UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION AND EDWARDS LIFESCIENCES LLC,	)	
	)	CASE
PETITIONERS,	)	IPR2022-00556
	)	
v.	)	PATENT
	)	10,987,236
AORTIC INNOVATIONS LLC,	)	
	)	
PATENT OWNER.	)	

VIDEOTAPED DEPOSITION OF NIGEL P. BULLER, MD
TAKEN REMOTELY VIA ZOOM VIDEOCONFERENCE
FRIDAY, NOVEMBER 11, 2022

REPORTED BY AUDRA E. CRAMER, CSR NO. 9901
JOB NO. 896045

MAGNA LEGAL SERVICES

Edwards v. Aortic Innovations
U.S. Patent 11,497,634
Edwards Ex. 1128

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EDWARDS LIFESCIENCES CORPORATION AND EDWARDS LIFESCIENCES LLC,	)	
PETITIONERS,	)	CASE IPR2022-00556
v.	)	PATENT 10,987,236
AORTIC INNOVATIONS LLC, PATENT OWNER.	)	

VIDEOTAPED DEPOSITION OF NIGEL P. BULLER, MD, TAKEN REMOTELY VIA ZOOM ON BEHALF OF THE PATENT OWNER, AT 9:02 A.M. PST, FRIDAY, NOVEMBER 11, 2022, BEFORE AUDRA E. CRAMER, CSR NO. 9901, PURSUANT TO NOTICE.

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WITNESS
NIGEL P. BULLER, MD

EXAMINATION PAGE
BY MR. LOWENSTEIN 5

NEW EXHIBITS MARKED (NONE)

REPORTER'S NOTE: All quotations from exhibits are reflected in the manner in which they were read into the record and do not necessarily indicate an exact quote from the document.

REMOTELY VIA ZOOM VIDEOCONFERENCE

FRIDAY, NOVEMBER 11, 2022, 9:02 A.M. PST

NIGEL P. BULLER, MD,

having been first duly sworn, was

examined and testified as follows:

EXAMINATION

BY MR. LOWENSTEIN:

Q. Good afternoon, I believe it is, Dr. Buller, where you are. How are you?

A. I'm very well. Thank you.

Q. Okay. I've asked my colleague, Mr. Katz, to display and Exhibit 1017, which is Cheung.

Okay. Dr. Buller, I trust you remember the Cheung reference?

A. I do.

MR. LOWENSTEIN: Okay. Could we go to the second page, please.

Okay. Let's zoom in on Figure 2 of Cheung.

Okay. Now, let's see if we can see the whole figure, if possible. Just bring it down a little bit.

Okay. Perfect.

Q. Dr. Buller, can you see Cheung's Figure 2 in front of you?

A. I can.

Q. Now, this is not quite a bird's-eye view, but it's a sort of tilted bird's-eye view; is that fair to say?

A. Yeah.

Q. Okay. And let's imagine that Cheung is like a clock face. I want to direct your attention to the interior diamond that is roughly around 3:00 o'clock.

Do you see that?

A. [Garbled.]

THE REPORTER: I can't hear the doctor. He's very muffled.

THE WITNESS: I see diamonds around the 3:00 o'clock mark. I can see -- which one do you mean?

MR. LOWENSTEIN: Perhaps, Will, you can zoom in a bit.

Q. Okay. Can you see right around 3:00 o'clock there's an interior diamond?

Perhaps you can highlight it for us, Will.

THE WITNESS: Yes.
BY MR. LOWENSTEIN:
Q. Okay. All right. So we're looking at the same thing?
A. Yeah, I think so. [Garbled.]
THE REPORTER: I'm sorry. The doctor is very, very muffled. I can't really understand him.
Counsel, what would you like me to do?
MR. SUMMERS: Yeah, this is Craig Summers. Let me bring our tech in to make sure that you can hear.
Do you want to go off the record for a minute, Nathan, while we do that, or...
MR. LOWENSTEIN: Would it be possible to -- I want to finish this line of questioning relatively quick.
THE REPORTER: Okay. Go ahead, then, Counsel.
BY MR. LOWENSTEIN:
Q. And then in the interim, Dr. Buller, just try to enunciate as best as you can under the circumstances.
A. I will.
Q. Okay. So looking at back at this

diamond, we see a diamond of the outer frame in shot, or at least part of a diamond; is that fair to say?

A. We see part of a diamond of the metallic brain in Cheung, yes.

Q. Okay. And on the outer surface of the frame, we see an outer cloth; is that fair to say?

A. There's a cloth wrapped around. So yes, you can see a little bit of a cloth through the space in the diamond.

Q. And the space in the diamond, are we seeing the inner surface of the outer cloth?

A. Yes, you will be seeing a little bit of the inner surface of the outer cloth in that space in the shade.

Q. Does the inner surface of Cheung's outer cloth appear smooth to you?

A. No, because I can see definite bubbles on it. I mean, looking at the lower strut that you can see, you can see darker areas where I think it is that little gaps between the cloth and the strut, if you can see what I mean.

Q. Well, let me ask you a different question.

Do you see any stray, outwardly extending fibers on the inner surface of Cheung's outer cloth?

A. In that little part, no, I can't.

Q. And aside from the -- I think you're referring to these two darker spots on the bottom edge of the frame.

Is that what you're referring to?

A. They're not on the frame. They appear -- it appears to be shadows. So it's not a smooth surface.

I think your first question for me was, was it a smooth surface. I'm saying it's not smooth, because my eye is seeing two sort of -- they look like sort of indentations, which give rise to darker shadow on the cloth.

Q. You agree that the inner surface of Cheung's outer cloth, to the extent there's any indentation, does not go past the full width of the bar of the outer frame; is that fair to say?

A. No, I can't tell that. Because I can see such a little bit, I can't see.

Q. You can see clearly the bar of the outer frame both at the top and the bottom; is that fair to say?

A. No, because parts of them are covered in sutures. I can see white material that I take to be sutures, which are being used, I presume, to attach the outer cloth to the frame, and the lower one may be partly to attach the inner cover to the frame, which occurs at a lower level than the outer cloth.

Q. Okay. That's fair. Perhaps my question wasn't very clear, so that's a fair distinction.

You agree that the -- we can clearly see the bars of the outer frame in this diamond, and you agree that the bars of the outer frame is not completely covered by the inner surface of the outer cloth; is that fair to say?

A. Correct. It's not -- it's definitely not completed covered. I can see chunks of the frame quite well.

Q. Okay. Now, I want to point to the sutures -- the suture which you just looked at. And you see there's a suture -- or two sutures, perhaps. I'm not sure how you would refer to it.

You see there's either one or a pair of sutures on the top of the bar for Mr. Katz's --

for the mouse.

Do you see that, sir?

A. Yes. It looks like two sutures to me there around the bar.

Q. Okay. And do you see that there's a bit of white that comes off of the suture perhaps?

Do you know what that is?

A. I really can't tell from this photo. I mean, it could be -- it could be light onto the pericardium, or it could be part of a suture or part of a knot for the sutures that are coming through the pericardium.

Q. Okay.

A. Because that's against the pericardium. That side appearance that I think you're asking me about is against the pericardium. It's wrapped around one of the internal bifold bars.

Q. Now, I want you to go back to the inner surface of the outer cloth.

Do you see any openings in the inner surface of the outer cloth?

A. Well, yes. These triangular shadows, these things that I've spoken about, look like, to me, to be indentations into the cloth.

Q. Do you believe an indentation is an opening?

A. Well, it can be classed as an opening. I mean, it can be like a little cave going in there.

I can see two dark shadows, but the resolution of the photograph might require that light. This isn't enough to give any detail. But it's certainly not smooth, and there's two shadows, suggesting that there is an indentation at least -- there may be more than that -- in that position.

Q. Now, the indentation, that would be caused by the bar; correct?

A. No. I mean, it's in the vicinity of the bar, but I have no idea what it's caused by.

Q. You would agree -- well, first of all, you don't know what those darker areas are; is that fair to say?

A. They look to me to be indentations. That's my opinion.

Q. But they could be a shadow; is that fair to say?

A. Well, the same: Because they're an indentation, there is less light in there, and

that is shadow.

So I don't think that the two are mutually exclusive. It's a shadow there because there's an indentation.

Q. But there could also be a shadow with no indentation; isn't that fair to say?

A. Well, there would have to be something to cast the shadow, and I don't see anything there to cast those very low-fly shadows. I think that is a shadow in an indentation.

Q. You agree, however, that the -- it's difficult to tell what those dark spots are; is that fair to say?

A. No. My opinion is it's not smooth, and there are indentations, and within them there's shadow, and that is why you can see them.

Q. To the extent that there is an indentation, would you agree that the indentation could be caused by pressure from the outer frame?

A. No.

Q. By pressing against the outer frame?

A. No.

Q. You don't think it's possible that the indentation which is just above the outer frame

could be caused by pressing against the outer frame?

A. No.

Q. You're aware that if you have a metal surface that presses against a fabric, the metal surface could cause an indentation of the fabric, of course; correct?

A. It could. But that would be along the direction of the strut. These are not. These are extending upwards from the strut, sort of fanning away from the top edge of the strut.

Q. Well, as a matter of fact, the two dark spots that you're referring to are just above the metal frame; isn't that correct?

A. They're extending up from the metal frame. They may be underneath the metal -- underneath the fabric adjacent to the frame, but where I can see them is extending up from the metal frame.

And they're two separate areas. They're not joined together; they're two areas.

Q. So I just want to make sure I understand your testimony.

Your testimony is we can see what appears to be two dark spots just above the

metal frame, and you know to a certainty that that is an indentation, and it's not an indentation caused by the metal frame; is that correct?

A. No.

Q. In what way does that misstate your testimony?

A. Because there are two dark spots there. It's not -- I mean, I'm looking at them. There are two dark spots there. They are certainly there.

They are caused by the fact that the fabric is not flat, is not smooth inside. My opinion is that they are shadow because the fabric is not smooth on the inside surface.

Q. Now, aside from those two dark spots that you're referring to, do you see any other openings in the inner surface of the outer cloth?

A. Well, I can only see a tiny bit of cloth there. They're the two main ones where it's darker. There are other areas where the light and dark is changing so that there are other areas that there are small -- two main areas where I can see that --

Q. Well, let's be precise: Is there any other opening that you can see in the inner surface of the outer frame aside from these two dark spots that you're referring to?

A. The two large dark areas are the two main ones I can see. There's some other light variation over the surface, which again tells me the surface is not smooth.

Q. What light variation are you referring to?

A. I can't point to it. I have no -- the surface is not a completely uniform color. It varies in grayness.

Q. Have you ever physically examined the valve shown in Cheung?

A. No.

Q. Have you ever asked anyone at Edwards Lifesciences about the valve shown in Cheung?

A. No.

Q. So is it fair to say that all of your opinions about what we see on the inner surface of the outer cloth of Cheung in Figure 2 is based upon your visual inspection?

A. Right. It's on my review of the paper, reading it. I'm looking at the figures from

that time. Because it's a prior art document, I have looked at it as it would have been published at the time and as I would have seen it through the eyes of a person looking at it at that time.

Q. Can we agree that Cheung says absolutely nothing whatsoever about indentations appearing on the inner surface of its outer cloth?

A. I don't remember anything being said about indentations on the inner surface of the outer cloth; that's true.

Q. Can we agree that the dark spots that you're referring to in Cheung's Figure 2 do not extend through a thickness of the cloth?

A. I don't know. I mean, you can see that dark, and it could well extend through the thickness. I can't tell from this two-dimensional, rather low-quality image.

Q. How deep is this indentation, based upon your visual examination?

A. I cannot tell. You can see the beginning of it. It could go through the fabric, as you've just said. I can't tell.

I can see the area which is not smooth.

I can see that it causes shadow and -- because it's going in, and this light is getting into it, and that could be an opening that goes through the cloth.

Q. Do you believe that the shadow we see in Cheung's Figure 2 will be -- what you identify as an indentation, you believe that could be a hole that goes all the way through Cheung's outer cloth?

A. There could be an opening. I'm not saying that I believe, because I'm saying it could be part of an opening that goes through it. It's a fibrous cloth, and there may well be openings between the fibers that go all the way through to the exterior.

MR. LOWENSTEIN: Okay. Let's go down a little bit, Will. Let's look at the outer cloth of Cheung.

Q. Do you see any openings in Cheung's outer cloth?

A. No, because it's fairly brightly lit.

But what I do see -- again, if you look at the lower edge, and now that you've changed the zone of the image I'm looking at, you see the outer edge, which you can clearly see has

both got fibers on it and is not smooth. It is waving in and out. It's undulating in and out, and that's the sort of appearance that I think you were seeing in that tiny segment of the inner surface.

Q. Now, if I were looking at a big, puffy cumulus cloud -- do you know what a cumulus cloud is?

A. I do.

Q. Okay. And I was looking at a big, puffy cumulus cloud.

Now, in your experience, do cumulus clouds -- are they -- conform to generic geometric shapes, like a square or a rectangle, or are they uneven in their surfaces?

A. Well, they certainly don't conform closely to geometric shapes, but you can often look at them and see things, like trains and things. I mean, I have enjoyed watching clouds pass by, and you can often see lots of interesting shapes in them, but it is completely random.

THE REPORTER: I cannot hear the doctor.

(Discussion held off the record.)

BY MR. LOWENSTEIN:

Q. So I think the last question and answer may have been a bit muffled, but I think it's fair to say that a cumulus cloud has an uneven surface.

Is that fair to say?

A. Yes. I'm not sure it has a surface, so I would rather talk about the photograph in front of me, because, obviously, if we talk about a cloud, it's very abstract.

I'm not really sure it has a surface. From a distance it looks as though it does, but if you get up there, it's just steamy air that you sort of slowly get into more and more and more of it. You know, there isn't -- you don't suddenly hit a surface when you fly in an airplane through a cloud.

Q. So if you were looking at a cumulus cloud and you saw the uneven surface -- the visually uneven surface, would you characterize the parts of the cumulus cloud that are a little bit closer to the center relative to other portions of the crowd as being an opening in the cloud?

MR. SUMMERS: Objection. Form.

THE WITNESS: No, I'm not really -- I'm not loving your analogy -- if that's what it is -- with a cumulus cloud, because it's gas. It's -- you're looking at something --

BY MR. LOWENSTEIN:

Q. Okay. We'll go to something else: cotton candy.

Have you ever been to -- you're familiar with cotton candy?

A. Yeah. Candyfloss we call it, yeah. I think cotton candy is candyfloss.

Q. So you've got a big, puffy stick of cotton candy, and we can agree that not all the fibers are exactly -- there may be some unevenness in the surface of the cotton candy; is that fair to say?

A. Yes.

Q. But let's assume you've got a big, puffy piece of cotton candy. You haven't taken any bites out of it. It's relatively circular, or spherical perhaps, as the case may be.

If there was a slight indentation on the outer surface of the cotton candy, would you refer to that as an opening?

A. Well, that's -- lots of cotton candy

has lots of openings into it and through it, because it's the fibers of sugar, spun sugar, heading in all directions, and there's lots of openings between the fibers of sugar.

Is that what you're asking me?

Q. So you've got a big, puffy piece of cotton candy, and it's maybe 20 inches in diameter. It's -- visually you don't see any holes.

You would look at that and you would say, "I see an opening"?

A. Without you showing me it, I can't tell you what I would say.

There are lots of openings between all the strands of sugar. It's covered in openings, and there'll be an unevenness all over the surface. It's not a smooth surface. It is a spun sugar, and there's lots of openings all over it.

Q. Would you agree that if I had a glass of water, that there could be some intermolecular space between water molecules?

MR. SUMMERS: Objection. Form.

THE WITNESS: Okay. You're now talking about intermolecular space.

Yes, there would be some space, but you can't see it.

BY MR. LOWENSTEIN:

Q. Are those openings?

A. No.

Q. Why not?

A. Well, because we're talking about a completely different scale. You can get down to there's space between the electrons and the protons when you get into an individual atom.

But we're not talking about that. We're talking about openings in the surface of fabrics on a stand, I hope.

Q. Well, actually, we're talking about cotton candy.

A. Yes. I answered about cotton candy as best I can.

Q. Okay. And I think we're talking about cumulus clouds.

A. Well, we were talking about water and intermolecular distances a minute ago.

Q. Okay. So an intermolecular opening is not an -- or space is not an opening.

So how large does something have to be to be an opening?

MR. SUMMERS: Objection. Form.

THE WITNESS: I don't know. You need to -- you need to, you know, quantitate it to what we're actually talking about.

And you'd have a very good idea with the cotton candy if you showed me a photo of the distance between the strands of the candy, which will lead to the sort of openings which are going into cotton candy. And you've got an idea, when you've got fabrics, about what the openings are, depending on the fabric.

BY MR. LOWENSTEIN:

Q. Now, when we look at Cheung, you pointed me to the bottom of the outer cloth, and you said you see openings there.

Aside from the bottom of the outer cloth, do you see any openings elsewhere in Cheung's outer cloth?

A. Yes. On the inside. Because if you look -- how you've got the photo now, I'm seeing part of the photo on my screen -- not all of it, but part of it. But you're seeing the outside of the bottom edge, but you're also seeing, because of the angle it's taken at, the inside of the top edge.

And you can see that that is not smooth. It is going along, undulating in a very similar way to the bottom. So you can see the inside is undulating to a much greater degree than I can see in that tiny, little diamond opening previously.

So you can see that the inside is not smooth. You can also see various fibers going in at various places and tufts actually extending off the fabric and going in between the struts --

Q. So when you --

A. -- very similar to what you see in Walther.

Q. So you said there's an undulating in surface in Cheung; is that fair to say?

A. Yes. On the inside, looking on the top, you can only see the outside of the bottom of the outer covering, but you can get a good idea of the inside profile along the top because of the angle the photograph is taken at.

Q. So to determine what the inside of Cheung's outer cloth look like, you would look to the top of the outer cloth and not an image of the inside of the outer cloth?

A. Because of the angle that this photograph -- we're looking at one photograph. This photograph is taken at something at more than a 45-degree angle, looking downwards, and, therefore, you're able to get an idea of the inside texture of the cloth at the top and the outside texture of the cloth at the bottom because they're against different, contrasting color and structure.

And you see that there is an undulating, very uneven surface with tufts and fibers extending inwards on the top, and at the bottom you see there is a very unsmooth surface running around the outside. So it looks as though the inner and outer surface are the same, and they are far from smooth and have tufts, fibers and undulations.

Q. So if I wanted to get a sense for what the inner surface of the outer cloth looked like, would it be better to look at the top of the outer cloth, or would it be better to look at the inner surface that we can see through the diamond at roughly 3:00 o'clock?

A. Well, the trouble is, you can only see a tiny little bit through the diamond at

3:00 o'clock. You can see a lot more of the circumference looking at the front photo.

I would look at all of it in the front photo, I mean, look at the different parts, but from everywhere I look in the diamond and looking at the front of the device, you can see that the inner surface is far from smooth. It's got toughs, fibers, and it's undulating, as is the outer surface.

Q. You would agree that if we're looking at 6:00 p.m., let's say from -- not p.m.

If we're looking from, say, 5:00 to 7:00 o'clock on Cheung's Figure 2 -- are you with me?

A. I think so. Someone's putting a cursor on it.

So you're looking between -- from one narrow bar -- not the bar with the stitch, but you're looking from one narrow bar round to the narrow bar at the other side of the initial --

Q. Yeah, so let's do this -- can you just zoom back a little bit.

Okay. Go down, please.

Okay. So you see roughly at 6:00 o'clock there's a commissure; correct?

Dr. Buller?

A. Yes?

Q. You can see there's a commissure at 6:00 o'clock?

A. At 6:00 o'clock there's a commissural post and the commissure of a valve in front of it.

Q. Okay. And then we can see two columns of the inner frame, for lack of a better term, on either side of the commissure; is that fair to say?

A. Yes. You see a zigzag each side connecting to the vertical bar on each side.

Q. You would agree from this angle, looking at this section, the commissure at 6:00 o'clock and the two columns on either side, that we cannot see the inner surface of the outer cloth; is that fair to say?

A. No. I think you can see the edge of the inner surface of the outer cloth between those two points.

Q. And you believe it is better, to get a sense for the outer cloth -- the surface of the inner -- sorry. Let me start over.

If I were to compare the top of the

outer cloth that we see at the commissure and the columns on either side of it versus the inner surface of the cloth that we see at the 3:00 o'clock diamond, which of those sections will give me greater insight into what the inner surface of the outer cloth is like?

A. I think I would look at both, because they're different parts of the same photograph, and I think they're in agreement.

What I'm saying with the two shadows we talked about within the diamond at 3:00 o'clock is very much in agreement with the undulating appearance you get on the inner cloth looking at the segment between 5:00 o'clock and 7:00 o'clock.

Q. You see at the commissure at 6:00 o'clock -- and I'm looking at the top of the outer cloth. I'm looking at the area encompassed by the two columns on either side of it.

We can see little pieces -- perhaps we can see little pieces of cloth sticking out; is that fair to say?

A. Yeah, I see it as undula- -- I mean, the surface is far from smooth, it is undulating

in and out, and there are little tufts of fabric, perhaps more so if you move around to 8:00 o'clock, where, because you're seeing that section more clearly because you're not looking front-on on it, you're looking more side-on on it, you see tufts and fibers extended inwards between the two vertical struts, the first being at 7:00 and the next being at 8:00 o'clock.

Q. You agree, however, that there are no tufts of fibers that can be seen in the diamond at 3:00 o'clock; correct?

A. No. I can see tufts that I think are fibers sticking inwards from the surface.

Q. Show me what tuft of fiber you see within the diamond at 3:00 o'clock.

A. How exactly do I show you?

Q. Describe where it is.

A. At the 3:00 o'clock one?

Q. Yes.

A. No, I couldn't see any. I think I already answered you at 3:00 o'clock I couldn't --

Q. Okay. So I just want to be totally clear, because you just said the opposite.

We don't see any tufts of fibers on the

inner surface of the diamond at 3:00 o' clock; correct?

A. I can't see any in that tiny bit. I can only see less than half of the diamond, but I can't see any in that little segment, no.

Q. Okay. Now, is it possible that -- if you have a fabric and you cut one edge of it, is it possible that you could have little tufts sticking up where you cut the fabric?

A. No, I don't think this is an artifact caused by cutting it. Because what I see, I see in --

Q. I don't think you're answering my question, because I didn't ask you about Cheung.

I asked you if you have a fabric and you cut one edge, is it possible to have tufts of fibers that stick up where you cut?

MR. SUMMERS: Objection. Form.

THE WITNESS: Yes. Depending on what it is and how you cut it and everything else, all the provisos. But I don't know what the fabric is or how you're cutting it or what [garbled] or how it's made up. The answer is definitely, yes, but I know so little about it.

MR. LOWENSTEIN: Okay. I can tell the

court reporter would like to take a break, so let's take a break.

(Recess from 9:36 a.m. to 9:41 a.m. PST.)

BY MR. LOWENSTEIN:

Q. Dr. Buller, if I were to cut -- let's say I have a woven PET fabric, and I were to cut lengthwise and separated two -- and turned it into two pieces of woven PET fabric: Might I see frayed edges where the cut occurs?

A. You might.

Q. Is it possible to have a graft covering where the surface on one side of the covering is -- has outwardly extending fibers but the inner surface of the covering is smooth and does not have inwardly facing fibers?

A. Not to my knowledge, no.

Q. You're not aware of any fabric that has outwardly facing fibers on one side of the cloth but no inwardly facing fibers on the other side of the cloth?

MR. SUMMERS: Objection. Form.

THE WITNESS: I'm not aware of a PET medical cloth -- talking about these sort of cloths -- that is like that, no.

BY MR. LOWENSTEIN:

Q. Are you familiar with velour woven PET?

A. Yes.

Q. Okay. And is it possible to have a velour woven PET with a woven base and loose structures on one side of the cloth but not the other?

A. Yes. But it still won't be smooth on the inside, because it will be -- it'll have a weave that'll undulate up and down, and it will undoubtedly have some fibers, but it's still going to be a woven PET cloth.

Q. But you could have the loose structures on one side of the velour woven PET cloth but not on the other; is that fair to say?

A. You can have them dominantly on one side, yes, or you can have them on both.

Q. Are there medical-grade, velour woven PET cloths with loose fibers on one side of the cloth but not the other?

A. I don't know.

Q. There could be, though?

A. I don't know. That's my answer: I don't know.

Q. Can there be medically available,

velour woven PET cloths with loose fibers on one side of the cloth but a weave on the other side of the cloth?

A. There could be, yes.

Q. So if you see one side of the cloth, that would not necessarily tell you anything about the other side of the cloth; is that fair to say?

A. That's true. If you can only see one side of the cloth, you wouldn't know what's going on on the other side of the cloth. I mean, I think that is -- that is straightforward.

MR. LOWENSTEIN: Okay. Let's show Exhibit 2087.

Q. Dr. Buller, as you can see -- or I'll represent to you that this document contains portions of Edwards Lifesciences' invalidity contentions in the district court case.

Do you understand my representation?

A. No. I'm sorry. It contains portions of Edwards' representations in --

Q. No. Maybe I misspoke. Let me clarify.

I'm going to represent to you that Exhibit 2087 is portions of Edwards

Lifesciences' preliminary invalidity contentions in the district court action.

Do you understand my representation?

A. I think so.

Q. Okay.

A. I've never seen this before.

MR. LOWENSTEIN: Let's go to page 7 of the PDF, which has "Page 50" at the bottom.

Q. And, Dr. Buller, do you see there's a figure, and underneath it, it says "Apogee [garbled]"?

A. I see it, yes.

Q. Let's look at this like a clock face, just like we did with Cheung.

And if we look at the commissure at 6:00 o'clock and the two columns on either side of it, if we look at that section, we can see outwardly extending fibers both on the top and on the outer surface; is that fair to say?

A. Yes, I think that's fair to say.

MR. LOWENSTEIN: Okay. And I want to now zoom into the cell at 3:00 o'clock.

Q. Okay. Can you see what I'm referring to?

A. I do. I see the cell you're talking

about.

Q. Now, this is the inner surface of the outer cloth; is it not?

A. Yes. This -- again, just like we looked at before, this will be a little bit of the inner surface of the outer cloth seen through the diamond-shaped cell.

Q. We do not see any inwardly facing fibers in the inner surface of the outer cloth; is that fair to say?

A. This resolution, this photograph, I can't see any. But again, I see some shadow, I see some bubbling, it doesn't look smooth to me, and I see a shadow coming off the strut.

Q. Does the inner surface of the outer cloth look just like the outer surface of the outer cloth?

A. Yes.

Q. It looks exactly the same?

A. No, it doesn't look exactly the same, because it's in the shadow. So, I mean, it looks several shades darker because it's in the interstices of the cell, and you've got the valve leaflet. So it isn't as well lit.

And because it's not as well lit, it

looks to be a darker shade of gray, and the clarity you get of the surface is not as good because you haven't got the high contrast on it because it's not lit in there.

Q. So you believe that the figure that we're looking at in the cell at 3:00 o'clock, that image is too dark and unclear for you to clearly assess the state of the inner surface of the outer cloth; is that your testimony?

A. I'm saying it's not very well lit.

So if you're saying does it look exactly the same, no, it doesn't look exactly the same. It looks several shades darker, and you're not seeing the clarity because it's not well litigation. It's not been taken, the photograph, to best show that area of cloth.

Q. But you can see on the outer surface of the outer cloth outwardly extending fibers, can't you?

A. I can. And I see them best when they're against the blue background. So there is a very -- a coarsely woven sort of fabric that the device is standing on, and where you see the fibers best is where they're contrasted against the blue background.

So I can see fibers very clearly at -- running around sort of 4:00 o'clock and 5:00 o'clock on that side and on the other side against the blue background, but you haven't got that contrast when you're looking inside through an internal cell in the shadow of the valve leaflets.

Q. But we can agree that there's no visible, inwardly facing fibers on the inner surface of the Apogee outer cloth; correct?

A. No, we can't agree, because I'm saying I can't see them.

Where I can see the fibers best is where you're seeing them against a contrasting color and surface. I can't see the fibers clearly looking directly at a little section of the white cloth, even on the front of the material.

If we take a little equivalent section right on the front of the device, I can't see the fibers nearly as clearly as when they're against a contrasting background and where they are well lit.

MR. LOWENSTEIN: Let's zoom in a bit on the cell at 3:00 o'clock.

Q. Okay. We've zoomed in further.

Can we agree that you cannot see any inwardly facing fibers on the inner surface of the outer cloth?

A. I cannot see individual fibers. The surface looks bubbly and is not smooth.

Q. Your testimony is that the inner surface that we see in Apogee is not smooth; is that your testimony?

MR. SUMMERS: Objection. Form.

THE WITNESS: No. You're just looking at a little bit at 3:00 o'clock or a little part of the fabric you can see in the cell, and in that I can see that it is bubbly and not smooth. But it is not well lit, and you're not seeing it against a contrasting surface to actually be able to pick out individual fibers.

BY MR. LOWENSTEIN:

Q. You would agree that just above the inner surface of the outer cloth in Apogee, the blue carpet -- the blue material is just above it; correct?

A. Where are you looking? Just above the 3:00 o'clock diamond?

Q. Yes.

A. Yes, there's blue cloth there.
Q. Providing a clear contrast for you; correct?
A. No, because it's not well lit in there.
You can see the color of the cloth compared with the front of it is not -- it's in the shade of a much taller leaflet, so it is darker. And again, I can see that it's not smooth, but it's very difficult to make out individual fibers there because it's in the shadows, even on the outside.
Q. All right. So I want you to look -- we see the -- inside the valve we see some stitching. There's some white stitching. There's a bluish-green stitch.
Do you see that, sir?
A. Yes. Inside -- you're looking down --
Q. Inside the valve.
A. Yes.
Q. Okay. And you see there's a white strip at the bottom?
A. I do.
Q. And you see that there are blue-green stitches spaced apart in a somewhat irregular fashion?

Do you see that?

A. Yes. Like a sort of cone -- like teeth running around, yeah, if that's what you mean.

Q. Yes.

A. There's -- below the valve there is appearance of a sort of almost alternating white and greeny-blue, as you say, slightly irregular.

Q. Do you see any inward-facing fibers on that white strip at the bottom?

A. No. It's too -- it's right down in the shadow. I can't. It's not well lit, and that is right down at the bottom end of the valve and inside, and you can see even the resolution on the blue fabric is different. It's sort of blurred compared with seeing where it's lit, and you can see the weave much more clearly.

Q. Now, let's go back to the diamond at 3:00 o'clock.

A. Yes?

Q. Do we see any openings on the inner surface of the outer cloth?

A. Again, I can see a shadow a bit. I can only see one this time. But just above/below stitching I can see perhaps four -- definitely three, perhaps four stitches running along the

strut, and then just above that I can see the same sort of shadow appearance, suggesting that the cloth is not smooth and is not lying in all places as close or against the strut.

Q. How do you know the shadow isn't cast by some other intervening object, perhaps part of the frame?

A. I can't see anything that would cast that shadow down in that position. I can see, you know, a fairly dark shadow just above the upper of the three/four sutures.

MR. LOWENSTEIN: Let's go up one page.

So we're going to go to page 6 of the PDF, which has the "Page 31" at the bottom, and I want you to move a little bit -- okay.

Q. Do you see it says "valve 33 French"?

A. Yes, "valve 33 French."

Q. Do you have any reason to believe that does not accurately reflect --

A. I've never seen this document nor read it. I really have no opinion about it. This is completely new to me. I have no reason to disbelieve anything in it. I've never seen it.

Q. So in other words, the representation is the crimp profile is 33 French, and you have

no reason to disagree with that; is that fair to say?

A. I've never seen this document. I haven't analyzed it. I haven't read it. I've got no reason to disagree with anything. It says "crimped valve 33 French," but I -- that's -- all I know is what it says there. I have not looked at the document.

MR. LOWENSTEIN: Okay. Let's pull up Exhibit 1012.

Okay. And let's go down a little bit.

Okay. Yes. Right here.

Q. All right. Dr. Buller, do you have the Exhibit 1012 in front of you?

A. I can't see an exhibit number or anything, but I can see it's the Cribier article, and what you've got is the photograph of the Sapien valve in front of me. I can't see an exhibit number.

Q. Well, we see, actually, at the top the filename, Exhibit 1012, and then --

A. I see the filename, but I can't see anything on the --

MR. LOWENSTEIN: Let's go down just a little bit.

Do we not have this marked?

THE WITNESS: It's the Cribier article from 2009, and the page you're on has a picture of the Edwards Sapien THV.

BY MR. LOWENSTEIN:

Q. Well, okay. Actually, I believe this is Petitioners' -- go to the first page.

Okay. Go down.

So we can see we're looking at Exhibit 1012?

A. I've got it, yeah.

MR. LOWENSTEIN: Okay. Let's go to the second page, which is 348 at the bottom.

Q. And we're looking at a picture of a Sapien valve; is that fair to say?

A. Yes.

Q. Okay. And you see that there is stitching connecting the inner skirt to the outer frame?

A. Yes.

Q. And would you agree that the inner skirt is attached to the -- or is connected to the inner surface of the outer frame?

A. Yes, the skirt is up against the inner surface of the outer frame, or part of it, and

is stitched to it with, you know, three or four sutures on each strut that go around the strut to the outside.

Q. Okay. So I'm wondering: Is it possible to open up Walther, and I want to have both Walther and Cribier side by side.

A. I now have Walther. I'm now back to Cribier. But I don't have both. I had Walther a bit ago, and now I've just go Cribier again.

Okay. I've got both.

MR. LOWENSTEIN: Okay. Will, I would like you to zoom in on Walther's bird's-eye view in Figure 1, and then zoom in on Cribier's picture of Sapien.

Q. Okay. So, Dr. Buller, do you agree that we are looking at a split screen, and on the left side we have a picture of Sapien, and on the right side we have a picture of the bird's-eye view from Walther's Figure 1?

Is that fair to say?

A. Yes, that whats I'm seeing.

Q. Okay. And you would agree Walther is a Sapien with an outer PET cloth on the outer surface of the outer frame; correct?

A. That's what Walther says it is, yes.

Q. Can -- now, we're looking down at the valve.

Can we see the stitches from -- that we see in Cribier in this bird's-eye view of Walther?

A. I think you may be able to see some of them, yes. But there's other material, because you're seeing some of the cloth poking through.

Because, obviously, Walther has the exterior cloth that comes higher than the internal skirt, you are seeing some of the Walther's cloth and some of the fibers poking through. And so it's difficult to make out exactly what is what.

Q. It's difficult for you to distinguish the sutures for the inner skirt from the fibers in the outer cloth; is that your testimony?

A. I think I can see some of them, because you know there are only three or four on a strut, as is shown in the Cribier photo in front of me on the left-hand side of the screen. You know there are only three or four a strut, and you know where the struts are, and you can see -- lower than the cloth of the outer skirt is poking through, you can see discretely three

or four per strut sutures, and I take it that they are the ones attaching the inner skirt to the frame.

You'll see them best -- I mean, because Walther is not quite central -- so the lens of the camera taking this bird's-eye view is more towards the bottom of the frame at 6:00 o'clock and that's why you're seeing less of the inside.

On the upper part between 9:00 o'clock and 3:00 o'clock -- so the upper half of the device -- you're seeing more of the inside wall because this is -- this is looked at not completely true down the center, and it is in the upper part where you can see these discrete three or four stitches below the Walther's cloth, which is also bulging in through some of the cells.

MR. LOWENSTEIN: Okay. So let's -- I want to zoom in to the lower right quadrant of Walther's bird's-eye view.

THE WITNESS: I see.

BY MR. LOWENSTEIN:

Q. All right. So we're looking -- let's go up a little bit. Let's try to get exactly the lower right quadrant of Figure 2 if we can.

I'm sorry. Figure 1.

No, no, no.

THE WITNESS: I can see the lower right, but I can also see some parts of the upper right. But you'll see it really emphasizes the fact that we're not looking truly in the center of the stent. We're seeing more of the internal surface on the upper half than we do on the lower half, where you see far less of the internal surface on the lower half.

BY MR. LOWENSTEIN:

Q. Okay. So do you believe right now we are looking at approximately the lower right-hand quadrant of Walther's Figure 1 bird's-eye view?

A. Approximately, yes. Not completely.

Q. Okay. And I want you to start at about 4:00 o'clock.

You'll see there's an attachment for the valve?

A. Yes. That's one of the commissures. You see the pericardium in this sort of McDonald's shape, the M somewhat upside down side-on. You can see the initial attachment that'll be to one of the commissural posts, and

you've got that M-shaped structure where it's wrapped around the bifold bars.

Q. Okay. And I want you to go down from there. So let's say that's at about 4:00 o'clock, and I want you to focus on the 4:00 to 5:00 o'clock space.

A. Okay. We're starting at the commissure, and we're looking at the space heading downwards from there?

Q. Yeah, down and to the left.

A. Yeah.

Q. Okay. And we can see -- on one side of the outer frame, we can clearly see fibers from the outer cloth; correct?

A. Yes. On both sides I think you can.

Q. Well, on the other side of the outer frame, is it possible that we are looking at -- on the inward side of the outer frame, is it possible that the fibers we're looking at are the sutures for the Sapien inner skirt?

A. No.

Q. It's not possible?

It's not possible that we're looking at the sutures for the inner skirt?

A. No.

Q. There's no possibility that we can see the sutures for the inner skirt; is that your testimony?

A. You can --

MR. SUMMERS: Objection. Form.

THE WITNESS: You can see, as I've said, at the top where you're saying it, but the fibers that you're looking at that you're asking me about on the inside and outside are the fibers from the outer skirt poking in through the openings of the stent frame.

BY MR. LOWENSTEIN:

Q. How do you know that?

A. Well, I can see they are.

Q. Explain to me how you know that the fibers we're looking at on the inside of the outer frame are not the sutures for the Sapien inner skirt?

A. They're much smaller than the sutures. They are small, little fibers like on the outside. The sutures are relatively big, as you can see on the Edwards Sapien valve.

Q. So it's your testimony that in this section we can't see the sutures for the inner skirt at all?

A. In that section I can't make them out to simply -- where you're seeing more on the top half -- because, as I've explained, this photograph isn't truly down the center; it's more towards the bottom -- you can see less detail of the inside on this lower quadrant than you can on either of the upper quadrants, where I think I can make out the sutures for the inner skirt of the Sapien.

Q. So I don't think you answered my question, and I'm going to ask it again. I want to be very clear. So please answer the question that I ask exactly.

Do you know to a certainty that we cannot see sutures for the Sapien inner skirt when we look on the inside of the outer frame in Walther's bird's-eye view at 4:00 to 5:00 o'clock?

A. I cannot clearly see them in this segment. As I said, I can see them in the upper segments, where you'll see more detail of the inside.

What I am seeing in this --

Q. I'm sorry. You're not answering my question. I need you to answer my question.

I started my question "Do you know with a certainty" -- "to a certainty?" I'm going to ask it again. I need you to answer that question. So let me -- I'm going to ask it again, and you need to answer that question.

Do you know to a certainty that the fibers we see on the inner side of the outer frame in Walther's bird's-eye view at 4:00 to 5:00 o'clock are not fibers associated with the sutures for Sapien's inner skirt?

A. Yes.

Q. You know to a certainty?

A. Yes.

Q. How do you know that?

A. Because there aren't fibers that appear like that from the sutures of the Sapien inner skirt.

Q. Now, let's just remove the word "fibers," and let's just say "the white material." Okay?

Do you know to a certainty that the white material that we see on the inner side of the outer frame in Walther's bird's-eye view at 4:00 to 5:00 o'clock do not, at least in part, include the sutures for the Sapien inner skirt?

A. I cannot see any of the sutures clear enough to say that they are visible.

Q. So you cannot say to a certainty that we can't see sutures in the segment that we're talking about; correct?

A. You keep saying "we," and this is why I'm having a trouble answer.

I'm telling you I cannot see the -- I certainly cannot see the sutures in this --

Q. I'm not saying "certainly." I'm saying "to a certainty."

A. No, you're saying "we."

Q. Can you see to a certainty, 100 percent certainty, that we cannot see -- that you cannot -- let me reask it. I'll revise the question.

Can you say to a certainty, under oath, that we cannot -- new question.

Can you saw to a certainty, under oath, that in the white material that is visible on the inside of Walther's outer frame in the bird's-eye view between 4:00 to 5:00, can you say to a certainty that that white material does not include, at least in part, sutures for the Sapien inner skirt?

A. I cannot see the sutures in the segment from 4:00 to 5:00 o'clock.

Q. That's not answering my question. Okay?

Can you say to a certainty that the white material we see on the inside of the outer frame in Walther at 4:00 to 5:00 o'clock does not include the sutures of the Sapien inner skirt?

MR. SUMMERS: Objection. Form.

THE WITNESS: I think I've answered to the best of my ability. I cannot see anything, which is the suture --

BY MR. LOWENSTEIN:

Q. That's not answering my question.

It's one thing to say you can't see it. It's another thing to categorically exclude it. Would you agree?

A. Yes. But I can only tell you what I can see or can't see. I mean --

Q. Okay. And I'm asking what you -- I'm not asking you what you can see. I'm asking what you can categorically exclude, and I'm asking what you know to a certainty, which is, you understand, different from "what I think I

see."

I'm not asking about a guess. I'm not asking about what you think you see. I'm asking about what is and what you know to a certainty and what you don't know to a certainty.

You understand?

MR. SUMMERS: Objection. Form.

THE WITNESS: Okay. I think I'm beginning to understand.

BY MR. LOWENSTEIN:

Q. Okay. So let me ask the question again.

Do you know to a certainty that the white material visible on the inner side of Walther's outer frame in the bird's-eye view at 4:00 to 5:00 o'clock does not include the sutures for the Sapien inner skirt?

A. I certainly cannot see the sutures.

Q. That's not answering my question. Okay?

We just went over the distinction between what you certainly can't see and what is to a certainty. If you can't answer my question, just say, "I don't know the answer," but you need to answer my question.

I'm going to ask it again: Do you know to a certainty that the white material on the inner side of the outer frame of Walther's bird's-eye view between 4:00 and 5:00 o'clock does not include the sutures for the Sapien inner skirt?

A. I don't know for a certainty that it doesn't contain the sutures, but I can't see them.

Q. Thank you for answering my question. Now, let's focus on this same section.

You see there's white material on the inner side of the outer frame, correct, that we've been talking about?

A. Yes.

Q. Do you know to a certainty -- well, let me ask you this: Do you believe that any of that white material that we see is associated with either the inner skirt or the sutures for the inner skirt?

A. Parts of it may be, but part of it is certainly the outer cloth poking through.

Q. What part of the white material at 4:00 to 5:00 o'clock is associated with the inner skirt?

A. I can't divide it up like that because you haven't got the resolution there.

But the fibers that are sticking in are from the outer skirt, where you can see individual wispy fibers, and the majority of the material, because you're looking down on it, close to straight down on it, is mostly material that's poking in from outside, in my opinion.

Q. So in your opinion, most of the material that we see is from the outer cloth.

That's your testimony?

A. Correct. At 4:00 to 5:00 o'clock.

Q. Is it possible that what we see in the white material at 4:00 to 5:00 o'clock is predominantly material associated with Levi's -- sorry, not Levi's -- Sapien's inner skirt and the sutures there to?

MR. SUMMERS: Objection. Form.

THE WITNESS: No. It's too rough, too wispy, too irregular to be the more dense inner skirt.

BY MR. LOWENSTEIN:

Q. So you know to a certainty that the white material we see on the inside of the outer frame is not associated with the inner skirt of

the Sapien or the sutures thereto; is that your testimony?

MR. SUMMERS: Objection. Form.

THE WITNESS: My opinion is that the majority of what you're seeing at 4:00 to 5:00 o'clock in this particular zone is related to the outer cloth poking through the holes in the frame -- the openings in the frame.

BY MR. LOWENSTEIN:

Q. Now, have you ever handled Walther's valve?

A. No.

Q. Did you ask anyone at Edwards Lifesciences about Walther's valve?

A. No.

Q. Did you contact any of the five authors of Walther's paper who are from Edwards Lifesciences to ask them about Walther's valve?

A. No. I wanted to analyze it as it was published -- as it was available at the time that it was published. I didn't want information from now. I wanted to look at it as I would have understood it at the time.

Q. And you agree that if you wanted to get the answer to what we actually -- if you wanted

to actually know what the inner surface of Walther's outer cloth was like, would you agree that the authors of this paper would have more insight into that question beyond what we see in this pixilated image?

MR. SUMMERS: Objection. Form.

THE WITNESS: They may have. This was published a long time ago. If you're talking now -- at the time I think they would have known a lot, but I don't know what -- I have no idea what they would know now or remember. They'd be looking at the images that I'm looking at and giving their opinions.

BY MR. LOWENSTEIN:

Q. You agree that the author does not discuss the inner surface of its outer cloth?

A. Sitting here, and without going through it, I can't remember any particular discussion about -- specifically about the inner surface. It's generally about the cloth.

Q. Beyond this specific image that we're looking at right now, do you have -- is there any other evidence in Walther that bears upon the inner surface of its outer cloth?

A. Yes. There are other images where I

think you can see little pieces of cloth. A bit like you've shown me on other devices where you're looking into the image, there are other photographs where you can look in and you can see bits about the cloth.

Q. I'm talking about the inner surface of the outer cloth.

A. Yes, I'm talking about the inner surface of the outer cloth.

Q. Direct me to -- make it bigger. Let's zoom out.

Which figure would you like to look at?

A. I'm not seeing them all yet. I think it's Figure 2. If you could zoom out so I can see all the figures.

Yes, it's Figure 2.

Q. And you agree that you did not cite Figure 2 for this proposition in your declaration; correct?

A. That's true. You're asking me now, and I'm answering your question.

Q. And you agree that the outer cloth in Figure 2 -- I'm asking you about the top left image in Figure 2.

Are you with me?

A. Top left image now, yeah. Yes.
Q. You agree that the outer cloth of Walther is wrapping around the apices at the proximal end of the valve; correct?
A. Yes, it's wrapping around the apices at the proximal -- the inflow end of the valve.
Q. And yet that's the exact opposite of your testimony in the '549 case, wasn't it?
A. No.
Q. Where you testified that the apices were uncovered, wasn't it?
A. Sorry. Are you talking about the lower apices or the upper apices? I'm confused now.
Because I'm looking at the --
Q. No. No. Nope, nope, nope. I said very clearly we were talking about the top left figure in Figure 2, and I clarified that we're looking at the proximal end.
So --
A. By "proximal," do you mean the inflow?
Q. I'm referring to the top left image of Walther's Figure 2.
A. Yes, but which --
Q. And you agree that the outer cloth wraps around the apices, don't you?

A. Yes. That's what I just said. It wraps around the lower apices.

Q. Okay. Does it wrap around from the outside of the outer frame or the inside of the outer frame?

A. It doesn't wrap around internally. It's wrapping around the external -- I think you -- it may be that I'm confused by your question.

It wrapping around the outer surface. It's not wrapping up inside the --

Q. So what we are seeing in Figure 2 is just the outer surface of the outer cloth as it's wrapping around, isn't it?

A. Wrapping around circumferentially. It's wrapping around the outside of the device, as the author says.

Q. So that wouldn't give you any insight into the inner surface of the outer cloth, would it?

A. No, that photo, the upper photo, does not give you any insight into the inner surface, because you're looking at it fairly straight on, so you're only seeing the outer surface.

Q. Okay. So that gives you no insight

whatsoever into the inner surface of the outer cloth; correct?

A. Well --

MR. SUMMERS: Objection. Form.

THE WITNESS: It only shows the outer surface, so that you're looking at the outer surface.

BY MR. LOWENSTEIN:

Q. So the answer to my question is yes, it gives you no insight whatsoever into the inner surface of the outer cloth; correct?

A. You're only seeing the outer surface.

Is that not answering your question?

Q. What I asked you was for evidence -- any other evidence aside from the bird's-eye view in Figure 1 from Walther that tells us anything about the inner surface of the outer cloth.

Is there anything else in Walther --

A. Yes. I --

Q. -- that tells us about the inner surface of the outer cloth beyond the bird's-eye view in Figure 1?

A. Yes. Figure 2, looking at -- I gave you that answer. You said that was not in your

report, and I agreed. And I'm saying now I've looked at it more closely, and I can see a bit of the cloth at around 9:00 o'clock between the valve and the frame, and you can see a bit of the inner surface.

It's a bit like looking into the cells, as you had me doing on the previous photographs -- not that figure. Figure 2, the lower one.

Yes, there. Yes, there.

If you look into the -- so looking in at 9:00 o'clock between the leaflet on the inside and the leaflet on the outside -- there are two pericardial leaflets, and it's the outer one that belongs to the surgical valve, which is darker in color. And between those two you can see part of the frame, and you can see a small piece of the cloth wrapping around.

I have no way of pointing it to you, but you can see it's a small piece of the cloth, and you can see part of the inside of it.

Yes, that there. You're zooming in on it now, but it's become very pixilated. But you can see it has a rough surface on the inside.

Q. So you're looking at this dark brown

coloration; is that correct?

A. Yes. It's in the shadows, so it's a bit like the photos --

Q. So you agree that we don't see anything that's white --

A. We don't see --

Q. -- in that section; correct?

A. We don't see anything that's white. It's in the shadows. It's several tones down, as we talked about in previous photographs, but in there you can see it has a rough surface.

Q. Would you agree that the color that we're looking at substantially matches the color of the existing valve that Walther is replacing?

A. Well, no, it doesn't, because you can make it out, and you can see that it's a rough surface.

So it's a different color, but it is in the shadow, so it is much darker than the other photos, where you're seeing brightly lit outer fibrous cloth.

Q. So I want to make sure I understand.

This image provides insight into the inner surface of the outer frame more so than the 3:00 o'clock diamond that we saw in Cheung

and Apogee; is that your testimony?

A. No.

And I think you misspoke. It's not about the frame. I'm looking at the fabric covering, Walther's outer cloth, which is wrapped around. And this certainly doesn't give you more image. It's very similar to the sort of quality that you're getting on your diamonds that you had me look at a few minutes ago.

Q. You believe that -- you would agree, though, that there's nothing in this section that is necessarily a white material, whether it's shadowed or not?

A. Well, it's in the shadow, and, therefore, it doesn't appear as white. It appears several shades darker.

But you can see the rough inner surface in that little segment, very much like you were showing me in the diamonds in the previous photographs.

Q. I don't see any white at all, and I don't see any cloth at all.

A. Okay.

Q. So how do you know that this is just -- not just more of the inner surface of the valve

that is being replaced?

A. Because it's in the position of the cloth. It's coming halfway around the vertical -- halfway up the vertical bar. And if you compare that with the front-on image, you'll see it's in position where the cloth is placed on Walther.

Q. So your testimony is that this provides more insight -- let me start over.

Your testimony is that the bottom image of Walther's Figure 2, which you did not reference in the petition or in your declaration thereto, provides more insight into the inner surface of Walther's outer cloth than the image at 3:00 o'clock in Cheung provides as to Cheung's inner surface of its outer cloth.

Is that your testimony?

A. They're about the same. It's not more. I'm saying that this is in the shadows. I didn't rely on it. I've spotted it since that it is there.

It's not in my report, as I said to you when you first asked that, but it is further information, which -- you asked me whether there was anything else, and so I'm answering that

yes, this agrees with my opinions about the surface -- the inner surface of the outer cloth.

I don't see any dents in the surface like Brecker sees, and the white line that Brecker refers to I think is just white light reflected off the frame.

Q. Did you ever see inwardly facing fibers in a Rorschach test?

A. Sorry. Ask that question -- I didn't --

Q. Have you ever seen inwardly facing fibers in a Rorschach test?

A. I don't understand the test. What's the term you're using? "Rorschach"?

Q. Rorschach.

A. I don't understand that. I'm sorry.

Q. You would agree that even if --

I'm getting a feedback or something.

(Discussion held off the record.)

MR. LOWENSTEIN: Well, we've been going for a bit, so why don't we take a break. And I think what I'm going to do is I'm going to log off and reconnect, and then hopefully that will address the issue.

(Recess from 10:32 a.m. to 10:40 a.m. PST.)

BY MR. LOWENSTEIN:

Q. Looking back at this same image where we left off, can you say to a certainty that the brownish portion that you have been directing us to in the bottom image in Walther's Figure 2 is not the artificial leaflet material for the valve that is being replaced?

A. Yes.

Q. You can say that to a certainty?

A. Yes.

Q. If interventional cardiologists said, "That's crazy. We're obviously looking at the native leaflets," they would be lying; is that your testimony?

MR. SUMMERS: Objection. Form.

THE WITNESS: They can have a difference of opinion. I'm giving you my opinion. I'm not accusing anyone of lying. I haven't heard anyone else give an opinion on it.

I'm telling you that I'm certain that that is part of the Walther's cloth because of the position and the height it comes up the vertical strut that you can see at a bit after

6:00 o'clock.

BY MR. LOWENSTEIN:

Q. Can you state to a certainty that this cloth that you imagine seeing, this brown -- this brown material which you identify as Walther's white cloth, can you say to a certainty that this image displays inward-facing fibers?

A. No. I can see it's a rough surface, but there's not the resolution there in the shadows down there to see fibers.

I wouldn't expect to see fibers, but I can see that it is a rough -- it's not a smooth inner surface, and I can see that it's fairly uniform across its thickness. It doesn't appear to have a brighter white inner layer of dense material as Brecker was suggesting from the other image.

Q. In this image that you're looking at in the white cloth that you imagine seeing that is actually brown, do you see openings?

A. No. I can see that it's not smooth, and, therefore, there are depressions and -- it's not smooth, and, therefore, it's got depressions in it by virtue of the fact it's not

smooth.

But again, there isn't any great resolution, and I certainly can't see fibers, and I can't see individual things that I can say are openings, but it is -- it is rough.

MR. LOWENSTEIN: Let's go back to Walther's Figure 1. I want to look at the top image this time.

Q. Do you see -- okay. So you agree we're looking at Walther's Figure 1, the head-on image, not the bird's-eye view, but the top image in Figure 1.

Do you see that?

A. The side-on image. The upper figure -- the upper photograph of Figure 1.

Q. Okay. Do you see any openings in this image?

A. Yes, I can see -- because it's brightly lit, I can see the fibers, and I can see, you know, shadows between them, and I can see that they -- between the fibers there are openings that go deep into the cloth.

Q. Do you see -- can you see the frame through the outer cloth?

A. No, I cannot see the -- in this picture

with this lighting, I can't see the frame through the outer cloth. If it was backlit, perhaps I could, but in this image I cannot see the frame through the cloth.

Q. Do you believe Walther's outer cloth is impermeable?

A. I think it's very unlikely to be impermeable until its squashed and blood clots in it. I think fluid would probably pour fairly easily through it, because it's a very loose -- very loose cloth with big gaps between the fibers, and, therefore, I think it would -- fluid would pour through it.

Q. You agree that woven PET -- I'm sorry.

It's your testimony that fluid would pour through Walther's outer cloth?

A. Yes. I think if you poured water on it, it would pour through it. That is my opinion of this cloth.

Q. Do you believe that woven PET is a gravity material?

A. Woven PET can be a graft material, but one thing I'm in agreement with Brecker is that it needs to be dense and nonporous to fulfill the graft material of the '236 patent and,

indeed, the other patents.

Q. You agree that you did not proffer any claim constructions in your declaration; correct?

A. Using plain and ordinary meaning.

Q. And you agree that you did not provide any testimony concerning whether Walther's outer cloth is porous or not; correct?

A. Sorry. Could you ask that -- I missed --

Q. You did not provide any testimony in your initial declaration concerning whether Walther's outer cloth is porous or not; correct?

A. I don't remember. I was just answering the question you just asked me.

Q. And you agree that you did not provide any testimony suggesting -- indicating that Walther lacked in outer cloth based upon its porosity or permeability; correct?

A. I don't remember saying anything like that. I said it's a very loose, compressible, voluminous cloth.

Q. You agree that Walther's outer cloth is added talk to address PVL between Walther's valve and the existing valve; correct?

A. Correct. That's why it's put there.
Q. Walther does not say that it is directed towards addressing PVL between its outer cloth and its outer frame; correct?
A. Sorry. Walther does not say...
Q. That it is directed towards addressing PVL between its outer cloth and its outer frame; correct?
A. Yes, it does. Walther specifically says on the first page, I think, that it forms a seal between the two valves and the --
Q. I'm not asking about the two valves. I'm asking about Walther's outer cloth and Walther's outer frame.
A. Yes. That is the frame -- one of the valves is the Sapien on which it's put, and the outside of the Sapien is the frame. And Walther teaches that there is a seal created between the two valves, one valve being the Sapien and its frame and the other valve being the surgical valve into which it's placed.
I --
Q. You're aware that Walther already has an inner skirt; correct?
A. The Sapien has an inner skirt, but it

doesn't come to the --

Q. I just -- you answered my question. That's it.

And we've already established that Walther's outer cloth wraps around the bottom apices at the proximal end; correct?

A. Not internally wraps around, which I think was where you were confusing my testimony. It's wrapping circumferentially around the outside.

Q. That's exactly what I said earlier.

So there's no indication in Walther that it is creating a PVL seal between the inner surface of its outer cloth and the outer surface of its inner skirt; correct?

A. Yes. Because you need to seal the gap, and the gap --

Q. There's no teaching in Walther that you're creating a seal between the inner surface of the outer cloth and the outer surface of the inner skirt; correct?

MR. SUMMERS: Objection. Form.

Please let the witness finish his --

MR. LOWENSTEIN: Don't interrupt my deposition.

MR. SUMMERS: Stop interrupting the --
BY MR. LOWENSTEIN:
Q. Answer my question.
MR. SUMMERS: Stop interrupting --
BY MR. LOWENSTEIN:
Q. Answer my question.
MR. SUMMERS: -- the witness.
BY MR. LOWENSTEIN:
Q. Answer my question.
MR. SUMMERS: He is.
BY MR. LOWENSTEIN:
Q. You said there's no teaching.
You answered yes; correct?
A. No. There is teaching that you seal against the Sapien valve, and against the Sapien valve includes the outer surface of the --
Q. Show me exactly what sentence you're talking about. I want to see exactly the disclosure you're referring to. Let's see it.
You want to look at page 1?
A. Yes, can you go to page 1, please, front page.
Right. On the right-hand column -- let me just put my glasses back on.
On the right-hand column in the

introduction, it says, "The addition of an outer cloth to the Sapien cloth valve is designed to reduce paravalvular leak by creating a seal between the two valves."

And that is telling you that it's creating a seal on one surface against the valve into which it's put, the surgical valve, and on the other surface, on the inside, against the Sapien valve. They are the two valves.

Q. If you were to refer to "Walther's valve," could that refer to -- could that encompass Walther's outer cloth as well?

A. No, because the two valves -- one of them -- it's just above it -- is the Sapien. The addition of an outer cloth to the Sapien cloth valve is designed to reduce paravalvular leak by creating a seal between the two valves.

Q. So Walther's valve -- if I refer to "Walther's valve," you would understand me to be excluding the outer cloth?

A. No, "Walther's valve," I would include the cloth. But when you talk about the Sapien valve, which is what it's built on, that is the second valve between the two valves.

Q. So in Levi -- if I refer to "Levi's

valve," I would be excluding its outer skirt; is that correct?

A. No. Because Walther is built on a known, used, marketed valve called the Sapien. That is the valve on which it is put. With Levi -- I think we're talking about the Levi patent, and we're talking about -- and you'd have to say which one, because there are lots of ones.

But Levi teaches lots of valves, and if you say what aspect of Levi you're talking about, I would know which valve. There's no one Levi valve that -- it's a patent disclosure with lots of different ideas and embodiments in it.

Q. But you would agree, though, that persons of ordinary skill in the art -- if there's a TAVR with a powder covering of some sort, you would agree that a person of ordinary skill in the art may refer to -- as the valve to include whatever the outer covering is; correct?

MR. SUMMERS: Objection. Form.

THE WITNESS: Well, different people saying different things may -- "may," as your question says -- be referring to different things. But this makes it very clear that it's

talking about, one, the Sapien valve and, two, the valve into which it's put, the surgical one, and is creating a seal between the two. And I think it is obvious to a person of ordinary skill in the art that that's what it's there for is to create a seal between the two valves.

BY MR. LOWENSTEIN:

Q. Is there any other statement in Walther that supports your understanding?

A. Well, all of it does, but that statement is very specific --

Q. I want you to point some me to any specific statement that you believe supports your position?

A. No. It would be a person's -- a person of ordinary skill in the art's understanding of the purpose. It's to stop paravalvular leak occurring between the two valves. You've added something to the Sapien to stop leaking between the two, and, therefore, you've got to seal to both surfaces. You've got a seal to the surface into which you've placed the device, and you've got a seal against the existing surface of the device onto which you've added Walther's fabric.

Q. So Walther, just again, that was

published in 2011; is that correct?

A. I can look and see.

It was published -- available online 3rd of April, 2011. Yes. It was published in 2011.

Q. And that was three years after you retired?

A. No, I hadn't retired by then. I'd stopped doing procedures. I'd stopped --

Q. Okay. And we know well that you've never implanted a TAVR; correct?

A. Correct, I've never implanted a TAVR device.

Q. And you've never handled a TAVR with an outer covering of any kind; correct?

A. No. I've handled lots of TAVRs without a covering.

Q. In the context of litigation; correct?

A. No. I've at meetings and things seen devices and handled devices, and in the context of litigation, I've handled devices without covers, like, you know, Sapien 3, Sapien 3 Ultra, and other manufacturers' devices.

Q. And you've never spoken to any of the authors of Walther about the nature of a TAVR

cloth; correct?

A. Correct. I mean, I've -- to my knowledge, I've never met any of them, and I've certainly never spoken to them.

I didn't wish to speak to any of them. I wished to rely just on the publication at the day it was published in 2011.

Q. And you can see that five of the six authors of Walther were at Edwards Lifesciences; correct?

A. Correct.

Q. And you did nothing whatsoever to verify your understanding of what Walther discloses outside of the four corners of Walther; correct?

A. I deliberately have not, because I don't want to know extraneous things. I want to know what is available in the prior art, and, therefore, I wanted to know what the interpretation would be of a person of ordinary skill reading the publication.

I don't want to know the opinions of the --

Q. Are you an expert in analyzing photographs?

A. Medical photographs, yes.
Q. Okay. I'm not asking about medical photographs. I'm asking about photographs of a valve.
A. Yes.
Q. Are you an expert in analyzing shadows and what is a fiber, what is not a fiber? Are you an expert in that?
A. Yes. In the field of medical interventional cardiology, yes.
Q. And so what is based upon?
Would every interventional cardiologist be an expert to the same degree, or do you have any special expertise that I should be aware of?
MR. SUMMERS: Objection. Form.
THE WITNESS: I can't answer for other interventional cardiologists. But I've spent my lifetime, my professional career, training in cardiology and interventional cardiology, and as part of that [unintelligible].
THE REPORTER: I cannot understand you.
THE WITNESS: As a result of that, I've worked with a lot of companies on developmental projects and looked at a very large number of photographs of devices, particularly in the

field of stents. And I'm very familiar with looking at photographs to see shadows, lighting, and ascertain the structure that I'm looking at in this field.

BY MR. LOWENSTEIN:

Q. Would you agree that Dr. Brecker has substantially more expertise than you in the field of TAVRs?

A. In clinically using them or placing them, yes, he has much more. I don't know that he has more experience in analyzing photographs or looking at devices, analyzing devices.

Q. Dr. Brecker, to my recollection, has implanted over a thousand -- I think it was on the order of 1300 TAVRs.

Do you have any reason to believe that's not true?

A. No, I have no reason to believe that's not true.

Q. And you have implanted zero TAVRs; correct?

A. Absolutely correct. And as I've said many times, I've never implanted a TAVR.

Q. And Dr. Brecker has published dozens of articles relating to TAVRs; is that correct?

A. Yes.
Q. And you have published zero articles relating to TAVRs; is that correct?
A. Correct, because I haven't done TAVRs. It's not -- I retired from performing procedures before TAVRs were available to me.
Q. Is there any reason to believe you have more insight into what Walther's photos reveal than Dr. Brecker does?
A. Yes. Because I think he's completely wrong about that white line. I think he's misinterpreting the photograph, and he is interpreting reflection of the metal frame as being a dense inner layer to the cloth. I think he's completely misinterpreted the photograph.
Q. Do you believe Dr. Brecker could contact people at Edwards Lifesciences to obtain further information about Walther?
A. He could if he so wished. I don't know why he would.
Q. You understand he's an expert in litigation retained by an opposing party, don't you?
A. Yeah, I understand that. But I --
Q. And you understand, therefore, that he

can't just pick up the phone and call just anyone at Edwards Lifesciences; correct?

A. Well, he could, but I'm absolutely he sure he wouldn't have. And --

Q. You understand that would be ethically improper; correct?

A. Yes. In the context of the litigation --

Q. Okay.

A. -- he wouldn't be doing it to obtain anything. But, you know, he is as capable as I am of ringing up a company outside litigation and asking for information.

Q. You got to just answer the questions I ask. I think you answered my question. Let's move on.

Now, you'll see Walther references a Model 9000 MIS; correct?

A. Yes. He does in the abstract, yes.

Q. And did you ask Edwards for samples of the Model 9000 MIS?

A. No.

Q. Do you believe that Dr. Brecker had asked Edwards for samples of the Model 9000 MIS?

MR. SUMMERS: Objection. Form.

THE WITNESS: He could ask --
BY MR. LOWENSTEIN:
Q. In the context of litigation, do you believe Dr. Brecker could pick up the phone and ask Edwards for samples of the Model 9000 MIS?
A. In the context of litigation, he wouldn't do that, because, as you've already said, it would be ethically suspect because he is acting for AI.
But in other contexts -- you're asking just a very general question --
Q. I'm talking about in the context of this case.
A. All right. Well, then no, if you're just asking about the context of this case. But I didn't remember you saying that in the question.
MR. LOWENSTEIN: Now, let's go back to the bird's-eye view in Figure 1, and let's zoom in again.
Q. Do we see on the inside of the frame, the white material, openings that extend through a thickness of the outer cloth?
A. Yes.
Q. Do those openings extend to the outer

frame?

A. Yes.

Q. Show me.

A. If you look at say -- if we go up to the top image, where you can see more of the inside, as I've said. So you go up to the upper quadrants, and if you look, for instance, at 11:00 o'clock, if you see the bright reflection of the frame where there's sort of five lines -- or what I see as five lines up it, immediately to the right of that there is a gap which is extending into the frame.

Yeah, someone's putting a cursor -- or was putting a -- they've moved it down, but quite close to where I see a gap. I see fuzzy bits coming in, and then a gap, and then more fuzzy bits coming in.

Q. Can you see the outer frame through this white material?

A. I can see the outer frame at the top. The outer frame looks variously bright light or dark black, depending on the light reflecting off it. So I can see the frame all the way around, around the --

Q. Do you see the frame through the cloth?

A. No, you can't see the frame through the cloth.

Q. Okay. Now, I want to go to the area between 12:00 o'clock and -- I'm not sure. I guess that would be between 1:00 and 2:00 o'clock. And you see there there's the attachment for the pericardium, and then there's two apices to the right.

Do you see the two apices to the right?

A. The apices -- so now where there's almost a sort of little oval, like, bright white reflection, yes, they're the two apices.

Q. Okay.

A. It goes apex, trough, apex. So I'm saying if you look at the commissural bar --

Q. Yeah, so I think there's an apex and a trough.

So could you highlight what we're --

THE WITNESS: Yes, there's a trough and an apex.

MR. LOWENSTEIN: Can you highlight from here to here.

Q. Okay. You see this section that I'm highlighting?

A. Yes. That goes apex, trough, apex. So

that --

Q. Okay. Very good.

So we're starting with the first apex to the right of 12:00 o'clock.

A. Yes.

Q. I'm going to ask you about the white material on the inside of the outer frame between those two apices.

Are you with me so far?

A. I am.

Q. Can we see the sutures from the Sapien inner skirt on the inside of the outer frame?

A. Yes, I think you can see the three sutures -- so if you look down into the gap between the valve leaflet, the pericardium, and the white material, you can see three very uniform bubbles between the apex and the trough, and I think they are three of the stitches that attach the inner material, the inner skirt, to the frame.

Do you see -- they're very clear, I think.

Q. Well, let's be more specific, because I'm not sure exactly what you're referring to.

I want to start with the first apex

just to the right of 12:00 o'clock.

A. Got it.

Q. Let's just focus on the area -- let's follow the bar frame down towards the troughs.

I just want you to highlight, Will, this area.

THE WITNESS: Yes.

BY MR. LOWENSTEIN:

Q. Do you see this area that I've highlighted -- or Will has highlighted?

A. Yes. That area -- so exactly in that area I can see three stitches, which I am certain are the attachment of the inner cloth to the frame, and they are -- they're not the top, much larger number of things sticking in; they are further down. They are three stitches that you can see exactly in that square you highlighted briefly, and they are attachments of the inner skirt to the frame.

Q. And just to be sure, you'll recall that the cells resemble diamonds, and we're looking at a bar that's going downwards diagonally.

Are we referring to sutures that are attached to that bar?

A. Yes, you're saying sutures attached to

that bar -- you're saying the sutures which are attaching the inner skirt to the frame to that bar you're speaking about.

Q. Now, if we go downwards from the sutures, are we looking at the Sapien inner skirt?

A. Yes, there you are.

Q. Okay.

A. And the reason you can see it up here on the top is because, as I've explained, the view is off center. You are seeing far more of the inside than you are when you look at the lower quadrants, where the camera lens is almost lined up with the frame down at 6:00 o'clock so you're looking straight down the frame.

Here you're looking slightly in, and that's why you can see the material of Walther's cloth. And then you're looking down, and you can see the stitches, and you can see what I'm certain is part of the inner skirt.

Q. Now, focusing just upon the inside of the outer frame, the white material between the first and second apices to the right of 12:00 o'clock, is all of the whitish material that we see the sutures for the Sapien inner

skirt and the inner skirt material?

A. I'm sorry. I'm lost with what you're asking me. Can you repeat that again.

Q. So you see there's a --

A. Which segment are we looking at first, so I'm looking at the same bit.

Q. We're looking at the same section we were talking about.

A. Okay.

Q. We're talking about --

A. Got it. Now I forget --

Q. -- starting at 12:00 o'clock, we're talking about the first two apices that we --

A. Sorry. This is confusing.

Starting at 12:00 o'clock, you would be much further over. That's where the -- at 12:00 o'clock, that's where the commissure is.

Q. Yeah. I'm talking about the first two apices to the right.

A. Yes. But you said "starting at 12:00 o'clock." If someone just highlighted the --

Q. What I'm trying to say is I'm starting at 12:00 o'clock to orient you, and then I'm talking about the two apices to the right.

A. Okay.
Q. So I'm not asking you about 12:00 o'clock. I'm trying to identify the apices relative --
A. So we're talking about 1:00 o'clock to 2:00 o'clock?
Q. Roughly. Roughly.
A. Roughly, I mean.
Q. Okay. I think that's a fair description. I think that's where we've been talking about in the last several questions, I think.
Is that fair to say?
A. Okay.
Q. Okay. So starting now with the apices at 1:00 and 2:00 o'clock, and I'm asking you about the white material that is on the inside of the outer frame.
Are you with me?
A. On the inside of the frame, yes.
Q. Okay. And we see both Sapien's inner skirt --
A. Yes.
Q. -- and the sutures for the inner skirt attaching it to the outer frame; correct?

A. Yes.

Q. Do we see any fibers from the outer cloth on the inside of the outer frame in this section?

A. You undoubtedly do, but I don't think that poking in is as clearly seen as when you get down to sort of closer round to 3:00 o'clock, because they're --

Q. You're seeing the sutures fairly clearly here; correct?

A. You can see the sutures because sutures are much larger than -- I mean, sutures are way bigger than fibers.

And you are seeing what I take to be some of the material, but it is poking in under the strut, where you see it very white. It looks fairly bright white above the internal skirt.

Q. Now, you agree that the outer cloth extends vertically higher than the sutures for the inner skirt; correct?

A. It does, yes. And so there's a bare space in which Walther's outer cloth can poke through because there is no inner cloth there.

Q. And yet you agree that we can see the

sutures clear as day without any -- without being blocked out by inwardly facing fibers made out of cloth; is that correct?

A. Well, the stent is coming -- because you're at this angle --

Q. Wait, wait, wait. Just answer my question.

Simple question: You agree that we can see the sutures for the Sapien inner skirt clear as day between the apices at 1:00 and 2:00 o'clock without being obscured by fibers from the outer cloth; correct?

A. Yes. And that's --

Q. That's it. That's it.

A. I think I'm --

Q. No, no. That's --

A. You're not letting me finish answering your question.

Q. I asked you a yes-or-no question. You answered it.

A. It is not a yes-or-no question.

Q. Yes, it is. If you want to do redirect, you can do redirect with your counsel later, which will allow me to cross -- will allow our discussion to continue even further.

A. Excellent.

MR. LOWENSTEIN: Let's show Exhibit 2100.

Okay. Let's just go down a little bit.

Q. Okay. Do you see in front of you there's a document that we've marked as Exhibit 2100?

A. I see.

MR. LOWENSTEIN: Okay. Let's go to the first image, please.

Q. Do you recognize the valve that we're looking at?

A. Do I?

Q. Do you recognize the valve that we're looking at?

A. It looks like an Ultra. It looks like a Sapien Ultra.

Q. Would you agree that the outer covering that we see here is free of an outer graft covering?

Let me ask you this: Do you see that the material on the outside, the white material, is free of an outer graft covering?

MR. SUMMERS: Objection. Form.

THE WITNESS: I haven't looked at it or

analyzed it. The Sapien 3 Ultra is not part of this case, as far as I know.

BY MR. LOWENSTEIN:

Q. I'm asking you to do it right now.

A. I can't. This is a photograph of it. I've not examined it or looked at it --

MR. LOWENSTEIN: Let's zoom in?

THE WITNESS: -- to be able to answer these questions.

MR. LOWENSTEIN: Let's zoom in -- let's be helpful. Let's zoom in.

Q. Can you see it better now?

A. I can see it better, yeah.

Q. Okay. Can you determine from the image that we're looking at whether the white material is free of an outer graft covering?

A. No.

Q. Why not?

A. Because I can't. You can't do it from just looking at that photograph.

Q. So it might be free of an outer graft covering; correct?

MR. SUMMERS: Objection. Form.

THE WITNESS: I said I can't tell from the photograph. It might; it might not.

I haven't done this analysis. I haven't examined any Sapien 3 Ultras for a long time, I haven't examined them for any purpose for this case, and I haven't got an opinion about it.

Q. So I'm just asking: Based upon your looking at this photograph, you can't tell one way or the other whether the white material is free of an outer graft covering; correct?

A. Right. I've said I can't tell from this photograph.

Q. You would agree that the white material is translucent; correct?

MR. SUMMERS: Objection. Form.

THE WITNESS: No. I mean --

BY MR. LOWENSTEIN:

Q. You don't see the bars through the white material?

A. Bars? You can see something I can't on this image. No, I can't.

Q. It's amazing how your vision comes and goes, because I can clearly see the bars of the stent.

You can't?

A. I can't clearly see them. I can see

some areas that probably has darkness for bars. So I can't clearly see the design of the stent.

Q. It's amazing, because I thought you could see parts of visual spectrum that were not available to normal humans when you sussed out the outer graft covering in Walther's Figure 2.

And yet you can't see the clear bars that are clear as day to everyone on this call?

MR. SUMMERS: Objection. Form.

THE WITNESS: Perhaps my monitor's not as good as yours here.

But no, I'm answering your questions. I can't.

MR. LOWENSTEIN: Okay. Let's help the good doctor again. Let's zoom in towards the middle between --

Q. You'll see that this is a Sapien 3 Ultra valve that's being held between two human fingers?

A. I can see the fingers.

Q. Okay. Now, I've zoomed in to just about the middle.

A. Yeah.

Q. You don't see the bars of the outer frame through the white material?

A. No. I mean, there may be odd places where I can see darkness, where it's darker, but I can't clearly see the bars of the frame through it.

MR. LOWENSTEIN: Okay. Let's zoom back just a little bit, just to the last image that we had.

Q. Okay. Does the outer surface of the Sapien 3 Ultra outer cloth have openings?

A. Sorry --

Q. Openings.

MR. SUMMERS: Objection. Form.

THE WITNESS: Yes. It's a bubbly outer surface. I mean, the image you're showing me doesn't even seem to be fully focused, but the outer surface is clearly not smooth.

BY MR. LOWENSTEIN:

Q. So it has openings?

A. Yeah.

Q. Okay.

A. It has indentations, as I said before. But it's not very finally focused. I can't see individual fibers. It's clearly not a smooth surface. But it really doesn't seem to be a very sharply focused image.

Even the frame above doesn't seem to be in focus on what I'm looking at. It looks as though the frame's out of focus.

Q. Does the outer edge of this white material that we see in the Sapien 3 Ultra, are the openings -- do they extend through the thickness of the outer surface?

MR. SUMMERS: Objection. Form.

THE WITNESS: If they're undulations, yes, they -- absolutely they extend. I can't tell from this photograph, and I can't give you dimensions, as you'll understand, but there are depressions, which you can call openings, and they extend a distance.

It's a rough surface. I can see there is a rough surface even though it's somewhat out of focus.

BY MR. LOWENSTEIN:

Q. Do the fibers define an opening that is created by spacing formed between adjacent fibers?

A. I don't know. As I said, I can't see the fibers. So I can't see individual fibers, so I can't see adjacent fibers.

Q. So you can can't tell in the image that

we're looking at whether the fibers define an opening that is created by spacing formed between adjacent fibers?

A. As I can't see individual fibers, I cannot answer anything about the adjacent fibers, because you would have to be able to see the fibers and adjacent fibers to answer that question.

Q. Okay. We're zoomed in at 300 percent here.

Would you like us to zoom out or zoom in?

A. As I've said, what I'm looking at, the image quality is not great, it's not very in focus, even the frame is not very clear above, and I can't see individual fibers. So I can't answer questions about what's happening between adjacent fibers, because I can't see even one fiber.

Q. Well, I want to make sure we get your clearest possible testimony about what this image shows.

Would you like us to zoom in or zoom out?

A. I don't think it's going to help, but

you can zoom any way you think.

You're asking the questions. I will do my best to answer your questions whether you zoom in or zoom out.

MR. LOWENSTEIN: Well, let's zoom out. Let's try it both ways.

Q. Okay. So now we're looking at it at 150 percent, according to Adobe at least.

Okay. At this level of zoom do the fibers in the Sapien 3 Ultra define an opening that is created by spacing formed between adjacent fibers?

MR. SUMMERS: Objection. Form.

THE WITNESS: I can't see individual fibers. I can't discern adjacent fibers. I can't answer the question.

BY MR. LOWENSTEIN:

Q. Okay.

A. It looks as though it's very wet, too. It's going to be -- I mean, part of the reason why it appears like it does is because it looks as though it's a very, very wet device. I'm judging that, really, from the reflection of the person's gloves.

Q. Do you see a inner surface of white

material?

MR. SUMMERS: Objection. Form.

THE WITNESS: On this photograph?

BY MR. LOWENSTEIN:

Q. Yes.

A. No, I can't see it. Because this is looked at essentially straight, side-on, I can't see easily an inner surface. It hasn't got enough angulation to judge the inner surface, either the top or the bottom.

Q. Do the fibers on the inner surface on the white material -- and by "inner surface," I mean the surface facing the outer frame.

Do those fibers define an opening extending through a thickness of the white material?

MR. SUMMERS: Objection. Form.

THE WITNESS: I can't see them. I haven't analyzed this. I've never seen this photograph before. It's not a good enough quality to even see individual fibers. I cannot see any individual fibers.

BY MR. LOWENSTEIN:

Q. Do the fibers on the inner surface of the white material have openings that extend to

the outer frame?

MR. SUMMERS: Objection. Form.

THE WITNESS: I can't answer that. I can't see any individual fibers, and I can't see any of the inner surface.

MR. LOWENSTEIN: Okay. So let's zoom in.

Where were we at before? 300? Let's go to 400.

Q. Okay. So we're now at a 400 magnification. Previously we had done 300 and also 150.

Do any of your answers to any of my previous questions change?

A. No. The image quality is now awful. It's completely out of focus, even the person's fingers. Like, in the frame there's -- and it doesn't help at all.

I can't discern -- it's the underlying quality of the photograph, not the magnification, that's helping. So this doesn't alter anything that I have said to you.

MR. LOWENSTEIN: Let's go back to 100.

Q. So your testimony is the photograph we see on Exhibit 2100 has insufficient resolution

for you to testify knowledgeably about the white material we see around the valve?

A. No, I just -- all the answers I've given you I stick to. I can see that it's a rough surface. I can see there are indentations on it. I can't see individual fibers. It looks as though it's very wet. So the fibers, even if they are there, may be stuck down.

But the resolution of the photograph is such that I doubt, even if it was dry, I would be able to see individual fibers.

MR. LOWENSTEIN: Let's go to the next page.

Q. Dr. Buller, we're now on page 2 of Exhibit 2100.

Is this a separate image of the Sapien 3 Ultra?

A. I think it's more out of focus than the last one. But yes, it's now on the palm of someone's hand, so it's a separate image, and it looks to me to be a Ultra.

But again, I have no knowledge of this. I haven't seen these photographs before. I've not analyzed the Ultra. I have not thought about the Ultra in the context of this IPR.

Q. Could we agree that this Ultra does not appear to be wet?

MR. SUMMERS: Objection. Form.

THE WITNESS: I can't tell. It's not -- I mean, the person's hand, it does not appear to be wet. But if it actually is an Ultra, it's probably come out of a bottle and was wet. But I can't tell from this image.

But certainly the last one I could see glistening on the person's gloves. This is on someone's hand with no glove. I don't see any evidence of fluid on it, but that's about as far as I can say.

BY MR. LOWENSTEIN:

Q. Can we agree that the white material in this second image on page 2 of -- the image on page 2 of Exhibit 2100, can we agree that the white material is translucent?

A. I can --

MR. SUMMERS: Objection. Form.

THE WITNESS: I can see through it a little bit more of the image of the frame, more than I could on the last image, but still it's not -- it's not clear. I wouldn't like to trace out the geometry of the frame if I didn't have

fairly good knowledge already of the geometry of the underlying frame, which is the same as Sapien 3, the same frame.

BY MR. LOWENSTEIN:

Q. We can agree, however, that it would be inaccurate to describe the white material on this valve as opaque?

MR. SUMMERS: Objection. Form.

THE WITNESS: Well, no. I think it is -- I still think opaque is -- you're not seeing clearly through it. I mean, it's not like looking through glass. It is significantly opaque.

