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

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 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 11,491,033
Edwards Ex. 1128

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4 EDWARDS LIFESCIENCES CORPORATION AND)
EDWARDS LIFESCIENCES LLC,)
5) CASE
PETITIONERS,) IPR2022-00556
6)
v.) PATENT
7) 10,987,236
AORTIC INNOVATIONS LLC,)
8)
PATENT OWNER.)
9 _____)
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14 VIDEOTAPED DEPOSITION OF NIGEL P. BULLER, MD,
15 TAKEN REMOTELY VIA ZOOM ON BEHALF OF THE PATENT OWNER,
16 AT 9:02 A.M. PST, FRIDAY, NOVEMBER 11, 2022, BEFORE
17 AUDRA E. CRAMER, CSR NO. 9901, PURSUANT TO NOTICE.
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1 I N D E X

2 WITNESS

NIGEL P. BULLER, MD

3

EXAMINATION PAGE

4 BY MR. LOWENSTEIN 5

5

6 NEW EXHIBITS MARKED (NONE)

7

8

9 REPORTER'S NOTE: All quotations from exhibits are

10 reflected in the manner in which they were read into the

11 record and do not necessarily indicate an exact quote

12 from the document.

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1 REMOTELY VIA ZOOM VIDEOCONFERENCE
2 FRIDAY, NOVEMBER 11, 2022, 9:02 A.M. PST
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4 NIGEL P. BULLER, MD,
5 having been first duly sworn, was
6 examined and testified as follows:
7
8 EXAMINATION
9 BY MR. LOWENSTEIN:
10 Q. