?
A. I'm not a patent lawyer. I'm a physician. But

if you tell me it does, then --

Q. It does.

So assuming that's correct, it says unfortunately a fabric skirt which necessarily has limited elasticity cannot elongate along with the frame, right?

A. Well, that's true. Unfortunately, fabric skirt which inherently has limited elasticity cannot elongate along the frame. That seems to me to be completely correct and completely clear.

But, again, it's a subset of known skirts.

Q. Now, you would agree that to the extent a fabric skirt has limited elasticity, you agree with Levi, however, that it cannot elongate along the frame; correct?

A. If it has limited elasticity, then it will only have limited ability to elongate in the direction that we're talking about.

Q. And you would agree with Levi that if a known fabric skirt has limited elasticity, that will tend to deform the struts of the frame and prevent uniform crimping, do you agree with that?

A. It could, yes.

Q. Okay. Mr. Hsieh is going to share Exhibit 2019 which is a reference called Meslmani.

Okay. Let's go to the third page of the

document. Zoom in on the Figure 1, page 3. Figure A and Figure 1 in Meslmani.

Are you able to see it?

A. I can, yes.

Q. You see there are fibers in this image?

A. I do.

Q. Do you consider these fibers to be radially extending?

A. Well -- what do you mean by "extending"? These are pictures of a couple of square millimeters, although fabric.

What's radially excepting from radially (sic) meaning what? These are pictures of the fabric.

Q. You're aware that certain claims refer to outwardly extending fibers, radially extending fibers, are you not?

A. Yes. I'm aware of the claims. What I'm saying is these are from -- there isn't a radial direction, because I think no -- what these are placed on are indeed on a stent. I don't think they are.

Q. Fair enough. Do you believe that these fibers are outwardly extending?

A. Yes. You could see -- actually look at A, the photograph labeled A in front of me, you could see ridges. The over and under forms ridges. So there's

also small ridges running along the surface and those ridges, if they were on a surface of something circular, that would be radially extending.

That language comes very much from the Palmer '407 Patent, which I think is incorporated by reference into the patents in this IPR.

Q. Have you ever heard of anyone referring to laser-cut woven PET as outwardly -- containing outwardly extending fibers?

A. I can't think of, as I sit here, anyone referring to that, but then I might not remember.

Q. Do you still have the image we were looking at from Meslmani?

A. A and B, yes, I have both of them.

Q. I'm asking about A. Is that what laser-cut woven PET looks like under magnification?

A. That's just a -- that's just a weave of PET. You're seeing the weave there. You're seeing it over and under. All I'm saying is you can see that creates a lot of small ridges. And those ridges, if they were on the surface of a tubular device, tend to be radially outwardly extending.

Q. I don't think I got an answer to my question. So I'm going to ask it again.

I'm asking about Meslmani's Exhibit 2019,

Figure 1, subpart A. Is this image, is that what laser-cut woven PET looks like?

A. Well, I can't see any cut. So I just don't really understand -- there's no cut on there. This is a high magnification. The -- the scale is on there, 300 mu, it is sort of a bit of the width of the picture. There's no cut edge there.

So I don't know why you keep saying does the laser cut looks like that.

There's no cut.

Q. Let me ask you this. Does woven PET look like this?

A. Some of it does. I mean woven PET could have lots of different appearances depending how dense it is, the fiber slides (sic), some of the fibers in the bundles.

But this is a representation of one sort of -- of PET at a highly magnified photo and therefore you're not seeing any edge. There's no cut edge.

Q. Is this medical grade woven PET that we're looking at?

A. I don't know. This wasn't the prior art publication, I don't believe. So I haven't paid an awful lot of notice that it may well be medical grade, but I don't think it's prior art.

The publication, I think it's 2014 I just saw flash past.

Q. You agreed, however, that there is something called -- there is a category of things that are medical grade and there are categories of things that are not; is that fair to say?

A. Yes.

Q. And it's fair to say that the sort of fabric you might use in a sweater is not medical grade; is that fair to say?

A. Yes, that's fair to say.

Q. Do you generally look at textile references for making things like sweaters in assessing what type of -- what woven PET might look like in a TAVR?

A. No, I wouldn't have thought so.

Q. That would be absurd, right?

A. It would be absurd. I would look at references that were before the prior art date and say do you have something which is prior art?

This is not prior art.

Q. Let's look at Rodrigues, Exhibit 2020.

A. Doesn't sound like that's the prior art.

Are you sharing it?

Q. I believe Mr. Hsieh will momentarily.

A. Because I don't have a copy of it.

Q. Let's go to the fifth page up.

I think it's 5F.

Okay. So we're looking at Figure 8 from Exhibit 2020 and I want you to look at B, which is identified as PET-LP fabric.

Do you see that?

A. I do.

Q. Do you consider these fibers to be outwardly extended?

A. To be?

Q. Outwardly extended.

A. The ridges that they're forming, the fibers are forming lots of little ridges and they could be outwardly extending or radially outwardly extending if they were on a stent or a rounded surface.

Q. So you believe a tightly woven set of fibers are nonetheless outwardly extending; is that fair to say?

A. Ridges can be fairly thought of as outward extending. A ridge on the surface can be thought of as being radially outwardly extending, that's what's taught in the patent specification by virtue of incorporation of the Palmaz '417 Patent.

Q. Before we leave that, do you know what the "-LP" means?

It says PET-LP. What does the "LP" refer to?

A. Yes. It's low profile. So this is a low profile fabric as opposed to -- at the same magnification, you see the bar of a hundred microns for each of them and this one lower profile means it's less coarse than the one that's on the left.

Q. Okay. Let's take a look at one of the patents.

Okay. So you see where we pulled up the '846 Patent from Aortic, which the party -- one of the parties in this case, which is one of the patents at issue in one of the four IPRs that we're talking about today; is that fair to say?

A. Yes.

Q. Okay. And can we look at Figure 9, Ed, which is on page 10.

Okay. Let's go down -- okay. Can you see Figure 9?

A. Yes.

Q. You agree this is an instance of radially or outwardly extending fibers that we see here?

A. Yes. These are collagen fibers that are radially outwardly extending.

Q. And you agree that the fibers --

A. The claim. The claim, it says, "claims radially outwardly extending." I don't think those words were in the specification.

Q. Do you disagree that the fibers that we're looking at are radially extending?

A. No. I'm saying that the words aren't used in the specification. They appear in the claims for the first time, I think, in 2020.

Q. Fair enough.

But we both agree, and there's no dispute, no sane person can disagree, that the fibers that we look at in Figure 9 are both radially extending and outwardly extending; is that fair to say?

A. Yes.

Q. Okay. Good.

Now, the fibers that we see in Figure 9 and many other figures in the patent, those are not tightly woven together; correct?

A. No. They're -- they're a patent drawing (sic), but they appear loose and unconnected.

Q. Okay. So the -- you can see that in sharp distinction to Walther, which we agreed had an opaque set of fibers, you can clearly see the frame through the fibers that we see in Figure 9; correct?

A. Yes. But this is a drawing.

Q. I'm just asking a question. You can answer yes or no.

A. Yeah, on this drawing, as shown very loosely, but

I'm not sure I'm limited to that.

Q. Now, so you've got this loose network of fibers that are each -- you can see that they're each tied or stitched as it may be directly to a strut of the frame; correct?

MR. SUMMERS: Object to the form of the question.

THE WITNESS: I have no idea. I don't think there's any teaching about how they're attached at all. I don't think there's any mention of --

BY MR. LOWENSTEIN:

Q. I'm just asking what we can see.

We can all see very, very clearly, can't we, that each fiber is attached directly to a strut of the outer frame, can't we?

A. That's what it appears to be, yes.

Q. It appears to be that way or it is that way?

A. It appears to be that way.

Q. Is there any question about that?

It is that way, isn't it?

A. About what?

Q. You can see, because we can all see, that each fiber is attached to a strut of the frame, can't we?

A. Yes, it appears to be that way.

Q. Is there any doubt in your mind?

A. There's no teaching of how they are attached and therefore I've got information missing as to how they are attached.

Q. I'm just looking at what we can see.

And we can all see clearly that there is no graft covering between the outer frame and the fibers; correct?

A. What do you mean by -- I mean, this could be seen as a graft covering, but a loose one. But it could be seen as a graft covering. The fibers of collagen which are there could easily be considered to be a graft covering.

Q. So your expert opinion is that the fibers that we see in Figure 9 can be a graft covering; is that correct?

A. It could be a cover. You could barely refer to it to as a covering of collagen.

Q. You just testified that you -- your expert opinion is that the fibers we see in Figure 9 can be a graft covering; correct?

A. Could be fairly said to be a covering.

Q. I didn't -- you left out the word "graft." I'm asking -- you answer the question that I'm asking.

You agree that the fibers we see in Figure 9 can be a graft covering; correct?

A. Yes.

Q. Now, I want you to think about what we're looking at in Figure 9.

Let me ask you this. There are many figures in the various patents at issue from Aortic, and you'll agree that this is fairly representative how the fibers appear exterior to the outer frame; is that -- is that fair to say?

A. I'm not sure. I think the drawing -- I think it is the same drawings that are reproduced many times. I think that this appearance of the fibers on this section of the frame 22A is what reproduced many times.

Q. You looked at -- you've analyzed various prior art references with an outer covering of one kind of or another and you've looked at Levi, which has an outer skirt; correct?

A. Yes.

Q. And you've looked at Walther, which has an outer cloth; correct?

A. Yes.

Q. And you've looked at Spenser 2, Figure 22, which has a sleeve, I think it's called, of compressible material; correct?

A. Yes.

Q. And you would agree that each of those outer

coverings in Levi, in Spenser 2, in Walther are opaque; correct?

A. No.

Q. Are opaque relative to the frame; correct?

A. No.

Q. You cannot see the frame underneath the outer coverings in Levi, Spenser 2, Figure 22, and Walther; correct?

A. I accept you can't see it. It's not drawn on the patent drawings. But that doesn't mean you couldn't see it. Patent drawings often representing a concept, representing an idea and --

Q. Let me ask you a question, which I think you'll agree with.

You agree that you cannot see the outer frame underneath Levi's outer skirt; correct?

A. I need to -- yeah, that's fair. You can't see the outer skirt in the patent drawings.

Q. And you cannot see the outer frame in Walther underneath Walther's outer cloth; correct?

A. That is true. Walther is a photograph. That is true. It is a photograph. I can't see the frame or the outer cloth.

Q. And you testified that Walther is an embodiment of Spencer 2's Figure 22, did you not?

A. An embodiment. Certainly there are lots of possibilities, but an embodiment to Spencer.

Q. Now, you agree that in Spenser 2, Figure 22, you cannot see Spencer 2's outer frame beneath the sleeve; correct?

A. It's not shown. You can't see it. It's not in the drawing.

Q. Okay. And you do not identify any reference that has an outer covering of any kind to a TAVR -- let me reask the question. Please let me ask the question.

You have not identified any reference that has an outer covering of any kind to a TAVR that looks like the fibers distributed as we see in Figure 9; correct?

A. No. I disagree.

I think Spenser 2 is showing exactly the same thing. It's drawing it in a different way, but it's showing the same thing.

Q. So you think that Spenser 2, Figure 22, looks the same as Figure 9 in the '846 Patent?

A. Conceptually, yes.

Q. So even though we have a loose-knit network of fibers where you can clearly see the outer frame in the '846, you believe that's conceptually the same as the thick, opaque, cannot see the outer frame through it's sleeve in Spencer 2's Figure 22; is that correct?

MR. SUMMERS: Object to the question.

THE WITNESS: I think Spenser 2 covers exactly the same concept. And how thick or thin it is, how opaque or -- or see through it is are just all possibilities which are easily within the range of a -- of a competent interventional cardiologist working with a competent engineer.

BY MR. LOWENSTEIN:

Q. You know, I have a two-year old son. And I'm pretty sure if I asked him, Adam, do you think the fibers in Figure 9 of the '846 Patent look the same as the outer sleeve of Spencer 2's Figure 22? And did I adequately explain to you what they were? I think he could tell the difference.

Do you believe he couldn't?

MR. SUMMERS: Object to the form of the question.

THE WITNESS: I've never met your son. I can't answer -- I can't possibly answer a question about what your son would or wouldn't think.

I'm giving you my opinion, and my opinion is conceptually it is the same thing. There is no requirement on the exact density and how opaque or -- or not opaque these things are in either of these teachings.

BY MR. LOWENSTEIN:

Q. You think Figure 9 of the '846 Patent, the fibers there look exactly the same?

A. I didn't say they look exactly the same. They don't look exactly the same.

Q. They look completely different, don't they? They look completely, 100 percent different, do they not?

A. You keep interrupting me when I am answering, which I think is extremely rude and I'd be grateful if you at least let me answer the question.

Q. Love to hear you.

A. I've told you conceptually what is being taught I think is the same.

Q. Okay. I'm not asking about conceptually. Let's dumb it down to my -- let's talk at my level.

We can see that the sleeve in Figure 22, Spenser 2 is okay, can we not?

We can't see the outer frame through it; correct?

A. It's not drawn there. Whether you could see it through it is -- I really I think you are being pedantic because the patent drawings are there to be --

Q. I'm sorry. You've got to answer my question.

A. I am trying to answer your question.

Q. Please answer my question. I don't want to --

A. I'm trying to answer the question and I will --

Q. We can all see, because it's plainly obvious to everyone in the world that in Spenser 2, Figure 22, which you acknowledge is the embodiment of Walther, where we can see the opaque outer cloth in the photograph, we all know --

A. I mean Walther -- sorry.

Q. I didn't ask my question.

A. Yeah, but I just want to say Walther is --

Q. Please let me ask my question.

I'll start again.

A. Good.

Q. Let me ask my question and then you can answer it.

We all can see when we look at Figure 22 in Spenser 2 that we look at that sleeve, we can see that it's thick and opaque, can we not?

A. That's not how I look at it. I'm not judging from a patent drawing how thick it is or how opaque it is. They're not characteristics that I think are being drawn.

Q. Do you agree that the appearance of Spencer, the sleeve in Spenser 2, Figure 22, is denser than the loose network of fibers we see in Figure 9 of the '846 Patent?

A. No.

Q. You don't agree that the opaque,

can't-see-through-it sleeve in Spenser 2, Figure 22, is not denser than the set of fibers in Figure 9 where I can plainly see every single fiber in the frame?

MR. SUMMERS: Object to the form of the question.

THE WITNESS: I don't judge density off a patent drawing. A patent drawing is a concept. I'm saying this is a compressible material. It could be very see-through. It might not be very see-through. There's a whole range of possibilities. The drawing is just a representation of where it is put, unless it's got scattered fibers on the outside of it.

BY MR. LOWENSTEIN:

Q. So we know to a hundred percent certainty, we know to a certainty that in Figure 22 of Levi -- 42 of Levi, we know to a certainty that that figure is the gospel truth of what Levi clearly intended was to show the outer skirt connected to the second row of the outer frame from the bottom, we know that to a certainty, don't we?

A. Ask a simple question, then I can answer it.

Q. You don't understand my question? I'm sorry, this is your cross-examination. I'm allowed to aggressively question you, don't you think?

A. Only if you give me a document.

Q. You're at trial. Don't you think you'd have to answer my questions?

A. If you give me -- if you will give me the document, I can answer you. I have on the screen in front of me Figure 9 from one of AI's patents and I have in front of me Spenser 2 that you're asking me about.

You're now asking me a question about Levi, but you never either put up in front of me or given me the document.

Q. That's not true. We talked about Figure 42 of Levi at some length.

Did you forget?

A. To answer your question now, I would prefer to have the document in front of me, if it's all right with you.

Q. No. No. Go back.

I just want you to focus on the image that we see. We're looking at Figure 9 of the '846 Patent; correct?

A. I have that in front of me.

Q. I don't want -- I just want you to look at the image that you see. Nothing else.

Do you understand that?

A. Yes.

Q. And my question is, have you ever seen an outer

covering to a TAVR in your life that looks anything like the loose-knit set of fibers that we see in Figure 9?

A. Yes.

Q. Which one?

A. Levi, too.

Q. Do you think Levi looks just like Figure 9 of the '846 Patent?

A. I wouldn't say "just like." It looks like it. It's considered --

Q. I'm just talking about fibers. Let's just compare the fibers we see in Figure 9 to the fabric skirt we see in Levi.

Do you think those two look exactly the same?

A. I don't -- you keep putting these words in which aren't my words. I'm not saying it looks exactly the same. It's a different figure. It's drawn differently. The concept I see is the same.

Q. Do you remember we were talking about, let's say, you had a resident and the resident looked at Figure 9 and the fibers therein and then looked at Spenser 2, Figure 22 and said, these are clearly entirely different. In Figure 9, I just see a couple of fibers and they're corrected to the frame. I see them connected clearly to the struts. I can plainly see the outer frame. It's not opaque. And there's clearly no

graft cover.

Let's say your resident said that.

Would you find any fault with his visual analysis of Figure 9?

A. I would need to put it into a context of whatever we were talking about.

Q. Is there anything incorrect that I just said?

A. Yes, because we're talking about patents and how to interpret patent drawings. We're not talking about art.

Q. Okay. That's good. That's good. Let's talk about Figure 9 in connection with some claims.

We can see in Figure 9 that there are a bunch of fibers and they extend radially from the frame, can't we?

A. Some do. Some don't. Some hang down.

Q. And we can see -- oh, I'm sorry. You think this is not radially extending, but you think woven PET is radially extending; correct?

A. No. That's not what I said. I said some hang down.

Q. So therefore they're not radially extending; correct?

A. That's not what I said. I said I can see the fibers. Some are hanging downwards at the front of the

device.

Q. And so therefore they're not radially extending; correct?

A. That's not what I said.

Q. Okay. So what did you say?

A. I said I can see some fibers and some are hanging down.

Q. I'm just trying to understand.

Does that have any relevance to when the fibers are radially extending in your view?

A. It may or it may not. I mean it depends when from the frame -- it's difficult to see exactly what's happening in some parts on the front because you're looking front on.

Q. And if your resident said we can see in Figure 9 clearly there's no graft covering, because I can see the frame, is he wrong?

A. You may be misunderstanding me. Some of the fibers almost appear and disappearing into the open cells of the frame and going behind the frame, that they're hanging down and they look as so they're sort of going in and possibly going behind.

Q. So you believe that the claims, your claim construction is that every single fiber must be radially extending?

A. We haven't talked about claim construction at all and I wouldn't --

Q. Is that claim construction?

A. No.

Q. Okay. So is it -- does it matter if some of the fibers go inward?

A. It may not. If it's just requiring a plurality, that just means two need to do whatever the characteristic is.

Two or more.

Q. Now, if your resident looked at Spenser 2 after just seeing Figure 9 and he looked at Figure 22 of Spenser 2 and said, my gosh, this is totally different because unlike Figure 9, which just has a bunch of loosely distributed fibers connected directly to each strut of the outer frame, and I can clearly see the outer frame in almost every strut within it in Figure 22 of Spenser 2, that's totally different because it's a thick band that's opaque, and I can't see the outer frame at all, would you correct your resident and say, that's just wrong, because they're exactly the same?