BY MR. LOWENSTEIN:

Q. Would it be more accurate to say it's translucent?

MR. SUMMERS: Objection. Form.

THE WITNESS: To a degree. But with all these things, there's -- you've got to sort of quantify it. I can't see anything clearly through it.

BY MR. LOWENSTEIN:

Q. You know, when you say "significantly opaque," it's like when I hear young people say "significantly unique." It's either one of a

kind, or it's not.

And "opaque" means you can't see through it; correct?

A. "Completely opaque" means you can't see through it. I can't see --

Q. No, no, no, no. "Completely opaque" --

MR. SUMMERS: Objection --

BY MR. LOWENSTEIN:

Q. -- means you can't see through it; correct?

A. Yes.

Q. And "translucent" means you can see through it, but it's not with clear visibility, let's say; correct?

A. I think that's not unreasonable.

Q. Okay. And "transparent" is you can see through it; correct?

A. Yes. Again, you know, there are degrees of even transparency, but yes.

Q. Okay. And as between transparent, translucent and opaque, which of those three terms most accurately describes the white material on page 2 of Exhibit 2100?

MR. SUMMERS: Objection. Form.

THE WITNESS: I can see something

through it, an outline, but it is not clear at all and not in any detail, and I can only see it on the sort of front surface facing me.

BY MR. LOWENSTEIN:

Q. You're not able to answer my question?

A. No.

Q. So you can't tell me whether the image we see on page 2 of Exhibit 2100, whether that is best described as transparent, translucent or opaque; is that fair to say?

A. No. I mean, of the three, the middle one is better. I mean, it's not completely opaque, as we've already established, and it's certainly not completely see-through. It is somewhere in the middle, but the -- what I'm seeing through it is extremely fuzzy.

Q. So I'm not sure I quite understood your answer.

Is it fair to say that "translucent" is a better descriptor than "opaque"?

A. Yes.

Q. Okay. Good.

A. But I never looked at this document, never looked at these images. I don't know how they were taken. I do not know that it actually

is an Ultra. I mean, it looks to have features of an Ultra, but I have no idea of the elements of whatever it is or, indeed, whose hand it is or how it's being treated or what's happened to it.

MR. LOWENSTEIN: Let's zoom in.

Q. Can you see an opening on the outer surface of the white material?

A. Again, it doesn't look smooth. So there are dimples, undulations, and exactly the same answers I gave you on the previous image. It doesn't look to be a smooth surface, and, therefore, there are at least shallow openings in it.

Q. And do the openings extend through a thickness of the material?

MR. SUMMERS: Objection. Form.

THE WITNESS: Of course if they are depressions and it's not a smooth surface, they must go into a certain depth, by definition. If it is not a smooth surface and there are dents and dimples and a rough surface, it must have a certain depth to those.

BY MR. LOWENSTEIN:

Q. Now, is the opening defined by spacing

formed between adjacent fibers?

A. I can't see individual fibers, so I can't --

Q. Would you like us to zoom in further?

A. It's not going to help. I cannot see individual fibers on the image I've got on the monitor in front of me.

Q. Would you like me to zoom out?

A. No. I'm not going to -- I don't think it's going to help. You can try if you wish to -- you're asking the questions -- but I don't think I'm going to be able to see individual fibers and answer questions about what's happening between adjacent fibers.

Q. Now, looking at this image, and with reference to the side of this white material that's facing the frame, are there openings on that side of this material?

MR. SUMMERS: Objection. Form.

THE WITNESS: I may not be understanding your question, but, I mean, the openings I'm talking about are on the outer surface, because this is --

BY MR. LOWENSTEIN:

Q. Yeah, I'm asking about the openings on

the inner surface.

A. I can't see the inner surface.

Q. Do you know whether there are openings on the inner surface?

A. No. I mean, I can't see any of the inner surface. So this photograph doesn't help me.

Q. Why can't you tell whether there are openings on the inner surface?

A. Because I can't see any inner surface.

Q. So you would need to be able to see openings in the inner surface to determine whether there are openings; correct?

A. Well, as I haven't done any analysis of this document or this device and I don't know for certainty what it is, where it comes from, how it's treated, I can't give you -- I can't even see any of the inner surface, and I haven't done any analysis of Ultra.

Q. The openings that may or may not exist on the inner surface of this white material, do they extend through a thickness of the material to the outer frame?

MR. SUMMERS: Objection. Form.

THE WITNESS: Since I can't see any, I

can't answer. If you're asking me to answer these questions off this image, I cannot.

BY MR. LOWENSTEIN:

Q. Because the image is not clear enough?

A. Well, because even if it was clearer, I wouldn't be able to see the inner surface. I can't answer questions about the inner surface off an image that doesn't show any of the inner surface.

MR. LOWENSTEIN: All right. Let's bring up Exhibit 1011, and let's go to Figure 22.

Q. Dr. Buller, I'm sure you're very familiar with this image, and you can see that we're looking at Figure 22 of Spenser II; is that fair to say?

A. Yes.

Q. You agree that from this image you cannot see the inside surface of layer 256; correct?

A. From the image, no, you can't. You can just see a top edge of it. I mean, you can see the inner circle. So you can see that just tiny bit of the top, which appears just to be a concentric circle.

Q. Does that bit that you see at the top, does that provide any insight to you about the --

A. Because this is a patent -- we're not talking about a photograph now. This is a patent. All it's representing is the position of the compressible material that Spenser teaches -- Spenser II teaches.

Q. Would you agree that Spenser II does not describe fibers on the inner surface of layer 256?

A. No. Spenser does describe fibers on the inner surface of this material, this compressible --

Q. You would agree that it refers to fibers on the surface, but it doesn't refer to the inner surface; correct?

A. No. But when it wants to refer to an individual surface, it does. In the same paragraph that it says "fibers on the surface," later when its talking about adding a growth factor, it talks about the outer surface.

So it is very clear that when Spenser says "fibers on the surface," he is not limiting it to one surface. He's talking about both

surfaces. Because when he wants to limit it to one surface, he does so. It's in the same paragraph as the disclosure about...

Q. Oh, I'm very familiar with that paragraph.

A. I'm sure you are.

So Spenser, when he wants to talk about one surface, does so. When he's talking about the surface, I mean, everybody, including myself as a person of ordinary skill in the art, would know that there's an inner and an outer surface, and there'll be fibers on both.

And, I mean, obviously with Figure 22, if the material wraps all the way around the back, you'd expect there to be fibers on the back as well that you can't see on the image -- on the patent drawing.

Q. So if I were to reference the surface of my car, you would understand me, for example, to not just refer to the exterior surface of my hood but also the interior surface; is that correct?

A. I'm not talking about cars. I don't --

Q. Well, I am. I just want to -- I want to understand.

So if I referred you to the surface of my car, you would understand me to refer, for instance, not only to the outer surface of my hood but also the inner surface?

A. It would depend on the context.

Q. Because when people refer to "the surface," you would agree sometimes they mean the outer-facing surface; correct?

MR. SUMMERS: Objection. Form.

THE WITNESS: Depending on the context, they might. But Spenser makes it absolutely clear that he differentiates between -- if he wants to say the outer surface, he says so, as he says a couple of lines lower, than saying "the surface."

He's not limiting the fibers to being on the outer surface. He's teaching that they are on the surface of the compressible material, and clearly it has inner and outer surfaces.

BY MR. LOWENSTEIN:

Q. Would you agree that outwardly extending fibers may facilitate attachment to native leaflets?

A. Yes. They may encourage sort of blood coagulation and tissue ingrowth, which help to

attach things. Blood clotting and tissue ingrowth help to attach things.

Q. Now, is there human tissue between -- well, let me ask you this: Are the native leaflets touching the outer surface of Spenser II's outer cloth?

A. There are no -- this diagram is just of the device. There are no --

Q. Okay. Let me rephrase it.

Would you agree that the outer surface of layer 256 is intended to contact either the leaflets or the annulus?

A. Well, the annulus extend -- the leaflets extend from the annulus. So yes, it will undoubtedly -- if it's put into a human valve, it will touch human tissue in the form of leaflet material.

Q. Would you agree that the inner surface of Spenser II's 256 -- that the leaflets or annulus are not interposed between the inner surface of the outer cloth and the outer frame?

A. The native leaflets are not interposed between the frame and the outer cloth, correct.

Q. And would you agree that a person of ordinary skill in the art may find a surface

advantageous when attaching to native tissue but less advantageous or not advantageous when connecting to a metal frame?

MR. SUMMERS: Objection. Form.

THE WITNESS: No. Because one of the main purposes for having the increased surface area with all the fibers is the blood clotting, which helps to seal up paravalvular leaks. And this is specifically put there, just like in Walther, to prevent paravalvular leaks. [Garbled.]

(The reporter requested clarification.)

THE WITNESS: The reason for having the increased surface area with all the fibers is to get blood clotting through the thickness of the cloth to help prevent paravalvular leakage, so that the increased surface areas with all the fibers matters all the way through to the frame.

BY MR. LOWENSTEIN:

Q. You would agree that a plausible interpretation of Spenser II is that the compressible material includes a plurality of fibers extending outward from the outer surface?

A. It does. It doesn't have to have. He teaches the fibers as being, you know, one of

the options for the compressible material having them, but it teaches fibers on the surface that would be the inner and outer.

Q. Okay. I want to direct you to claim 29 of Spenser II.

A. Yes.

Q. And we can see --

A. Can I see claim 29? Because I --

MR. LOWENSTEIN: It's 44 and 45 of the PDF.

Q. Okay. So we agree in claim 29 it's claimed that the compressible material includes a plurality of fibers extending outward from the outer surface; correct?

A. Yes.

Q. Is there a claim that refers to fibers extending from the inner surface.

A. No, because this is talking about the grace factor and saying the grace factor --

Q. I'm just asking a yes-or-no question: We can agree there's no claim that says the fibers extend from the inner surface?

A. I haven't looked at all the claims. You're asking me to look at something -- I can only see -- on the screen you put in front of

me, I can only see claim 28 and 29. Those clearly --

Q. Okay. Let's help you out.

Will, can you do a Control-F for the word "inner."

A. I'll take your word for it if you say. What I'm saying is I just can't see the claims, and you're asking me a question about all of them.

Q. Okay. So you're not aware of any express disclosures -- I'm not talking about your inference.

You're not aware of any express disclosure concerning fibers extending from the inner surface of the compressible material; is that fair to say?

MR. SUMMERS: Objection. Form.

THE WITNESS: I consider the disclosure of them extending from the surface to cover the inner surface. So it isn't --

BY MR. LOWENSTEIN:

Q. No, no, no, no, no. I'm not asking for your inference. I said "express disclosure."

Is there any express disclosure that says that?

Because we see in claim 29 it refers to the compressible material, including a plurality of fibers extending from the outer surface.

It doesn't say the inner surface, you would agree; correct?

A. Correct.

Q. Okay. And the only thing you're pointing to is something about the surface, but there's no express disclosure about the inner surface; correct?

A. Right, there is no -- if by that you mean a specific statement that fibers are on the inner surface, there is a statement that covers the inner surface about fibers being on the surface.

Q. I'm not asking for your interpretation. I'm just asking you about an express disclosure.

So let me ask it again: You would agree there is no express disclosure about fibers extending from the inner surface of compressible material 256; correct?

A. No, because my opinion is that the disclosure is an express disclosure.

Q. Okay. No, no. Because you're making an inference. You're making your inference as

to what you understand it to mean.

I'm not asking about what you believe. I'm asking about what it expressly says unmistakably, without editorialization.

A. I don't think --

Q. I think you've already answered the question, but I'd like you to just answer it cleanly without putting in what you think is helpful, because you need to answer my questions.

MR. SUMMERS: Objection. Form.

BY MR. LOWENSTEIN:

Q. So just answer my question.

You admit that there is no express disclosure of fibers extending from the inner surface of the compressible material; correct?

MR. SUMMERS: Objection --

THE WITNESS: No. I regard the disclosure of fibers from the surface to include the inner surface. That is my opinion.

BY MR. LOWENSTEIN:

Q. So if I refer to the surface of my car, that necessarily refers to both the outside of the hood and the inside of the hood; correct?

A. So it depends on context. I'm not

talking about your car. I'm talking about this disclosure about a medical device and about the characteristics of the --

Q. So let's say I get a wax job on my car, and they say, "We're going to cover the surface of your car." I should get angry because "Wait a minute. You didn't wax the inside of my hood. What's going on? I've been cheated."

Is that what I should -- is that how I should react?

MR. SUMMERS: Objection. Form.

THE WITNESS: No.

BY MR. LOWENSTEIN:

Q. Because that's absurd; right?

Everyone knows the surface, at least in that context, refers to the exterior surface; correct?

A. It depends on context. I'm not talking about or giving an opinion about your car. I'm giving an opinion about a patent disclosure about having fibers on the surface, and that is an express disclosure of fibers on the outer and inner surface of the material that Spenser II is talking about, to my knowledge.

Q. How about in the context of a patent

with a claim that expressly says "a plurality of fibers extending outward from the outer surface," where I can see those outward fibers in Figure 22 and yet I see no express description of fibers from the inner surface and I don't see the inner surface?

Could a reasonable interventional cardiologist conclude that Spenser II doesn't say anything about the inner surface of compressible layer 256?

MR. SUMMERS: Objection. Form.

THE WITNESS: No.

BY MR. LOWENSTEIN:

Q. No interventional cardiologist could honestly disagree with you?

MR. SUMMERS: Objection. Form.

THE WITNESS: I don't think so, no. The express disclosure of having fibers on the surface covers the inner and outer. They are the surface.

BY MR. LOWENSTEIN:

Q. Just like the inner and outer surface of the hood of my car.

That's the surface; correct?

A. No. Because it's to do with context.

Q. So I just want to make sure: If Dr. Brecker says, "I've looked at Figure 22. I see fibers on the exterior. I know that fibers are used in contact with native tissue, and I know that Figure 29 of Spenser II specifically refers to outwardly extending fibers on the outer surface," and if he were to conclude, based upon that evidence, that Spenser II doesn't say or show anything about the inner surface of compressible material, you would conclude that he's lying?

A. I'm not concluding anything about Stephen Brecker lying. I do not believe he would lie. I hope he wouldn't lie.

What I am doing is giving you my opinion, having --

Q. I'm not asking about your opinion. I asked you if a reasonable interventional cardiologist could reach a different conclusion based upon the evidence we just discussed.

A. I don't think an objective interventional cardiologist who's skilled in this art would have a different opinion. Spenser clearly teaches that you can have fibers on the surface, and that includes both the outer

and inner.

Q. Are you aware of any aspect of Dr. Brecker's testimony in any of these cases where he has said anything that you think is dishonest?

A. No. He's got --

Q. Okay. You answered the question.

Have you seen anything from Dr. Brecker's analysis that you believe was not careful and well thought through even if you ultimately disagree with him?

A. Yes.

Q. What?

A. The reflection of light off the frame. As I've already mentioned, because you were showing me various similar images to the ones he relied on, he has an analysis of Walther, and his analysis concludes that there is a dense inner layer on the fabric, and I think he's completely wrong.

I think it is quite clear that it is light reflected off the edge of the frame. My opinion is entirely different. I think he is completely mistaken on that, and I hope he will have another look at it.

Q. Now, aside from that, anything else?
A. I can remember that one because I've already spoken about it. I'm sure there are other things, but as I sit here, I can't remember them.
Q. As you sit here, you can't remember anything elsewhere where you believe Dr. Brecker's account was dishonest or mistaken?
A. I didn't say it was dishonest. I said he is mistaken by his interpretation.
I didn't suggest for one minute that he's being dishonest. I'm saying that his interpretation I believe is wrong, and I hope he'll have another look at it.
MR. LOWENSTEIN: Why don't we -- it is almost lunchtime on our end. Can we break for, let's say, one hour and reconvene at -- well, in one hour.
So it's 11:51 on our end. 12:51 on our end? Does that work for you-all?
MR. SUMMERS: This is Crag. So, you know, it's not lunchtime here. You know, we're doing this at an hour that -- we're in different time zones. It's not our lunchtime here. I'd like a shorter break.

I don't know if you guys can eat a little faster, because, you know, it's kind of getting late in the day --

MR. LOWENSTEIN: We can go off the record, Audra.

(Recess from 11:51 a.m. to 12:08 p.m. PST.)

MR. LOWENSTEIN: Let's put up Exhibit 2026.

Q. Okay. Dr. Buller, do you see a document that's been marked Exhibit 2026?

A. Yes. Again, I can't see the exhibit number, but yes, I'm familiar with it.

Q. Do you see it at the bottom in the footer.

A. No. I can't see the bottom.

Yes, now I can.

Q. Okay. So let's go to page -- well, you see the document is titled "Sapien 3 Ultra Valve First-in-Human Experience"?

A. I do.

MR. LOWENSTEIN: Okay. Let's go to page 8.

Q. Okay. Do you see that there's an image of the Sapien 3 fabric skirt on one side and the

Sapien 3 Ultra skirt on the other?

A. I do.

Q. Okay. And how were these images taken?

A. I don't know. They're some form of photography, I'm guessing. I don't know whether they're CGI or that.

But, I mean, again, I haven't studied this, because I've had no reason to study the Sapien 3 Ultra. But they may be photographs, they may be CGI, and just -- I can't tell.

Q. Does -- looking at the Sapien 3 Ultra image, do you see a graft covering?

A. Do I see a...

Q. Graft covering.

MR. SUMMERS: Objection. Form.

THE WITNESS: Well, of the two images there, one will be much less porous than the other, perhaps to a certainty, but how nonporous it is I don't know. The one -- I'm talking about the image on the left.

BY MR. LOWENSTEIN:

Q. You can't say whether the Sapien 3 Ultra discloses or doesn't disclose a graft covering?

A. I haven't analyzed -- as I said a

number of times, I just haven't analyzed or looked at or thought about or inspected or anything the Sapien 3 Ultra. I didn't know it was relevant to the IPR.

Q. Just looking at the image, you'll see there are many openings in the Sapien 3 Ultra fibers; is that fair to say?

A. You're talking about the right-hand image now?

Q. Yes.

A. Yeah, on the right-hand image there are openings between the fibers.

Q. And would you believe that Sapien 3 Ultra, based upon this image, is leaking?

MR. SUMMERS: Objection. Form.

THE WITNESS: It depends what you mean by -- the fabric would not be nonporous on the right for certainty. I mean, it's not nonporous fabric.

BY MR. LOWENSTEIN:

Q. You said "would not be nonporous." That was a double negative.

A. Sorry.

Q. Do you mean to say --

A. Would not be nonporous. No, I said it

right.

Q. Yeah. So is another way to say that "would be porous"?

A. Yeah, it would be a porous fabric on the right for certainty. Because this isn't a very -- this is a -- I'm looking at the little thing that says "Lens times 20," so this suggests to me it's a 20 magnification. You've blown it up on the screen, so there may be more, so I can't judge.

But again, I just don't know the quality of this image, who took it, how it's taken. I haven't looked through this. I haven't analyzed the Sapien 3 Ultra. But what you're showing me is clearly a loose fabric, and there are clearly holes between the fibers. And if the black is behind it, it looks as though on this image holes are going all the way through it.

Q. So do you see a graft covering in the Sapien 3 Ultra image?

MR. SUMMERS: Objection. Form.

THE WITNESS: The left-hand image may be a graft --

BY MR. LOWENSTEIN:

Q. No, no, no, no. I'm asking about Ultra.

Do you see a graft covering in the Sapien 3 Ultra image?

MR. SUMMERS: Objection. Form.

THE WITNESS: Well, I see -- because I don't know which material is on the inside. So no, I don't think that that would constitute a graft covering, because it would be porous.

BY MR. LOWENSTEIN:

Q. Do you see in the Sapien 3 Ultra image openings that extend through a thickness of the fibers?

MR. SUMMERS: Objection. Form.

THE WITNESS: Again, I know nothing about the provenance of the image, and I haven't analyzed it, but the image in front of me has openings that appear to be going all the way through the fabric. But I don't know how this was taken or where it comes from.

BY MR. LOWENSTEIN:

Q. Now, the Sapien 3 on the left, would that be a graft covering?

A. Could be.

Q. You're not sure?

A. Well, no. I mean, it's obviously much tighter weave, it's got a density to it which there isn't on the Sapien 3 Ultra, and it may well be nonporous. But I can't -- I mean, you know, porosity is something that one judges better by measuring porosity rather than the image.

And again, I haven't done -- I haven't done an analysis of Sapien 3. I haven't done an analysis of Sapien 3 Ultra nor Sapien 3. They're not prior art, and they weren't important to me for the purposes of the IPR.

Q. In the Sapien 3 image that we're looking at, do you see openings that extend through a thickness of the fibers?

A. There are openings, because you can see it's not a flat -- it's a woven surface. You can see it's woven with fibers running up and down, vertically and crosswise. There are dimples between them. So that's saying there are openings.

Q. So can you say whether this is a graft covering in view of those openings?

A. No, because I don't think that makes a

difference as to whether it's a graft covering or not. I'm not sure that's relevant to whether it's a graft covering or not.

Q. So you can have a graft covering with openings in it; is that your understanding?

A. They're not openings that make it -- if the openings are large enough that it's then porous, then it's not a graft covering. Because on thing that I think one thing Brecker and I are in agreement on is that the graft covering needs to be dense and nonporous, as taught in the specification.

And this is dense in comparison with the image on the right-hand side. It has a higher density. I think one can see that from the photograph. They're both at the same magnification, as far as I can tell: times 20, times 20. So it is more dense, and it may well be nonporous.

But I would need to do more analysis and check these really are true images and these haven't been CGI'd or altered. Because this looks like a marketing document, and very often the images are not exactly what they appear to be.

MR. SUMMERS: Nathan, while you're thinking of your next question, one of my colleagues on the phone says they're getting a little bit of feedback when you start your questions, and I'm wondering if Will's microphone might be on or something that he can use to address that possibly.

(Discussion held off the record.)

BY MR. LOWENSTEIN:

Q. Now, Dr. Buller, I believe earlier you referred to Walther as leaky or porous, if memory serves.

Do you recall that?

A. Yes. Because it's -- we like -- well, not dissimilar from what we were saying with Sapien 3 Ultra in front of me.

Q. But you agree with me that Walther is opaque, at least from the photograph we saw, whereas Sapien 3 Ultra is translucent, at least from the images we saw; correct?

A. Yes. But as I said when I was talking about Walther, in fact, before you showed me the images, wherever they were from and whoever they were with, of Sapien 3 Ultra, it wasn't backlit. I mean, you can change -- depending on lighting,

you could achieve different things, and I don't know that Walther, taken in a different way, wouldn't be a bit more translucent.

Q. What methodology did you use to determine how leaky Walther's cloth is?

A. My knowledge about the material that he's talking about and the appearance of it, the very light, fluffy, fibrous appearance of it.

Q. You agree that Walther just refers to its outer covering as a PET cloth; correct?

A. Yes, a PET cloth. But just like I've been able to look at the Sapien 3 Ultra, which, as I said, I don't know a lot of things about it, but I can look at that, and I've told you that would definitely leak.

There are images you could look at and you could say it would be leaky, as I've just done for you with the Sapien 3 Ultra cloth in front of me.

Q. Now, you agree that Sapien 3, Sapien 3 Ultra and Walther all have PET coverings; correct?

A. As far as I know, they're all made of PET. As I say, I haven't -- this photograph in front of me doesn't say it's PET, but as far --

I mean, I've got a distant memory of it that it is PET.

And I'll take your -- and as I keep saying, I haven't analyzed Sapien 3 Ultra. I haven't looked at it. The image in front of me doesn't tell me it's PET. So I would much rather look at a document and read things and analyze it if I have to answer questions about Sapien 3.

Q. Now, do you have a sense for whether Sapien 3 -- whether its skirt is opaque or translucent?

A. Again, it would likely depend on the lighting and whether it's wet. Things tend to become more translucent when they're wet. And it depends on the lighting. If it's backlit, you may -- I've never looked at -- again, I haven't analyzed Sapien 3 as any part of this case, and I certainly haven't looked at it from the point of view can I see any of the frame through it.

I haven't looked at it. I didn't know it was relevant.

MR. LOWENSTEIN: Okay. Let's pull up Exhibit 2083.

Q. Now, you'll see we have Exhibit 2083. It's a little bit obscure, but I think you'll see the footer.

A. Yeah.

MR. LOWENSTEIN: Okay. Let's go to page 54, please.

Q. I want you to look at the statement at the beginning of this first paragraph. It says, "In fact, Levi teaches against a tight-fitting outer skirt."

You see that?

A. I do.

Q. Is that statement true?

A. No -- I mean yes. It's not the only thing he teaches. He teaches a tight-fitting outer skirt as well, but one embodiment and part of his teaching is a bulging, loose-fitting outer skirt. But it can't -- that is one of his aspects of his teaching.

Q. Well, I don't think you answered my question, because this statement says, "Levi teaches against a tight-fitting outer skirt."

And the question is do you believe that statement is correct?

A. No. I think Levi teaches various

things, and one of his embodiments is a very loose-fitting, baggy skirt. But that's only one of the embodiments.

If that -- I'm not a lawyer, so I don't know. I mean, "teaching against" -- I mean, he's got an embodiment which is definitely not a tight-fitting skirt, but I wouldn't regard that as teaching against -- as just a cardiologist, a person of ordinary skill, it sounds as though he would be telling you under no circumstances should you, could you, can you have a tight-fitting skirt, and that's not my reading of Levi.

But I'm not a lawyer, and it may be that "teaches against" has a specific legal meaning.

I'm not sure -- what document is this?

Is this a legal document?

Q. Yes. This is Edwards' statements to the patent office.

A. Right. Well, then --

Q. My question is do you believe Edwards should correct its misstatement to the patent office that Levi teaches against a tight-fitting outer skirt?

A. I'm not a lawyer, so I can't give you -- I don't know a definition of "teaches against."

As I've said, Levi has an embodiment that has a baggy, loose skirt, but I don't read it as he's in any sense teaching against saying there's no possibility of having a tight-fitting skirt. But I'm not a lawyer.

Q. Well -- okay. So we can agree that the reference to Levi that you rely upon is an Edwards patent; correct?

A. The Levi patent, that's -- you've raised another good point. I don't know which one that -- there may -- for all I know, there are other Levi patents.

Q. Yes. This is a related patent with almost all of the figures in common.

And so the question is do you believe --

A. I assume because we've got --

Q. Hold on a second. I didn't finish my question. I was getting a lot of feedback, so I wasn't sure I was being clear. Let me try again, and hopefully it'll be clearer.

Is it fair to say that Edwards would

not knowingly make a false statement to the United States Patent Office, particularly concerning one of its own references?

A. I think that's fair. I mean, I don't know internal workings, but I know them to be a very reputable company, and I don't believe they would knowingly make anything.

And also, on my previous question I thought we were talking about the Levi that I know. You've now told me you're talking about some other one that I've never been shown, and I feel that's a bit unfair. I would like to be shown what Levi we're talking about, because if it's talking about a different one --

Q. Well, I'm asking if this statement is true as it applies to the Levi that you analyzed.

A. If it's not -- you just told me it's not about that one.

Q. I understand.

Let's say the statement did concern the Levi you are familiar with, the one that shares 40-some-odd figures with the Levi that's being discussed here and that shares many of the same disclosures.

And the question is, as to the Levi that you're familiar with, is it a correct statement to say Levi teaches against a tight-fitting outer skirt?

MR. SUMMERS: Objection. Form.

THE WITNESS: No. I think I've answered that, because I thought you were asking me about the Levi that I'm familiar with, which is in this case.

I mean, it seems very unfair to me to suddenly put something in front of me about Levi which is a different Levi. I have no knowledge of a different Levi.