A. The thickness is different. The appearance is different. The concept, as I've said several times, I believe is the same.

Q. On what basis do you conclude that the concept is

the same when the figures look completely different?

A. Because the figures in the illustration, I'm not aware that there is any teaching in Spenser 2 about how dense it has to be, how nonradiant -- how nonopaque it has to be.

I don't believe for one moment that if you have a covering that has the characteristics of the TAVR and yet you can see the frame through it so that would in any sense alter the teaching.

Q. Okay. Have you ever seen a prior art reference that has fibers connected directly to the frame where you can still see pretty much the entirety of the frame in a TAVR?

A. No, I can think of a teaching of that. I can't think of a diagram in a patent that looks like that.

Q. Have you ever seen a medical device in your life that had a loose network of fibers where you could see the entirety of the outer frame like we see in Figure 9?

A. Probably.

Q. You're -- you don't know though, do you?

A. No, I probably have. I mean stents have been taken out of patients for various reasons and they would be covered in what's called fibrin, and that would be fiber, they would be on the struts.

But I think we must be at cross-purposes because

what I'm saying -- I'm not suggesting for one moment that one drawing is identical to the other.

I'm saying that the concept that they teach is the same concept.

Q. Okay. So you think that the concept that the figure teaches, I can't draw anything -- a person of ordinary skill in the art, he can't draw anything from the figure that you're looking at?

A. You can draw lots from the figure you're looking at. But what you can't do is draw limitations on the disclosure from a drawing of one embodiment.

Q. Okay. So let's just -- let's just focus upon you can't -- as you sit here today -- identify a single prior art device or figure that looks like -- looks like what we see in Figure 9; correct?

A. No. That isn't what I said. I said I think I've seen one that looked like.

Q. You said probably. Which one?

A. Probably.

Q. Which one?

A. A former stent removed from patients got fibrin all over it.

Q. So you're talking about stuff that grows from the body, that happens to be after you take it out of the human body, that's what you're talking about?

A. Yes.
Q. So an inventor did not add those fibers; correct?
A. No. You're saying whether I had seen such a thing.
Q. Correct. You've never seen anything that's the product of human design, any stent in your entire life that looks like the fibers we see in Figure 9; correct?
A. I don't think I understand what you're wanting -- you're wanting me to find a patent drawing that looks like that, which I have seen?
Q. I'm asking you to draw upon your entire body of experience, all of your years as an expert witness for Edwards, the stents procedures you've worked on in your life, every patent you've ever seen, every prior art reference you've ever seen, every article you've ever seen, every prototype you've ever seen in your entire life, and my question is, have you ever seen a stent that has fibers purposely attached to the outer frame in the stent prior to insertion into a human body?
A. I don't remember seeing one that looks like Figure 9, no.
Q. Never?
A. Well, I don't remember. I'm sitting here today, I don't remember seeing one that's illustrated like Figure 9 is.

Q. Now, we can agree that if there's a less dense, loosely arrayed network of fibers, if you compress it, all else being equal, you're going to get a narrower crimp profile, won't you?

A. It depends on the density.

Q. You can agree that if we compress what we see in Figure 9, you're going to get a much narrower crimp profile, in addition to the fibers, than we would if you crimped down Walther's outer cloth, correct?

A. No.

Q. You're certain of that?

A. Well, I'm very certain that in the embodiments that have this on some of them, they go down to less than 60 Fr., so how you're saying the embodiment in the very patent that we're looking at, Figure 9, but this isn't one of the dual-valve embodiments. All of the dual frames -- I would say dual-frame embodiments have a minimum diameter of something over 60 Fr.

Q. Let's look at Figure 11.

Okay. You can see we have an outer frame with fibers connected to the outer frame. At least somewhat similar in terms of the fibers in relation to the outer frame as what we looked at in Figure 9; is that fair to say?

A. Yes.

Q. Okay. Now, let's forget everything else, the delivery system, and let's just focus on the outer frame without all the fibers.

A. Yes.

Q. And that's what gets crimped; correct?

A. Yes.

Q. Okay. Now, you agree that if I crimped something that looked like Figure 11 --

A. Yes.

Q. -- you would have a narrower crimped profile than if I crimped something like Figure 11, except I took out the fibers there and I added Walther's outer cloth in its place; correct?

A. No.

Q. You don't believe that if I crimp something like Figure 11 and the only difference that I made was that I replaced the fibers that I saw with Walther's outer cloth, you don't believe that the former would have a narrower crimp profile than the latter?

A. I said no, I don't.

Q. Why not?

A. Because it's taught that Figure 11 won't go down to a size less than about 60 Fr., 20 millimeters across, because the inner frame is attached to the outer frame and the unexpanded inner frame is of the order of 20

millimeters across.

Q. Let's -- let's talk about -- let's just -- let's go to a SAPIEN.

A. Let's go to --

Q. A SAPIEN. A SAPIEN.

A. SAPIEN. Sorry. Got it.

Q. And we've discussed earlier how SAPIEN -- Walther rather, is a SAPIEN with an outer cloth attached; correct?

A. That's what Walther teaches is a SAPIEN valve with a cloth on the exterior.

Q. Okay. So let's say we took the SAPIEN valve and we took off Walther's outer cloth and we instead attached in its place a loose network of fibers where you could still see the outer frame to the SAPIEN.

Do you have the scenario in mind?

A. I think so. These are collagen fibers that are shown in Figure 11.

Q. Would you agree that the crimped profile of, let's say, the modified Walther device would have a narrower crimp profile than Walther after this?

A. I don't know.

Q. You don't know?

A. No, I don't know.

Q. It's certainly possible, isn't it?

A. Well, of course it's possible. Depending on the density and the width of the fibers and the number of fibers and all of those things, yes, it is possible.

But I don't know. Without knowing -- again, I don't know the density of the fibers, the width of the fibers, the length of the fibers.

There's no teaching that allows you to come to any real conclusion about what it would collapse down to.

Q. I'm sorry. You can see the fibers in Figure 11, can't you?

A. I can see what's drawn, but I've got no idea of the actual --

Q. You can see that Figure 11 is far less dense, the fibers in Figure 11 are far less dense than Walther's own cloth, can't you?

A. Yes. I think that that is fair. You can narrow that space down more, but they may be much thicker for all I know.

Q. You believe the network of fibers we see in Figure 11 is much thicker as a possibility as what we see in Walther?

A. I don't think there's a network of stuff and that seemed to me to be connected together. They all look like individual fibers, so I don't think that's a

network.

Q. You corrected my question. You're right. It was a bad question.

You agree that the collection of fibers that we see in Figure 11 reinforcements is significantly less dense than the network of fibers we see in Walther; correct?

A. But it's a diagram. I mean, we just don't seem to be --

Q. I'm just asking about pictures.

A. I can't -- the picture is a diagram. I don't think it is limiting or really teaching the density of fibers that you would achieve on an actual device. It's a diagram.

Q. So I just want to clarify -- I just want to make sure I understand. Because you couldn't recall any instance in your entire career where you ever saw an array of fibers on the outside of a stent like what we see, for example, in Figure 11 until you saw the patents in this case; correct?

MR. SUMMERS: Object to the form of the question.

THE WITNESS: Yes. I think I said conceptually what's in Spenser 2 is exactly the same, that I've seen them.

BY MR. LOWENSTEIN:

Q. No. No. No. That was not my question.

My question was, you agree you'd never ever in your entire life seen a network -- a collection of fibers like we see in Figure 11 on any stent; correct?

A. I did not see that exact image before, no.

Q. You've never seen a loose collection of fibers where you can clearly see frame, narrow frame, each strut of the frame, you've never seen anything like that in your career prior to this set of cases; correct?

A. Like I told you I think I have, Spenser's like it. You keep changing the question. I think Spenser is exactly like it.

Q. I'm just asking about the picture. The image, the image that you see.

Have you ever seen anything like that loose collection of fibers where you can clearly see the outer frame, you've never seen that in your life before this set of cases; correct?

A. Yes. I think Spenser features that.

Q. Spenser 2?

A. Spenser 2 teaches --

Q. You think Spenser 2, Figure 22, is exactly the same as Figure 11, that's your take?

A. I'm not suggesting it's exactly the same as

Figure 11. No, it's far from it.

It's not exactly the same as Figure 11.

Q. And you drew nothing, nothing, from the images you see in the Aortic patents; correct?

A. I can't -- I can't understand the penultimate word. In the what patents?

Q. The Aortic patents, like the '847.

A. Aortic patents. I hadn't heard of AI patents, yeah?

Q. Sure.

A. I'm not sure of the terminology you're using. I think conceptually they are the same. Can't we just leave it there?

That's my answer.

Q. No. We cannot leave it there. Definitely not. 100 percent cannot leave it there. Absolutely not.

No. I don't know why we don't let the witnesses choose the questions, but we don't. That's just the way it is.

A. It wasn't a question. It was an attempt at an answer.

Q. Okay. That's not going to happen. It wasn't going to happen anyway.

We can agree that the density in fibers almost be (sic) equal can affect the crimp profile; correct?

A. Yes.
Q. And we agree that the denser the fibers, the higher the crimp profile; correct?
A. Not necessarily. If all other things -- if recall other things are equal, yes.
Q. And we can see that Figure 11 is less dense in terms of fibers than Walther's outer cloth; correct?
A. No. We can't. There's probably less fibers on Walther's outer cloth.
Q. So your testimony is that Walther's outer cloth, those fibers are more dense than --
A. I haven't counted the number of fibers on Walther's outer cloth, but looking at it I think there are probably less than there are figuring out in front of me.
Q. Okay. You think density is just counting the number of fibers and that's all you do?
A. What else do you do if you --
Q. How about you look whether you can see the frame behind the fibers? Because you can do that and reinforce it very easily. It would be hard to miss it. But you can't do it in Walther; correct?
A. (No audible response.)
Q. Correct?
A. No. Not correct. I think I've very clearly

answered your question.

Walther is a diagram. Whether or not you can see the frame through it --

Q. Walther is a photograph. You've testified to that many times. Have you taken that back?

A. No. Sorry. I'm misspeaking. Spenser 2 is a diagram in a patent.

Q. I wasn't asking you about Spenser 2.

A. I beg your pardon. My mistake.

Q. Okay. Would you like to correct your testimony and clarify that outer photograph you see in Walther, the outer cloth is much, much, much denser than the collection of fibers that we see in Figure 11 of the '846 Patent?

A. I don't believe that that is a fair characterization, it's "much, much denser." It's a real photograph, real --

Q. Let's go back through history, because I think we seem to have lost the significance of the crimp profile, which was very important to Edwards, wasn't it?

It was very, very important to Edwards to get a narrow crimp profile, wasn't it?

A. Narrow crimp profile is important.

Q. You have two things that you really want to do at this time, don't you? You want to narrow the crimp

profile and you want to prevent PVL or reduce PVL, correct?

A. Yes. Those are two important things to try and achieve and address.

Q. And those two goals can be in tension with one another, correct?

A. It could be.

Q. If I add an outer seal to a stent, that will almost be equal (sic), increase the crimp profile of the stent; correct?

A. Potentially, yes.

Q. So we know that -- and we've known at least since 2004, if not earlier, that adding an outer seal could help address PVL; correct?

A. Yes. Since before 2004.

Q. In fact, what Spenser 2 is trying to do with Figure 22 is add compressible material, sleeve, to the stent to address PVL; correct?

A. Yes. To add compressible material to the outside of the stent.

Q. And what Walther is trying to do is add an outer cloth to address PVL; correct?

A. Yes.

Q. And yet the SAPIEN had no outer cloth at all; correct?

A. Original SAPIEN -- SAPIEN original had no outer cloth; correct.

Q. And the SAPIEN XT had no outer cloth at all; correct?

A. Correct. Just like SAPIEN, it had no outer cloth.

Q. The key advantage, the SAPIEN XT, relative to the SAPIEN, was Edwards -- amazingly -- was able to get crimp profile down from 22 to 24 Fr. down to 16 to 18 Fr.; isn't that correct?

A. I wouldn't use your word "amazing" or anything, but they reduce the profile down.

Q. So you think that was no big deal?

A. I didn't say it was no big deal.

Q. I bet you if I went through the security filings and the like, I'll find plenty of quotes where they're saying it's a pretty big deal.

A. Well, big deal is different. You used the word "amazing" and I'm saying that was slightly emotive.

Q. Do you think it was not amazing?

A. It wasn't amazing. It was an important improvement to reduce crimp profile.

Q. Okay. So we are trying to reduce crimp profile even though we use transfemoral, 24 is too big, we need to go down to 18, 16 Fr., correct?

A. The smaller the better.
Q. And if you added a dense outer cloth to the outside of SAPIEN or the SAPIEN XT, that would be at cross-purposes with narrowing the crimp profile as much as possible; correct?
A. It could be. Not necessarily --
Q. You don't know?
A. It could be.
Q. If I add a thick Walther-like outer cloth to a SAPIEN XT, you think that's not going to dramatically increase the crimp profile?
MR. SUMMERS: Object to the form of the question.
THE WITNESS: No. Again, you're using very emotive dramatically. Depends how you would choose a cloth that could compress down significantly and wasn't so dense it's going to have a bad effect. This is just engineering choices.
BY MR. LOWENSTEIN:
Q. Okay. Engineering choices, because it doesn't matter what the crimp profile is, right?
A. The profile matters.
Q. It matters a lot, doesn't it?
A. Yes. We've talked about it lots.
Q. And we know that Walther had a 33 Fr. delivery

system, correct?

A. No. They used what was available. I don't know. They couldn't have gone through a much smaller --

Q. Walther used as 33 Fr. delivery system, correct?

A. Yes. I don't know that he had to, but he did.

Q. There's no teaching in Walther that we could use a 24 Fr. delivery system, right?

A. There's no teaching in it that he could, yes.

Q. And there's no teaching in Walther that he can use an 18 Fr. delivery system; correct?

A. That's correct.

Q. So do you think that Walther transapical, they don't care because -- Walther, they don't care about crimping because it's transapical; correct?

A. They care, but it's much less important for transapical delivery. Of course they care.

Q. Now, we know that SAPIEN -- I think within a 24 Fr. delivery system (sic); correct?

A. Yes, it could.

Q. And that's at the widest end; correct?

A. That's at the wide -- I don't understand --

Q. The widest delivery system for SAPIEN. SAPIEN was 22 Fr. and 24 Fr., correct?

A. The larger valve is 24 Fr., correct.

Q. And they didn't use a 24 Fr. delivery system,

they had to go 9 Fr. sizes in Walther; correct?

A. I don't know they had to. You used the words "they had to." I don't know that. They did because that was what was available.

The standard Ascendra delivery system that was being used, and one of them was the 33 Fr., and that's what they used. I don't know that they had to.

Q. Well, they couldn't use the 24 Fr., could they?

A. I -- well, I don't know that. They didn't say they could use a 24 Fr.

Q. Do you have any reason to believe that Walther could have used the 24 Fr. delivery system?

A. No. I don't have any reason to believe. I don't know they couldn't.

Q. Yet you have no reason to believe that; correct?

A. That's what I just said, yeah.

Q. Would an interventional cardiologist use a larger delivery device than is necessary when the entire industry is trying to crimp as much as possible?

A. Yes. Obviously. But this was an in vitro experiment. There was no -- no requirement of small or reduced complications or access. This was a benchtop in vitro experiment.

They used the available delivery system that was the 33 Fr. Ascendra.

Q. I'm sorry. There was no 24 Fr. available delivery system?

A. What I'm saying is, there -- you asked me the question, would they use a larger than was necessary? I'm saying for in vitro experimentation, there is no limit.

Q. We know that SAPIEN was approved, got a CE-mark in 2007 for 24 Fr. delivery system; correct?

A. That -- that sounds right.

Q. And Walther is a 2010 paper; correct?

A. That's correct.

Q. There were no shortage (sic) of 24 Fr. delivery system for SAPIEN devices; is that fair to say, at the time of Walther?

A. I wouldn't expect there were, no.

Q. Walther probably had access to a 24 Fr. delivery system if he wanted it, didn't he?

A. Well, if he wanted it, he probably did have access. They're different delivery systems. It's much longer, the 24 Fr., in doing benchtop experiments in what I characterized earlier as a prospect for.

It doesn't surprise me at all that they used a transapical delivery system, which is shorter, larger and probably more suited to the procedure, experimental procedure that they were performing.

Q. Well, you remember we saw the question and answer between the Italian doctor and Dr. Walther at the end of Walther, didn't we?

A. Yes, we did.

Q. And didn't the Italian doctor, I forget his or her name, ask essentially, "Don't we have a crimping problem given this big, fat outer cloth"?

MR. SUMMERS: Object to the form of the question.

THE WITNESS: I don't think that's what was said, but we can go back and look at it.

BY MR. LOWENSTEIN:

Q. That was the import of the question, was it not?

MR. SUMMERS: Object to the form of the question.

THE WITNESS: I think the question was what size could you crimp it down and Walther wasn't able to answer that.

BY MR. LOWENSTEIN:

Q. Walther said obviously it's a concern, didn't he?

A. Yes. He said obviously it is a concern. It is a concern.

Q. But we're talking about transapical where type crimping doesn't matter. That's what he said; correct?

A. Yeah. But much less critical for transapical

procedures, the size doesn't have the same constraints for transapical.

Q. There was no suggestion whatsoever anywhere in Walther that any delivery system smaller than 33 Fr. could have been used; correct?

A. There isn't.

MR. LOWENSTEIN: So I believe it has been approximately five hours on the record. Hopefully the court reporter can get us a more precise time later.

But if it's acceptable to everyone else, I suggest that we adjourn for the day and start up again tomorrow.

Is that acceptable?

THE WITNESS: It is as long as we've done it in these five hours. I have a plane to catch tomorrow.

(Short recess.)

MR. LOWENSTEIN: Let me clarify. I will hold to five hours for my initial round of questioning. If there's a redirect and a recross, I can't say. But I will -- I will hold to my five hours tomorrow regardless of what time we start.

Is that fair?

THE WITNESS: I -- I don't know how much redirect. All I'm saying is that what I would much prefer is we got more done at the beginning of the

thing. I think you said to me that you're prepared or there was an agreement to do up to six hours today.

We're now --

MR. LOWENSTEIN: I don't think I'm within an hour of finishing.

THE WITNESS: No. I wasn't expecting you were. All I want to make sure is we're not doing less today than we're going to do tomorrow with everyone asking me questions because I have a plane to catch.

MR. LOWENSTEIN: When is your plane?

We're off the record, Madam Court Reporter.

THE REPORTER: Okay.

(Off-record discussion.)

MR. LOWENSTEIN: Let's conclude for today and I'll see you all tomorrow. Thank you very much.

(Off record at 2:07 p.m.)

REPORTER'S CERTIFICATION

I, MARCELINE F. NOBLE, a Certified Shorthand Reporter in and for the State of California, do hereby certify:

That the foregoing witness was by me duly sworn; that the deposition was then taken before me at the time and place herein set forth; that the testimony and proceedings were reported stenographically by me and later transcribed into typewriting under my direction; that the foregoing is a true record of the testimony and proceedings taken at that time.