BY MR. LOWENSTEIN:

Q. Okay. I want to go down to the sentence starting, "This allows the skirt to lie flat against the outer surface of the frame when it is readily compressed. As the frame is expanding, the portion of the frame between the attachment locations of the skirt foreshortens, thereby creating excess material in the skirt that can buckle outwardly away from the frame."

Do you see that?

A. I see it.

Q. Do you believe that the Levi that you

analyzed has teachings to that effect?

A. Yes. I mean, clearly Levi teaches what it teaches. But as I've said to you in my previous answers, Levi has an embodiment that has a bulging skirt that has excess material.

But I have no knowledge of this other Levi patent, and, therefore, I am -- you know, I would love to see it and be -- know what I'm talking about. Because if this is about something different, I have no knowledge of it.

Q. Sorry. I was on mute. Let me start again.

You see the paragraph on page 52 of the PDF in Exhibit 2083 there's -- at the end of that page there's a paragraph starting "the skirt 18."

Do you see that?

A. I do.

Q. Okay. So that reads, "The skirt 18 in Levi is designed to have excess material between the upper and lower edges of the skirt that does not lie flat against the frame when the prosthetic valve is radially expanded. This allows the skirt to bulge or buckle outwardly away from the frame of the prosthetic valve."

Do you believe those statements would accurately describe your Levi's disclosure?

A. Yes. Again, I'm very confused about this, because it's not talking about my disclosure.

But yes, the Levi that I'm familiar with has an embodiment -- it's not limited to it, but it has an embodiment in which it has a skirt that can bulge out. It doesn't, obviously, always bulge out everywhere and stay away from the frame everywhere. It can, but it depends on the circumstances.

It is -- there's excess material, which allows it to bulge out in places.

Q. Now, let's go to the last sentence on this same page within the same paragraph, starting -- there's a typo, but I think we know what that word means.

So it says, "By buckling outwardly, the skirt" --

A. Where are you reading from?

Q. At the very last sentence.

A. "Levi further discloses"?

Q. No. "By buckling outwardly."

A. But that's not the beginning of a

sentence. That's -- oh, I see. The very last -- on the bottom, "By buckling outwardly, the skirt can" --

Q. Okay. So what this reads is "By buckling outwardly, the skirt can fill in gaps between the frame and the native annulus to assist in forming a seal with the surrounding anatomy."

Do you believe that would be a fair statement if describing your Levi?

A. The word "buckling" is not -- I mean, "bulge" is Levi, "bulges out." You seem to have missed a sentence which talks about fibers.

I just have no knowledge. You're asking me about a patent and disclosure I have no knowledge of.

I wouldn't have described the Levi I know -- because I know the word as "bulge." I'm not familiar with it being "buckling" in there. I'm not exactly sure what it means by that. But I would need to read and analyze the patent. I have no knowledge of this other Levi patent.

Q. Well, I'm not asking you about this other Levi patent.

I'm asking you whether -- and I thought

this was clear. But I'm asking the extent to which these statements are applicable to your Levi, not this other Levi.

A. I wouldn't use the work "buckling."

Q. I'm sorry?

A. I wouldn't have using the word "buckling."

Q. Okay. Yeah, I think that was the question I was about to ask.

Supposing instead of the sentence that we just read, supposing it said "bulging" instead of "buckling" --

A. Yeah.

Q. -- would that correctly characterize your Levi?

A. Yes, I think that's fair.

Q. Okay.

A. Because that's the word I remember. I mean, again, you've not even shown me my Levi, but I remember it teaching about bulging out. I just don't know what they mean by the word "buckling," really. It's --

Q. No, fair enough. Fair enough.

Just one second.

So you agree that Walther discloses

using a 33 French delivery sheath?

A. I think that's right. I mean, I haven't got it in front of me, and I haven't focused, but I think both Walther and Cheung use a 33.

But that was an available catheter to use in patients, and I think Walther used what was -- Walther is clearly a in vitro experiment, but I think he used what was available as a --

Q. You're well aware, of course, that narrower sheaths were also available to deliver, for instance, a Sapien valve at that time; correct?

A. Narrower sheaths were available, but this was a sheath that was used or transapical in that timeframe.

Q. Now, do you recall that you were looking at -- I can show it to you again if you'd like.

You recall in Exhibit 2087 we were looking at a valve that was referred to as Apogee, and do you recall that that valve also had a 33 French crimp?

A. You showed me a photograph that had "33 French" next to it, yes.

Q. Okay.
A. Again, I don't know what that is.
Q. Now, each of these -- each of these references describe a 9000 MIS model number; correct?
A. I don't know. I don't remember seeing that in the Apogee document.
Q. You can take my representation. You can verify it if you'd like, but it's there.
A. Well, I'd like to see the document before I say -- I mean, you know, I'll take your representation if that's saying that they do, yeah.
Q. Are you aware of any 9000 MIS model TAVR that was delivered using anything other than a 33 French delivery sheath?
A. I don't know. I've never -- I've never looked at that. And I haven't taken these code numbers, which I'm sure mean something to Edwards; don't mean a great deal to me.
I think in the last deposition you asked me whether I was familiar with that. I think I said no then, and I'm no more familiar with it now. It's clearly a code number for something to do with these devices, but I don't

know what it codes for.

Q. Do you agree that if you're implanting a TAVR into a person, that you would not use a wider delivery sheet than was necessary?

MR. SUMMERS: Objection. Form.

THE WITNESS: I think as a general statement, that is entirely reasonable, but I don't know that you never would. Because if things are being done operatively, sometimes bigger is better.

You know, if you're talking about doing things percutaneously, you always want as small as possible. But if you've actually got a surgeon opening up things and exposing the apex of the heart, for instance, I don't know that the same is true. You just want to make it easy. They're in control, they have purse strings around that, and they may choose size because they're the surgically in control of it.

So I can't answer the completely general question, but for percutaneous deliveries you always want to use the smallest you could.

BY MR. LOWENSTEIN:

Q. For a transapical approach -- if you're

implanting a TAVR via transapical approach, would you use a 33 French sheath if the valve could be delivered via a 24 French sheath?

A. I don't know. Because obviously more space allows for more movement, more freedom of movement, and you could be measuring things with a sidearm. I just don't know.

Q. Have you ever heard of any transapically delivered TAVR using a larger sheath than what was necessary to deliver the TAVR?

A. I don't know. I can't answer that I'm afraid. I just don't know.

Q. When using a larger sheath -- I have another question. Let me withdraw that.

Are you aware that Edwards had approved the 26 French transapical delivery sheath at the time of Walther?

A. No. I'm not familiar with the approval dates of the transapical devices. I do not have any knowledge about the dates for approval on the sizes.

Q. We can agree that if a 26F Edwards sheath had been approved at the time, it would have been available to the authors Walther and

Cheung; correct?

A. I just don't know. I have no idea.

Q. We can reasonably infer that if a 26 French Edwards delivery sheath was publicly approved, that it would have been available to the authors of Walther, given that five of the six Walther authors were at Edwards Lifesciences; correct?

A. I don't know.

Q. That seems like a reasonable inference, though, doesn't it?

A. Well, no. Because this is a French -- this isn't in a patient and things, and they may have been using up old product deliberately.

I mean, it doesn't seem there was anything about the experiments that Walther did that was the critical thing about the sizes of sheath, and, therefore, they may have been using up available old stock to do the experiment and keep the costs down.

It's a benchtop experiment. It wasn't in a patient.

Q. So you believe that Edwards Lifesciences in a paper with five different authors from their company, they could not spare

a 26 French delivery sheath; that that was just the only one they had available?

That's your -- what you surmise?

A. That wasn't what I said at all. I'm not saying they couldn't spare it. I'm saying there was no necessity.

If they had a 33 available to do a benchtop experiment on the thing, I don't see any disadvantage of using it.

Q. Can you think of any plausible universe in which they also wouldn't have had a 26 French sheath available, assuming it was approved at the time?

A. I really don't understand the question.

I've told you that in a benchtop experiment I don't think the sheath size is of any real consequence, and, therefore, I have no knowledge of why they chose to use the 33, assuming something else was available. I have no knowledge that something else was available, but I have no knowledge about their choice.

Q. You understand that Cheung was delivered in a human being; correct?

A. Right. Cheung was much earlier. I think it was in 2008 that the Cheung device was

delivered. This was to treat a patient.

Q. That was not a bench test; correct?

A. Correct. It was to treat a patient.

Q. And if you were to have a TAVR that could be delivered by a 33 French or 26 French and it was a transapical approach, an interventional cardiologist of skill in the art with experience with TAVRs would have opted for the 26 French; correct?

Because that has the higher likelihood of avoiding complications; isn't that fair to say?

A. They may. I don't know. Because this is done surgically through the apex, and I just don't know.

As I've said to you, I don't know what the decision-making is. I certainly don't know whether a smaller device was available in 2008, a smaller sheath was available. I don't know the familiarity of the surgeon, Cheung, with it. I don't know.

Q. And you have no evidence that suggests that a 9000 MIS was ever crimped down to a 26 French diminution; correct?

A. Correct. And as I've said to you, I'm

not really familiar -- I don't know what devices the 9000 MIS applied to and whether it applied to other devices or whether -- I don't know what the code stands for, the 9000 MIS.

MR. LOWENSTEIN: Okay. Why don't we take a short break, and then I'll determine whether they need a long break.

Is that reasonable to everyone?

MR. SUMMERS: Sure.

(Recess from 12:46 p.m. to 12:52 p.m. PST.)

BY MR. LOWENSTEIN:

Q. Dr. Buller, you were an expert for Edwards Lifesciences in a litigation with Boston Scientific; is that correct?

A. I was.

Q. And was the accused product -- or was an accused product in that case the Sapien 3 valve?

A. Yes.

Q. And through your work in that case, did you become very familiar with Sapien 3?

A. Yes, I think that's fair. I am very familiar with Sapien 3.

But that case was a long time ago. I

mean, many years ago. So -- but yes.

Q. You're aware that there's a district court litigation between Aortic and Edwards Lifesciences that is ongoing; is that fair to say?

A. As far as I know, I'm aware, as I think I told you last time, that there is one that Aortic has sued, but that's the extent of my knowledge.

Q. Okay.

A. I don't have any other knowledge than that.

Q. Are you aware that Sapien 3 Ultra is an accused device in that litigation?

A. Yes, I was aware of Sapien. I think fairly obvious, yeah. I think I was -- I don't know whether I was actually told that, but I kind of worked that out for myself.

Q. Are you now or have you ever been an expert witness or consultant in the district court case?

A. No. I haven't been asked to give any -- I've not seen anything, not been talked to about, other than to tell that Aortic had sued Edwards. They told me that some time ago,

but that didn't come as a surprise.

I can't remember if they told me that it was Ultra, but as I say, I think I worked that out for myself. And I've not been instructed in it or asked to give any advice or look at anything.

MR. LOWENSTEIN: Okay. Unless there is redirect, I have concluded my examination. I thank you for your time, Dr. Buller, and I pass the baton.

THE WITNESS: Thank you very much.

MR. SUMMERS: I have no questions. Thank you, Dr. Buller.

MR. LOWENSTEIN: Thank you all.

And, Audra, should we hold on?

THE REPORTER: I just need your orders.

Do you need this expedited?

MR. LOWENSTEIN: I would like it expedited, if that's okay.

(Discussion held off the record.)

MR. LOWENSTEIN: Would Monday be okay?

THE REPORTER: Yes.

MR. LOWENSTEIN: Okay. Let's do Monday.

MR. SUMMERS: We'd like a copy.

THE REPORTER: And do you want your transcript on Monday as well, Mr. Summers?

MR. SUMMERS: No, I don't think we need it on Monday. I think we're good with getting it a little later.

(At 12:55 p.m. PST the deposition of NIGEL P. BULLER, MD, was adjourned.)

STATE OF CALIFORNIA)
COUNTY OF LOS ANGELES) SS.

I, NIGEL P. BULLER, hereby certify under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed this _____ day of _____, 2022, at _____, California.

_____
NIGEL P. BULLER, MD

STATE OF CALIFORNIA)
COUNTY OF LOS ANGELES) SS.

I, AUDRA E. CRAMER, CSR No. 9901, in and for the State of California, do hereby certify:

That, prior to being examined, the witness named in the foregoing deposition was by me duly sworn to testify the truth, the whole truth and nothing but the truth;

That said deposition was taken down by me in shorthand at the time and place therein named, and thereafter reduced to typewriting under my direction, and the same is a true, correct and complete transcript of said proceedings;

I further certify that I am not interested in the event of the action.

Witness my hand this ____ day of _____, 2022.

Audra Cramer

Certified Shorthand
Reporter for the
State of California

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54:12
able
26:5 39:17 46:6 97:8 102:6 106:11 110:5 112:12 113:11 114:6 137:12
above/below
41:23
absolutely
17:7 83:22 85:3 101:10 117:11
abstract
20:10 85:19
absurd
124:14
account
128:8
accurate
108:15
accurately
42:19 109:22 145:2
accused
155:17,18 156:14
accusing
69:20
achieve
137:1
acting
86:9
action
35:2 160:16
added
73:24 79:18,24
adding
115:21
addition
77:1,15
address
68:24 73:24 136:7
addressing
74:3,6
adjacent
14:17 101:20,24
102:3,5,7,18 103:12 103:15 112:1,14
adjourned
158:8
admit
123:14
Adobe
103:8
advantageous
119:1,2,2
advice
157:5
afraid
151:13
afternoon
5:10
ago
23:21 45:9 59:8 66:9 155:25 156:1,25
agree
9:17 10:11,13 12:17 13:11,18 17:6,13 21:13 22:20 27:10 28:14 30:9 38:8,11 39:2,19 44:21 45:15 45:22 54:18 58:24 59:2,15 60:17,22 61:2,24 65:4,12 66:10 68:17 71:9 72:14 73:2,6,16,23 78:15,18 83:6 94:19 94:25 95:8 96:18 98:12 107:1,15,17 108:5 114:18 115:9 115:15 117:7,21 118:10,18,24 119:20 120:11,21 122:5,19 136:17 137:9,20 141:9 147:25 150:2 151:23
agreed
64:1
agreement
29:9,12 72:23 135:10
agrees
68:1
ahead
7:18
AI
86:9
air
20:13
airplane
20:17
ALI
3:17
allow
95:24,25
allows
143:16 144:24 145:14 151:5
alter
105:22
altered
135:22
alternating
41:6
amazing
98:21 99:3
analogy
21:2
analysis
98:1 113:14,19 127:9 127:17,18 134:10 134:11 135:20
analyze
58:19 138:8 146:21
analyzed
43:4 97:1 104:19 106:24 130:25 131:1 132:14 133:18 138:4,18 142:17 144:1
analyzing
81:24 82:6 83:11,12
anatomy
146:8
ANGELES
159:2 160:2
angle
24:24 25:21 26:1,4 28:14 95:5
angry
124:6
angulation
104:9
annulus
118:12,13,14,20 146:6
answer
20:2 31:23 33:23 51:12,25 52:3,5 53:7 55:23,24,25 58:25 63:9,25 76:3 76:6,9 82:16 85:14 95:6 97:8 102:5,7 102:17 103:3,16 105:3 110:5,18 112:13 114:1,1,7 123:7,9,13 138:8 150:20 151:12
answered
23:16 30:21 51:10 54:11 75:2 76:13 85:15 95:20 123:6 127:7 139:20 143:7
answering
31:13 51:24 54:3,15 55:19 56:10 60:21 63:13 67:25 73:14 95:17 99:12
answers
105:13 106:3 111:11 144:4
Aortic
1:7 2:7 156:3,8,24
apart
40:24
apex
88:14,14,16,20,25,25 89:3,17,25 150:14 154:14
apices
61:3,5,10,13,13,25 62:2 75:6 88:8,9,10 88:12 89:8 91:23 92:13,19,25 93:4,15

95:10
Apogee
35:10 38:10 39:8,20 66:1 148:22 149:7
APPEAL
1:2 2:2
appear
8:18 9:10 52:15 66:15 70:15 107:2,6 133:19 135:24
appearance
11:16 19:3 29:13 41:6 42:2 137:7,8
APPEARANCES
3:1
appearing
17:8
appears
9:10 14:25 66:16 103:21 114:24
applicable
147:2
applied
155:2,2
applies
142:16
approach
150:25 151:1 154:6
approval
151:19,21
approved
151:16,24 152:5 153:12
approximately
48:13,16
April
80:4
area
17:25 29:18 37:16 88:3 90:3,6,9,11,12 119:7,14
areas
8:21 12:18 14:20,21 15:22,24,25 16:5 99:1 119:17
art
17:1 78:16,19 79:5 81:18 116:10 118:25 126:23 134:12 154:7
article
43:17 44:2
articles
83:25 84:2
artifact
31:10
artificial
69:8
art's
79:16
ascertain
83:3
aside
9:5 15:16 16:3 24:16 63:15 128:1
asked
5:13 16:17 31:15 63:14 67:23,24 73:15 85:24 95:19 126:18 149:22 156:22 157:5
asking
11:16 22:5 50:8 54:21,22,22,24 55:2 55:3,3 60:20,23 74:12,13 82:2,3 85:13 86:10,15 92:3 93:2,16 97:4 98:6 103:2 112:11,25 114:1 120:20,24 121:8,22 122:16,17 123:2,3 126:17 133:2 142:15 143:7 146:15,23,25 147:1
aspect
78:11 127:2
aspects
139:19
assess
37:8
assist
146:7
associated
52:9 56:18,24 57:15 57:25
assume
21:18 141:20
assuming
153:12,19
atom
23:10
attach
10:4,5 89:19 118:1,2
attached
44:22 90:24,25
attaching
47:2 91:2 93:25 119:1
attachment
48:19,24 88:7 90:13 117:22 143:20
attachments
90:18
attention
6:11
Audra
1:23 2:17 129:5 157:15 160:4
author
59:15 62:17
authors
58:16 59:3 80:25 81:9 151:25 152:6,7 152:25
available
33:25 58:20 80:3 81:18 84:6 99:5 148:6,9,11,14 151:25 152:5,19 153:2,7,12,19,20 154:18,19
avoiding
154:11
aware
14:4 32:18,23 74:23 82:14 121:10,13 127:2 148:10 149:14 151:16
156:2,6,13,15
awful
105:15
a.m
2:16 5:2 32:3,4 69:1 69:2 129:6

B

back
7:25 11:19 27:22 41:17 45:7 69:4 71:6 76:24 86:18 100:5 105:23 116:15,16
background
37:21,25 38:4,22
backlit
72:2 136:24 138:16
baggy
140:2 141:5
bar
9:20,23 10:25 11:4 12:14,16 27:18,18 27:19,20 28:13 67:4 88:15 90:4,22,24 91:1,3
bare
94:22
BARNES
3:5
bars
10:12,13 11:18 49:2 98:17,19,22 99:1,7 99:24 100:3
base
33:5
based
16:23 17:20 73:18 82:11 98:6 126:8,20 131:14
baton
157:10
BEAR
3:4
bears
59:23

beginning
17:23 55:9 139:8 145:25
BEHALF
2:15
believe
5:10 12:1 18:5,7,11 28:22 37:5 42:18 44:6 48:12 56:17 66:10 72:5,20 79:13 83:16,18 84:7,16 85:23 86:4 123:2 126:13 127:9 128:7 128:13 131:13 136:10 139:23 140:22 141:19 142:6 143:25 145:1 146:9 152:23
belongs
64:15
bench
154:2
benchtop
152:21 153:8,15
best
7:22 23:17 37:16,20 37:24 38:13 47:4 54:12 103:3 110:9
better
26:20,21 28:9,22 97:12,13 110:12,20 134:7 150:10
beyond
59:4,21 63:22
bifold
11:18 49:2
big
19:6,10 21:12,18 22:6 50:21 72:11
bigger
60:10 94:13 150:10
bird's-eye
6:5,6 45:12,19 46:4 47:6,20 48:15 51:17 52:8,23 53:22 55:15 56:4 63:15,22 71:11 86:19
bit
5:25 6:21 8:10,14 9:22 11:6 15:20 18:17 20:3,22 26:25 27:22 31:3 36:5 38:24 39:12 41:22 42:15 43:11,25 45:9 47:24 60:1 64:2,4,6 65:3 68:21 69:25 92:6 96:4 100:6 107:22 114:24 115:1 136:4 137:3 139:2 142:12
bites
21:20
bits
60:5 87:16,17
black
87:22 132:17
blocked
95:2
blood
72:8 117:24 118:1 119:7,15
blown
132:9
blue
37:21,25 38:4 39:21 39:21 40:1 41:14
blue-green
40:23
bluish-green
40:15
blurred
41:15
BOARD
1:2 2:2
Boston
155:14
bottle
107:7
bottom
9:7,24 24:14,16,23 25:3,18 26:7,13 35:8 40:21 41:9,12 42:14 44:13 47:7 51:5 67:10 69:7 75:5 104:10 129:14 129:16 146:2
BOULEVARD
3:12
brain
8:5
break
32:1,2 68:21 128:16 128:25 155:6,7
Brecker
3:18 68:4,5 70:17 72:23 83:6,13,24 84:9,16 85:23 86:4 126:2,13 135:9
Brecker's
127:3,9 128:8
BRIAN
3:5
brian.barnes@kno...
3:8
briefly
90:18
bright
87:8,21 88:11 94:17
brighter
70:16
brightly
18:21 65:20 71:18
bring
5:24 7:11 114:11
brown
64:25 70:4,5,21
brownish
69:6
bubbles
8:19 89:17
bubbling
36:13
bubbly
39:6,14 100:13
buckle
143:22 144:24
buckling
145:19,24 146:2,5,11 146:19 147:4,7,12 147:22
built
77:23 78:3
bulge
144:24 145:9,10,14 146:12,18
bulges
146:12
bulging
47:16 139:17 144:5 147:11,20
Buller
1:14 2:14 4:2 5:4,11 5:16 6:2 7:21 28:1 32:6 34:16 35:9 43:13 45:15 106:14 114:13 129:10 136:10 155:13 157:9,13 158:7 159:5,14

C

C
3:5
California
3:6,13 159:1,7,10 160:1,5,25
call
21:10 85:1 99:8 101:13
called
78:4
camera
47:6 91:13
candy
21:7,9,11,13,15,19 21:23,25 22:7 23:15 23:16 24:6,7,9
candyfloss
21:10,11
capable
85:11
car
116:19 117:2 123:22 124:1,4,6,19 125:23

cardiologist
82:12 125:8,14 126:19,22 140:8 154:7
cardiologists
69:13 82:17
cardiology
82:10,19,19
career
82:18
careful
127:10
carpet
39:21
cars
116:23
case
1:5 2:5 21:21 34:19 61:8 86:13,15 97:2 98:4 138:19 143:9 155:18,21,25 156:21
cases
127:3
cast
13:8,9 42:5,8
categorically
54:17,23
catheter
148:6
cause
14:6
caused
12:14,16 13:19 14:1 15:3,12 31:11
causes
18:1
cave
12:4
cell
35:22,25 36:7,23 37:6 38:6,25 39:13
cells
47:17 64:6 90:21
center
20:22 47:13 48:7 51:4 91:11
central
47:5
certain
69:22 90:13 91:20 111:20,23
certainly
12:9 15:10 19:16 53:9,10 55:18,22 56:22 66:6 71:3 81:4 107:9 110:14 138:19 154:17
certainty
15:1 51:14 52:2,2,6 52:12,21 53:3,11,13 53:14,17,19,23 54:5 54:24 55:4,5,13,23 56:2,7,16 57:23 69:5,11 70:3,7 113:16 130:18 131:18 132:5
Certified
160:23
certify
159:5 160:5,15
CGI
130:6,10
CGI'd
135:22
change
105:14 136:25
changed
18:23
changing
15:23
characteristics
124:3
characterize
20:20 147:14
cheated
124:8
check
135:21
Cheung
5:15,17,22 6:9 8:5 16:15,18,22 17:6 18:18 24:13 25:16 31:14 35:14 65:25 67:15 148:4 152:1 153:22,24,25 154:20
Cheung's
6:2 8:17 9:3,18 17:14 18:6,9,19 24:18 25:23 27:13 67:16
choice
153:21
choose
150:18
chose
153:18
chunks
10:17
circle
114:23,25
circular
21:20
circumference
27:2
circumferentially
62:15 75:9
circumstances
7:23 140:10 145:12
cite
60:17
claim
73:3 120:4,8,11,16 120:21 121:1 122:1 125:1
claimed
120:12
claims
120:23 121:7
clarification
119:12
clarified
61:17
clarify
34:23
clarity
37:2,14
classed
12:3
cleanly
123:8
clear
10:9 30:24 40:2 51:12 53:1 78:25 89:21 95:1,9 99:7,8 102:15 107:24 109:13 110:1 114:4 115:23 117:12 127:21 141:23 147:1
clearer
114:5 141:24
clearest
102:21
clearly
9:23 10:11 18:25 30:4 37:8 38:1,16 38:21 41:16 49:13 51:19 61:16 94:6,10 98:22,25 99:2 100:3 100:16,23 108:11 108:20 117:19 121:2 126:24 132:15,16 144:2 148:8 149:24
clinically
83:9
clock
6:10 31:1 35:13
close
42:4 57:7 87:15
closely
19:17 64:2
closer
20:22 94:7
cloth
8:7,9,10,13,15,18,22 9:3,16,18 10:4,7,15 11:20,22,25 15:19 15:21 16:22 17:9,12 17:15 18:4,9,13,17 18:20 24:14,17,18 25:23,24,25 26:6,7 26:19,21 28:18,20