IN WITNESS WHEREOF, I have subscribed my name this 20th day of June, 2022.

Marceline F. Noble

MARCELINE F. NOBLE, CSR No. 3024

DEPOSITION ERRATA SHEET

Our Assignment No. 832612

Case Caption: Edwards Lifesciences Corporation vs. Aortic Innovations, LLC

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I declare under penalty of perjury that I have read the entire transcript of my Deposition taken in the above captioned matter or the same has been read to me, and the same is true and accurate, save and except for changes and/or corrections, if any, as indicated by me on the DEPOSITION ERRATA SHEET hereof, with the understanding that I offer these changes as if still under oath.

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION AND EDWARDS LIFESCIENCES LLC,

Petitioners,

v. CASE NO. IPR2021-01527
IPR2021-01584
Aortic Innovations LLC, IPR2021-00034
IPR2021-00193
Patent Owner. Patent 10,792,172

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INFORMATION REQUESTED

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INDEX TO EXHIBITS

Exhibit	Description	Page
2050	Article entitled "How to Adapt the Implantation Technique for the New SAPIEN 3 Transcatheter Heart Valve Design"	286

DEPOSITION OF NIGEL P. BULLER, M.D.

THE REPORTER: Hello, my name is Marceline Noble, a California Certified Shorthand Reporter, and this deposition is being taken via remote videoconferencing.

The court reporter and the witness are not present in the same room.

The witness will be sworn in remotely.

NIGEL P. BULLER, M.D.,
having been first duly sworn, testifies as follows:

THE REPORTER: Thank you.

EXAMINATION

BY MR. LOWENSTEIN:

Q. Good morning, Dr. Buller. Welcome back.

A. Good morning.

Q. I'm going to share with you one of your exhibits, Exhibit 1017, and it's the Cheung reference, which I think you'll be familiar with.

And I believe Mr. Hsieh has already shared it. And if you could please share your screen as well.

MR. HSIEH: One second, please.

BY MR. LOWENSTEIN:

Q. Okay. Very good.

I guess I'll ask both Dr. Buller and Mr. Summers, can you both see the Cheung on your screen adequately?

A. Yes.

Q. And, Craig, this is okay with you?

MR. SUMMERS: Yes, it is.

MR. LOWENSTEIN: Okay. Very good.

Q. So, Dr. Buller, I trust you're familiar with the Cheung reference?

A. Yes, I am.

Q. And this is, in fact, one of your exhibits, correct?

A. Yes.

Q. Okay. And we see that the title of Cheung, again Exhibit 1017 is, quote, "Transapical Transcatheter Mitral Valve-in-Valve Implantation in a Human," closed quote.

Do you see that, sir?

A. Yes.

Q. Okay. And "transapical," I think we know what that is. That's not in the vascular approach; correct?

A. It's through the apex of the heart.

Q. And "mitral," that's a different valve from the aortic valve; is that correct?

A. Yes. It's the second valve that -- it does the inflow to the left ventricle. It's called the mitral valve.

Q. Is it correct that the diameter of the mitral valve is larger than the diameter of the -- is it correct that the diameter of the mitral valve at the annulus is greater than the diameter of the aortic valve at the annulus, generally speaking?

A. Generally, yes. It has a larger diameter, a slightly different shape to it. It's not quite so circular.

Q. Let's go back to the title. So next we have "valve-in valve implantation." So "valve-in valve," we saw that yesterday with Walther, did we not?

A. Yes. And this is the same sort of concept. This is now in a patient and it's in a prosthetic valve which is inside the patient.

Q. You actually anticipated by next question. So you're ahead of the game.

And, in fact, it's implanting the same SAPIEN valve with an outer covering, which we'll get to, into the same Carpentier-Edwards Perimount valve that we saw in Walther; is that correct?

A. Yes. It 's obviously not the same valve as -- I mean, it's -- it's the one that would not have been

sterile and used there with a long --

Q. I've got the same model, if that's fair.

A. Yeah. It will be similar, but it will be a new sterile one made for a -- a natural treatment in a patient.

Q. You are very liberal. You should have been a lawyer.

Okay. So let's go to the next page and let's look at Figure 2. And is Figure 2 familiar to you?

A. Yes.

Q. And does this -- this is referred to as a fabric cuff; is that correct?

A. That's what it says, Figure 2, "The fabric cuff surrounding the Cribier-Edwards transcatheter valve..."

Q. Does this look to you to be the same type of material as the outer cloth in Walther, or do you believe it's been different?

A. It looks very similar. Also, the valve looks very similar, but it is worth noting that this says this is the Cribier-Edwards, which was actually an earlier version of the SAPIEN.

Q. Okay. So there's the SAPIEN that we talked about that was approved of a CE-mark, I think it's referred to, in 2007 in Europe --

A. Yes.

Q. -- that's referring to a SAPIEN?
A. Yes.
Q. And this was a precursor to --
A. That's what it says there. But it looks to me to be like a SAPIEN valve. So I'm just pointing out because you highlighted it a minute ago. I mean, it says, "surrounding the Cribier-Edwards transcatheter valve." I don't know if that's a typo. As far as I know, that wasn't approved in the United States. But this is in Canada, so it could have been.

But it doesn't -- if it is true that it's the Cribier-Edwards valve, it's an earlier precursor of the SAPIEN.

Q. So there -- there was something called, quote, unquote, "a Cribier-Edwards valve"?
A. Yes, there was.
Q. That was distinct from the SAPIEN valve?
A. Yes. The Cribier-Edwards came about and then it became SAPIEN.
Q. And what were the differences, if any, between the Cribier-Edwards valve and the SAPIEN valve?
A. I cannot remember. I think there may have been a difference in the pericardium where it came from, but I can't remember. There are more similarities than differences. It was earlier in time frame, so

Cribier-Edwards preceded SAPIEN.

Q. Do you understand there to have been any differences in the frame between the Cribier-Edwards and valve and the SAPIEN valve?

A. I don't know.

Q. Okay. Now, let me ask you about the fabric cuff. I think you said -- well, I mean -- remind what did you say about the fabric cuff that we see in Cheung relative to the outer cloth that we saw in Walther?

I think you said it was very similar or --

A. They look -- they look -- in appearance, looking at this Figure 9, to be very similar. This whole valve and the outer, what's now called fabric was called cloth in Walther, looked to be very similar.

Q. It looks to me like there are fewer fibers sticking out in Cheung versus Walther, if you remember the Figure 9 we looked at yesterday.

Do you think that's fair or do you disagree?

A. No. No. That might be fair from the picture. It has the appearance to me that it's actually wet, this one. I mean, it looks as though it may look different and less little fibers sticking out because it may be wet. It may have just have come out of the bottle. These valves are typically kept moist because of the pericardium.

Now, that wouldn't necessarily apply to what's being used in a bench top experiment, but this is -- this is either the one that was implanted in a human and it's on a sterile drape that it's being on. But is it (sic) likely it would be wet having just been taken out of the glutaraldehyde or just rinsed.

Q. And you're referring to procedures that are taken shortly before implantation into a person?

A. Yes.

Q. And the idea is to sterilize the valve?

A. The valve is sterilized. It already is sterile, but it has to be rinsed and washed before it's put into the patient. But at every stage, it has to be kept moist because the pericardium needs to be kept moist.

So the appearance of this outer fabric, as they call it, "cuff," is actually damp and that's why it may appear slightly different with less things sticking out because if it was wet, they would potentially droop down more.

Q. Okay. So if you go down just a little bit -- let's go to the second sentence that we see. Yeah. So it says, "A 26-millimeter Cribier-Edwards 9000MIS."

Do you see where it says "9000MIS"?

A. Yes.

Q. Do you recall that that is the same model that we

saw in Walther?

A. I'll take your word for it. I don't remember it was exactly that. But I remember we talked yesterday about numbers and I said I didn't know what it was, but it would be a cave (phonetic) number. If that is the cave number, it suggests it is the same valve even thought they're using different terminology.

Q. Is it fair to say you do not know what the acronym "MIS" stands for?

A. No, I don't know.

Q. Okay. If I were to suggest that it -- to proffer that it meant "minimally invasive surgery," would you have any reason to disagree with that?

A. No.

Q. Okay. And can we agree that a transapical procedure is a surgery?

A. Yes.

Q. Okay. And we can agree that a transfemoral approach is not a surgery; correct?

A. Well, typically not. You can obviously cut down on the femoral artery if you need to, but typically it's done percutaneously. There is a little incision, but it's usually just literally less than a centimeter with a scalpel to make a nick in the skin and then put the needle through. It wouldn't be regarded by any

interventional cardiologist as surgery as such.

Q. And we can both agree that a common iliac approach is a surgery and not percutaneous; correct?

A. It is a surgery for the access, the procedure then becomes very similar once you've created the -- the access route that would typically be done by a surgeon.

Q. But we can agree that a common iliac approach would not be percutaneous?

A. Correct.

Q. Now, looking down just a bit more, we see -- it continues on, and let's look where it says, "Surrounded by a fabric cuff." Obviously the entire sentence just so the record is clear.

Again, I'm reading from page 2 of Cheung in the first paragraph on page 2, second sentence, and the sentence reads, quote, "The 26-millimeter Cribier-Edwards 9000MIS," parenthesis, (Edward Lifesciences) transcatheter valve - constructed of equine pericardial leaflets with a stainless steel stint, surrounded by a fabric cuff (Figure 2) - was delivered through a 33 Fr. sheath."

Do you see that, sir?

A. Yes.

Q. So we can agree that Cheung, when delivering its valve with its fabric cuff, is being delivered through a

33 Fr. sheath?

A. Correct.

Q. And can we agree that -- I think we saw yesterday in Walther, that Dr. Walther said that narrow crimping is not an issue in a transapically approach.

Do you recall that?

A. Yeah. In the discussion, but yes.

Q. I don't know if I said "narrow crimping." I think you said "tight crimping" is not an issue.

A. I think that's right. I can't remember the exact words, but it was related to, it's not important or not an issue.

Q. Correct.

And nonetheless, even if you're going transapically, would you agree that, all else being equal, you would still prefer to use the narrowest sheath possible given a -- a given valve?

A. Within reason, yes. I mean, you clearly have to use something that's available to you and made for the purpose. And as we talked about yesterday, the 33 Fr. sheath was one of the standard sheaths in that time frame and therefore it doesn't surprise me that it was delivered through a 33 Fr. sheath. I guess it would be the Edwards delivery sheath that was made for this purpose.

Q. We know that the 24 Fr. Ascendra system -- I'm not sure if it was Ascendra, actually. Let me start over.

We do know that SAPIEN was being delivered via a 24 Fr. valve -- sorry -- 24 Fr. delivery system at the time; is it fair to say?

A. Yes. Femorally, it was being delivered at 22 or 24.

Q. And this article is from 2009, Cheung is from 2009; is that correct?

A. I can't see that on the page. I think -- it sounds right.

Q. So can we see the Cribier 2009?

A. Yes. 2009.

Q. So depends on when the CE-mark in 2007 was and when in 2009 Cheung was published, we can -- oh, okay. Here we go. This is more precise. We can see it was accepted for publication on October 8th, 2008?

A. Yes.

Q. Okay. So we can agree that this article was written, you know, shortly before October 8th, 2008; is that fair to say?

A. Certainly before October the 8th, 2008. I don't know when.

Q. Sure.

And -- so we know that SAPIEN had been delivered via a 24 Fr. delivery system for some time before Cheung was accepted for publication; is it fair to say?

A. That's correct.

Q. And so, therefore, we can reasonably deduce that a 24 Fr. delivery system would have been available to Cheung's office at the time; is that fair to say?

A. Well, not one, they are different in many other ways. I don't believe one that I mentioned was ever made for transapical. They were larger for transapical delivery.

Q. Wasn't the SAPIEN also approved for transapical as well?

A. Yes.

Q. Wasn't it approved with a 24 Fr.?

A. I don't -- I think the system for the delivery was always larger for the apical because it didn't require it to be smaller.

Q. Were smaller French delivery systems available transapically at -- by October 8th, 2008?

A. I don't know.

Q. My question was a little bit imprecise on that. I know your answer, but I'm going to ask a more precise question.

The more precise question is, was a transapical

delivery system available as of October 8th, 2008, with a French size smaller than 33 Fr.?

A. I don't know.

Q. Is there any suggestion in Cheung that its valve can be delivered transfemorally?

A. I'm not aware there's any suggestion in Cheung, if that's the case.

Q. Is there any suggestion in Cheung that its valve could be delivered via the common iliac?

A. I don't think it discusses any route other than what was done. This is a report of the transapical delivery.

Q. Okay. So we agree that -- well, I don't know if we agree.

But I think you believe that the fabric cuff in Cheung looks similar to the outer cloth in Walther; I think that's fair to say?

A. Yes. Similar.

Q. And we can agree that both Walther and Cheung are valve-in valve procedures; correct?

A. Yes.

Q. And we can agree that both Walther and Cheung are delivered via a 33 Fr. delivery system; correct?

A. Yes.

Q. And we can agree that neither Walther nor Cheung

suggests that there their respective valves can be delivered transfemorally; correct?

A. That's true. They don't discuss that at all.

Q. And we can agree that neither Cheung nor Walther suggest that their valve can be delivered via the common iliac; is that correct?

A. Again, it's not discussed.

Q. Now, aside from Spenser 2, sticker 22, Cheung and Walther, are you aware of any TAVRs that have an outer covering that looks like what we see in Walther, Cheung and Spenser 2's Figure 22?

A. I'm just not sure what you mean by "looks like," but yes, Cribier -- you will know in the Cribier patent there is a -- a teaching of a valve with an internal and an external cover as a diagram, which I think I've referred to in my declaration, which -- I think it's one of Figure 6. I can't remember if it's 60. But there is a diagram of a device with a valve in and an internal cover and an external cover, that is similar.

Q. Can you think of any other similar such covers?

A. Anderson drew one in his patent with a covered device, that's going back to the early '90s.

I can't think -- I'm just trying to think through the actual ones I've relied on. The Anderson patent has one. The Cribier patent has one. The Spenser 1 has one

with a -- with a cuff on the outside of the device.

I mean, there are many teachings, as I've referred to in my declaration, of covers on the outside for the purpose of sealing.

Q. Let me ask a more precise question.

If I put a picture of Figure 2 from Cheung, next to the -- next to the photograph of Walther's valve with the outer cloth in Figure 1 in Walther, next to Figure 22 of Spenser 2. Let's say we have those three images all in a row.

Do you have that in mind?

A. Yes.

Q. We can agree that the outer covering in those three images would look very similar; is that fair to say?

A. Well, we talked at great length yesterday how one is a patent drawing -- two are photographs of actual devices that are similar to each other and one is a patent drawing. And I wouldn't say -- I mean, it is the same concept, I think, and I used that word yesterday, but there are obvious differences between the patent drawing and a photograph of actual devices.

Q. Sure. Let's focus upon the outer covering in Figure 22 of Spenser 2.

A. Yes.

Q. And we compare that to the outer coverings that we see in the two images that I reference from Cheung and Walther, recognizing that it's a patent drawing.

You would agree that if you were trying to make a patent drawing of the outer coverings that you see in Walther and Cheung, would it be fair to say that the sleeve in Spenser 2 is a pretty good rendition as patent drawings go of the outer coverings that we see in Walther and Cheung?

A. I think they represent the same concept, but one is completely schematic, the patent drawing is schematic, and you have to interpret it with the text in the patent.

The other two are photographs, and, therefore, you can fairly talk about there's a lot more detail and a lot more in there because they are actual photographs of actual devices and, therefore, I would regard the patent drawing in Spenser 2 as a schematic, and one would only interpret it with all the associated texts and teaching.

Q. Of course. Of course. But I'm just asking about the images. You would agree we recognize that a patent drawing is a schematic drawing, but we can agree that just looking at the image in Figure 2 of Spenser 22, if you asked a patent drawer -- I'm not sure if those

two -- but someone who draws the figures of a patent -- to recreate what we see in Walther and in Cheung, and let's say the artist came up with Figure 22 from Spenser 2, would you think the artist had done a pretty good job of representing the outer covering?

A. No. I just -- I may be missing something, but I mean it's just completely schematic what is shown in -- in Spenser 2. It is shown as a sort of geometrical circular cylinder with the fibers on the outside and it's only by reading the text that you understand what he's talking about. You need to read the compressibility and things which I wouldn't get from looking at the -- at the schematic drawing, which is in the -- in the patent.

Q. You clearly didn't understand my question. So let me ask my question again, because I want you to answer the question that I'm asking.

So let me ask it again. I want you to imagine that you hired an artist who makes patent figures. You hired that person.

Are you with me so far?

A. Yeah.

Q. And then you showed that artist the photograph from Walther and then you --

Are you with me so far?

A. Yes.

Q. And then the artist -- if you told the artist please recreate Walther in a schematic patent figure.

Are you with me so far?

A. Yes, I am.

Q. And let's say the artist that you hired to recreate patent figure version of Walther created Spenser 2, Figure 22.

Are you with me so far?

A. I'm with you.

Q. Do you think that the artist that you hired to make a patent figure drawing of Walther did a good job of representing the outer cloth?

A. With a -- with associated text and teaching, I can understand what it was.

But just from the drawing of Figure 22, I wouldn't understand what it was without the associated text and teaching.

Q. I'm just asking whether if you asked the artist you hired, the artist, you asked him to do a drawing, you showed him the picture of Walther, he showed you Figure 22 in Spenser 2, and he asked you, "Dr. Buller, did I do a good job of representing the outer cloth in Walther in this drawing that I made?"

Would your answer be yes or no?

A. No. If I was being asked as an art critic, I would say no, there isn't nearly as much detail as there is in the photographs. There isn't as much --

Q. You've looked at many patent figures before, haven't you?

A. I've looked at many patent figures.

Q. We're not talking about the collection from the Louvre, are we?

A. No. I was giving an answer as to whether he's done a good job. It wouldn't look like the photograph. It doesn't look like the photograph. It doesn't have as much detail in it as the photograph.

Q. Okay. I just want to make sure we're talking about patent figures and not --

A. I'm talking about patent figures. I was just using it to describe my answer. It's not an artistic rendition of what there is in Walther. It is a diagram which needs associated text.

Q. Okay. But I'm not asking about the associated text. I'm just asking about the image.

A. I'm talking about the image.

I'm saying you can't get the information that you can get from looking at Walther from the patent drawing.

Q. I just want to make sure you understand. I'm not asking whether you would hang the patent figure that you

commissioned in the Louvre or -- yeah, in your office or whatever. I'm just asking within the context of patent drawings.

That's clear to you, isn't it?

A. Yeah. It has less detail. It has significantly less detail than the photograph.

Q. Yes. Okay. So my question for you, in the context of patent drawings, which we know you've seen very many of -- I sadly think I've seen more than you -- in the context of patent drawings, you hired the patent drawer to make a patent figure and you show him the photograph of Walther and he creates an image that looks just like Figure 22 from Spenser 2. And he asked you, "Dr. Buller, in the context of a patent drawing, did I do a good job of representing Walther's outer cloth?"

Is the answer yes or no?

A. It's an all right job. It's not a good job. It's not a bad job. It has similarities. It has very real differences.

Q. And what are the differences?

A. There's less texture. It seems to have, you know, two very circular lines around the top. It's not as fluffy. It is a very geometrical shape. It's drawn as sort of a mathematical cylinder with the -- with the fibers represented on the -- the outside of it, a few of

those scattered over it.

It doesn't look like a photograph in either Walther or Cheung.

Q. Well, that's a bit of a strong conclusionary statement, isn't it?

As patent figure renditions go, it's a reasonable job, isn't it?

A. Along with the text. As I say, it seems I'm likely saying that, but I've never interpreted a patent without reading the text. Along with the text, it's very good and you can interpret it. But you need the text.

Q. I'm just asking about the images.

A. I know.

Q. Now, you just stated an answer about Walther versus Figure 22 in this scenario that I've given you. Would your answers be the same if I asked you about Cheung's image in Figure 2 of Cheung versus Figure 22 of Spenser 2?

A. Yeah. It would be the same answers.

Q. Okay. Now, we can agree that the figure -- the photograph in Walther, the photograph in Cheung and the Figure 22 from Spenser 2, we can agree that the height of the outer covering relative to the stent frame is very similar; correct?

A. I haven't -- if you want to put them up side by side, I mean I literally haven't put them up side by side to make a comparison.

MR. LOWENSTEIN: Let me ask you, Ed, is that feasible for all three?

MR. HSIEH: I will be able to fit two. I don't know whether I can fit three.

MR. LOWENSTEIN: Why don't we put Cheung --

THE WITNESS: I'm simply saying they're similar. They are certainly similar.

BY MR. LOWENSTEIN:

Q. You say that. Just to be clear, we're talking about the height of the outer covering of the three images relative to the frame.

A. Yes. The height of the outer cloth is called variously cloth, fabric cuff, and what is drawn in Figure 22, the heights are within the same ballpark.

Q. And is it fair to say that the width of the outer covering in each of the photographs from Walther Figure 1, the photograph from Cheung Figure 2 and Figure 22 of Spenser 2, the width of the outer covering is similar in those three images?

A. I don't think you can judge width off a patent drawing unless you're given more information. I've got no scale on that.

But you can certainly judge, as we talked about yesterday, at some length from the photographs because you know things about the device and there is a photograph.

But I wouldn't -- I mentioned off a patent drawing, I would look to see if there was text that told you what it was, but I wouldn't choose, as I said yesterday, a dimension off a patent drawing unless there was teaching that really supported that.

Q. Fair enough.

Do you recall that Figure 22 of Spenser 2 is in the expanded state not the crimped state?

A. That is true. The drawing Figure 22 is in the expanded state with the valve open.

Q. And is it correct that we only see the sleeve, I think it's referred to in Spenser 2, in the expanded state?

A. I think that's right. But I -- I -- it wasn't in front of me now, my file. I'm looking at -- yes, I think that's right. But we only see it in the expanded state.

Q. Do you recall that Spenser 2 describes the sleeve in Figure 22 as having a diameter of 1 millimeter to 5 millimeters?

A. It -- it describes it as compressible material in

the range 1 to 5 millimeters, but that would be uncompressed, therefore, in the range 1 to 5 millimeters.

Q. But you agree that the 1 to 5 millimeter figure is of the cloth in the expanded state; correct?

A. Yes.

Q. Okay. So it does not reveal the dimensions of the cloth in the crimped state; correct?

A. No. But this is -- I'm talking about the cloth, it's compressible cloth that is 1 to 5 millimeters when it's not compressed.

Q. Okay. So the expanded SAPIEN valve can be on the order of -- of 26 millimeters in diameter; is that correct, not counting any covering?

A. There is one of 26 and I think the one they're showing in some of the examples is the -- I think they say 26 in -- in both Walther and Cheung. They -- they -- they reference the 26 millimeter valve.

Q. Do you recall whether in Spenser 2, Figure 22, the expanded diameter of the frame is given?

A. I don't recall as I sit here. I can have a look if you want me to or you can direct me to it.

Q. Well, we'll get to that in a moment.

Spenser 2 is a 2004 publication; is that correct?

A. Yes. I've got the international publication date

was the 12th of January 2006.

Q. And so is it --

A. The priority date is June 2004.

Q. Oh, I'm sorry. Yeah, that's what I'm referring to, priority date.

A. Okay.

Q. I misspoke. You are correct. I misspoke. I meant the priority date, or at least the filing date probably.

Ed, I'm sorry. I'm getting all this confused. I think you said the expanded dimension of the frame not counting the outer covering is not given for the valve depicted in Spenser 2, Figure 22; is that correct?

A. No. I said I can't remember saying that figure for the valve and you said a minute ago that we might come to that later.

I said you could direct me to it, but I can't remember there being a dimension for the valve of Figure 22.

Q. I'm going to put up -- hold on just one second.

Okay. Just to be sure, could you share Spenser 2 as well.

MR. HSIEH: Actually, let me do that.

MR. LOWENSTEIN: Okay.

Q. So I believe Mr. Hsieh is about to share the file

for Spenser 2. I believe, Dr. Buller, you have a hard copy of Spenser 2 in front of you anyways; is that correct?

A. Yes. It's one of the references that I do have a hard copy of. So I've got Spenser 2 in front of me, which I'm --

Q. And you agree that on the screen we're looking at Figure 22 from the Spenser 2?

A. Yes.

(Off-record discussion.)

THE WITNESS: We were when I last glanced up.

BY MR. LOWENSTEIN:

Q. All right. Very good.

Now, you agree that the compressible material that we see in Figure 22 may be formed from PET?

A. Yes. That it teaches, it may be formed of PET.

Q. And we see that in paragraph 55 of Spenser 2, for instance?

A. I'll go to paragraph 55.

Yes, I see paragraph 55 in front of me.

Q. Well, my question is, we see that in paragraph 55 it indicates that the compressible material may be formed of PET?

A. Yes.

Q. Now, let's go to paragraph 85, please.

Dr. Buller, do you see paragraph 85 from Spenser 2 in front of you?

A. Yes.

Q. And paragraph 85 states, quote, "Figure 22 illustrates a valve device, in accordance with another preferred embodiment of the present invention, wherein a layer of compressible material, such as a cloth material, is provided along an exterior surface of a stented valve."

Do you see that sentence?

A. Yes.

Q. So we see that Figure 22, the compressible material may be a cloth material?

A. May be.

Q. And so if see -- if we take the teachings in paragraph 55 and paragraph 85 together, Figure 22, the compressible material may be a cloth made of PET?

A. It may be, yes.

Q. And am I correct that the outer cloth from Walther is made of PET?

A. Yes. Walther said that the actual cloth on that one was made of PET.

Q. Yes. For the court reporter's benefit, I should clarify that I've been intentionally mispronouncing

Walther's name for a few days now.

(Off-record discussion.)

BY MR. LOWENSTEIN:

Q. Dr. Buller, I think you may have already said this, but I'm informed that there is no dimension given for the frame in Spenser 2, Figure 22.

Is that inconsistent with your understanding?

A. No. That fits with my memory. I don't remember seeing a dimension. That's why I said you can direct me to it when you asked me, but I can't remember seeing one.

Q. Neither did I.

A. But one has sort of a rough idea. You know, obviously, as a physician, that you've got an idea of the size you want it to be. If you're thinking of putting this in the aortic valve and the range of sizes, we all say there this is a percutaneous valve, so you want it to go down to a size such that you can deliver it percutaneously.

Q. We do not know that.

A. I know that.

Q. Well, let's test that, shall we?

Okay. So we go to paragraph 144-145. Aside from -- correct me if I've got the paragraph numbers incorrect -- aside from paragraphs 55, 85, 144 and 145

in Spenser 2, are there any other paragraphs in Spenser 2 that are specifically talking about Figure 22?

A. Yes. The abstract.

Q. You believe that the abstract is specifically talking about Figure 22?

A. Yes. I believe it talks about other things, too, but there is a sentence in the abstract, which is specifically about Figure 22.

Q. Which sentence is that?

A. If we go to the abstract, I can show you. You've got the abstract there. It says on the fourth line down, "And finally" -- because it's talking -- "the resent invention provides a series of new percutaneous concepts of paravalvular repair."

And then it goes on. And then it says, "And finally, built in means for leak prevention built on percutaneous valves," and that is clearly talking about Figure 22, that's built on the percutaneous valve.

Q. Now, if I took the 22. Let's say I ripped off the compressible material, so the compressible material wasn't there, could that valve be called a percutaneous valve?

A. It could. I don't know what you'll be left if you ripped it off. I mean --

Q. Wait. Let's not be so dramatic.

Let's just say I didn't add the compressible material to the valve in Figure 22. We have Figure 22 without an outer sleeve.

Are you with me so far?

A. I am.

Q. What is left could correctly be described as a percutaneous valve; is that correct?

A. I don't know.

Q. You would agree that the valve depicted in Spenser 22, to the extent that we can see it, looks at least in some respects, at least the outer frame, looks a bit like SAPIEN; is that fair to say?

A. It -- it has some appearances similar to SAPIEN, but it has obvious differences, like commissures and that. So I -- I don't know. It's a patent drawing.

Whether it would actually be a valve in any real sense, I don't know.

Q. You know that SAPIEN and SAPIEN XT were both percutaneous valves; correct?

A. They both could be used as percutaneous valves. They could also be used as transapical valves, as we talked about. So they were capable of being used as both percutaneous valves, yes.

Q. I mean without limitation. I'm not trying to pull a fast one on you, at least on that question.

The -- and you agree -- I think we've beat this to death, but just so we're on the same page, you agree that the inner SAPIEN nor SAPIEN XT has any outer covering of any type around the outer frame; is that fair to say?

A. As we spoke yesterday, other than the suture, it has no cloth around the outside or no cuff around the outside, but it has sutures that go over many of the bars.

Q. And the fact that there's no outer covering in SAPIEN and SAPIEN XT does not in any way prevent those valves from being implanted percutaneously; correct?

A. Correct. Then they were very important in their time, in their day.

Q. And is it fair to say that the first commercially available TAVR of any kind with any type of outer covering was the SAPIEN 3?

A. I think that's right. I mean, in other places in the world there could be other things that I've forgotten or never knew about. But as far as I know, as I sit here today, I think that is true.

Q. And we can -- if we want to go back to Figure 22.

We can agree that if you hired a patent drawer to give you a replica of the outer skirt in SAPIEN 3, can we agree that if the patent drawer that you hired came

back to you with Figure 22, he did a very poor job of depicting the outer skirt?

A. Well, it's got an outer -- it's got an outer covering on it, but it certainly not got all the features that you wanted. What he was actually trying to do is draw a SAPIEN 3, it would need an awful lot of explanation going with it to explain all the features that are missing. And you would obviously sort of say, look, this isn't really the drawing I wanted, if what you wanted was a drawing of SAPIEN 3.

Q. You would agree that the figures that we looked at in Levi would do a better job of depicting SAPIEN 3 than Figure 22 of Spenser 2; is that fair to say?

A. I think I know where you're going, yes. I mean absolutely. There's a relationship. You can look at the -- at least some of the figures in Levi, the whole device figures, and see a direct relationship with the figures in -- in the commercial SAPIEN 3, which came later, and it's got much more detail in of the structure and design of SAPIEN 3.

Q. Can we agree that there is no TAVR that is percutaneously implanted that we have ever seen in a photograph that looks like Spenser 2, Figure 22?

A. I missed something there, because I thought we were talking about Walther and Cheung look a bit like

Spenser 2, Figure 22.

Q. You'll agree that those are not percutaneously implanted; correct?

A. Oh, there was a -- I think I said I thought I missed something.

Q. Okay. Fair enough.

A. I think Figure 22 is percutaneously implantable.

Q. That is not my question. That is not my question.

A. Ask your question again. As I said, I thought I missed something and I did.

Q. Okay. Very good. I'm happy to ask it again.

A. Ask it again.

Q. You need to answer my questions, particularly on important matters.

Okay?

A. (No audible response.)

Q. I'll ask it again. You're not aware of any -- any valve that is percutaneously implanted, like an actual photograph, an actual device that has been used in the world that is intended for percutaneous implantation that has an outer covering that looks like what we see in Spenser 2; is that correct?

A. No. And I think we talked about this yesterday. I mean, Edwards ultra now -- assuming you're not

limiting me to the priority date, but Edwards ultra has similarities with Figure 22 of Spenser 2.

Q. So let me ask you. First of all, we can agree that SAPIEN 3 ultra is not prior art; correct?

A. You're absolutely correct.

Q. And aside from SAPIEN 3 ultra, can you identify any other valve that exists in the world in a bench test, photograph, in a paper, that is designed for percutaneous -- a TAVR -- it's designed for percutaneous implantation that looks like the valve with the cover sleeve that we see in Figure 22 in Spenser 2?

So aside from the SAPIEN 3 ultra.

A. I'm not aware of one. That doesn't mean there isn't one. But I'm not aware of one before the priority date.

Q. Now, we can agree that in 2012 it was very important to have a percutaneous valve that addressed PVL; is that fair to say?

A. Yes. It was recognized before 2012 that it was necessary to -- to further address PVL.

Q. And it was addressed -- it was known in 2004 that it would be desirable to have a percutaneous valve that addressed PVL; correct?

A. I'm going to put --

THE REPORTER: (Clarification.)

BY MR. LOWENSTEIN:

Q. Let me -- I'm going to withdraw the question because I don't think you're answering my question. So I'm going to ask the question again.

We can agree that in 2004 it was recognized in persons of ordinary skill in the art that it would be very highly desirable to have a percutaneous TAVR that addressed PVL; correct?

A. There -- PVL was already being addressed. I mean, we -- we wanted to address it more than had already been done in 2004, even the first valves that Cribier implanted in 2002 were designed to address PVL, but the importance of PVL became more apparent and the need to do yet more to further address it was recognized increasingly over the early years of TAVR implants.

Q. Okay. So let me -- let me see if I -- we're on the same page.

I think what you're essentially saying was there was a recognition, including in 2004, that it would be desirable to have a percutaneous TAVR that addressed PVL, but the recognition of the gravity of the problem of PVL increased over time; is that fair to say?

A. That's fair.

And the important point is that all the valves right from the beginning were attempting to address PVL.

I mean, I'm absolutely sure -- I know for a fact that Alain Cribier thought the design that he used in the first case in 2002 was going to sufficiently address PVL.

It's just that we came with time we knew we needed even more solutions to address and improvements to be made, but he didn't put in a valve that didn't have something there to address PVL.

His original valve did address PVL, but just not as adequately as the current day ones do.

Q. Now, SAPIEN, we recall, was commercially released in Europe in 2007; is that correct?

A. Yes.

Q. And when did it become known that the SAPIEN valve had a significant problem with PVL?

A. The knowledge grew over time as more studies were published and more information and more experience was gathered. The -- the importance of PVL and data that shows the importance of PVL, it came about over the years that followed.

Q. What years?

A. The years. I mean, this is before and after its CE-marking in 2007. As you've already said, we knew PVL was an issue from the very early days, 2004, the information about it, and carefully performed studies

with data about it and then follow-ups to look at patients' survival and patient progress came about over the years.

Q. Well, here's what I'm trying to get at, because -- let me just set the stage.

I think what you're saying is it was known that PVL was an issue in TAVRs in 2004, but with respect to percutaneous TAVRs, the appreciation for the risk of PVL grew over time. And my -- what I'm trying to get at is what -- what -- what -- how do you -- with more precision -- identify the years when that concern became more aggregated?

Do you understand what I'm asking you?

A. I think I do.

I mean -- to try and put a time frame on it, by 2010, I think it was obvious that things were going to have to be done to improve the then-current generation of valves.

This isn't just the Edwards 1 Medtronic, which was also on the market. Something further needed to be done to improve on the source of residual PVL that we were left with at that point in time.

Q. Did anyone inform Edwards, say, in 2010, what on earth are you talking about? There is no problem with a percutaneous TAVR that addresses PVL. We invented that

in 2004 in Spenser 2, Figure 22.

Did anyone at Edwards ever say that?

A. Not aware of it.

Q. Now, we're talking about a matter of life and death. A patient can die from PVL; correct?

A. Sorry. Is that -- yes, a patient can die of PVL.

Q. And many patients did die from PVL; correct?

A. I -- I think you're overdramatizing. I mean, PVL is a complication which we would love to avoid in everybody. We still can't even today.

But we would love to be able to avoid it in everybody. Case recognize complication and it increases a patient's risk of both death and -- and other consequences.

Q. Because I'll bet Edwards thought it was a pretty big deal when it introduced SAPIEN 3, that it had introduced a TAVR with a better solution for addressing PVL.

Do you think that's incorrect?

A. No. I'm sure they thought it -- launching a new generation, it's an improvement, is always a big deal. I'm sure at Edwards it was a big deal.

I have no doubt about that.

Q. Are you aware that Lynn Wood -- do you know who Lynn Wood is?

A. I've heard the name. But you have to remind me who they are in terms of title.

Q. Well, I'll have to see if I've got the name correctly. But I believe, if I've got the name correctly, he's the head of TAVR at Edwards, or at least he was at one point in time.

Does that refresh your recollection?

A. No. Sorry. It wasn't who I was thinking of. So -- so -- but if you're telling me that at one point in time that that name is someone at the head of TAVR, must be in days gone by, I think.

Q. Larry Wood.

A. I know Larry and Kate. Larry Wood. Thank you.

Q. Okay. I know who Lynn Wood is.

A. I mean Larry Wood I know.

Q. Okay. Very good. So if I listen to a podcast from Larry Wood, let's say, and Larry Wood is agonizing about the patients who were dying because in blind clinical trials they're not allowed to use a SAPIEN, and he's agonizing over it, do you think he's being overly dramatic?

A. He can be overly dramatic. I know him quite well. I mean, I can't -- without listening -- you're asking me something in such abstract form, I can't give you an opinion as to whether he is or isn't being overly

dramatic unless I hear what you're talking about.

Q. If -- if he is being overly dramatic and he's saying things like, "It was just terrible because we had blind studies where people couldn't use a SAPIEN valve and therefore they were dying because of it."

If you're saying things to that effect, do you believe that Edwards needs to issue a press release to its shareholders to comply with securities regulations to clarify Mr. Woods's overly dramatic and imprecise statements?

A. (No audible response.)

Q. No?

Would Mr. Wood know whether that was a deep concern at least on his part as the head of TAVR at Edwards Lifesciences?

A. I'm sure -- I know him. I'm sure he would be very -- if this is a public statement, I'm sure he'd be very careful and measured. He is a passionate person and he feels very deeply for patients.

And if he thinks that someone is not getting something that would help them, he is greatly affected by it.