28:23 29:1,3,6,13 29:18,22 32:19,21 32:24 33:6,12,14,20 34:2,3,5,7,10,11 36:3,6,9,16,17 37:9 37:16,18 38:10,17 39:4,20 40:1,5 41:21 42:3 45:23 46:8,10,12,17,24 47:16 49:14 56:22 57:10 58:7 59:2,16 59:20,24 60:1,5,7,9 60:22 61:2,24 62:13 62:19 63:2,11,18,22 64:3,18,20 65:21 66:5,22 67:3,6,14 67:16 68:2 69:23 70:4,6,20 71:22,24 72:2,4,5,11,16,19 73:8,13,18,22,23 74:4,7,13 75:5,14 75:20 77:2,2,12,15 77:16,20,22 81:1 84:14 86:23 87:25 88:2 90:13 91:18 94:3,19,23,24 95:3 95:12 100:9 118:6 118:21,23 119:16 137:5,10,11,18

cloths 32:25 33:19 34:1

clots 72:8

clotting 118:1 119:7,15

cloud 19:7,8,11 20:4,10,17 20:19,21,24 21:3

clouds 19:13,19 23:19

coagulation 117:25

coarsely 37:22

code 149:18,24 155:4

codes 150:1

colleague 5:13

colleagues 136:3

color 16:12 26:9 38:15 40:5 64:16 65:12,13 65:18

coloration 65:1

column 76:23,25

columns 28:8,16 29:2,19 35:16

come 75:1 107:7 157:1

comes 11:6 46:10 69:24 98:21 113:16 133:21

coming 11:12 36:14 67:3 87:16,17 95:4

COMMISSION 161:25

commissural 28:5 48:25 88:15

commissure 27:25 28:3,6,10,15 29:1,16 35:15 49:8 92:17

commissures 48:21

common 141:17

companies 82:23

company 85:12 142:6 152:25

compare 28:25 67:5

compared 40:6 41:15

comparison 135:13

complete 160:13

completed 10:17

completely 10:14 16:12 19:21 23:8 42:22 47:13 48:16 84:10,15 105:16 109:4,6 110:12,14 127:20 127:24 150:20

complications 154:11

compressed 143:18

compressible 73:21 115:7,14 117:18 119:22 120:1,12 121:15 122:2,21 123:16 125:10 126:10

concentric 114:25

concern 142:21

concerning 73:7,12 121:14 142:3

conclude 125:8 126:7,11

concluded 157:8

concludes 127:18

concluding 126:12

conclusion 126:19

cone 41:2

conform 19:13,16

confused 61:13 62:8 145:3

confusing 75:8 92:14

connected 44:22

connecting 28:13 44:18 119:3

consequence 153:17

consider 121:18

constitute 133:9

constructions 73:3

consultant 156:20

contact 58:16 84:17 118:11 126:4

contain 56:8

contains 34:17,21

contentions 34:19 35:1

context 80:18,20 85:7 86:3,6 86:12,15 106:25 117:5,10 123:25 124:16,18,25 125:25

contexts 86:10

continue 95:25

contrast 37:3 38:5 40:2

contrasted 37:24

contrasting 26:8 38:14,22 39:16

control 150:17,19

Control-F 121:4

copy 157:25

corners
81:14
CORPORATION
1:4 2:4
correct
10:16 12:14 14:7,14 15:4 27:25 30:11 31:2 38:10 39:22 40:3 45:24 49:14 53:5 56:13 57:12 60:19 61:4 63:2,11 65:1,7 73:4,8,13,19 73:25 74:1,4,8,24 75:6,15,21 76:13 78:2,20 80:1,11,12 80:15,18 81:1,2,10 81:11,15 83:21,22 83:25 84:3,4 85:2,6 85:18 93:25 94:10 94:21 95:3,12 97:22 98:9,13 109:3,10,14 109:17 113:13 114:20 115:17 116:22 117:8 118:23 120:14 122:5,6,10,21 123:16,24 124:17 125:24 136:20 137:10,22 139:24 140:23 141:11 143:2 148:13 149:5 152:1,8 153:23 154:2,3,9,24,25 155:15 159:7 160:13
correctly
147:14
costs
152:20
cotton
21:7,9,11,13,15,19 21:23,25 22:7 23:15 23:16 24:6,9
counsel
3:1,19 7:9,19 95:23
COUNTY
159:2 160:2
couple
117:14
course
14:7 111:18 148:10
court
32:1 34:19 35:2 156:3,21
cover
10:6 121:19 124:5
covered
10:1,14,17 22:15
covering
25:19 32:12,13,15 66:5 78:17,20 80:15 80:17 96:18,20,23 97:16,22 98:9 99:6 130:12,14,24 132:20 133:4,10,24 134:24 135:1,3,4,8 135:10 137:10
coverings
137:21
covers
80:22 122:13 125:19
Crag
128:21
Craig
3:4 7:10
craig.summers@k...
3:7
CRAMER
1:23 2:17 160:4
crazy
69:14
create
79:6
created
74:18 101:20 102:2 103:11
creating
75:13,19 77:3,6,17 79:3 143:21
Cribier
43:16 44:2 45:6,8,9 46:4,20
Cribier's
45:13
crimp
42:25 148:23
crimped
43:6 154:23
critical
152:17
cross
95:24
crosswise
134:20
crowd
20:23
CSR
1:23 2:17 160:4
cumulus
19:7,7,11,12 20:4,18 20:21 21:3 23:19
cursor
27:15 87:13
cut
31:7,9,16,17,20 32:6 32:7,10
cutting
31:11,22

D

D
4:1
dark
12:6 13:12 14:12,25 15:8,10,16,23 16:4 16:5 17:13,17 37:7 42:10 64:25 87:22
darker
8:21 9:6,16 12:18 15:22 36:22 37:1,13 40:8 64:16 65:19 66:16 100:2
darkness
99:1 100:2
dates
151:20,21
day
81:7 95:1,10 99:8 129:3 159:8 160:17 161:23
deal
149:20
decision-making
154:17
declaration
60:19 67:12 73:3,12
deep
17:20 71:22
define
101:19 102:1 103:10 104:14
defined
111:25
definite
8:19
definitely
10:16 31:24 41:24 137:15 140:6
definition
111:20 141:2
degree
25:4 82:13 108:18
degrees
109:19
deliberately
81:16 152:14
deliver
148:11 151:10
delivered
149:15 151:3,9 153:23 154:1,5
deliveries
150:22
delivery
148:1 149:16 150:4 151:17 152:4 153:1
dense
57:20 70:16 72:24 84:14 127:18 135:11,13,18
density
134:3 135:15
dents
68:3 111:21

depend
117:5 138:13
depending
24:11 31:19 87:22 117:10 136:25
depends
123:25 124:18 131:16 138:16 145:12
Deponent
161:20
deposition
1:14 2:14 75:25 149:21 158:7 160:7 160:10
depressions
70:23,25 101:13 111:19
depth
111:20,23
describe
30:17 108:6 115:10 115:12 145:2 149:4
described
110:9 146:17
describes
109:22
describing
146:10
description
93:10 125:5
descriptor
110:20
design
99:2
designed
77:2,16 144:20
detail
12:8 51:6,21 110:2
determine
25:22 97:14 113:12 137:5 155:6
developmental
82:23
device
27:6 37:23 38:20 47:11 62:16 79:22 79:24 80:13 103:22 113:15 118:8 124:2 153:25 154:18 156:14
devices
60:2 80:20,20,21,23 82:25 83:12,12 149:25 151:20 155:1,3
diagonally
90:22
diagram
118:7
diameter
22:8
diamond
6:11,23 8:1,1,2,4,11 8:12 10:12 25:5 26:23,25 27:5 29:4 29:11 30:10,15 31:1 31:4 39:24 41:17 65:25
diamonds
6:17 66:8,19 90:21
diamond-shaped
36:7
difference
69:19 135:1
different
8:24 23:8 26:8 27:4 29:8 41:14 54:25 65:18 78:14,22,23 78:24 126:19,23 127:23 128:23 137:1,2 142:14 143:12,13 144:10 152:24
differentiates
117:12
difficult
13:12 40:9 46:13,15
dimensions
101:12
diminution
154:24
dimples
111:10,22 134:21
direct
6:10 60:10 120:4
directed
74:3,6
directing
69:6
direction
14:9 160:12
directions
22:3
directly
38:16
disadvantage
153:9
disagree
43:1,5 125:15 127:11
disbelieve
42:23
discern
103:15 105:19
disclose
130:23
discloses
81:14 130:23 145:23 147:25
disclosure
76:19 78:13 116:3 121:14,18,23,24 122:9,17,19,23,23 123:15,19 124:2,20 124:22 125:18 145:2,5 146:15
disclosures
121:11 142:25
discrete
47:14
discretely
46:25
discuss
59:16
discussed
126:20 142:24
discussion
19:25 59:18 68:19 95:25 136:8 157:20
dishonest
127:5 128:8,9,12
display
5:14
displays
70:7
dissimilar
136:15
distance
20:12 24:7 101:14
distances
23:21
distant
138:1
distinction
10:10 55:21
distinguish
46:15
district
34:19 35:2 156:2,20
divide
57:1
doctor
6:15 7:6 19:24 99:15
document
4:12 17:1 34:17 42:20 43:3,8 96:6 110:23 113:15 129:11,19 135:23 138:7 140:17,18 149:7,10
doing
64:7 80:9 85:10 126:15 128:23 150:11
dominantly
33:16
double
131:22
doubt
106:10
downwards
26:4 49:9 90:22 91:4
dozens
83:24

Dr
5:11,16 6:2 7:21 28:1 32:6 34:16 35:9 43:13 45:15 83:6,13 83:24 84:9,16 85:23 86:4 106:14 114:13 126:2 127:3,9 128:8 129:10 136:10 155:13 157:9,13
drawing
116:17
dry
106:10
duly
5:5 160:7

E

E
1:23 2:17 4:1 160:4
earlier
75:11 136:10 153:24
easily
72:10 104:8
easy
150:17
eat
129:1
edge
9:7 14:11 18:23,25 24:23,25 28:19 31:7 31:16 101:4 114:22 127:22
edges
32:10 144:21
editorialization
123:4
Edwards
1:4,4 2:4,4 16:17 34:18,22,25 44:4 50:22 58:13,17 81:9 84:17 85:2,20,24 86:5 140:19,22 141:11,25 149:20 151:16,23 152:4,7 152:23 155:14 156:3,25
effect
144:1
either
10:24 28:10,16 29:2 29:19 35:16 51:7 56:19 104:10 108:25 118:11
electrons
23:9
elements
111:2
embodiment
139:16 140:6 141:4 144:4 145:7,8
embodiments
78:14 140:1,3
emphasizes
48:6
encompass
77:12
encompassed
29:19
encourage
117:24
enjoyed
19:19
entirely
127:23 150:7
enunciate
7:22
equivalent
38:19
ERRATA
161:1
ESQUIRE
3:4,5,5,11,12
essentially
104:7
established
75:4 110:13
ethically
85:5 86:8
event
160:16
everybody
116:9
evidence
59:23 63:14,15 107:12 126:8,20 154:22
exact
4:11 61:7
exactly
21:14 30:16 36:19,20 37:12,12 46:14 47:24 51:13 75:11 76:17,18 89:24 90:11,17 111:10 135:24 146:20
examination
4:3 5:8 17:21 157:8
examined
5:6 16:14 97:6 98:2,3 160:6
example
116:19
Excellent
96:1
excess
143:21 144:5,20 145:13
exclude
54:17,23
excluding
77:20 78:1
exclusive
13:3
Executed
159:8
exhibit
5:14 34:15,25 43:10 43:14,15,19,21 44:10 96:3,7 105:25 106:15 107:17 109:23 110:8 114:11 129:9,11,12 138:25 139:1 144:14 148:20
exhibits
4:6,9
exist
113:20
existing
65:14 73:25 79:23
expanded
144:23
expanding
143:19
expect
70:12 116:15
expedited
157:17,19
experience
19:12 83:11 129:20 154:8
experiment
148:8 152:19,21 153:8,16
experiments
152:16
expert
81:24 82:6,8,13 84:21 155:13 156:20
expertise
82:14 83:7
EXPIRES
161:25
Explain
50:15
explained
51:3 91:10
exposing
150:14
express
121:11,13,23,24 122:9,17,19,23 123:14 124:22 125:4,18
expressly
123:3 125:1
extend
17:15,17 86:22,25 101:6,10,14 104:25 111:15 113:22 118:13,14 120:22 133:13 134:15
extended

30:6
extending
9:2 14:10,15,18 25:10 26:12 32:14 35:18 37:18 87:12 104:15 117:22 119:23 120:13,17 121:14,19 122:3,20 123:15 125:2 126:6
extends
94:20
extent
9:18 13:17 147:1 156:8
exterior
18:15 46:10 116:20 124:16 126:3
external
62:7
extraneous
81:17
extremely
110:16
eye
9:14
eyes
17:4

F

fabric
14:5,7,17 15:13,15 17:24 24:11 25:10 30:2 31:7,9,15,22 32:7,9,18 37:22 39:13 41:14 66:4 79:24 127:19 129:25 131:17,19 132:4,15 133:20
fabrics
23:13 24:10
face
6:10 35:13
facilitate
117:22
facing
32:16,19,20 36:8 38:9 39:3 68:7,11 95:2 104:13 110:3 112:17
fact
14:12 15:12 48:6 70:25 136:22 139:9
factor
115:22 120:19,19
fair
6:7 8:3,7 9:20,25 10:8,9,15 12:19,23 13:6,13 16:20 20:4 20:6 21:16 25:16 28:10,18 29:23 33:15 34:7 35:19,20 36:10 43:1 44:15 45:20 93:9,13 110:10,19 114:16 121:16 131:7 141:25 142:4 146:9 147:16,23,23 154:11 155:23 156:4
fairly
18:21 42:10 62:23 70:14 72:9 94:9,17 108:1 156:16
false
142:1
familiar
21:9 33:2 83:1 114:14 116:4 129:13 142:22 143:2,8 145:6 146:19 149:22,23 151:19 155:1,22,24
familiarity
154:20
fanning
14:11
far
26:16 27:7 29:25 48:9 89:9 91:11 97:2 107:12 135:17 137:23,25 156:6
fashion
40:25
faster
129:2
features
111:1
feedback
68:18 136:4 141:22
feel
142:12
fiber
30:14 82:7,7 102:19
fibers
9:2 18:14 19:1 21:14 22:2,4 25:8 26:12 26:17 27:8 30:6,10 30:13,25 31:17 32:14,16,19,20 33:11,19 34:1 35:18 36:9 37:18,24 38:1 38:9,13,15,21 39:3 39:5,17 40:10 41:8 46:12,16 49:13,19 50:8,10,16,20 52:7 52:9,15,19 57:3,5 68:7,12 70:8,11,12 71:3,19,21 72:12 94:2,13 95:2,11 100:23 101:19,21 101:23,23,24 102:1 102:3,4,6,7,7,16,18 103:10,12,15,15 104:11,14,21,22,24 105:4 106:6,7,11 112:1,2,6,13,14 115:10,12,16,20,24 116:12,15 117:16 117:22 119:7,14,18 119:23,25 120:2,13 120:16,22 121:14 122:3,12,14,20 123:15,19 124:21 124:22 125:2,3,5,18 126:3,3,6,24 131:7 131:12 132:16 133:14 134:16,19 146:13
fibrous
18:13 65:21 137:8
field
82:9 83:1,4,8
figure
5:21,24 6:3 16:22 17:14 18:6 27:13 35:10 37:5 45:13,19 47:25 48:1,14 60:12 60:14,16,18,23,24 61:17,17,22 62:12 63:16,23,24 64:8,8 67:11 69:7 71:7,10 71:12,14,15 86:19 99:6 114:12,15 116:13 125:4 126:2 126:5
figures
16:25 60:15 141:17 142:23
filename
43:21,22
fill
146:5
finally
100:22
find
118:25
fingers
99:19,20 105:17
finish
7:16 75:23 95:17 141:21
first
5:5 9:12 12:17 30:7 44:7 67:23 74:10 89:3,25 91:23 92:5 92:13,18 96:10 139:8
First-in-Human
129:20
five
58:16 81:8 87:9,10 152:6,24
flat
15:13 134:18 143:17

144:22
FLOOR
3:6
fluffy
137:8
fluid
72:9,13,15 107:12
fly
20:16
focus
49:5 56:11 90:3 101:2,3,17 102:15 105:16 106:18
focused
100:15,22,25 148:4
focusing
91:21
follow
90:4
follows
5:6
footer
129:15 139:3
foregoing
159:7 160:7
foreshortens
143:20
forget
92:11
form
20:25 22:23 24:1 31:18 32:22 39:10 50:5 54:10 55:7 57:18 58:3 59:6 63:4 69:17 75:22 78:21 82:15 85:25 96:24 97:23 98:14 99:9 100:12 101:8 103:13 104:2,17 105:2 107:3,20 108:8,17 109:24 111:17 112:19 113:24 117:9 118:16 119:4 121:17 123:11 124:11 125:11,16 130:4,15 131:15 132:22 133:6,15 143:5 150:5
formed
101:20 102:2 103:11 112:1
forming
146:7
forms
74:10
four
41:24,25 45:1 46:19 46:22 47:1,15 81:14
frame
8:1,7 9:7,9,20,24 10:4,6,12,13,18 13:20,22,25 14:2,14 14:16,17,19 15:1,3 16:3 28:9 42:7 44:19,23,25 45:24 47:3,7 49:13,17,18 50:11,17 51:16 52:8 52:23 53:21 54:7 55:15 56:3,13 57:25 58:8,8 62:4,5 64:4 64:17 65:24 66:4 68:6 71:23 72:1,4 74:4,7,14,15,17,20 84:13 86:21 87:1,9 87:12,18,20,21,23 87:25 88:1 89:7,12 89:20 90:4,14,19 91:2,14,15,22 93:18 93:20,25 94:3 99:25 100:3 101:1 102:15 104:13 105:1,17 107:22,25 108:2,3 112:17 113:23 118:21,23 119:3,18 127:14,22 138:20 143:17,18,19,22 144:22,25 145:11 146:6
frame's
101:3
frayed
32:10
free
96:19,23 97:16,21 98:9
freedom
151:5
French
42:16,17,25 43:6 148:1,23,25 149:16 151:2,3,17 152:4,12 153:1,11 154:5,5,9 154:24
FRIDAY
1:16 2:16 5:2
front
6:3 20:9 27:2,3,6 28:6 38:17,20 40:6 43:14,18 46:20 76:22 96:5 110:3 112:7 120:25 133:18 136:16 137:19,25 138:5 143:11 148:3
front-on
30:5 67:5
fulfill
72:24
full
9:19
fully
100:15
further
39:1 67:23 84:18 90:16 92:16 95:25 112:4 145:23 160:15
fuzzy
87:15,17 110:16

G

gap
75:16,17 87:11,15,16 89:14
gaps
8:22 72:11 146:5
garbled
6:14 7:5 31:23 35:11 119:11
gas
21:3
general
86:11 150:6,21
generally
59:20
generic
19:13
geometric
19:14,17
geometry
107:25 108:1
getting
18:2 66:8 68:18 129:3 136:3 141:22 158:4
give
9:15 12:8 29:5 62:18 62:22 66:6 69:21 101:11 113:17 141:1 156:22 157:5
given
106:4 152:6
gives
62:25 63:10
giving
59:13 69:19 124:19 124:20 126:15
glass
22:20 108:12
glasses
76:24
glistening
107:10
glove
107:11
gloves
103:24 107:10
go
5:19 7:13,18 9:19 11:19 17:23 18:14 18:16 21:6 27:23 35:7 41:17 42:12,13 43:11,24 44:7,8,12

45:2,9 47:24 49:3 71:6,22 76:21 86:18 87:4,6 88:3 91:4 96:4,9 105:9,23 106:12 111:20 114:11 129:4,18,22 139:5 143:15 145:15
goes 18:3,8,12 88:14,25 98:22
going 12:4 18:2 24:9 25:2,8 25:10 33:12 34:11 34:24 42:13 51:11 52:2,4 56:1 59:17 68:20,22,22 89:6 90:22 102:25 103:20 112:5,9,10 112:12 124:5,8 132:18 133:19
good 5:10 24:5 25:19 37:2 89:2 99:11,15 104:20 108:1 110:22 141:13 158:4
grace 120:19,19
graft 32:12 72:22,25 96:19 96:23 97:16,21 98:9 99:6 130:12,14,23 132:20,24 133:4,10 133:24 134:23 135:1,3,4,8,10
gravity 72:21
gray 37:1
grayness 16:13
great 71:2 102:14 149:20
greater 25:4 29:5
greeny-blue 41:7
growth 115:21
guess 55:2 88:5
guessing 130:5
guys 129:1

H

half 31:4 47:10 48:8,9,10 51:3
halfway 67:3,4
hand 106:20 107:5,11 111:3 160:17
handled 58:10 80:14,16,20,21
happened 111:4
happening 102:17 112:14
heading 22:3 49:9
head-on 71:10
hear 6:15 7:12 19:23 108:24
heard 69:21 151:8
heart 150:15
height 69:24
held 19:25 68:19 99:18 136:8 157:20
help 99:14 102:25 105:18 112:5,10 113:6 117:25 118:2 119:16 121:3
helpful 97:11 123:9
helping 105:21
helps 119:8
he'll 128:14
high 37:3
higher 46:10 94:20 135:15 154:10
highlight 6:24 88:18,21 90:5
highlighted 90:10,10,18 92:21
highlighting 88:24
hit 20:16
hold 141:21 157:15
hole 18:8
holes 22:9 58:7 132:16,18
honestly 125:15
hood 116:21 117:4 123:24 123:24 124:7 125:23
hope 23:13 126:14 127:24 128:13
hopefully 68:23 141:24
hour 128:17,18,23
human 99:18 118:3,15,16 153:23
humans 99:5

I

idea 12:16 24:5,10 25:20 26:5 59:10 111:2 152:2
ideas 78:14
identify 18:7 70:5 93:3
II 114:15 115:8,9 119:21 120:5 124:23 125:8 126:5 126:8
II's 118:6,19
image 17:19 18:24 25:24 37:7 59:5,21 60:3 60:24 61:1,21 65:23 66:7 67:5,10,14 69:4,7 70:7,18,19 71:8,11,12,14,17 72:3 87:5 96:10 97:14 98:20 100:6 100:14,25 101:25 102:14,22 105:15 106:16,20 107:8,16 107:16,22,23 110:7 111:11 112:6,15 114:2,4,8,14,18,21 116:16 129:24 130:12,20 131:5,9 131:11,14 132:12 132:18,21,23 133:5 133:12,17,18 134:8 134:14 135:14 138:5
images 59:12,25 110:24 127:16 130:3,16 135:21,24 136:20 136:23 137:16
imagine 6:9 70:4,20

immediately
87:10
impermeable
72:6,8
implanted
80:11,12 83:14,20,23
implanting
150:2 151:1
important
134:13
improper
85:6
inaccurate
108:6
inches
22:7
include
52:25 53:24 54:8 55:16 56:5 77:21 78:20 123:19
includes
76:16 119:22 120:12 126:25
including
116:9 122:2
increased
119:6,14,17
indentation
9:19 12:1,10,13,25 13:4,6,10,18,19,25 14:6 15:2,3 17:20 18:7 21:22
indentations
9:15 11:25 12:20 13:15 17:7,11 100:21 106:5
indicate
4:11
indicating
73:17
indication
75:12
individual
23:10 39:5,17 40:10 57:5 71:4 100:23 101:23 102:4,16 103:14 104:21,22 105:4 106:6,11 112:2,6,12 115:19
infer
152:3
inference
121:12,23 122:25,25 152:10
inflow
61:6,20
information
58:22 67:24 84:18 85:13
ingrowth
117:25 118:2
initial
27:20 48:24 73:12
inner
8:13,15,17 9:2,17 10:6,14 11:19,21 15:18 16:2,21 17:8 17:11 19:5 26:15,19 26:22 27:7 28:9,17 28:20,24 29:3,5,13 31:1 32:15 36:2,6,9 36:15 37:8 38:9 39:3,7,20 41:20 44:18,21,23,24 46:16 47:2 49:20,24 50:2,18,24 51:8,15 52:7,10,16,22,25 53:25 54:8 55:14,17 56:3,6,13,19,20,24 57:16,20,25 59:1,16 59:19,24 60:6,8 62:19,22 63:1,10,17 63:21 64:5 65:24 66:17,25 67:13,16 68:2 70:14,16 74:24 74:25 75:13,15,19 75:21 84:14 89:12 89:19,19 90:13,19 91:2,5,20,25 92:1 93:21,24 94:21,24 95:9 103:25 104:8,9 104:11,12,24 105:5 113:1,2,4,6,9,10,12 113:18,21 114:6,7,8 114:23 115:10,13 115:17 116:11 117:4,19 118:18,20 120:3,17,22 121:5 121:15,20 122:4,9 122:13,14,20 123:15,20 124:23 125:5,6,9,19,22 126:9 127:1,19
INNOVATIONS
1:7 2:7
inside
15:13,15 24:19,24 25:4,7,17,20,22,25 26:6 33:9 38:5 40:13,17,18 41:13 47:8,11 50:9,16 51:6,16,22 53:21 54:6 57:24 62:4,11 64:13,21,24 77:8 86:21 87:6 89:7,12 91:12,21 93:17,20 94:3 114:19 123:24 124:7 133:8
insight
29:5 59:4 62:18,22 62:25 63:10 65:23 67:9,13 84:8 115:2
inspected
131:2
inspection
16:23
instance
87:7 117:3 148:12 150:15
instructed
157:5
insufficient
105:25
intended
118:11
interested
160:15
interesting
19:21
interim
7:21
interior
6:11,23 116:21
intermolecular
22:22,25 23:21,22
internal
11:18 38:6 46:11 48:8,10 94:17 142:5
internally
62:6 75:7
interposed
118:20,22
interpretation
81:20 119:21 122:16 128:10,13
interpreting
84:13
interrupt
75:24
interrupting
76:1,4
interstices
36:23
intervening
42:6
interventional
69:13 82:10,12,17,19 125:7,14 126:18,22 154:7
introduction
77:1
invalidity
34:18 35:1
inward
49:18
inwardly
32:16,20 36:8 38:9 39:3 68:7,11 95:2
inwards
26:12 30:6,13
inward-facing
41:8 70:7
IPR
106:25 131:4 134:13

IPR2022-00556
1:5 2:5
irregular
40:24 41:7 57:20
IRVINE
3:6
issue
68:24
it'll
33:9 141:24

J

J
3:5
job
1:23 124:4
joined
14:21
JOSHUA
3:5
joshua.stowell@kn...
3:8
judge
104:9 132:10
judges
134:6
judging
103:23
JUSTIN
3:19

K

Katz
3:12 5:14
Katz's
10:25
katz@lowensteinw...
3:14
keep
53:6 138:3 152:20
kind
80:15 109:1 129:2 156:18
KNOBBE
3:4
knot
11:12
know
11:8 12:18 15:1 17:16 19:7 20:15 24:2,3 31:21,24 33:21,23,24 34:10 42:5,10 43:7 45:1 46:19,22,23 50:13 50:15 51:14 52:1,6 52:12,14,21 54:24 55:4,5,13,24 56:1,7 56:16 57:23 59:1,10 59:11 66:24 71:20 78:12 80:10,22 81:17,18,19,22 83:10 84:19 85:11 97:2 101:22 108:23 109:18 110:24,25 113:3,15 116:11 119:25 126:3,5 128:22,22 129:1,2 130:4,5,19 131:3 132:11 133:8,16,20 134:6 137:2,13,23 138:22 140:5 141:2 141:13,14 142:5,5 142:10 144:7,8 145:17 146:18,18 147:21 149:2,6,11 149:17 150:1,8,11 150:15 151:4,7,12 151:13 152:2,9 154:13,15,16,17,19 154:21 155:1,3 156:6,17
knowingly
142:1,7
knowledge
32:17 81:3 106:22 108:1 124:24 137:6 143:12 144:6,10 146:14,16,22 151:21 153:18,20 153:21 156:9,11
knowledgeably
106:1
known
59:9 78:4
knows
124:15

L

lack
28:9
lacked
73:18
large
16:5 23:24 82:24 135:7
larger
90:15 94:12 151:9,14
late
129:3
laws
159:6
lawyer
140:4,14 141:1,8
layer
70:16 84:14 114:19 115:11 118:11 125:10 127:19
lead
24:8
leaflet
36:24 40:7 64:12,13 69:8 89:15 118:17
leaflets
38:7 64:14 69:15 117:23 118:5,12,14 118:19,22
leak
77:3,17 79:17 137:15
leakage
119:16
leaking
79:19 131:14
leaks
119:8,10
leaky
136:11 137:5,17
left
45:17 49:10 60:23 61:1,16,21 69:5 130:20 133:23
left-hand
46:21 132:23
legal
140:15,18
lengthwise
32:8
lens
47:5 91:13 132:7
letting
95:17
let's
5:21,23 6:9 16:1 18:16,17 21:18 27:11,21 32:2,6 34:14 35:7,13 38:24 41:17 42:12 43:9,11 43:24 44:12 47:18 47:23,24 49:4 52:18 52:19 56:11 60:10 71:6 76:19 85:15 86:18,19 89:23 90:3 90:3 96:2,4,9 97:7 97:10,10,11 99:14 99:15 100:5 103:5,6 105:6,8,23 106:12 109:14 111:6 114:10,11 121:3 124:4 128:17 129:8 129:18,22 138:24 139:5 142:21 145:15 157:23
level
10:7 103:9
Levi
77:25 78:6,6,10,11 78:13 139:9,21,25 140:13,24 141:4,10 141:12,15 142:9,13 142:16,22,23 143:1 143:3,8,11,12,13,25 144:2,4,7,20 145:6 145:23 146:10,12 146:17,22,24 147:3 147:3,15,19