But I -- I can't talk in the abstract. I mean if -- if you show me or play me what he said, I can give an opinion on it. I cannot give a global opinion on

statements that he's made that I don't even know if they were public.

Q. Maybe -- perhaps we can listen to it later on. We can table that for now.

But for the time being, I just want to make sure we're adequately appreciating the significance of what we're talking about with respect to PVL.

PVL for some patients, they will die from it if it's -- if you have a TAVR that doesn't address it adequately; correct?

A. Correct. We've said this. PVL is an important complication. It's one that can be measured in magnitude. A trivial amount of PVL may not be of any consequence to the patient and they can be reassured.

As it gets worse and worse and as it gets severe, it has more -- more import in terms of their prognosis, and so it's a graded thing as to how severe it was.

What happened in the late '90s, early '20s is that we appreciated more and more -- some studies came out that really shows relatively modest levels of PVL were potentially important for a patient's prognosis.

And that made it much more important that we included in the medical device industry concentrated on it and came out with a solution to try to improve it still further.

Q. You can agree that paravalvularly, or PVL, that was a significant concern with respect to TAVRs by 2012; correct?

A. Yes. It's a significant concern. Agreed.

Q. And we can also agree that starting with SAPIEN in 2007, the next generation of SAPIEN XT we talked about yesterday, our driving concern in that shift was reducing the crimp profile from 24 -- 22 to 24 Fr. to 16 to 18 Fr., that was the major advancement from SAPIEN to SAPIEN XT; correct?

A. It is certainly one of the major advancements because that allowed more patients to be treated.

I mean PVL is an issue that occurs once you can be treated, but there are whole cohort of patients that couldn't be treated, and reducing the size down meant that further patients that had smaller size vessels, diseased vessels could be treated.

So it's a very important thing as well. Some patients were dying through not being eligible to have a TAVR procedure, and getting the size down meant a larger number of patients were eligible for the treatment.

So, again, it was equally important, just a different consideration.

Q. I just want to make sure I understand.

Edwards, to your understanding, never reduced

Figure 22 in Spenser 2 to an actual TAVR that could be delivered percutaneously; correct?

A. We're talking before the priority date?

What time frame are we talking?

Q. Sure. Let's talk about before 2012.

A. They didn't go to produce one that was commercially approved, no.

Q. Okay. So we can agree that in 2004 people are dying because the crimp profile isn't sufficient to be percutaneously delivered. TAVRs were being transapically delivered. People were dying as a consequence of that.

Correct?

A. I'm sorry, that's a very complicated question that you're -- that is a compounded question I think.

Could you ask it --

Q. You could agree that if there's not a percutaneous TAVR option available, some patients will die as a consequence of that circumstance; correct?

A. Well, if they're not eligible for another route, such as transapical. But with clinical -- we look at patients and see what we can do --

Q. I'm just asking for a yes-or-no question. Because I think it's a really simple --

A. But it's not a yes-or-no answer I'm afraid.

Q. You don't know whether some patients will die if there's not a percutaneous TAVR solution available?

A. It's more complicated than a yes-or-no answer.

Some patients that can't have it percutaneously could have it transapically. That's what I'm saying.

Q. Of all of the patients who may be in need of a TAVR procedure, if there's not a percutaneous option available, will some of those patients die?

A. Yes. Sadly, it will be likely that some will die, but some will be able to be treated by other routes.

Q. I'm -- yes, the answer is yes. We know the answer is yes, because Larry Wood said so, correct?

And because everyone in the world knows that people were dying because there was not a percutaneous TAVR solution prior to 2007 that was commercially available in Europe.

Isn't that true?

A. That was a ridiculous tirade.

Clinical medicine --

Q. You need to answer my question, sir. I don't need your commentary on my questions.

I need you to answer my questions.

A. I think I already had. Some patients --

Q. You agree because everyone knows that people were

dying because there were not percutaneous TAVRs available; correct?

A. Some patients, very sadly, would have died because the treatment wasn't available, but many patients would have been treated by other means.

Q. Okay. I just asked you a yes-or-no question. You need to answer the question that I'm asking.

I'm just asking if some patients died as a consequence. I think the answer to that is yes, isn't it?

A. I think I've said several times, yes.

Q. Okay. Good. Good. That's it.

Now -- so in 2004 people were dying because of the unavailability of a percutaneous TAVR, correct?

A. It likely happened, yes.

Q. And in 2005, people were dying from the lack of a percutaneous TAVR; correct?

A. I don't know that.

Q. You don't know that? Really?

A. I've already said, I think, that some patients would have died, but the emphasis you're putting on this is just inappropriate.

Q. Do you know if Jupiter existed in the solar system in 2005?

A. Yes.

Q. Okay. With that level of confidence, do you know that patients died in 2005 from the unavailability of a percutaneous TAVR?

A. I believe some may have. It's very sad, but sometimes patients will die because treatment is not available for another reason.

Q. Are you any less confident in your answer that you just gave me than the fact that Jupiter existed in the solar system in 2005?

A. Yes.

Q. You are less sure?

A. Yes. Individual patients on complicated matters and there are alternatives for treatment in patients.

As far as Jupiter existing in the solar system is something I think we can just agree between us, as far as I know, is and was a fact.

Q. I thought we could until you told me you weren't sure patients died in 2005 from percutaneous TAVRs. And now I think I'm listening to the loss of few data (sic) here again where we don't know if the sun will rise tomorrow.

Because I think we all know, not to reference -- I don't know if you have some ill-will towards the Scots, but I think we all know that people died in 2005 because a percutaneous TAVR was not available; correct?

A. As I said several times, I don't know why you keep on -- I said that yes, some will very sadly have died.

Q. Good. I'm just happy that we --

A. I'm glad you don't think it's good.

Q. I'm very sorry that people died in 2005.

A. Me too. Me too. On the record.

Q. We can agree that people died in 2006 from the lack of a percutaneous TAVR; correct?

A. Yes. Sadly, some people will have died. Very sad, but lack of resources, lack of equipment, lack of possibilities and individual circumstances with the patients and what the right or wrong treatment is for them will all affect this, and some will have died.

Q. Okay. And then in 2007, SAPIEN was introduced, and we finally have a commercially available percutaneous TAVR, correct?

A. Yes.

Q. And that's a big deal, because some people who would have died were no longer dying because at least for some of those people they could have a percutaneous TAVR.

So that's a big deal, isn't it?

A. Yes. It was a big deal and we're agreeing on that. It was the launch of TAVR when it was first

commercially approved was a very important event.

Q. And that was a very important event, but it wasn't quite perfect for safety, was it? Because it had to be delivered in a 22 Fr. or 24 Fr. sheath; correct?

A. Absolutely. It's not perfect. Nothing is perfect even today. There's no such thing as perfect in medicine, sadly.

Q. And thus it was very important to move from 22 to 24 Fr. to 16 to 18 Fr. with SAPIEN XT; correct?

A. All of these -- all of these intricate steps were important in their own way, yes.

Q. But if SAPIEN -- if Edwards could have produced SAPIEN XT in 2007, it would have; correct?

A. I don't know that.

Q. Do you -- okay. Let's -- let's think about that launch for a minute.

We can all agree that Edwards Lifesciences does not want people to die needlessly; correct?

A. That's a fair assumption.

Q. Okay. And we can all agree that if Edwards was able to put out a superior medical device at an earlier point in time, all else being equal, it would?

A. All else being equal is an important caveat.

Yes. All else being equal, I think that is fair.

Q. Now, can you think of any reason why if SAPIEN XT

could have been approved by 2007 it wouldn't have been?

A. It takes a long time to do the sort of research and development work that is required to have the data to convince regulator authorities and -- and particularly so in the U.S. with the FDA, and, therefore, sometimes you are locked into a generation of device that you have to go ahead with in order to bring it to fruition to get more data. And trying to jump to the next generation that may already be available before the launch of the older generation is a problem.

It takes a long time to collect the data set that's required for regulatory authority.

Q. So it would be really easy, though, for an interventional cardiologist to design -- just look at Spenser 2, Figure 22 -- and design such a device that can be implanted intravascular. That would be really easy, wouldn't it?

A. None of these things are easy in any sense at all, because there's lots of tradeoffs. You get tradeoffs between the sealing and size and durability and strength and other characteristics of delivery.

There are many tradeoffs. And what you are doing in the design process for this is often accepting these tradeoffs and making one decision over a competing decision, and it's a complicated process.

I'm sure that the people that actually do it within companies like Edwards, and many other companies, actually spend an awful lot of time and an awful lot of agonizing on whether one choice versus another choice that are competing with each other.

Q. SAPIEN we know is a 22 Fr., 24 -- or 24 Fr, and we know that SAPIEN has no outer covering at all, correct?

A. Correct.

Q. We can agree, and you're right at with 24 Fr., you're right at the maximum for percutaneous delivery; correct?

A. 24, as we talked about yesterday, is just sort of 8 millimeters is the -- the upper limit for the size of the femoral -- in most people. Not in all. Some will be a bit bigger, but for the majority of people, that's a reasonable upper limit.

It won't allow you to treat everybody because some will be diseased and smaller than 8 millimeters. But 8 millimeters is sort of the textbook size for the femoral artery.

Q. And we can agree that even at 24 Fr., that level cannot be used in 50 percent of TAVR patients; correct?

A. I haven't got a number on the tip of my mind, but there's certainly a significant number will have disease

or other things there that you can't use it and you'll need to consider some other route like transapical.

Q. And -- okay. So we know that if you add any outer covering at all around a SAPIEN, all else being equal, you will increase the crimp profile; correct?

A. Yes. If you add something around the outside, all else being equal, but what you would have to do, as I said as a tradeoff, is change the design or the material of the valve.

Q. I'm just asking a question. I think you answered my question. I don't need anything beyond the answer to my question.

A. All else being equal if you add something to the outside you're going to make it larger, everything else staying the same.

Q. Okay. And we can agree that if you add a material in the expanded state that is 1 millimeter through a SAPIEN, we can reasonably infer that the SAPIEN will no longer be capable of transfemoral delivery; correct?

A. No. No. You can't do that.

Q. So you're already at the limit, 24 Fr., and you add a cloth that's 1 millimeter in the expanded state, which will be more in the crimped state, won't it?

A. No, because it will be maybe compressible

material and you've got the smaller size valve. So you can take the valve that can go through the smaller sheath and you can add something that's very compressible to the outside, and that smaller valve with the cover on the outside may be able to be delivered through a 24 Fr. sheath. This would be engineering to see whether you --

Q. Hold on. Hold on. You could do it. You could do it, no problem.

So Edwards could have, in 2004, have created a percutaneous TAVR that addressed PVL via an outer covering. In 2004. No problem. Edwards. Which is just a part of PVT. And Alain Cribier for 30-, $40 million according to Mr. Wood, 10 percent of what it was worth.

And Edwards with PVT just decided not to release the Spenser 2, Figure 22 valve in 2004, correct?

MR. SUMMERS: Object to the form of the question.

THE WITNESS: I lost that question halfway along.

BY MR. LOWENSTEIN:

Q. Let's just ask it this way, because I think we know the answer.

Edwards did not release a real-world embodiment

of Spenser 2, Figure 22 in 2004, did it?

A. You know the answer is no. We've already talked about.

Q. I knew the answer was no in 2005, too. And in 2006 and 2007, every single year right until the present; isn't that true?

A. They were working on bringing --

Q. I'm just asking, did they do it?

A. We've already -- I've already answered it.

Q. I know they didn't. But I want you to admit it.

A. There's nothing to admit.

Q. Well, let's see. Let's see about that.

Because every year that Edwards decided not to create a TAVR that was percutaneous with a big, fat compressible material like we see in Spenser Figure 22, patients were dying every year. That seems to be at odds with Spenser, Edwards having this Eureka invention in 2004, isn't it?

MR. SUMMERS: Object to the form of the question.

THE WITNESS: No.

BY MR. LOWENSTEIN:

Q. It's not.

A. That's what "no" means.

Q. Okay. Very good.

So let me just make sure I understand.

You have never implanted a TAVR in a human being in your life; correct?

A. Correct.

Q. And you have never implanted a TAVR in an animal; correct?

A. Correct.

Q. You have only implanted a TAVR in a bench test; correct?

A. Correct.

Q. And that was in 2013; correct?

A. That was one of the times, yes. Correct.

Q. And at the time you were working as an expert witness; correct?

A. Correct.

Q. And you have never written a paper on aortic vascular replacement; correct?

A. A TAVR, no, I haven't.

Q. I said aortic vascular replacement.

A. I don't know what -- aortic vascular replacement?

Q. AVR. AVR.

A. Atrial valve replacement you mean.

Q. I'm sorry. I didn't get much sleep. Thank you.

(Off record discussion.)

MR. LOWENSTEIN: Let me ask it again. I

appreciate your correction. Thank you.

Q. You have never written a paper on AVR; correct?

A. Correct.

Q. And you have never written a paper on TAVR; correct?

A. Correct.

Q. And you have never written a paper on outer seals or outer coverings in stent devices; correct?

A. No. I have written papers on stent devices, but not TAVR.

Q. I'm asking about outer coverings in stent devices.

A. Yes, I've been associated with research and development of coverings on -- on stents and drug relating stents, but this is in a study of stents not for use with valves and not tablet devices.

Q. I've asked if you've written a paper. Have you written a paper on that subject?

A. Yes. With coverings on stents, yes.

Q. And you retired as an interventional cardiologist in 2008; correct?

A. I've retired from doing procedures in 2008 and then went on seeing patients in private practice until 2014.

Q. But did you implant any stents in human beings

after 2008?

A. No. I stopped doing procedures, implanting stents and doing interventional procedures in 2008.

Q. And you agree that there was -- and I think it's fair to say that TAVR was not a core area of research for you at any point between 1990 and 2008?

A. No. It wasn't an area of research for me.

Q. And was TAVR a core area of research for you between 2008 and 2012?

A. No.

Q. Have you ever designed a TAVR?

A. No.

Q. Have you ever designed an outer covering for a TAVR?

A. No.

Q. Have you ever designed -- selected materials for an outer covering for a TAVR?

A. No.

Q. Have you ever assessed crimp profile in a TAVR prior to your work in various litigations?

A. Yes. As a -- as a clinician and -- and considering patients for these procedures, yes.

Q. A crimp profile for TAVRs?

A. Yes. I've -- I've referred patients of mine for TAVR procedures and part of the workup for them is

looking at the disease in the legs and what could go up in talking to the physicians and therefore one of the considerations is the -- is the crimp profile.

That -- that is influenced by what disease they have down their legs and on the way up and things like that.

Q. I understand. I think I understand what you're saying.

You were an interventional cardiologist, you would take a C.T. scan or an angiogram of a patient; is that correct?

A. Yes. I mean the sort of assessments you've made to look in their vasculature, and I've done lots of that.

Q. And then you would refer the patient if you thought they had aortic stenosis to an interventional cardiologist who implanted TAVR devices; is that fair to say?

A. Yes. To -- To a team. So they would be discussed and considered for surgery, or -- or percutaneous ever.

Q. Okay. We've been going for quite some time. Why don't we take a break and can we resume in 10 minutes?

Is that okay with you, Dr. Buller?

A. That's okay with me.

Thank you.

(Off record from 9:14 till 9:31.)

BY MR. LOWENSTEIN:

Q. Okay. I think you agreed, Dr. Buller, before we had a pause just now, that it sounds about right that prior to 2007 one third of patients with symptomatic severe aortic stenosis were not surgical candidates; is that fair to say?

A. Fair to say.

Q. Okay. And I believe on Edwards Lifesciences website, they indicate that 3 percent of people in the -- is it -- over the age of 75 in the United States have symptomatic severe aortic stenosis, does that sound reasonable to you?

A. That sounds perfectly reasonable. I mean, it's horrible, but it's perfectly reasonable.

Q. And my team of interventional cardiologists also told me that the average lifespan of untreated symptomatic severe aortic stenosis is two years from diagnosis; is that fair to say?

A. Yes. That's a sort of -- yeah, that's a -- a widely quoted figure I think.

Q. So we had some discussion before where you thought I was being dramatic because I kept saying people died year after year after year. You thought I

was being dramatic, didn't you?

A. Yeah. I think you were putting the wrong emphasis if you're asking me that. Because there's still people dying. I mean, it's true today unfortunately.

We don't have the penetration that we need to cross the globe --

Q. The only question was whether you thought I was being dramatic and I think you did.

A. I did. I thought you were being dramatic and I think that --

Q. That's it. You answered my question.

A. All right.

Q. Now, let's do some math, which is not my strong suit, which is why I went to law school.

Do you have a -- okay. So I only have a statistic for people in the United States aged 75 to 84, which obviously doesn't account for people older than 84. But that statistic is 14.9 million people in the United States between the ages of 75 and 84.

Does that sound wrong to you?

A. If you're doing the -- I don't have a calculator. I'm not doing the math. I don't know even know what population you're using for the United States. But I'll accept it. I mean, if you're just doing the math based

on those numbers --

Q. I'll pull out my calculator and I'll just round up to 15 million, but we'll know that's conservative because I'm not counting the people over 84.

And so we'll do 15 million times .03, which gives me 450,000.

So according to Edwards, at least 450,000 people in the United States have symptomatic severe aortic stenosis; is that correct?

A. I don't --

MR. SUMMERS: Object to the form of the question.

THE WITNESS: I don't know that's correct. But it doesn't sound an unreasonable estimate. It's a -- it's a calculation.

BY MR. LOWENSTEIN:

Q. It's an under- -- it's a deliberate underestimate. It's not deliberate, because I can't get the full of the 75-age population, which I would rather use if I had it. It's an underestimate, because it doesn't account for the people who are over 84.

A. I couldn't understand that word. It doesn't account for --

Q. The people who are over 84.

A. Okay.

Q. Now, I'm going to divide 450,000 by 3 and I don't even need a calculator to do that.

That's 150,000 people; correct?

A. Divided by -- 450 divided by 3 is 150, so yes.

Q. Okay. So what that means is 450,000 people in the United States alone, which we know to be an underestimate of symptomatic severe aortic stenosis, one-third, meaning 150,000 of those people, are not surgical candidates; that's reasonable?

A. Yeah. Ballpark figures, yes.

Q. Okay. And for those 150,000 people, they have a life expectancy of two years if their symptomatic severe aortic stenosis is untreated; correct?

A. On average. I mean, clearly you don't as a doctor tell all of these people you're going to die in two years. That's not how it works.

It's an average life expectancy. Some will live much longer and some will die tomorrow.

Q. So I believe that that estimate for the U.S. Civil War, which is probably not on the top of your mind, not on the top of mine either. I know it pales in comparison to some European disputes, but I believe the number of people who died in the Civil War was roughly 700,000 people.

Do you have any reason to disagree with that?

A. I have no reason to disagree with it. I have no knowledge of it. I mean, I don't know the number of people that died in the U.S. Civil War.

Q. We have had the relative fortune to prevent beyond our worst war in terms of fatalities.

A. If it remains your worst war, we never have worse.

Q. Very good. I endorse that. I agree on that. But let's start counting.

2004, that's 150,000 people. In 2005, that's 300,000 people. 2006, 450,000 people. 2007, 600,000 people.