Levi's
57:15,16 77:25 145:2
lie
126:14,14 143:16 144:22
Lifesciences
1:4,4 2:4,4 16:18 34:18 35:1 58:14,18 81:9 84:17 85:2 152:8,24 155:14 156:4
lifetime
82:18
light
11:10 12:8,25 15:23 16:6,9 18:2 68:5 87:21,22 127:14,22 137:8
lighting
72:1 83:2 136:25 138:14,16
likelihood
154:10
limit
116:1
limited
145:7
limiting
115:24 117:16
line
7:16 68:4 84:11
lined
91:14
lines
87:9,10 117:14
lit
18:21 36:24,25 37:4 37:10 38:23 39:15 40:4 41:11,15 65:20 71:19
litigation
37:15 80:18,21 84:22 85:8,12 86:3,6 155:14 156:3,14
little
5:25 8:10,14,22 9:4 9:22 12:4 18:17 20:21 25:5 26:25 27:22 29:21,22 30:1 31:5,8,24 36:5 38:16,19 39:12,12 42:15 43:11,25 47:24 50:20 60:1 66:18 88:11 96:4 100:6 107:22 129:2 132:6 136:4 139:2 158:5
LLC
1:4,7 2:4,7
LLP
3:4,11
Ln
161:2
locations
143:20
log
68:22
long
59:8 98:2 155:7,25
look
9:15 11:24 12:20 18:17,22 19:18 22:10 24:13,20 25:23,23 26:20,21 27:3,4,5 29:7 35:13 35:15,17 36:13,16 36:20 37:11,12 40:12 51:16 58:22 60:4,12 64:11 66:9 71:7 76:20 80:2 87:4,7 88:15 89:14 91:12 111:9,12 120:24 127:25 128:14 137:12,14 137:16 138:7 139:7 157:6
looked
10:20 17:2 26:19 36:5 43:8 47:12 64:2 82:24 96:25 97:6 104:7 110:23 110:24 120:23 126:2 131:2 132:13 138:5,17,19,22 149:18
looking
7:3,25 8:20 15:9 16:25 17:4 18:24 19:6,10 20:18 21:4 25:17 26:2,4 27:2,6 27:10,12,17,19 28:15 29:13,17,18 30:4,5 37:6 38:5,16 39:11,23 40:17 44:9 44:14 45:16 46:1 47:23 48:6,13 49:8 49:17,19,23 50:8,16 57:6 59:12,12,22 60:3 61:14,18 62:23 63:6,24 64:6,11,25 65:13 66:4 69:4,14 70:19 71:10 83:2,3 83:12 90:21 91:5,15 91:16,18 92:5,6,7 96:12,15 97:15,20 98:7 101:2 102:1,13 103:7 108:12 112:15 114:15 130:11 131:5 132:6 134:15 148:18,21
looks
11:3 20:12 26:14 36:19,22 37:1,13 39:6 87:21 94:17 96:16,16 101:2 103:19,21 106:6,21 111:1 132:17 135:23
loose
33:5,13,19 34:1 72:10,11 73:21 132:15 141:5
loose-fitting
139:17 140:2
LOS
159:2 160:2
lost
92:2
lot
27:1 59:10 82:23 137:13 141:22
lots
19:20 21:25 22:1,3 22:14,18 78:8,10,14 80:16
love
144:8
loving
21:2
LOWENSTEIN
3:11,11 4:4 5:9,19 6:20 7:2,15,20 18:16 20:1 21:5 23:3 24:12 31:25 32:5 33:1 34:14 35:7,21 38:24 39:18 42:12 43:9,24 44:5 44:12 45:11 47:18 47:22 48:11 50:12 54:14 55:10 57:22 58:9 59:14 63:8 68:20 69:3 70:2 71:6 75:24 76:2,5,8 76:11 79:7 83:5 86:2,18 88:21 90:8 96:2,9 97:3,7,10 98:16 99:14 100:5 100:17 101:18 103:5,17 104:4,23 105:6,23 106:12 107:14 108:4,14,22 109:8 110:4 111:6 111:24 112:24 114:3,10 117:20 119:19 120:9 121:21 123:12,21 124:13 125:13,21 128:15 129:4,8,22 130:21 131:20 133:1,11,22 136:9 138:24 139:5 143:14 150:24 155:5,12 157:7,14 157:18,21,23

lowenstein@lowen...
3:14
lower
8:20 10:5,7 18:23 46:24 47:19,25 48:3 48:9,10,13 51:6 61:12 62:2 64:9 91:13 117:14 144:21
low-fly
13:9
low-quality
17:19
lunchtime
128:16,22,24
lying
42:3 69:15,20 126:11 126:13

M

M
48:23
magnification
105:11,21 132:8 135:17
main
3:6 15:21,24 16:6 119:6
majority
57:5 58:5
making
122:24,25
manner
4:10
manufacturers
80:23
mark
6:18
marked
4:6 44:1 96:6 129:11
marketed
78:4
marketing
135:23
MARTENS
3:4
matches
65:13
material
10:2 38:18 39:21 46:7 52:20,22 53:20 53:23 54:6 55:14 56:2,12,18,23 57:6 57:7,10,14,15,24 66:12 69:8 70:5,17 72:21,22,25 86:22 87:19 89:7,16,19 91:17,22,24 92:1 93:17 94:15 96:22 96:22 97:15 98:8,12 98:18 99:25 101:5 104:1,12,16,25 106:2 107:15,18 108:6 109:23 111:8 111:16 112:16,18 113:21,22 115:7,13 116:14 117:18 118:17 119:22 120:1,12 121:15 122:2,21 123:16 124:23 126:10 133:8 137:6 143:21 144:5,20 145:13
matter
14:12
matters
119:18
McDonald's
48:23
MD
1:14 2:14 3:17,18 4:2 5:4 158:8 159:14
mean
6:19 8:20,23 11:10 12:4,15 15:9 17:16 19:19 27:4 29:24 34:12 36:21 41:3 47:4 54:20 61:20 81:2 93:8 94:12 98:15 100:1,14 103:20 104:13 107:5 108:11 110:11,12 111:1 112:21 113:5 114:22 116:9,13 117:7 122:12 123:1 130:7 131:16,18,24 134:2,5 136:25 138:1 139:14 140:5 140:5 142:4 143:10 144:2 146:11 147:19,21 148:2 149:11,19,20 152:15 156:1
meaning
73:5 140:16
means
109:2,4,9,12 145:18 146:20
measuring
134:7 151:6
medical
32:24 82:1,2,9 124:2
medically
33:25
medical-grade
33:18
meetings
80:19
memory
136:12 138:1
mentioned
127:15
met
81:3
metal
14:4,5,14,15,16,19 15:1,3 84:13 119:3
metallic
8:5
methodology
137:4
microphone
136:6
middle
99:16,22 110:11,15
minute
7:14 23:21 124:7 128:11
minutes
66:9
MIS
85:18,21,24 86:5 149:4,14 154:23 155:2,4
misinterpreted
84:15
misinterpreting
84:12
missed
73:10 146:13
misspoke
34:23 66:3
misstate
15:6
misstatement
140:23
mistaken
127:24 128:8,10
model
85:18,21,24 86:5 149:4,14
molecules
22:22
Monday
157:21,24 158:2,4
MONICA
3:13
monitor
112:7
monitor's
99:10
mouse
11:1
move
30:2 42:15 85:16
moved
87:14
movement
151:5,6
muffled
6:16 7:7 20:3
mute
144:11

mutually
13:3
M-shaped
49:1

N

N
3:11 4:1
named
160:6,11
narrow
27:18,19,20
narrower
148:11,14
Nathan
3:11 7:14 136:1
native
69:15 117:23 118:4 118:22 119:1 126:4 146:6
nature
80:25
nearly
38:21
necessarily
4:11 34:6 66:12 123:23
necessary
150:4 151:10
necessity
153:6
need
24:2,3 51:25 52:3,5 55:25 75:16 113:11 123:9 135:20 146:21 155:7 157:16,17 158:3
needs
72:24 135:11
negative
131:22
never
35:6 42:20,23 43:3 80:11,12,14,24 81:3 81:4 83:23 104:19 110:23,24 138:17 142:11 149:17,17 150:8
new
4:6 42:22 53:18
NIFONG
3:19
NIGEL
1:14 2:14 4:2 5:4 158:7 159:5,14
nonporous
72:24 130:18 131:17 131:18,21,25 134:5 135:11,19
nope
61:15,15,15
normal
99:5
Notary
161:25
NOTE
4:9
NOTICE
2:17
NOVEMBER
1:16 2:16 5:2
number
43:15,19 82:24 90:15 129:13 131:1 149:4 149:24
numbers
149:19

O

o
31:1
oath
53:17,19
object
42:6
Objection
20:25 22:23 24:1 31:18 32:22 39:10 50:5 54:10 55:7 57:18 58:3 59:6 63:4 69:17 75:22 78:21 82:15 85:25 96:24 97:23 98:14 99:9 100:12 101:8 103:13 104:2,17 105:2 107:3,20 108:8,17 109:7,24 111:17 112:19 113:24 117:9 119:4 121:17 123:11,17 124:11 125:11,16 130:15 131:15 132:22 133:6,15 143:5 150:5
objective
126:21
obscure
139:2
obscured
95:11
obtain
84:17 85:10
obvious
79:4 156:16
obviously
20:9 46:9 69:14 116:13 134:2 145:10 151:4
occurring
79:18
occurs
10:6 32:10
odd
100:1
office
1:1 2:1 140:20,24 142:2
oh
116:4 146:1
okay
5:13,16,19,21,23 6:1 6:9,22 7:3,18,25 8:6 10:8,19 11:5,14 18:16 19:10 21:6 22:24 23:18,22 27:23,24 28:8 30:23 31:6,25 33:4 34:14 35:5,21,23 39:1 40:20 42:15 43:9,11 43:12 44:6,8,12,17 45:4,10,11,15,22 47:18 48:12,17 49:3 49:7,12 52:20 54:4 54:21 55:8,11,20 62:3,25 66:23 71:9 71:16 80:10 82:2 85:9 88:3,13,23 89:2 91:8 92:9 93:1 93:9,14,15,21 96:4 96:5,9 97:14 99:14 99:21 100:5,8,20 102:9 103:7,9,18 105:6,10 109:16,20 110:22 118:9 120:4 120:11 121:3,10 122:7,24 127:7 129:10,18,22,24 130:3 138:24 139:5 141:9 143:15 144:19 146:4 147:8 147:17 149:1 155:5 156:10 157:7,19,21 157:23
old
152:14,19
OLSON
3:4
ones
15:21 16:6 47:2 78:9 127:16
ongoing
156:4
online
80:3
opaque
108:7,10,13,24 109:2 109:4,6,21 110:10 110:13,20 136:18 138:11
open
45:5
opening
12:2,3 16:2 18:3,10 18:12 20:23 21:24

22:11 23:22,23,25 25:6 101:19 102:2 103:10 104:14 111:7,25 150:14
openings 11:21 15:18 18:14,19 22:1,4,14,15,18 23:4,12 24:8,11,15 24:17 41:20 50:11 58:8 70:21 71:5,16 71:21 86:22,25 100:9,11,18 101:6 101:13 104:25 111:13,15 112:17 112:22,25 113:3,9 113:12,13,20 131:6 131:12 133:13,19 134:15,17,22,24 135:5,6,7
operatively 150:9
opinion 12:21 13:14 15:14 42:21 57:8,9 58:4 69:19,20,21 72:19 98:4 122:22 123:20 124:19,20 126:16 126:17,23 127:23
opinions 16:21 59:13 68:1 81:22
opposing 84:22
opposite 30:24 61:7
opted 154:8
options 120:1
order 83:15
orders 157:16
ordinary 73:5 78:16,18 79:4 79:16 81:20 116:10 118:25 140:9
orient 92:24
outer 8:1,6,7,13,15,18 9:3 9:18,20,24 10:4,7 10:12,13,15 11:20 11:22 13:20,22,25 14:1 15:18 16:3,22 17:8,12 18:9,17,20 18:25 21:23 24:14 24:16,18 25:19,23 25:24,25 26:15,19 26:21 27:9 28:18,20 28:23 29:1,6,18 35:19 36:3,6,9,15 36:16,17 37:9,17,18 38:10 39:4,20 41:21 44:19,23,25 45:23 45:23,24 46:17,24 49:13,14,16,18 50:10,17 51:16 52:7 52:23 53:21 54:6 55:15 56:3,13,22 57:4,10,24 58:7 59:2,16,24 60:7,9 60:22 61:2,24 62:4 62:5,10,13,13,19,24 63:1,5,6,11,12,17 63:22 64:14 65:20 65:24 66:5 67:14,16 68:2 71:24 72:2,5 72:16 73:7,13,18,23 74:4,4,7,7,13,14 75:5,14,14,20,20 76:16 77:1,12,15,20 78:1,20 80:15 86:23 86:25 87:18,20,21 89:7,12 91:22 93:18 93:25 94:2,3,19,23 95:12 96:18,19,23 97:16,21 98:9 99:6 99:24 100:8,9,13,16 101:4,7 104:13 105:1 111:7 112:22 113:23 115:22 116:11 117:3,13,17 117:19 118:5,6,10 118:21,21,23 119:23 120:3,14 122:3 124:22 125:2 125:19,22 126:7,25 137:10 139:10,16 139:18,22 140:25 143:4,17
outer-facing 117:8
outline 110:1
outside 3:19 24:22 25:18 26:7,14 40:11 45:3 50:9,21 57:8 62:4 62:16 64:13 74:17 75:10 81:14 85:12 96:22 123:23
outward 119:23 120:13 125:2 125:3
outwardly 9:1 32:14,19 35:18 37:18 117:21 126:6 143:22 144:24 145:19,24 146:2,5
oval 88:11
OWNER 1:8 2:8,15 3:10
o'clock 6:12,18,23 26:23 27:1,13,25 28:4,5 28:16 29:4,11,14,15 29:17 30:3,8,11,15 30:18,21 35:16,22 37:6 38:2,3,25 39:12,24 41:18 47:7 47:9,10 48:18 49:5 49:6 51:18 52:9,24 54:2,7 55:16 56:4 56:24 57:12,14 58:6 64:3,12 65:25 67:15 70:1 87:8 88:4,6 89:4 90:1 91:14,24 92:12,15,17,21,24 93:3,5,6,16 94:8 95:11

P

P 1:14 2:14 4:2 5:4 158:7 159:5,14
page 4:3 5:20 35:7,8 42:12 42:13,14 44:3,7,13 74:10 76:20,21,22 106:13,14 107:16 107:17 109:23 110:8 129:18,23 139:6 144:13,15 145:16
pair 10:24
palm 106:19
paper 16:24 58:17 59:3 152:24
paragraph 115:20 116:3,5 139:8 144:13,15 145:16
paravalvular 77:3,16 79:17 119:8 119:10,16
part 8:2,4 9:4 11:11,12 18:12 24:21,22 39:12 42:6 44:25 47:9,14 52:24 53:24 56:21,23 64:17,21 69:23 82:20 91:20 97:1 103:20 138:18 139:16
particular 58:6 59:18
particularly 82:25 142:2
partly 10:5

parts
10:1 20:21 27:4 29:8 48:4 56:21 99:4
party
84:22
pass
19:20 157:9
patent
1:1,2,6,8 2:1,2,6,8,15 3:10 72:25 78:7,13 115:4,6 116:17 124:20,25 140:20 140:23 141:11,12 141:16 142:2 144:7 146:15,21,22,24
patents
73:1 141:15
patient
152:13,22 154:1,3
patients
148:7
PDF
35:8 42:14 120:10 144:14
penalty
159:6
people
78:22 84:17 108:24 117:6
percent
53:13 102:9 103:8
percutaneous
150:21
percutaneously
150:12
Perfect
6:1
performing
84:5
pericardial
64:14
pericardium
11:11,13,15,17 48:22 88:7 89:15
perjury
159:6
permeability
73:19
person
17:4 78:18 79:4,15 81:20 116:10 118:24 140:9 150:3
persons
78:16
person's
79:15 103:24 105:16 107:5,10
PET
32:7,9,23 33:2,5,12 33:14,19 34:1 45:23 72:14,20,22 137:10 137:11,21,24,25 138:2,6
petition
67:12
Petitioners
1:5 2:5 3:3 44:7
Pg
161:2
phone
85:1 86:4 136:3
photo
11:9 24:6,20,21 27:2 27:4 46:20 62:21,21
photograph
12:7 20:8 25:21 26:2 26:2,3 29:8 36:11 37:16 43:17 51:4 71:15 84:12,15 97:5 97:20,25 98:7,11 101:11 104:3,20 105:20,24 106:9 113:6 115:5 135:16 136:18 137:24 148:24
photographs
60:4 64:8 65:10 66:20 81:25 82:1,3 82:3,25 83:2,11 106:23 130:9
photography
130:5
photos
65:3,20 84:8
physically
16:14
pick
39:17 85:1 86:4
PICO
3:12
picture
44:3,14 45:14,17,18 71:25
piece
21:19 22:6 64:18,20
pieces
29:21,22 32:9 60:1
pixilated
59:5 64:23
place
160:11
placed
67:6 74:21 79:22
places
25:9 42:4 100:1 145:14
placing
83:9
plain
73:5
plausible
119:20 153:10
please
5:20 27:23 51:12 75:23 76:21 96:10 139:6
plurality
119:22 120:13 122:2 125:1
point
10:19 16:11 79:12 138:20 141:13
pointed
24:14
pointing
64:19 122:8
points
28:21
poke
94:23
poking
46:8,12,25 50:10 56:22 57:8 58:7 94:6,15
porosity
73:19 134:6,7
porous
73:8,13 130:17 132:3 132:4 133:10 135:8 136:11
portion
69:6 143:19
portions
20:23 34:18,21,25
position
12:12 42:9 67:2,6 69:24 79:14 115:6
possibility
50:1 141:7
possible
5:24 7:15 13:24 31:6 31:8,16 32:12 33:4 45:5 49:17,19,22,23 57:13 102:21 150:13
possibly
136:7
post
28:6
posts
48:25
pour
72:9,13,16,18
poured
72:17
powder
78:17
precise
16:1
predominantly
57:15
preliminary
35:1
PRESENT

3:16
presses
14:5
pressing
13:22 14:1
pressure
13:19
presume
10:4
prevent
119:10,16
previous
64:7 65:10 66:19 105:14 111:11 142:8 144:4
previously
25:6 105:11
prior
17:1 81:18 134:12 160:6
probably
72:9 99:1 107:7
procedures
80:9 84:5
proceedings
160:14
product
152:14 155:17,18
professional
82:18
proffer
73:2
profile
25:20 42:25
projects
82:24
proposition
60:18
prosthetic
144:23,25
protons
23:10
provenance
133:17
provide
73:6,11,16 115:2
provides
65:23 67:8,13,15
Providing
40:2
provisos
31:21
proximal
61:4,6,18,20 75:6
PST
2:16 5:2 32:4 69:2 129:7 155:11 158:6
Public
161:25
publication
81:6,21
publicly
152:4
published
17:3 58:20,21 59:8 80:1,3,4 81:7 83:24 84:2
puffy
19:6,11 21:12,19 22:6
pull
43:9 138:24
purpose
79:17 98:3
purposes
119:6 134:13
purse
150:17
PURSUANT
2:17
put
74:1,16 76:24 77:7 78:5 79:2 118:15 119:9 120:25 129:8 143:11
putting
27:15 87:13,14 123:8
PVL
73:24 74:3,7 75:13
p.m
27:11,11 129:7 155:10,11 158:6

Q

quadrant
47:19,25 48:14 51:6
quadrants
51:7 87:7 91:13
quality
66:8 102:14 104:21 105:15,20 132:12
quantify
108:20
quantitate
24:3
question
8:25 9:12 10:9 20:2 31:14 51:11,12,25 51:25 52:1,4,5 53:16,18 54:3,15 55:11,19,24,25 56:10 59:4 60:21 62:9 63:9,13 68:9 73:15 75:2 76:3,6,9 78:24 85:15 86:11 86:17 95:7,8,18,19 95:21 102:8 103:16 110:5 112:21 120:20 121:8 123:7 123:13 127:7 136:2 139:21,23 140:22 141:18,22 142:8 143:1 147:9 150:21 151:15 153:14
questioning
7:16
questions
85:14 93:11 97:9 99:12 102:17 103:2 103:3 105:14 112:11,13 114:2,7 123:10 136:5 138:8 157:12
quick
7:17
quite
6:5 10:18 47:5 87:15 110:17 127:21
quotations
4:9
quote
4:11

R

radially
144:23
raised
141:13
random
19:22
reach
126:19
react
124:10
read
4:10 42:20 43:4 138:7 141:5 146:21 147:11 161:2
readily
143:18
reading
16:25 81:21 140:12 145:21
reads
144:19 146:4 161:2
real
153:17
really
7:7 11:9 20:11 21:1 42:21 48:5 100:24 103:23 135:21 147:22 153:14 155:1
reask
53:15
reason
42:18,22 43:1,5 83:16,18 84:7 91:9 103:20 119:13 130:8 161:2
reasonable
125:7 126:18 150:7 152:10 155:8
reasonably

152:3
recall
90:20 136:13 148:17 148:20,22
Recess
32:3 69:1 129:6 155:10
recognize
96:11,14
recollection
83:13
reconnect
68:23
reconvene
128:17
record
4:11 7:13 19:25 68:19 129:5 136:8 157:20
rectangle
19:14
redirect
95:23,23 157:8
reduce
77:3,16
reduced
160:12
refer
10:22 21:24 77:10,11 77:18,25 78:19 115:16,18 116:20 117:2,6 123:22
reference
5:17 67:12 112:16 116:18 141:10
references
85:17 142:3 149:4
referred
117:1 136:11 148:21
referring
9:6,8 14:13 15:17 16:4,9 17:14 35:23 61:21 76:19 78:24 89:24 90:23
refers
68:5 115:15 120:16 122:1 123:23 124:16 126:6 137:9
reflect
42:19
reflected
4:10 68:6 127:22
reflecting
87:22
reflection
84:13 87:8 88:12 103:23 127:14
regard
123:18 140:7
related
58:6 141:16
relating
83:25 84:3
relative
20:22 93:4
relatively
7:17 21:20 50:21
relevant
131:4 135:2 138:23
relied
127:17
rely
67:20 81:6 141:10
remember
5:16 17:10 59:11,18 73:14,20 86:16 128:2,5,6 147:18,20 149:6 157:2
REMOTELY
1:15 2:15 5:1
remove
52:18
repeat
92:3
rephrase
118:9
replaced
67:1 69:9
replacing
65:14
report
64:1 67:22
REPORTED
1:23
reporter
6:15 7:6,18 19:23 32:1 82:21 119:12 157:16,22 158:1 160:24
REPORTER'S
4:9
represent
34:17,24
representation
34:20 35:3 42:24 149:8,12
representations
34:22
representing
115:6
reputable
142:6
requested
119:12
require
12:7
resemble
90:21
resolution
12:7 36:11 41:13 57:2 70:10 71:3 105:25 106:9
result
82:22
retained
84:22
retired
80:7,8 84:5
reveal
84:8
review
16:24
revise
53:15
right
6:22 7:3 16:24 38:20 40:12 41:10,12 43:12,13 45:18 47:19,23,25 48:4,5 48:12 59:22 76:23 86:14 87:11 88:8,9 89:4 90:1 91:23 92:19,25 97:4 98:10 114:10 122:11 124:14 131:18 132:1,5 140:21 148:2 153:24
right-hand
48:14 76:23,25 131:8 131:11 135:14
ringing
85:12
rise
9:16
Rorschach
68:8,12,14,15
rough
57:19 64:24 65:11,16 66:17 70:9,13 71:5 101:15,16 106:5 111:22
roughly
6:12 26:23 27:24 93:7,7,8
round
27:19 94:7
running
26:14 38:2 41:3,25 134:19

S

S
3:4
samples
85:20,24 86:5
SANTA
3:13
Sapien
43:18 44:4,15 45:14 45:17,23 49:20 50:17,22 51:9,15 52:16,25 53:25 54:8 55:17 56:5 58:1 74:16,17,19,25

76:15,15 77:2,9,14 77:15,22 78:4 79:1 79:19 80:22,22 89:11 91:5,25 95:9 96:17 97:1 98:2 99:17 100:9 101:5 103:10 106:17 108:3 129:19,25 130:1,9,11,22 131:3 131:6,13 132:14,21 133:5,12,23 134:4 134:10,11,11,14 136:16,19,24 137:12,18,20,20 138:4,9,11,18 148:12 155:18,22 155:24 156:13,15
Sapien's 52:10 57:16 93:21
saw 20:19 53:19 65:25 136:18,20
saying 9:13 18:11,11 29:10 37:10,11 38:11 50:7 53:6,10,10,12 64:1 67:19 73:20 78:23 86:16 88:15 90:25 91:1 117:14 120:19 121:7 128:12 134:21 136:15 138:4 141:6 149:12 153:5,5
says 17:6 35:10 42:16 43:6,7 45:25 62:17 74:10 77:1 78:24 115:20,24 117:13 117:14 120:21 121:25 123:3 125:1 126:2 132:7 136:3 139:8,21 145:19
scale 23:8
Scientific 155:15
screen 24:21 45:16 46:21 120:25 132:9
seal 74:11,18 75:13,16,19 76:14 77:3,6,17 79:3,6,20,21,23 119:8 146:7
second 5:20 44:13 77:24 91:23 107:16 141:21 147:24
section 28:15 30:4 35:17 38:16,19 50:24 51:1 56:11 65:7 66:11 88:23 92:7 94:4
sections 29:4
see 5:23,23 6:2,13,17,18 6:22 8:1,4,7,10,19 8:21,21,23 9:1,22 9:22,23 10:2,12,17 10:21,24 11:2,5,21 12:6 13:8,16 14:18 14:24 15:17,20,25 16:2,6,21 17:16,22 17:25 18:1,5,19,22 18:24,25 19:18,20 22:8,11 23:2 24:15 24:17 25:1,3,5,7,8 25:13,18 26:10,13 26:22,24 27:1,6,24 28:3,8,12,17,19 29:1,3,16,21,22,24 30:6,12,14,20,25 31:3,4,5,11,11 32:10 34:5,9,16 35:9,12,17,23,25 36:8,12,12,13,14 37:17,20,24 38:1,12 38:13,15,20 39:2,5 39:8,13,14 40:5,8 40:13,13,16,20,23 41:1,8,13,16,20,22 41:23,24 42:1,8,9 42:16 43:15,16,18 43:20,22,22 44:9,17 46:3,4,6,18,24,25 47:4,14,21 48:3,4,5 48:9,19,22,24 49:12 49:13 50:1,6,14,22 50:24 51:5,15,19,20 51:21 52:7,22 53:1 53:4,8,9,13,14 54:1 54:6,12,16,20,20,22 55:1,3,18,22 56:8 56:12,18 57:4,10,13 57:24 59:4 60:1,5 60:15 64:2,4,17,17 64:20,21,24 65:4,6 65:8,11,16 66:17,21 66:22 67:6 68:3,7 69:25 70:9,11,12,13 70:14,21,22 71:3,4 71:9,13,16,18,19,19 71:20,23,23,25 72:1 72:3 76:18,19 80:2 81:8 83:2 85:17 86:21 87:5,8,10,15 87:15,18,20,23,25 88:1,6,9,23 89:11 89:13,16,21 90:9,12 90:17 91:9,17,19,19 91:25 92:4 93:21 94:2,11,16,25 95:9 96:5,8,19,21 97:12 97:13 98:17,19,22 98:25,25 99:2,4,7 99:17,20,24 100:2,3 100:22 101:5,15,22 101:23,24 102:4,6 102:16,18 103:14 103:25 104:6,8,18 104:21,22 105:4,4 105:25 106:2,4,5,6 106:11 107:9,11,21 108:20 109:2,4,5,9 109:12,16,25 110:2 110:8 111:7 112:2,5 112:12 113:2,5,10 113:11,18,25 114:6 114:14,19,22,22,23 115:1 116:16 120:7 120:8,25 121:1,7 122:1 125:3,4,6 126:3 129:10,12,14 129:16,19,24 130:12,13 131:5 132:20 133:4,7,12 134:15,17,19 135:15 138:20 139:1,3,11 143:23 143:24 144:8,13,17 146:1 149:10 153:8
seeing 8:13,14 9:14 19:4 24:20,22,23 30:3 37:14 38:14 39:15 41:15 45:21 46:8,11 47:8,11 48:7 51:2 51:23 58:5 60:13 62:12,24 63:12 65:20 70:4,20 91:11 94:9,14 108:11 110:16 149:6
seen 17:3 30:10 35:6 36:6 42:20,23 43:3 68:11 80:19 94:6 104:19 106:23 127:8 156:23
sees 68:4
see-through 110:14
segment 19:4 29:14 31:5 51:20 53:4 54:1 66:18 92:5
segments 51:21
sense 26:18 28:23 138:10 141:6
sentence 76:17 143:16 145:15

145:22 146:1,13 147:10
separate 14:20 106:16,20
separated 32:8
serves 136:12
shade 8:16 37:1 40:7
shades 36:22 37:13 66:16
shadow 9:16 12:22 13:1,3,5,8 13:10,16 15:14 18:1 18:5 36:12,14,21 38:6 41:11,22 42:2 42:5,9,10 65:19 66:14
shadowed 66:13
shadows 9:10 11:23 12:6,10 13:9 29:10 40:11 65:2,9 67:19 70:11 71:20 82:6 83:2
SHAHRIARI 3:17
shallow 111:13
shape 48:23
shapes 19:14,17,21
shares 142:22,24
sharply 100:25
sheath 148:1,15 149:16 151:2,3,10,14,17,24 152:4,18 153:1,12 153:16 154:19
sheaths 148:11,14
sheet 150:4 161:1
short 155:6
shorter 128:25
shorthand 160:11,23
shot 8:2
show 30:14,16 34:14 37:16 76:17 87:3 96:2 114:8 126:9 148:18
showed 24:6 136:22 148:24
showing 22:12 66:19 100:14 127:16 132:15
shown 16:15,18 46:20 60:2 142:11,13 147:19
shows 63:5 102:22
side 11:16 27:20 28:10,12 28:13,16 29:2,19 32:13,19,20 33:6,14 33:17,19 34:2,2,5,7 34:10,11 35:16 38:3 38:3 45:6,6,17,18 46:21 49:12,16,18 52:7,22 55:14 56:3 56:13 112:16,18 129:25 135:14
sidearm 151:7
sides 49:15
side-on 30:5 48:24 71:14 104:7
Signature 161:20
significantly 108:12,23,25
similar 25:3,13 66:7 127:16
Simple 95:8
simply 51:2
sir 11:2 40:16
sit 128:4,6
Sitting 59:17
six 81:8 152:7
size 150:18 153:16
sizes 151:22 152:17
skill 78:16,19 79:5,16 81:21 116:10 118:25 140:9 154:7
skilled 126:22
skirt 44:18,22,24 46:11,16 46:24 47:2 49:20,24 50:2,10,18,25 51:9 51:15 52:10,17,25 53:25 54:9 55:17 56:6,19,20,25 57:4 57:16,21,25 74:24 74:25 75:15,21 78:1 89:12,19 90:19 91:2 91:6,20 92:1,1 93:22,24 94:18,21 95:9 129:25 130:1 138:11 139:10,16 139:18,22 140:2,7 140:12,25 141:5,8 143:4,16,20,21 144:5,16,19,21,24 145:9,20 146:3,5
slight 21:22
slightly 41:7 91:16
slowly 20:14
small 15:24 50:20 64:17,20 150:12
smaller 50:19 154:18,19
smallest 150:22
smooth 8:18 9:11,13,14 12:9 13:14 15:13,15 16:8 17:25 19:1 22:17 25:2,8 26:16 27:7 29:25 32:15 33:8 36:13 39:6,8,14 40:9 42:3 70:13,22 70:24 71:1 100:16 100:23 111:9,12,19 111:21
someone's 27:15 87:13 106:20 107:11
somewhat 40:24 48:23 101:16
sorry 7:6 28:24 34:21 48:1 51:24 57:16 61:12 68:9,16 72:14 73:9 74:5 92:2,14 100:10 131:23 144:11 147:5
sort 6:6 9:14,15 14:10 19:3 20:14 24:8 32:24 37:22 38:2 41:2,6,14 42:2 48:22 66:7 78:18 87:9 88:11 94:7 108:19 110:3 117:24
sounds 140:9
space 8:11,12,16 22:22,25 23:1,9,23 49:6,8

94:23 151:5
spaced
40:24
spacing
101:20 102:2 103:11 111:25
spare
152:25 153:5
speak
81:5
speaking
91:3
special
82:14
specific
59:21 79:11,13 89:23 122:12 140:15
specifically
59:19 74:9 119:9 126:5
specification
135:12
spectrum
99:4
Spenser
114:15 115:7,8,9,12 115:23 116:7 117:11 118:6,19 119:21 120:5 124:23 125:8 126:5 126:8,24
spent
82:17
spherical
21:21
split
45:16
spoken
11:24 80:24 81:4 128:3
spots
9:6 13:12 14:13,25 15:8,10,16 16:4 17:13
spotted
67:20
spun
22:2,18
square
19:14 90:17
squashed
72:8
SS
159:2 160:2
stand
23:13
standing
37:23
stands
155:4
start
28:24 48:17 67:9 89:25 136:4 144:11
started
52:1
starting
49:7 89:3 92:12,15 92:20,23 93:15 143:16 144:15 145:17
state
37:8 70:3 159:1,6 160:1,5,25
statement
79:8,11,13 122:12,13 139:7,13,21,24 142:1,15,21 143:3 146:10 150:7
statements
140:19 145:1 147:2
States
1:1 2:1 142:2
stay
145:10
steamy
20:13
stent
48:7 50:11 95:4 98:23 99:2
stents
83:1
Stephen
3:18 126:13
stick
21:12 31:17 106:4
sticking
29:22 30:13 31:9 57:3 90:15
stitch
27:18 40:15
stitched
45:1
stitches
40:24 41:25 46:3 47:15 89:18 90:12 90:16 91:19
stitching
40:14,14 41:24 44:18
stock
152:19
stop
76:1,4 79:17,19
stopped
80:9,9
STOWELL
3:5
straight
57:7 62:23 91:15 104:7
straightforward
34:13
strands
22:15 24:7
stray
9:1
STREET
3:6
strings
150:18
strip
40:21 41:9
structure
26:9 49:1 83:3
structures
33:6,13
strut
8:20,23 14:9,10,11 36:14 42:1,4 45:2,2 46:20,22 47:1 69:25 94:16
struts
25:11 30:7 46:23
stuck
106:8
studied
130:7
study
130:8
SUBSCRIBED
161:22
substantially
65:13 83:7
suddenly
20:16 143:11
sued
156:8,25
sugar
22:2,2,4,15,18
suggest
128:11
suggesting
12:10 42:2 70:17 73:17
suggests
132:8 154:22
Summers
3:4 7:10,11 20:25 22:23 24:1 31:18 32:22 39:10 50:5 54:10 55:7 57:18 58:3 59:6 63:4 69:17 75:22 76:1,4 76:7,10 78:21 82:15 85:25 96:24 97:23 98:14 99:9 100:12 101:8 103:13 104:2 104:17 105:2 107:3 107:20 108:8,17 109:7,24 111:17 112:19 113:24 117:9 119:4 121:17 123:11,17 124:11 125:11,16 128:21 130:15 131:15

132:22 133:6,15 136:1 143:5 150:5 155:9 157:12,25 158:2,3
supports 79:9,13
supposing 147:10,11
sure 7:11 10:22 14:22 20:7,11 65:22 85:4 88:4 89:24 90:20 102:20 110:17 114:13 116:6 126:1 128:3 134:1 135:2 140:17 141:23 146:20 149:19 155:9
surface 8:6,13,15,17 9:2,11 9:13,17 10:14 11:20 11:22 14:5,6 15:15 15:18 16:3,7,8,12 16:21 17:8,11 19:5 20:5,7,11,16,19,20 21:15,23 22:17,17 23:12 25:16 26:11 26:13,15,19,22 27:7 27:9 28:17,20,23 29:3,6,25 30:13 31:1 32:13,15 35:19 36:2,6,9,15,16 37:2 37:8,17 38:10,15 39:3,6,8,16,20 41:21 44:23,25 45:24 48:8,10 59:1 59:16,19,24 60:6,9 62:10,13,19,22,24 63:1,6,7,11,12,17 63:22 64:5,24 65:11 65:17,24 66:17,25 67:14,16 68:2,2,3 70:9,14 75:14,14,19 75:20 76:16 77:6,8 79:21,23 100:8,14 100:16,24 101:7,15 101:16 103:25 104:8,9,11,12,13,24 105:5 106:5 110:3 111:8,12,19,21,22 112:23 113:1,2,4,6 113:9,10,12,18,21 114:6,7,9,19 115:10 115:13,16,17,19,20 115:22,24,25 116:2 116:8,9,11,18,20,21 117:1,3,4,7,8,13,15 117:17,18 118:5,10 118:18,21,25 119:6 119:14,17,23 120:2 120:14,17,22 121:15,19,20 122:3 122:4,8,10,13,14,15 122:20 123:16,19 123:20,22 124:5,15 124:16,21,23 125:3 125:5,6,9,19,20,22 125:24 126:7,10,25 134:18 143:17
surfaces 19:15 79:21 116:1 117:19
surgeon 150:14 154:20
surgical 64:15 74:20 77:7 79:2
surgically 150:19 154:14
surmise 153:3
surprise 157:1
surrounding 146:7
suspect 86:8
sussed 99:5
suture 10:20,21 11:6,11 54:13
sutures 10:2,3,20,21,25 11:3 11:12 42:11 45:2 46:16 47:1 49:20,24 50:2,17,19,21,24 51:8,15 52:10,16,25 53:1,4,9,24 54:1,8 55:17,18 56:5,8,19 57:17 58:1 89:11,14 90:23,25 91:1,5,25 93:24 94:9,11,11,12 94:20 95:1,9
sworn 5:5 160:7 161:22

T

take 10:3 32:1,2 38:19 47:1 68:21 94:14 121:6 138:3 149:8 149:11 155:6
taken 1:15 2:15 21:19 24:24 25:21 26:3 37:15 110:25 130:3 132:13 133:21 137:2 149:18 160:10
talk 20:8,9 73:24 77:22 116:7
talked 29:11 65:10 156:23
talking 22:24 23:7,11,12,14 23:18,20 24:4 32:24 35:25 53:5 56:14 59:8 60:6,8 61:12 61:16 76:18 78:6,7 78:11 79:1 86:12 92:8,10,13,18,25 93:5,11 112:22 115:5,21,25 116:8 116:23 120:18 121:11 124:1,1,18 124:24 130:19 131:8 136:21 137:7 142:9,10,13,14 144:9 145:4 150:11
talks 115:22 146:13
taller 40:7
taught 135:11
TAVR 78:17 80:11,12,14,25 83:23 149:15 150:3 151:1,9,11 154:4
TAVRs 80:16 83:8,15,20,25 84:3,4,6 154:8
teaches 74:18 78:10 115:8,8 119:25 120:2 126:24 139:9,15,15 139:22,25 140:15 140:24 141:2 143:3 144:2,3
teaching 75:18 76:12,14 117:17 139:17,19 140:5,8 141:6 147:20
teachings 144:1
tech 7:11
teeth 41:2
tell 9:21 11:9 13:12 17:18,22,24 22:12 31:25 34:6 54:19 97:24 98:7,10 101:11,25 107:4,8 110:7 113:8 130:10 135:17 138:6 156:24
telling 53:8 69:22 77:5 140:10

tells
16:7 63:16,21
tend
138:14
term
28:9 68:14
terms
109:22
test
68:8,12,13 154:2
testified
5:6 61:10
testify
106:1 160:8
testimony
14:23,24 15:7 37:9 39:7,9 46:17 50:3 50:23 57:11 58:2 61:8 66:1 67:8,10 67:17 69:16 72:15 73:7,11,17 75:8 102:21 105:24 127:3
texture
26:6,7
thank
5:12 56:10 157:9,11 157:13,14
thereto
58:1 67:13
They'd
59:11
thickness
17:15,18 70:15 86:23 101:7 104:15 111:16 113:22 119:15 133:13 134:16
thing
7:4 54:16,17 72:23 122:7 132:7 135:9,9 139:15 152:17 153:8
things
11:24 19:18,19 71:4 78:23,25 80:19 81:17 90:15 108:19 118:1,2 128:4 137:1 137:13 138:7,14 140:1 150:9,12,14 151:6 152:13
think
7:5 8:22 9:5,12 11:16 13:2,10,24 19:3 20:2,3 21:11 23:18 27:15 28:19 29:7,9 30:12,20 31:10,13 34:12 35:4,20 46:6 46:18 49:15 51:8,10 54:11,25 55:3,8 59:9 60:1,13 62:7 66:3 68:5,22 72:7,9 72:12,17 74:10 75:8 78:6 79:4 83:14 84:10,11,14 85:15 88:16 89:13,18,22 93:9,10,12 94:5 95:15 102:25 103:1 106:18 108:9,10 109:15 112:9,12 123:5,6,8 125:17 126:21 127:4,19,21 127:23 133:9 134:25 135:9,15 139:2,20,25 142:4 143:6 145:17 147:8 147:16 148:2,4,7,9 149:21,23 150:6 153:10,16,25 155:23 156:6,15,16 157:3 158:3,4
thinking
136:2
thought
99:3 106:24 127:10 131:2 142:9 143:7 146:25
thousand
83:14
three
41:25 45:1 46:19,22 46:25 47:15 80:6 89:13,16,18 90:12 90:16 109:21 110:11
three/four
42:11
THV
44:4
tighter
134:3
tight-fitting
139:9,15,22 140:7,12 140:24 141:7 143:4
tilted
6:6
time
17:1,3,5 41:23 58:20 58:23 59:8,9 71:8 98:3 128:24 148:12 151:18,24 153:13 155:25 156:7,25 157:9 160:11
timeframe
148:16
times
83:23 131:1 132:7 135:17,18
tiny
15:20 19:4 25:5 26:25 31:3 114:23
tissue
117:25 118:1,3,16 119:1 126:4
titled
129:19
told
137:14 142:10,18 153:15 156:7,17,25 157:2
tones
65:9
top
9:24 10:25 14:11 24:25 25:18,20,24 26:6,12,20 28:25 29:17 35:18 43:20 50:7 51:2 60:23 61:1,16,21 71:7,11 87:5,20 90:14 91:10 104:10 114:22,24 115:1
totally
30:23
touch
118:16
touching
118:5
toughs
27:8
trace
107:24
TRADEMARK
1:1 2:1
training
82:18
trains
19:18
transapical
148:15 150:25 151:1 151:17,20 154:6
transapically
151:9
transcript
158:2 160:13
translucent
98:13 107:18 108:16 109:12,21 110:9,19 136:19 137:3 138:12,15
transparency
109:19
transparent
109:16,20 110:9
treat
154:1,3
treated
111:4 113:17
TRIAL
1:2 2:2
triangular
11:23
trouble
26:24 53:7

trough
88:14,17,19,25 89:17
troughs
90:4
true
17:12 34:9 47:13 60:20 83:17,19 135:21 139:13 142:16 150:16 159:7 160:13
truly
48:6 51:4
trust
5:16
truth
160:8,8,9
try
7:22 47:24 103:6 112:10 141:23
trying
92:23 93:3
tuft
30:14
tufts
25:9 26:11,16 30:1,6 30:10,12,25 31:8,16
turned
32:8
two
9:6,14 10:21 11:3 12:6,9 13:2 14:12 14:20,21,25 15:8,10 15:16,21,24 16:3,5 16:5 28:8,16,21 29:10,19 30:7 32:8 32:9 35:16 64:14,16 74:11,12,19 77:4,9 77:13,17,24 79:1,3 79:6,18,20 88:8,9 88:12 89:8 92:13,18 92:25 99:18 130:16
two-dimensional
17:19
typewriting
160:12
typo
145:17

U

ultimately
127:11
Ultra
80:23 96:16,17 97:1 99:18 100:9 101:5 103:10 106:17,21 106:24,25 107:1,7 111:1,2 113:19 129:19 130:1,9,11 130:23 131:3,6,14 132:14,21 133:3,5 133:12 134:4,11 136:16,19,24 137:12,18,21 138:4 156:13 157:3
Ultras
98:2
unclear
37:7
uncovered
61:11
underlying
105:19 108:2
underneath
14:16,17 35:10
understand
7:8 14:23 34:20 35:3 54:25 55:6,9 65:22 68:13,16 77:19 82:21 84:21,24,25 85:5 101:12 116:19 116:25 117:2 123:1 142:20 153:14,22
understanding
79:9,16 81:13 112:21 135:5
understood
58:23 110:17
undoubtedly
33:11 94:5 118:15
undula
29:24
undulate
33:10
undulating
19:2 25:2,4,15 26:11 27:8 29:12,25
undulations
26:17 101:9 111:10
uneven
19:15 20:4,19,20 26:11
unevenness
21:15 22:16
unfair
142:12 143:10
uniform
16:12 70:15 89:17
unintelligible
82:20
unique
108:25
United
1:1 2:1 142:2
universe
153:10
unmistakably
123:4
unreasonable
109:15
unsmooth
26:13
upper
42:11 47:9,10,14 48:5,8 51:7,20 61:13 62:21 71:14 71:15 87:6 144:21
upside
48:23
upwards
14:10
use
136:7 137:4 147:4 148:4,7 150:3,22 151:2 153:18

V

v
1:6 2:6
valve
16:15,18 28:6 36:24 38:6 40:13,18 41:5 41:12 42:16,17 43:6 43:18 44:15 46:2 48:20 50:22 58:11 58:14,18 61:4,6 64:4,15 65:14 66:25 69:9 73:25,25 74:19 74:20,21 76:15,16 77:2,6,7,9,11,16,18 77:19,21,23,24 78:1 78:4,5,12,13,19 79:1,2 82:4 89:15 96:11,14 99:18 106:2 108:7 118:16 129:19 144:23,25 148:12,21,22 151:2 155:19
valves
74:11,12,16,19 77:4 77:9,13,17,24 78:10 79:6,18
variation
16:7,9
varies
16:13
various
25:8,9 127:16 139:25
variously
87:21
velour
33:2,5,14,18 34:1
verify
81:13 149:9
versus
29:2
vertical
28:13 30:7 67:4,4 69:25
vertically
94:20 134:20
vicinity
12:15
VIDEOCONFER...
1:15 5:1

VIDEOTAPED
1:14 2:14
view
6:6,6 45:12,19 46:4 47:6,20 48:15 51:17 52:8,23 53:22 55:15 56:4 63:16,23 71:11 86:19 91:11 134:24 138:20
virtue
70:25
visibility
109:13
visible
38:9 53:2,20 55:14
vision
98:21
visual
16:23 17:21 99:4
visually
20:20 22:8
vitro
148:8
voluminous
73:22

W

wait
95:6,6,6 124:6
wall
47:11
Walther
25:14 45:5,6,7,8,22 45:25 46:5,9 47:5 54:7 59:23 61:3 63:16,19 65:14 67:7 73:18 74:2,5,9,17 74:23 75:12,18 78:3 79:8,25 80:25 81:9 81:13,15 84:18 85:17 119:10 127:17 136:11,17 136:22 137:2,9,21 147:25 148:4,7,8 151:18,25 152:6,7 152:16
Walther's
45:12,19 46:12 47:15 47:20 48:14 51:17 52:8,23 53:21 55:15 56:3 58:10,14,17,18 59:2 61:22 66:5 67:11,14 69:7,23 70:6 71:7,10 72:5 72:16 73:7,13,23,24 74:13,14 75:5 77:10 77:12,18,19,21 79:24 84:8 91:17 94:23 99:6 137:5
want
6:10 7:13,16 10:19 11:19 14:22 30:23 35:21 40:12 42:15 45:5 47:19 48:17 49:3,5 51:11 58:21 65:22 71:7 76:18,20 79:12 81:17,17,22 88:3 89:25 90:5 95:22 102:20 116:24,24 120:4 126:1 139:7 143:15 150:12,16,22 158:1
wanted
26:18 58:19,22,24,25 81:19
wants
115:18 116:1,7 117:13
wasn't
10:9 61:8,11 136:24 141:23 152:21 153:4
watching
19:19
water
22:21,22 23:20 72:17
waving
19:2
wax
124:4,7
way
15:6 18:8,14 25:3 64:19 87:23 94:12 98:8 103:1 116:14 119:18 132:2,18 133:19 137:2
ways
103:6
WEATHERWAX
3:11
weave
33:10 34:2 41:16 134:3
went
55:21
weren't
134:12
wet
103:19,22 106:7 107:2,6,8 138:14,15
We'll
21:6
we're
7:3 23:7,11,12,14,18 24:4 26:2 27:10,12 37:6 42:13 44:9,14 46:1 47:23 48:6,7 49:7,8,19,23 50:16 53:4 59:21 61:17 65:13 69:14 71:9 78:6,7 88:18 89:3 90:21 92:7,10,12 93:5 96:11,14 97:15 102:1,9 103:7 105:10 106:14 114:15 115:4 124:5 128:22,23 134:14 142:13 158:4
we've
39:1 56:14 68:20 75:4 93:10 96:6 110:13 141:20
whats
45:21
whatsoever
17:7 63:1,10 81:12
white
10:2 11:6 38:17 40:14,20 41:6,9 52:19,22 53:20,23 54:6 55:14 56:2,12 56:18,23 57:14,24 65:5,8 66:12,15,21 68:4,5 70:6,16,20 84:11 86:22 87:19 88:11 89:6,16 91:22 93:17 94:16,17 96:22 97:15 98:8,12 98:18 99:25 101:4 103:25 104:12,15 104:25 106:1 107:15,18 108:6 109:22 111:8 112:16 113:21
whitish
91:24
wider
150:4
width
9:19
Will's
136:5
wish
81:5 112:10
wished
81:6 84:19
wispy
57:5,20
withdraw
151:15
witness
4:2 6:17 7:1 21:1 22:24 24:2 31:19 32:23 39:11 44:2 47:21 48:3 50:6 54:11 55:8 57:19 58:4 59:7 63:5 69:18 75:23 76:7 78:22 82:16,22 86:1 88:19 90:7 96:25 97:8,24 98:15 99:10 100:13 101:9 103:14 104:3,18 105:3 107:4,21

108:9,18 109:25 111:18 112:20 113:25 117:10 119:5,13 121:18 123:18 124:12 125:12,17 130:16 131:16 132:23 133:7,16 143:6 150:6 156:20 157:11 160:6,17
wondering 45:4 136:5
word 52:18 121:5,6 145:18 146:11,18 147:6,18 147:21
words 42:24
work 128:20 147:4 155:21
worked 82:23 156:18 157:3
workings 142:5
wouldn't 34:10 62:18 70:12 85:4,10 86:7 107:24 114:6 126:14 137:3 140:7 146:17 147:4 147:6 153:11
woven 32:7,9 33:2,5,5,12,14 33:18 34:1 37:22 72:14,20,22 134:18 134:19
wrap 62:3,6
wrapped 8:9 11:18 49:2 66:6
wrapping 61:3,5 62:7,10,11,14 62:15,16 64:18 75:9
wraps 61:25 62:2 75:5,7 116:14
wrong 84:11 127:20 128:13

X

X 4:1

Y

yeah 6:8 7:5,10 21:10,10 27:21 29:24 41:3 44:11 49:10,11 61:1 84:24 87:13 88:16 92:18 97:13 99:23 100:19 112:25 131:11 132:2,4 139:4 147:8,13 149:13 156:16
years 80:6 156:1
yes-or-no 95:19,21 120:20
young 108:24
you-all 128:20

Z

zero 83:20 84:2
zigzag 28:12
zone 18:24 58:6
zones 128:24
zoom 1:15 2:15 5:1,21 6:21 27:22 35:22 38:24 45:12,13 47:19 60:11,14 86:19 97:7 97:10,11 99:15 100:5 102:11,11,23 102:23 103:1,4,4,5 103:9 105:6 111:6 112:4,8
zoomed 39:1 99:21 102:9
zooming 64:22

1

1 45:13,19 48:1,14 63:16,23 71:7,10,12 71:15 76:20,21 86:19
1:00 88:5 93:5,16 95:10
10,987,236 1:7 2:7
10:32 69:1
10:40 69:2
100 53:13 105:23
1011 114:11
1012 43:10,14,21 44:10
1016 3:12
1017 5:14
11 1:16 2:16 5:2
11:00 87:8
11:51 128:19 129:6
12:00 88:4 89:4 90:1 91:24 92:12,15,17,21,24 93:3
12:08 129:7
12:46 155:10
12:51 128:19
12:52 155:11
12:55 158:6
1300 83:15
14TH 3:6
150 103:8 105:12
18 144:16,19

2

2 5:21 6:3 16:22 17:14 18:6 27:13 47:25 60:14,16,18,23,24 61:17,22 62:12 63:24 64:8 67:11 69:7 99:6 106:14 107:16,17 109:23 110:8
2:00 88:6 93:6,16 95:11
20 22:7 132:7,8 135:17 135:18
2008 153:25 154:18
2009 44:3
2011 80:1,4,5 81:7
2022 1:16 2:16 5:2 159:9 160:18 161:23
2026 129:9,11
2040 3:6
2083 138:25 139:1 144:14
2087 34:15,25 148:20
2100 96:3,7 105:25 106:15 107:17 109:23

110:8
22
114:12,15 116:13
125:4 126:2
236
72:25
24
151:3
256
114:19 115:11
118:11,19 122:21
125:10
26
151:17 152:3 153:1
153:11 154:5,9,23
26F
151:23
28
121:1
29
120:4,8,11 121:1
122:1 126:5

3

3
80:22,22 97:1 98:2
99:17 100:9 101:5
103:10 106:17
108:3 129:19,25
130:1,9,11,22 131:3
131:6,13 132:14,21
133:5,12,23 134:4
134:10,11,11,14
136:16,19,24
137:12,18,20,20
138:4,9,11,18
155:18,22,24
156:13
3rd
80:4
3:00
6:12,18,23 26:23
27:1 29:4,11 30:11
30:15,18,21 31:1
35:22 37:6 38:25
39:12,24 41:18
47:10 65:25 67:15
94:8
300
102:9 105:8,11
307-4500
3:13
31
42:14
310
3:13
33
42:16,17,25 43:6
148:1,5,23,25
149:16 151:2 153:7
153:18 154:5
348
44:13

4

4:00
38:2 48:18 49:5,6
51:17 52:8,24 53:22
54:2,7 55:16 56:4
56:23 57:12,14 58:5
40-some-odd
142:23
400
105:9,10
44
120:9
45
120:9
45-degree
26:4

5

5
4:4
5:00
27:12 29:14 38:3
49:6 51:18 52:9,24
53:22 54:2,7 55:16
56:4,24 57:12,14
58:6
50
35:8
52
144:13
54
139:6
549
61:8

6

6
42:13
6:00
27:11,25 28:4,5,16
29:17 35:16 47:7
70:1 91:14

7

7
35:7
7:00
27:13 29:15 30:8
760-0404
3:7

8

8
129:23
8:00
30:3,8
896045
1:23

9

9:00
47:9 64:3,12
9:02
2:16 5:2
9:36
32:3
9:41
32:4
9000
85:18,21,24 86:5
149:4,14 154:23
155:2,4
90405
3:13
92614
3:6
949
3:7
9901
1:23 2:17 160:4