Correct?

A. But you're just doing the math. It really isn't simple like that, but I'll accept what you're doing. You're just doing the math year after year after year.

Q. That is -- I want to represent to you that that is exceptional math for a lawyer, top rate math for a lawyer.

A. I can't comment on that.

Q. It's true.

Now, that's just in the United States; correct?

A. You're telling me that so you've done the figures for the United States. So if that's what you've done, that's correct.

Q. Well, it's just for the age 75 to 84. These are approximate. You'd have to figure it out each year and so on and so forth. But we're talking roughly.

A. Are we going anywhere with this?

Q. Well, that's for me to decide, isn't it?

A. It is. That's why I asked.

Q. Okay. So you've been editorializing quite a lot on my questions. I don't critique your step (sic) work, so please don't critique my questioning.

Now, approximately 300 million people in the United States; is that fair?

A. I -- I don't know the current number. I thought it was a bit more than that. I thought it was more like 350.

Q. 330.

A. 330, okay.

Q. And I believe the world population is on the order of less than seven and a half billion by now, seven billion, something in that range?

A. I don't have that number. I didn't know it was that much.

That's frightening. Yeah, okay.

Q. So if we take 330 million and we multiply by 22, we get 7.2 billion; is that right?

A. If you've got the calculator there to check it,

but, yeah, it sounds about right.

Q. Okay.

Is that right?

Yeah. So I get 330 times 22, which gives me 7,260. So you now trust my math now?

A. Yes.

Q. Okay. And we can agree that the U.S. probably has an older population relative to most other countries; is that fair to say?

A. Some, yeah, absolutely. To developed world, you've got a lot older population than some of the developing world.

Q. So it wouldn't be right to just multiply my 150,000 number by 22. That would not be reasonable; correct?

A. It wouldn't.

Q. Okay. But what would be a reasonable multiplier?

A. I don't know.

Q. Would it be 10? Does that sound -- does that sound out of the realm of possibility?

A. We need to know about the age, because there are clearly countries in the world where life expectancy is very much lower and therefore the instance of senile of age-related aortic stenosis is going to be much lower, because they don't live to the age where their aortic

valves calcify.

Q. I think you can allow that I am recognizing that in my questions. And we can both agree that it may not be 150,000 by 22, but we can agree that it's 150,000 by some multiple; correct?

A. By some multiple; correct.

Q. Probably at least 5 or 10; correct?

A. I'd rather just leave it at some multiple. I can't give you an estimate of that because you need to know an awful lot about populations, what's going on in the same instances of the disease.

So it's difficult to multiply it without having some data to base it on.

Q. Sure. Let's just say for ease of math it were 10.

A. Okay.

Q. So again, we're talking about 1.5 million people every year; correct?

A. By that math, that's what you come to.

Q. More than twice the number of people who died in the American Civil War?

A. Based on your figure of how many died in the American Civil War, that's correct.

Q. Well, the figure I learned in school is 500,000. Then I heard it was something else. So who knows, but

either way.

So we can agree that it's not just some people dying. It's at least hundreds of thousands, if not millions of people, were dying every year between 2004 and 2007. Is that a reasonable estimate from what we've just discussed?

A. It's -- it's too simplified, but yes, it's the math we've just discussed and we've gone through and I don't want to go through it again, but clearly there are other diseases and conditions that affect people. Some of these people will be dying of infection, some will be dying of malaria, some will be dying of malignancy.

There are other things that affect this population. Aortic stenosis is not the only thing killing people in those older years.

Q. You know, it's funny, Larry Wood addressed that very thing, too. And what he said in the podcast was something like the improvement in life expectancy was basically unprecedented from the introduction to SAPIEN. It was unlike anything he had ever seen before.

Let's suppose -- let's just assume he said something like that.

Would that sound wrong to you?

A. It would sound wrong because obviously treatment of conditions like malaria and dehydration and -- and --

and malnutrition, you know, have utterly dramatic effects in worldwide label terms but are probably more important. And not belittling, aortic stenosis is very important. It's more important in developed countries where we have an older age population --

Q. I think I can clarify, because I think -- because what Mr. Wood was referring to, I believe, I'll have to go back and check, was the clinical test group verses the control group, which I assume was one in the United States. And with respect to those two populations, he said something to the effect that the life improvement based upon percutaneous TAVR was essentially unprecedented with that additional context.

Does that sound wrong to you?

A. I would need to hear it. I mean, you must accept that I cannot comment on what Larry Wood said without knowing what Larry Wood did say and in what context.

Q. Fair enough. Fair enough.

We can agree -- and we can agree you haven't heard the podcast and so I'll allow that there's some level of unfairness in me asking you about it.

But I think we can agree that Larry Wood knows a whole lot more about the SAPIEN clinical trials and the various outcomes for the patients in those trials than you do.

Is that fair to say?

A. Yes. I -- that wouldn't surprise me at all. I still haven't heard what he said and you're asking me to --

Q. I'm not asking you about what he said. All I'm asking you is confirm, which I think you just did, that Larry Wood, the head of TAVR at Edwards Lifesciences knows a whole lot more about the SAPIEN in clinical trials and the health outcomes for the control versus the test group than you do?

A. I think that's correct. And I've agreed with that.

Q. Okay. Good. So it's not just -- if someone said some people -- some people die in 2004, some people died in 2005, that wouldn't be dramatic, would it?

It would be a massive, massive understatement, wouldn't it?

A. No. It was most dramatic how you were saying it. Sadly people are dying of these conditions every day. They continue to do so. It is -- it is the emphasis you're putting on it and the sort of connection with Edwards not bringing out the device.

Q. Fair enough.

Would you agree that if I said in the American Civil War some people died in it, would that be overly

dramatic?

A. It doesn't sound overly dramatic. It sounds true. Some people did die in it, sadly.

Q. Does it -- could it also be considered a gross understatement?

A. It depends on context and how you're doing it. I mean, it depends on the context. Some people did die. A lot of people died, according to you.

I don't have the figures, nor do I need the figures to -- to give this deposition about the subject matter that I'm here to be deposed about.

Q. But you are being deposed. That's exactly what the subject matter is.

A. The number of people that died in the American Civil War, I just don't have the data. I don't have the data.

Q. It's a baseline.

You can tell me how many people died in the -- the, you know, the bombings in London in World War II, we can use that as a benchmark if you'd prefer.

I don't know the number. But I'm happy to use any other casualty list that you'd like and we can go through the same exercise.

A. There's no purpose for me. I'm happy to accept and take it that what you're telling me is accurate.

Q. We can agree that Edwards Lifesciences would not let millions of people die if it had a medical device solution on hand; is that fair to say?

MR. SUMMERS: Objection. Object to the form of the question.

THE WITNESS: Edwards obviously, I think, would not wish people to die in any sense unnecessarily, but Edwards have constraints on them in terms of actually getting approval, getting devices through clinical trials and going through responsible development. It's very easy to use hindsight and say it would have been really good to have it out earlier, but we need to know the clinical data and need to know what level of benefit it is in order to make judgments about these things, and all of that takes a long time.

I'm actually sure that Edwards were very busy as were PVT before them working hard to develop and bring to fruition this sort of device.

Q. We can agree that you are not aware of any physical substantiation of Spenser 2's Figure 22 where Edwards tried to create a prototype; correct?

A. We've -- we've looked at --

Q. A prototype in accord with Figure 22, Spenser 2. We -- we agree that Edwards did not create a percutaneous TAVR that looks like Figure 22 of

Spenser --

A. Also was a prototype.

The first question that you asked didn't have percutaneous. Walther was a prototype and all I know was a prototype to go on to percutaneous development.

Q. That's not true. That's not true. Let's go through that. Let's go through that, shall we?

A. Please.

Q. I'd like you to answer my actual question first.

A. I was.

Q. Okay. Now, we know that Walther is a valve-in-valve bench test; correct?

A. Correct.

Q. And we know that it's a SAPIEN with an outer cloth wrapped around it, correct?

A. Correct.

Q. And we know that the SAPIEN device could only be delivered in a 22 Fr. or 24 Fr. delivery system; correct?

A. Correct.

Q. And we know that SAPIEN did not have an outer cloth around it; correct?

A. Commercially-approved SAPIEN did not have an outer cloth around it.

Q. Right. Fair enough.

And we know that Walther had a SAPIEN with an outer cloth; correct?

A. We've already said that. We've done that one, yeah. Correct.

Q. And we know that Walther used a 33 Fr. delivery system for its SAPIEN with its outer cloth wrapped around it; correct?

A. Walther used a 33 Fr. delivery system; correct.

Q. And we know that there's no suggestion of Walther whatsoever that anything less than a 33 Fr. delivery system would be suitable; correct?

A. There's nothing in Walther that talks about that issue.

Q. And then we looked at Cheung, didn't we?

A. We did.

Q. And in Cheung, we have -- maybe it's a Cribier-Edwards valve, maybe it's a SAPIEN valve. Either way, it's pretty close to a SAPIEN.

Is that reasonable?

A. It looks similar in the photographs to a SAPIEN.

Q. And we can agree that Cheung, unlike Walther, is in vivo. It's implanted in an actual patient; correct?

A. Yes. It's treated -- it's a clinical procedure treating a patient with disease.

Q. And we can agree that Cheung did not take a

percutaneous route; correct?

A. Did not. He did a procedure transapically.

Q. And we can agree that Cheung, like Walther, used a 33 Fr. delivery system; correct?

A. Yes. He used a -- what I take to be a commercially-available 33 Fr. delivery system.

Q. And we already agreed, did we not, that if you added an outer cloth to a SAPIEN to the outer frame, you will increase the crimp profile at least to some degree; correct?

A. You will increase the crimp profile of SAPIEN to some degree with putting a cloth on the outside.

Q. And we know that no one, or at least we are not aware of any commercially-available TAVR with any sort of outer covering that was made available prior to SAPIEN 3; correct?

A. Commercially approved, no, there wasn't one before SAPIEN 3 that I'm aware of.

Q. And we know that the SAPIEN 3 outer skirt -- it's not called an outer cloth, is it?

A. No. It's made of cloth, but it's called an outer skirt.

Q. And we know that the SAPIEN 3 stent frame is designed to elongate further; correct?

A. The -- I didn't get -- the stent frame? I'm not

familiar.

Q. Designed to elongate further.

A. Well, I'm just confused. Are we talking about the outer skirt?

Are we talking about the frame?

Q. The frame.

A. The frame elongates when it is crimped down, that's true.

Q. And you agree that in SAPIEN 3, there's what we sometimes refer to as the proximal end of the frame versus the distal end of the frame, at least using the terminology in the AI patents.

You agree that the proximal end of the SAPIEN 3 frame is narrower than the distal -- well, the proximal portion of the frame is narrower than the distal portion of the frame; is that correct?

A. That's my understanding, yes.

Q. And the reason why the proximal portion of the SAPIEN 3 frame is narrower than the distal portion of the SAPIEN 3 frame is to accommodate the additional outer skirt never before present in a commercially-approved device so that you can add that skirt without increasing the crimp profile; isn't that correct?

A. Yes. It -- in part, I don't know whether it

completely avoids any increase in -- in crimp profile for having that taper in the frame. I don't know whether that compensates fully for the presence of the skirt.

But it certainly contributes to the ability to put the skirt on and have an acceptable crimp profile.

Q. And we know -- we know that there is no teaching with respect to the frame in Spenser 2, Figure 22 about the frame elongating; correct?

A. No. But you would know from the geometry of the frame that it would elongate. I mean, that that's a geometry thing. Elongation is a straightforward geometric change, and you would know that it was going to elongate.

Q. You would agree that there's no teaching in Spenser 2 with respect to Figure 22 of having a proximal portion of the frame being narrower than the distal portion of the frame; correct?

A. That's correct.

Q. And you would agree that there's no explanation with respect to Figure 22 specifically as to how you would deliver that TAVR endovascularly; correct?

A. Yes. There is an explanation. There's an explanation for how you make it a percutaneous valve. You have compressible material that can squash down to

much less when it's expanded dimension and by putting that on the device, you can minimize the addition that you're adding to the device and it can remain as a percutaneous device.

Q. Well, that's not quite true, isn't it? All Spenser 2 says is it's compressible material; correct?

A. If you're going on a percutaneous device.

Q. We can agree that in connection with Figure 22 in paragraph 55, paragraph 85, paragraph 144, paragraph 145, there's no mention in any of those paragraphs of the Figure 22 embodiment being percutaneous; is that fair to say?

A. In those paragraphs, there isn't. But as we looked at earlier in the abstract, there is.

Q. And we can agree that Figure 22 is not specifically referenced in the abstract; correct?

A. Yes, it is by virtue of the description. It is a percutaneous device that has something added to it.

Q. We can agree that the cover figure for Spenser 2 is not Figure 22; correct?

A. The total figure, no. The cover figure is not Figure 22.

Q. Now, we can agree in Spenser 2 in relation to Figure 22, there's no statement concerning the degree to which a compressible material will increase the crimp

profile; is that fair to say?

A. Yes, there's no specific discussion about that.

Q. And we can agree that in Walther there's no specific discussion of the degree to which the outer cloth will increase the crimp profile; correct?

A. There's no discussion of that. Or no discussion of the -- the numbers.

Q. Do you have Figure 22 in mind, Spenser 2, Figure 22?

A. I have it here, yes. I've got a hard copy in front of me. So I've got Figure 22 here.

Q. Why don't we show it on the screen again.

A. I have it in front of me, if that helps.

Okay. I've got it both on paper and on the screen now.

Q. I think we have -- I think we marked it yesterday. In fact, I'm fairly certain we did. But I think we can agree that the outer sleeve is opaque, at least as it appears in this figure?

A. Yeah, we talked about this yesterday that you can't -- the struts aren't drawn as if they're visible through the covering.

Q. So you cannot see the frame through the outer sleeve, at least insofar as the outer sleeve covers the crimp; correct?

A. On this device, you can't, no. On this drawing.

Q. And you see we're looking at a -- I'm not sure what you would recall it -- but I guess I would call it the side-view from a slightly downward-looking angle; is that fair to say?

A. Yeah, I understand exactly. You can see slightly into it, into the valve that's open and therefore you're looking at it from slightly above horizontal.

Q. We cannot see the proximal end of Figure 22; is that fair to say?

A. We can see the proximal end of the -- of the cloth, of the outer covering, because that's the line at the bottom, just above Figure 22.

But we can't see any of the bottom of the frame or the bottom of the valve leaflets.

Q. Now, if the frame extended below the -- that outer cloth, would you be able to see that?

A. Oh, if it was drawn. I mean, if it extended far enough below and it was drawn there, you'll be able to see it.

But, again, this is a patent drawing for you to understand the concept. It's not limiting it to this exact -- it's not limiting it to this exact configuration.

Q. Is it fair to say we cannot tell just from

looking at Figure 22 alone whether the frame extends more proximally than the compressible material?

A. I think we can't tell.

Q. And is it fair to say that we can't tell, just from looking at the image alone, whether the compressible material covers the tips, the proximal tips of the frame?

A. Well, it would appear -- I think you can say that as far as you can tell it does from this figure, but it is a patent drawing. It's -- you need to interpret it with the teaching.

Q. Okay. Let's bring up this one.

Ed, can you share the file as well?

(Off-record discussion.)

BY MR. LOWENSTEIN:

Q. Okay. So I believe we've shift -- hold on.

(Off-record discussion.)

THE WITNESS: Which document are we going to? I may have a paper copy of.

BY MR. LOWENSTEIN:

Q. I don't believe so. I don't remember it being an exhibit. Did you just upload it?

(Off-record discussion.)

BY MR. LOWENSTEIN:

Q. Maybe I'll just try to lay some groundwork.

You haven't seen the document yet I recognize, but just for the record, we're about to share a document from the Journal of Interventional Cardiology with a copyright date of 2014 and the title of the paper -- or the lead author is Gerhard Schymik. I'm butchering the pronunciation I'm sure. We'll see the spelling when we get the document.

The title of the document is "How to Adapt the Implantation Technique for the New SAPIEN 3 Transcatheter Heart Valve Design."

We're going to share the document. I just shared the title of it.

(Off record discussion.)

MR. LOWENSTEIN: Let's just go off the record momentarily. Seems like it's going to be a minute or two. So if you want to stretch your legs, feel free. But it's up to you.

We can go back on the record.

(Off record.)

BY MR. LOWENSTEIN:

Q. Okay. So it looks like he just shared it and -- Okay.

Just, Madam Court Reporter, just so you are aware, so there's no confusion later, we accidentally uploaded a different document. It's actually a document

we talked about yesterday. So don't look at the first document of the two we just uploaded. Look at the second one, please.

Now, Dr. Buller, do you see the article in front of you?

A. I do.

Q. Okay. And we can see this is -- this article reads from the title is about implantation technique for the SAPIEN 3 TAVR; is that fair to say?

A. Yes.

Q. Okay. And let's go to the abstract. It's not titled as such. So I'm -- just for the court reporter's benefit, I'm going to paraphrase. I'm going to do an initial paraphrase and quoting.

You'll just have to bear with me.

You'll see in the first sentence, it says that the SAPIEN 3 THV has significant design improvements as compared to the previous generation of SAPIEN XT.

Do you see that, sir?

A. Yes.

Q. And is that a reasonable statement?

A. Yes.

Q. And -- and that sentence is, quote, "Basically, the new valve requires less oversizing to the outer skirt, which, if positioned underneath the annulus, can

reduce the occurrence and severity of paravalvular leak," closed quote.

Do you see that?

A. I do.

Q. And what that sentence essentially means is that the SAPIEN 3 requires less oversizing due to the outer skirt, which, if you positioned the outer skirt below the annulus, you can reduce the occurrences of PVL; is that fair to say?

A. It seems to be saying something of that ilk. This is not prior art, so it's not something I've taken notice of or studied, and I'd obviously like to read all of it because this is just summary at the beginning.

Q. Of course.

And then skipping the next sentence, we're going to go to the sentence starting with "Once the SAPIEN 3." That sentence reads, "Once the SAPIEN 3 valve is positioned with the initial orientation of the middle balloon marker at the level of the leaflet hinge points, the outer skirt will remain under the annulus, despite the foreshortening of the lower inflow portion of the valve."

Do you see that?

A. That's what it says, yes.

Q. And so we see in the abstract of this paper, at

least, it is stressed that the skirt is positioned below or underneath the anulus in the SAPIEN 3.

Is that fair to say?

A. I can't say more what it says (sic). It says what it says, but I haven't been allowed to read the whole paper.

Q. Well, that's -- that's fair. I'm just asking if you believe I'm correctly characterizing the abstract of the paper.

A. I would rather just say to what it says. I mean, it says what it says. There's no point in characterizing it further, particularity because I haven't had a chance to study the whole document and see if there's further or important explanation of what they're talking about in the main text, because this is just from the summary.

Q. We can see from the summary, however, that the authors think it's important to place -- position the outer skirt underneath the annulus and for the outer skirt to remain under the annulus; is that fair to say?

MR. SUMMERS: Object to the form of the question.

THE WITNESS: If they say what they say, then I can't say more than that. What they say is what they say. This not prior art. I have not taken it into

account and I've not had a chance to read or study the document.

BY MR. LOWENSTEIN:

Q. Did you talk to your attorney between yesterday's deposition and today about the deposition?

A. No.

Q. Because you seem to be taking an awfully different approach from yesterday and so I'm just curious, what did you talk -- what did you do after the deposition?

Did you talk to Mr. Summers?

A. No. I didn't. I just told you I had not talked to any attorney between yesterday and the deposition and this morning.

Q. So you walked out of the room, you didn't speak to Mr. Summers at all, you just left the room?

A. Other than to say I'm going to go back to the hotel, I didn't say anything. We're at different hotels. I didn't talk to him. I didn't meet with him.

I didn't have any conversation with him regarding the substance of the deposition.

Q. Did you exchange any communications?

A. I said good-bye.

Q. Did you exchange any written communications?

A. No. Nothing.

Q. Did you exchange any written communications with any other attorneys?

A. No. Of course not.

Q. Okay. So we see -- okay. Then if we go -- we skip a sentence and then we skip the first phrase up to the comma and the next sentence, you'll see it says, quote, "PVL is common with the SAPIEN XT THV but dramatically reduced with the SAPIEN 3 THV."

Do you see that?

A. Yes.

Q. That's a fair statement, isn't it?

A. It's their statement. It's what they're writing. I take it that they're telling the truth in their experience.

Q. You don't know whether "PVL is common with the SAPIEN XT THV but dramatically reduced with the SAPIEN 3 THV"?

A. No. It was, but this is talking about a particular paper. Again, I haven't read the paper and they may be summarizing here what they found. This may be data that they present later on.

What it says, I have no reason to dispute at all, but I haven't had a chance to study the paper, nor have I taken particular notice of it because it's not prior art.

Q. I'm just asking you about that statement. We can forget whether it's in the paper or not. I'm just asking, I think you agree to this, but let's just make sure we're on the same page.

Do you agree that it's a fair statement to say, "PVL is common with the SAPIEN XT THV but dramatically reduced with the SAPIEN 3 THV"?

That's a fair statement, isn't it?

A. I believe it is.

Q. Thank you.

Okay. Let's go to the second page. We're going to go sort of like a third -- starting with the sentence "However?"

Could you highlight that, please.

And you see the authors state, quote, "However, the most important changes are related to the SAPIEN 3 frame and the new 'outer skirt.'"

"Outer skirt" being in quotations.

Do you see that?

A. Yeah, I see it.

Q. Is it a fair statement to say that "the most important changes between the SAPIEN XT and the SAPIEN 3 are related to the frame and the new outer skirt"?

A. Yes. I think that's not an unfair thing for them to say. It's not saying they're the only changes,

because clearly they aren't the only changes. But it's -- it doesn't appear to me to be unfair. But, again, I would like to have had a chance to read the whole paper.

Q. I'm really going to ask you specific statements and whether you think they're reasonable in isolation or not.

A. Okay.

Q. If you don't know the answer, you can tell me you don't know. But I think you will know the answer to a lot of these questions.

A. Okay. And I'm talking about today. I'm not giving the answers for the priority date of 2012. This is not a pre-priority date publication and therefore I'm talking about now.

Q. Okay. You've said this many times, I'm aware.

Okay. And then this, I think, captures a concept that we've discussed.

Okay. And I'm going to read from starting with "while" through the end of this column to the beginning of the next column. Let's just start with here.

And I'll just quote what it says. Quote, "While the foreshortening of the SAPIEN XT valve is homogeneous, it is more pronounced in the lower 2/3 than in the upper 1/3 of the SAPIEN 3 frame (Figure 1),"

closed quote.

Let's stop there.

Do you agree that the foreshortening the SAPIEN XT valve is homogenous?

A. I'm not exactly sure what they mean by this, and I haven't studied this. It's what they say, but I'm not quite sure what they mean by it.

Q. I think -- well, I think what they're trying to say, and you can tell me if it's unreasonable, is they're contrasting the -- how the frame crimps in SAPIEN 3 versus how the frame crimps in SAPIEN XT.

And I believe what they're saying is that while the SAPIEN XT crimps in a homogeneous fashion, by contrast, and SAPIEN 3, it is more pronounced in the lower 2/3 than in the upper 1/3 of the SAPIEN 3 frame.

Do you think that's a reasonable interpretation of the sentence?

A. Yes. That may be -- that may well be what they are saying.

Q. Okay.

A. And, again, you know, I don't want to keep saying the same caveat and using up your time, but I haven't read the paper and it helps to read it to have an insight into what it's all about and what they are saying.

Q. Let's keep going on. I remember you have a flight.

A. Thank you.

Q. Time is everyone's time. Particularly my time.

And let's -- let's continue on. So it says, "In contrast" -- quote, "In contrast to the SAPIEN XT, where foreshortening is similar for all sizes, the SAPIEN 3 foreshortening varies between" --

(Off record discussion.)

BY MR. LOWENSTEIN:

Q. Okay. Looks like there's a lag. Fair enough. So give us -- give it some time.

Do you have the document -- okay. There we go.

Okay. I'm sure we've all lost the sentence by now, so I'm just going to reread it.

A. I can't -- I can't see the top of the next column. You've read the part of the sentence --

Q. Just so we're clear, there's a time lag on his computer. So the movements he made a minute ago are just now manifesting themself and they're completely beyond his control.

A. Just so you know, they haven't happened at my end at all. I'm still looking at the highlighted bottom of the left-hand paragraph.

Q. Really? Because right now what I see on the

share is the top of the next column.

A. No. It's like my screen is frozen. I'm seeing in blue highlighted the last five and a bit lines of the bottom of the paragraph. I can't even see the -- I can't read it or see the top of the next paragraph, the top of the next column.

Q. Your screen is still frozen?

A. The highlighting's come off it, but it's still the same page. I can't see the top of the next column. It's now highlighted "In contrast to the SAPIEN XT," but I can't see where the sentence goes.

Q. All right. I'm going to try to read it very slowly starting from the beginning of the sentence and I'll read extra slowly for the end of the sentence and hopefully by the time I finish, you'll have it.

So I'm going to start from the portion we've already heard, or we've already seen, and I'll make a note when I'm flipping to the next -- the end of the sentence. It's going to be relatively short on the next line.

So let me start reading, quote, "In contrast to the SAPIEN XT, where foreshortening is similar for all sizes, the SAPIEN 3 foreshortening varies between" -- now, I'm on the next column -- "6.5 millimeters in the 23-millimeter size and 8.5 millimeters in the

29-millimeter size."

I suppose you haven't seen that. But did you get that?

A. I can see. It's now flicked to the top of the 6.5 onward is highlighted now. But I can't see the bottom of the other ones. I've seen it in parts, but that's fine.

I heard what you said and I listened carefully.

Q. Does that sound reasonable to you? Do you take any issue with those statements?

A. I just don't know. I mean, I haven't studied any of this for this deposition because it's outside the time zone that I was looking at, so I am left with dimensions for the commercial SAPIEN 3 for this deposition.

Q. Fair enough.

Okay. Can we go to -- we're now on page 5.

Should we get this document we've been talking about an exhibit number that we can mark later?

Do you know what the next exhibit is?

MR. HSIEH: I believe it is -- give me one second. I will find it.

BY MR. LOWENSTEIN:

Q. Okay. Are you able to see Figure 4?

A. No. I'm still on the highlighted top of the

right-hand column "6.5 millimeter." There's no figure visible at all.

MR. LOWENSTEIN: Madam Court Reporter, if we could just stop typing for a second and go off the record for just a second.

(Off-record discussion.)

MR. LOWENSTEIN: Okay. For the record -- let's go back on the record.

The document we've been talking about, the one titled, quote, "How to Adapt the Implantation Technique for the New SAPIEN 3 Transcatheter Heart Valve Design." That, we believe, is Exhibit 2050.

(Deposition Exhibit 2050 was marked for identification by the court reporter.)

BY MR. LOWENSTEIN:

Q. Dr. Buller, I don't suppose you're able to see Figure 4 of Schymik yet?

A. It hasn't moved at all. I've got exactly the same as what I last said.

Q. Are you able to -- perhaps Mr. Summers might be able to help you if you're not -- are you able to download --

A. It's just gone to Figure 2. Now, it's just flipped to Figure 3. Now, it's going to Figure 4, but it's just gone too far because Figure 4 -- it's coming

down. Yes. Somebody is moving it down.

I can see now Figure 4. There are three separate -- there are two radiographic images and one that looks like an artist graphic.

MR. LOWENSTEIN: Mr. Summers, I think it's time to move away from the dialup modem I think.

I'm just kidding.

Q. So you can see Figure 4 now?

A. Yes.

Q. And Figure 4, again, which is Schymik, is going to be Exhibit 2050.

Okay. So if you see the -- does that appear to be an image of the SAPIEN 3 -- I'm not sure what you called this. You called this a cartoon or a -- what's the phrase you would use to characterize this type of image?

A. It's a -- it's a graphic of some sort. It's a clearly highly artistic graphic, but it's a -- it's a drawn graphic.

Q. Okay. And can you in Figure 4B of Schymik, Exhibit 2050, do we see an implanted SAPIEN 3?

A. That's what it is, we see the two radiographic images that look like one in the process of being implanted on the left and then on the far right expanded, these are X ray images and in the middle there

is an artist graphic of a sort of cut-open aorta and the side-view of an implanted -- what I take to be a SAPIEN 3.

Q. Are you able to see that the outer skirt in the SAPIEN 3 in Figure 4B lies below the annulus?

A. Part of it does. Part of it doesn't.

Q. What would you call the part of the skirt that is at the very bottom of the leaflet?

A. I'm not sure what you mean by "at the very bottom of the leaflet." There's the --

Q. Let me ask a better question, just so it's clearer. I think I can, perhaps, get past the confusion.

You'll see there's the portions of the skirt that are stitched -- but we can't see it, but I think we know it's stitched -- to the top of the first row of cells.

Do you see that?

A. Yeah.

Q. And you see how they're -- I don't know what you would call them, whatever, the things that are attaching, the things that are being stitched, what would you call that portion of the skirt?

A. The -- the -- the upper part of the skirt. "Upper" being the most distal part of the skirt, using the same proximal distal the way we were using

yesterday, if -- if not today. So those parts clearly seem to be at the level of the actual bowel leaflets.

Q. You see that Schymik says with respect to Figure 4B that the, quote, "Outer skirt" -- he says, quote, "Outer skirt located in LVOT."

Do you see that?

A. Yes.

Q. Do you know what the acronym "LVOT" refers to?

A. Yes. It refers to left ventricular outflow tract.

Q. Do you believe that the LVOT is below the annulus?

A. Yes. Because the annulus isn't just sort of a straight structure, it goes up and down, the LVOT also is not a -- not a straight structure across, it has a sort of a wavy outline.

Does that help?

Q. I just want to make sure. The LVOT is below the annulus and, according to Schymik at least, Schymik says at the outer skirt is located in the LVOT.

Is that fair to say?

A. It says what it says, but it doesn't label on the figure I'm looking at, it's not labeled in the actual drawing.

The graphic is not drawing, so I'm not sure

whether they're just referring to part of the -- the outer skirt because part of the outer skirt is clearly overlapped with leaflets, part of the outer skirt is below the leaflets in this -- in this -- in this artistic graphic.

Q. Can you -- okay. So let's look at the leaflet. And so -- and so what happened is the valve has expanded and we can imagine there's maybe some aortic stenosis and so the, perhaps, diseased leaflets have been pushed to the side and pressed against the arterial wall; is that fair to say?

A. Yes. I think that's what they're trying to illustrate in this -- in this graphic.

Q. And is it fair to say that the majority of the leaflets are not touching any portion of the outer skirt?

A. Well, I clearly see the two sides. I mean obviously this is just a cross-section, it's sort of cut through and the two sides appear to be overlapping the skirt by about a third, I would say.

Q. Now, if you go -- if you look at where the annulus is, do you see that the -- when you go below the leaflet to where the annulus is, do you see that the skirt for the SAPIEN 3 expands outward?

A. In the graphic?

Q. Yes.

A. Yes. It does -- it appears to so on the right-hand side, but it doesn't appear to as much on the left-hand side.

Do you follow?

Q. It seems like it does on both ends to me.

A. Does it? Okay.

Q. It's your testimony. So -- and is it your understanding that the way the outer skirt is meant to function in the SAPIEN 3 is that it billows out when implanted, so as to provide a seal with the annulus so that -- to prevent paravalvular leakage; is that your understanding?

A. I mean, some of it is squashed and obviously it can't billow out where it comes in. But what it is capable of doing is where there would otherwise be gaps. If not for the skirt, it's then in those areas which may be, you know, limited around the circumference, it's able to billow out and fill the gap.

So some places it will be very squashed and be pushed against the frame by the disease that's there, the native tissue that's there. In other places, it will be able to billow out to fill gaps.

So it will be different as you go around the circumference.

Q. Now, we see a portion that -- of the outer skirt that is overlapping with a leaflet.

When you see that that is the point of connection with -- between the -- the point of attachment, I think is probably more precise -- between the outer skirt and the outer frame; is that fair to say?

A. Well, it includes -- it's more than that. But this is a graphic. This isn't actual real valve or tissue or patient, but what it appears to be depicting is that some of the skirt at a third is lying under the leaflets in this image and about half to 2/3 is below the leaflets.

Q. Well, I wasn't real precise about what portion of the skirt. So let's talk about that.

What we see is the portion of the skirt where the -- sort of the most distal end of -- of the skirt is sutured to the struts of the frame; is that correct?

A. Yes. It's wrapped around the struts and sutures. There's a little sort of tuck over the top of the strut and it's sutured at those areas, I believe.

Q. And I think we can agree -- and you'll have to excuse my imprecision, I'm sure there's a better way to phrase it -- but we can see that the portion of the outer skirt that is overlapping, at least to some degree with a leaflet, we can see that that's not a straight

line, correct?

A. Now I'm really lost now.

Q. Let me put it this way.

The portion of the outer skirt that seems to overlap, roughly speaking, with the native leaflet, what you're saying for lack of a better word is a series of hills.

Is that fair to say?

A. Okay. I think I understand what you're saying now.

The top of the skirt in SAPIEN 3 is -- is undulating. It's going up and down.

Yeah?

Q. Yeah, okay. I don't know if that's -- I'm going to refer to it as hills and valleys because --

A. Okay. I get it.

Q. -- that's more precise to my primitive brain.

A. All of the hills and valleys section appear to be overlapping the leaflet in the two little bits we can see, with the leaflet to either side. Of course we don't know what's going on with the cutout there that's been removed or behind.

Q. And we can see that the depth of the valley or the depth from the valley seem to be right in alignment with the lowest portion of the annulus; is that fair to

say?

A. Now I'm lost. Sorry. What is in -- what is -- the --

Q. Maybe you can help me with -- can we zoom in on Figure 4B yet as much as you can.

A. That's much better actually, because I was looking at a tiny little image.

Thank you.

Q. Sure. Okay.

A. The bigger you can go the better. Because I'm looking at it on a 13-inch screen and therefore the image I was looking at was tiny. That is a lot better.

Q. Okay. So do you see now what I'm referring to by hills and valleys?

A. I can see the hills and valleys. I can see it much better now that you've made it up for me. I can see what you're referring to as the hills and valleys, which is the top shape of the SAPIEN 3 outer skirt.

Q. Okay. Now, I want you to look at the annulus iteration to the lowest parts of the three valleys that we see.

Are you with me?

A. Yeah. But I don't know what you mean by "annulus." And I should say we haven't gone to any of my reports. But I have a correction in my report about

annulus. I can give you that now if that helps. But if we're using the word "annulus," I probably ought to correct my report.

Q. What is your correction?

A. My correction only affects the -- for this correction, it only affects the '538 -- no. I beg your pardon.

It's in three of my reports, the latter three reports. They're not in the '172. And it's about the position of the annulus.

If you could pull up my report 011, it's in paragraph 50 of the 011 report.

Q. Okay. 50 goes for several pages. Which page?

A. Oh, I've got to change the wording.

If you look at Figure 2, which I reproduced Figure 2 from AI patents and I've put in yellow the numerals 210. Under the stage I write these reports, I thought the lead line from 210 went to the bottom of the valve but in fact it goes to the center of the valve. It loops around and comes to the center of the valve.

I don't know if you could see that on the -- on the image in the patent that I've reproduced, but you can certainly see it easily on the patent.

So the corrections I want to make are in the first sentence of paragraph 50. I've got to change

"point to area and left ventricle" to "aorta."

Over the page on page 16 --

Q. I may be -- why don't we put it up on the screen.

So are we looking at the sentence that you're referring to?

A. Yes. This is paragraph 50, so it's the bottom of page 15. We've got to change "point to area," so this is on the second line of paragraph 50, change "point to area" and change "left ventricle to aorta" at the end of the sentence.

And then over a page, on the paragraph below Figure 2, the last sentence on that page, it says, "The '011 Patent identifies the green line as the annulus," and we've got to change that to, "The '011 Patent identifies the middle of the red crown as the annulus."

Q. You're referring to the next page?

A. Yes. The paragraph is referring to the next page where the crown is shown. The crown-like ring. And then the last change to complete this is just under these figures. So if you go down to the first couple of lines of text under these figures, I've got to change on the second line, it says "Is the point where the leaflets begin," we need to delete "point where the leaflets begin," and insert "middle of the red crown."

Q. So where is -- let's go back to the image we were

looking at before in the other document.

MR. HSIEH: Okay.

BY MR. LOWENSTEIN:

Q. And I want you to point me where you think the annulus is.

A. This is where your patents teach where the annulus is. What I'm correcting is that I've misinterpreted a patent figure in AI's patents.

Q. Okay. So I'm going to ask you two different questions.

A. Yes.

Q. The first one I'm going to ask you about your -- your understanding of the word "annulus outside of AI's patents."

A. Yes.

Q. And I'm going to ask you about your understanding of "annulus inside AI's patents."

Is that clear to you?

A. Yes.

Q. Okay. So can you explain to us -- we're going back to Exhibit 2050 and we're looking at a blowup of Figure 4B.

Do you agree with me in that, Dr. Buller?

A. I'm with you there. This isn't the best diagram to show where the annulus is. The much better one is

the prior up publication that I illustrate and reference in my report because it's -- it is specifically about the annulus and where it is and has the appropriate diagrams. That's reproduced in my declarations.

Q. Be that as it may, I'm sure you'll be very comfortable showing the image I've just produced, which seems very noninterventional cardiologist (sic), seems a bit clearer. So in the image that we're looking at right now, the graph --

A. Yes.

Q. -- where is the annulus as you would typically understand it?

A. The red crown runs from the bottom of the leaflet, so the line drawn really across -- someone's got a cursor on the sketch -- the bottom from there, that sort of level, and then it goes up and down as a semilunar structure, the red crown, up to the level where the commissures are of the native valve, but you can't see one in this -- in this graphic, you can't see. So there's presumably one hidden somewhere behind the implanted SAPIEN 3.

But it -- it goes up and down, exactly as is shown in my report on the red crown in the Piazza reference, which is prior art.

Q. I'm sorry. I'm a little -- I'm a little lost.

Are you saying that the aortic -- I'm sorry, the annulus, as you would typically understand it, is it essentially a line that goes around the bottom of the most proximal end of the leaflets?

A. It starts at the bottom of the leaflets. But then it goes up and down. As Piazza says, most surgeons at that time would have regarded the red crown as the annulus.

So it starts at the bottom of the leaflets and then it zigzags up and down in this -- as he calls it crown-like ring.

Q. Does Levi's skirt -- do the hills and valleys that we see, would that seem to track the iron-like ring of the annulus according to your typical understanding?

A. No. It doesn't track. There are many more on Levi's preferred embodiments. There are more. There are only the three -- the crown-like ring is a three-pronged crown.

Q. Just so we're clear, the hills and valleys that we see in -- in this image from -- I said Levi, I meant to say Figure 4B, it has nothing to do with what you typically understand the annulus to be; correct?

A. Correct. They're completely separate, because there are many more of them. There are more hills and valleys going round than the three leaflets of the

valve.

They're not meant to match up or have anything to do with the -- the -- the number of undulations that there are in the aortic annulus.

Q. Okay. Now, show me in Figure 4B where you believe the annulus is in the context of AI's patents.

A. Somewhere on this, it will be somewhere around the middle of the leaflet. If you look at any of the figures on AI's patents. And I apologize that I got it wrong. But if you look at any of AI's paths (sic) that show the anatomy -- and it's the same figures in all of them -- they point roughly to the middle of the leaflets.

Q. Okay. So if we use that understanding of annulus, is it fair to say that the outer skirt from the SAPIEN 3 that we see in Figure 4B of Exhibit 2050, according to the definition that AI apparently gives to annulus, at least according to your understanding, would the outer skirt lie beneath the annulus using that definition?

A. No. No. Because the annulus isn't a sort of point. It's going up and down as I've said. That's why I've referenced --

That's exactly why I've put in the Piazza reference in my declarations, all of them, that require

this annulus definition, so you can see -- but it's a more complicated structure.

I think everyone's agreed where it starts at the bottom of the leaflets, and my understanding is -- is all are agreed that it starts at that level. It just extends up further and that explains why AI put the arrow to the middle of the -- the valve in most of their figures -- in all of their figures of the anatomy.

Q. So essentially what you're saying is that the -- the native leaflets made -- the three of them, they have -- I'm not sure whether they call it length or a width given what we're talking about, but they have some size to them and you believe that AI identifies essentially the midpoint of each leaflet as the annulus?

A. You -- you can see --

Q. Is that -- is that fair?

A. All of their reference numbers point just to the center of the valve, valve leaflets. And I -- I misinterpreted the figures because I didn't see the line went through the drawing. I thought it went to the bottom of the drawing and not through the drawing.

Q. Okay.

A. And just to be clear on this --

Q. Can I try to crystalize what I think the difference is between the two definitions?

A. Yeah.

Can I just say one last thing because I'm sure it's important for you?

But I made exactly the same equivalent changes in the '846 Patent and the '538 Patent because the paragraph was just copied across -- the paragraphs are just copied across, same diagram, same images. So the changes that I have read in for the first patent, the '011 are the equivalent changes I am making in the '846 Patent and the '538 Patent.

Q. Let me restate that. So you're saying you have an identical paragraph to paragraph 50 from your declaration in the -- 154?

MR. HSIEH: It is the 538735 --

MR. LOWENSTEIN: No. No. What patent -- what is this number we're looking at?

MR. HSIEH: This one that we're looking at is the '011 Patent.

MR. LOWENSTEIN: Okay. So let me just --

THE WITNESS: I have read -- I have read the changes in from the '011.

BY MR. LOWENSTEIN:

Q. Declaration -- let me state it clearly. You're making equivalent changes to the otherwise identical paragraph in the other two proceedings that you

identified; is that correct?

A. Yes. So the '846 and '538, and they are the identical paragraph other than the change in the patent number. Obviously the patent number is different for -- for each of the reports --

Q. Okay.

A. -- in the -- in the paragraph.

Q. And the critical distinction between the two understandings -- I want to make sure I'm understanding you correctly.

In the -- your general prior understanding of annulus, you believe the annulus follows the bottom of the leaflets as they sort of rise across -- for lack of a better term -- while in the AI patents you believe the annulus is more like the middle point of the leaflets, a line drawn around the middle points?

A. Yes. It's the center of -- center of red crown-like ring as shown in Piazza. I think that is fair. And I think that I've looked at the patents more carefully because I got a new iPad so I could sort of mag up images, and I suddenly saw that the lead line doesn't go to where I thought it went to. It just goes to the center of the valve. And it's in about a half a dozen images in the patent.

Some are much easier to see than others.

Q. Okay.

A. And if I may, on that subject of correction, I've got one other correction to make to just one of my reports, which is a much simpler one, because it only affects the '538 Patent.

Q. Okay.

A. It's in my declaration concerning the '538 Patent. It's in paragraph 80.

Q. Bring that up.

A. Eight-zero.

Q. Just give us a second.

A. Sure.

Q. I think for the court reporter's benefit, we should wait until we get the --

A. Yes. Sure.

Q. Is it this --

A. This patent '538 is on page 41, paragraph 80.

Q. Okay.

A. Paragraph 80, I just need to delete on the second line "through a patient's common femoral artery."

So it will read "The '538 specification discloses that the valve assembly may be implanted by first passing a stiff wire through the aortic valve."

Q. You have -- the sentence continues on "and into the left ventricle." You're not going to delete that,

are you?

A. No. No. The only thing that I'm deleting is "through a patient's common femoral artery," it's just those six words.

Q. I see. So you're just basically conforming it to the description of the passage that you quoted; is that fair to say?

A. Yes. And also, as we talked about yesterday, it is my belief that the -- the dual-frame embodiment could not be delivered either percutaneously or through the femoral artery and so it was wrong of me to put this in, because the embodiment we're focusing on is the dual frame -- in and out of frame embodiment and they've got dimensions associated which would make it impossible to percutaneously deliver the valve.

Q. You agree that you did not offer that opinion in your expert report -- I'm sorry, your declaration?

A. Correct. What I'm change -- I'm changing it now --

Q. I just want to be clear. I'm going to -- I'm going to object to preserve our rights as to making any changes to the declaration. And I'm going to -- I wouldn't ordinarily at least -- so as to preserve our rights move to strike any changes in the expert declarations.

So I think we've been going for some time. Why don't we take a break and then reconvene shortly.

Does that work?

THE WITNESS: Should we take like -- it's now like 2 o'clock in the afternoon in Washington. It's later than we took lunch yesterday.

Is this a convenient time to take that longer break or slightly longer break than 10 minutes?

MR. LOWENSTEIN: Sure. That's fine. So how long -- do you want to take an hour?

THE WITNESS: I'm happy with less. But it's entirely up to you. Yesterday you said -- when I said a half an hour.

MR. LOWENSTEIN: Let's do this. Can you give me just five or 10 minutes to -- let's take a short break and I'll confirm within five or 10 minutes whether we should take a lunch break or not.

Does that make sense?

THE WITNESS: That's fine.

MR. LOWENSTEIN: Okay.

THE WITNESS: It's fine with me if it's fine with everybody else.

MR. LOWENSTEIN: Great. So I'll be back on in, let's say, five or 10 minutes?

THE WITNESS: Okay. See you in 10.

(Off record from 11:01 till 11:06.)
THE REPORTER: So I think we can take a lunch break. An hour?
MR. SUMMERS: I think Dr. Buller wants 30 minutes.
MR. LOWENSTEIN: That's fine. I'll see you at 11:35.
(Lunch recess from 11:07 till 11:42.)
MR. SUMMERS: We're ready.
MR. LOWENSTEIN: Let's go back on the record.

Q. Dr. Buller, I read in a deposition you gave back in 2017 that you had received approximately 500,000 British Pounds from Edwards for your services as an expert witness as of the date of that deposition.

Does that seem correct to you?

A. If I said so, then it would have been correct, yes. I can't remember which -- do you remember which deposition it was?

Q. I believe it was a Boston Scientific --

A. Yes. Yes. That sounds about right.

Q. Okay. Do you have an estimate of the amount of money you've received from Edwards for your services as an expert since that time?

A. No, I don't. I would guess that I have billed in

total for this case something like a couple of hundred hours I would guess. Talking about this -- the four IPRs, the more -- for this deposition and the other two.

So that would be on top of whatever I said in -- in 2017.

Q. Did you -- what is your hourly rate?

A. 480 Pounds Sterling charged in British Pounds.

Q. And did you serve as an expert or did you work with Edwards as an expert during 2018?

A. I -- I can't remember doing anything with them and I certainly haven't been to the States in the last three years at all. I -- I think I've done relatively little or -- or only this work since that deposition.

I think that would have been the last case, the Boston Scientific case.

Q. Are you saying that this is the first deposition you've taken or you've -- where you've been deposed as an expert for Edwards since 2017?

A. I'm honestly not sure as I sit here.

Do you know what case -- what -- okay. I haven't --

Q. I can tell you in a moment.

A. That would help.

Q. It was an IPR in Boston Scientific.

A. Okay. There was a -- there was an IPR, but that

came along -- simultaneously with that, there was a court case. But I've got no recollection as to which happened before the other, because they happened so simultaneously.

Q. I believe it was IPR 2017-00060. And the deposition is dated June 15th, 2017, I believe.

So let me ask you again. Dr. Buller, do you believe you've been deposed as an expert for Edwards since your deposition that I just alluded to you in June 2017?

A. It may have been, because there was a court case, a district court case, I mean, separate from -- along the subject matter. There was IPRs in a district court case and that wasn't stayed. So it happened around the same time.

I mean, the IPR result didn't come about until way after the court case actually had been done and dusted. So they happened around the same time and I can't remember which came first.

So there could be a deposition related to the U.S. court case related to the same subject matter, Boston Scientific, the same patents.

Q. Since that IPR and the associated district court case, did you -- new question.

Did you testify in the district court case that

you just alluded to?

A. I did. In Delaware. It was in Delaware. But I can't remember the date.

Q. Was it a trial, or is it some other sort of proceeding?

A. It was a trial in -- in -- in court in Delaware.

Q. All right. Okay. So let's go back to Walther. I'm sure we all have in mind Walther's outer cloth by now, but can you agree with me that you can clearly see the outer surface of the outer cloth; is that fair to say?

A. In the photograph in Walther?

Yes.

Q. Okay. You cannot see the inner surface -- inner surface of Walther's outer cloth; correct?

A. You cannot see the inner surface -- well, there was a photograph -- because I remember Walther. It might be good to put up. There's a side-view image and there's an on-top image and you may well be able to see a little bit of it on the -- down the barrel image so-to-speak from on top.

Do you remember, you showed me three images. You put them up where there were three from memory. One showing from below, one showing from on top and one showing the side?

Q. So which image are you referring to?

A. Yes. So these -- these images, you can see a little of the inside of the skirt, perhaps, from the view on top. So the one -- the lower one of Figure 1.

Q. Okay. Let's look at a blowup of the lower one of Figure 1.

A. Yes. Do you see how you may be seeing some bulge through? And I think actually for one of your claims I've talked about the fibers that are protruding inwards.

Are you with me?

Q. Well, let me ask a better question.

A. Sure.

Q. You can -- is it fair to say that we can agree that the SAPIEN valve has an inner graft covering; is that fair to say?

A. The SAPIEN valve has fabric on the inside of the frame, which, using your position, becomes the inner frame. It's a graft covering which becomes an inner frame because you said an inner frame can be a graft covering.

Q. And you agree that you may be able to see that inner graft covering from this angle; correct?

A. You may. You're looking down on it. So you're saying, yes, it's quite difficult to work out what

you're seeing looking down on the valve, but you may be able to see a little bit of it. You'd expect to see the top of it in places.

Q. Now, if we look at the outer portion of the outer cloth of Walther --

Are you with me?

A. Yes. Looking at the Walther's cloth wrapped around the outside of the stent.

Q. Can we agree that the outer surface of the outer cloth is hairier or the fibers seem to extend further in an outward direction than we see on the inside of the frame?

A. No. It all looks the same to me. I mean, it all looks very -- very fibrous and furry, the whole thickness. I mean, there are fibers that are poking out so you can see individual fibers, but the whole thing looks like a -- a -- a hairy, fury structure.

Q. So I just want to make sure I understand. You believe fibers on the exterior of the outer frame of Walther look the same to you as the fibers that you see on the inside of the outer frame in the second -- the bottom figure -- picture in Figure 1, Walther; is that fair to say?

A. All fibers protruding inwards into the frame I can see, particularly if you look at sort of 3 o'clock

on the inside, sort of inside the crown, you can see what I take to be little fibers.

They look like --

Q. That wasn't quite my question. So let me ask it again.

A. All right.

Q. The -- let me ask it slightly differently.

Do you believe that the outer cloth that we see on the exterior -- exterior of Walther's outer frame looks the same to you as the material that you see on the interior of Walther's frame as depicted in the top down view in Walther's Figure 1; is that correct?

A. No. You could see all fibers coming in, but you can't see -- most of the cloth is on the exterior. The cloth is put on the exterior.

All that is happening, I think, is some fibers are poking through the -- the cellular structure, and so they're poking to the inside in places.

Q. If the cloth is the same on both sides, wouldn't it look the same?

Why wouldn't the interior portion of the outer cloth look like the exterior portion relative to the frame?

A. Well, potentially for lots of reasons. The lighting is different. It's kind of in the shade

because the valve -- the highest part on this device is the valve and therefore what you're seeing on the inside is in the shadow of the valve leaflet. So there are lots of reasons why it might look different even if it wasn't different.

Q. Can we agree that -- okay. Do you believe -- we're looking at the top down on Walther's Figure 1.

A. Yes.

Q. And I may have answered you this question, so I apologize.

Do you believe you can see a SAPIEN inner graft covering in this picture?

A. You may be able to see a bit of the top of it. You're looking at it sort of end on, so-to-speak, inside the frame. But where someone is moving a cursor around the top, that may be a little bit of the inner fabric. It's very difficult to tell, because you're looking top down and it's a photograph, you're looking down into the -- into the shadow, inside the -- the valve leaflets or outside the valve leaflets.

Q. How high up does the mirror graft covering in the SAPIEN -- how tall -- what is -- what are the relative heights of the outer cloth in Walther versus the inner graft covering?

A. The outer one is coming higher. I think you can

see on the -- if you look at the upper picture of Figure 1, you can see that -- you can only see -- you can't see any inner cloth looking at it, and that's looking fairly straight side on.

So you -- you can't see any inner cloth. So the outer cloth is coming at least as high or higher than the inner cloth. Otherwise, you would be able to see some.

Q. I'd like to ask you now about Spenser 2, Figure 22.

A. Yes.

Q. I think this is a simple question. I think you could probably answer it.

A. Try.

Q. But is it fair to say that you can only see the outer surface of the compressible material sleeve in Spenser 2, Figure 22?

A. You can see mainly the outer surface. You can also possibly see the top edge. There are two concentric circles. But you can see the top edge, which I take to be representing the range sort of 1 to 5 millimeters as taught in the specification.

So -- but you can see that it has a fitness in this unsquashed, uncompressed state as shown by the concentric curves.

Q. Yes. That's a completely fair clarification I should say.

Is it fair to say that you cannot see an inner graft covering in Spenser 2, Figure 22?

A. I don't see anything illustrated as an inner graft covering. But then you probably wouldn't see it because if it were there, it's likely covered by the outer cloth.

So if it was there, you wouldn't see it.

Q. Okay. Hold on a second. Let me confer. I think you may have answered this yesterday, but I just can't remember.

Have you ever seen a Walther valve in person, meaning a SAPIEN with an outer cloth that we see in Walther?

A. A Walther valve, I've never seen the one -- if it still exists -- I've not seen the one that they used or that they experimented on. No, I've not seen that.

Q. And have you ever seen in person any -- any SAPIEN valve with an outer covering?

A. Yes. Well, SAPIEN 3 -- I mean, not before the priority date, no, but I've seen it handle SAPIEN 3, I've seen it handle SAPIEN 3 ultra. I've seen it handle some other -- not Edwards valve, but other valves with outer coverings from other manufacturers. But none of

this was before the priority date.

Q. Have you spoken to anyone at Edwards about the type of SAPIEN valve with an outer cloth as we see in Walther or Cheung?

A. Not as far as this case. In fact, I don't believe I've spoken to anyone at Edwards since I was hired through Knobbe, Martens.

In this time period, I haven't spoken to anyone within Edwards or written or communicated with anyone at Edwards over this case.

Q. Okay. Give me one minute.

(Off record.)

MR. LOWENSTEIN: All right. Dr. Buller, thank you for your time both today and yesterday.

I wish you a safe journey back. I have no further questions for you at this time, unless there's redirect in which, of course, I'll have recross.

But thank you.

THE WITNESS: Thank you very much.

MR. SUMMERS: I have no questions.

MR. LOWENSTEIN: All right. Thank you, Craig, Madam Court Reporter, everyone else for your patience and diligence and so forth. Have a good day.

THE REPORTER: Hold on a second.

MR. LOWENSTEIN: Before we get off, Madam

Court Reporter, let's clear up anything --

THE REPORTER: But we're going by Code.

MR. LOWENSTEIN: I'm sorry?

THE REPORTER: We're going by Code.

Let me just ask Mr. Summers. Are you getting a copy of the deposition, Mr. Summers?

MR. SUMMERS: Yes, we are.

THE REPORTER: Is 2050 an exhibit?

MR. LOWENSTEIN: We are planning to file those in our forthcoming --

(Off record at 12:15 p.m.)

REPORTER'S CERTIFICATION

I, MARCELINE F. NOBLE, a Certified Shorthand Reporter in and for the State of California, do hereby certify:

That the foregoing witness was by me duly sworn; that the deposition was then taken before me at the time and place herein set forth; that the testimony and proceedings were reported stenographically by me and later transcribed into typewriting under my direction; that the foregoing is a true record of the testimony and proceedings taken at that time.

IN WITNESS WHEREOF, I have subscribed my name this 21st day of June, 2022.

Marceline F. Noble

MARCELINE F. NOBLE, CSR No. 3024

DEPOSITION ERRATA SHEET

Our Assignment No. 832613

Case Caption: Edwards Lifesciences Corporation vs. Aortic Innovations, LLC

DECLARATION UNDER PENALTY OF PERJURY

I declare under penalty of perjury that I have read the entire transcript of my Deposition taken in the above captioned matter or the same has been read to me, and the same is true and accurate, save and except for changes and/or corrections, if any, as indicated by me on the DEPOSITION ERRATA SHEET hereof, with the understanding that I offer these changes as if still under oath.

Signed on the _____ day of _____, 20____ ,

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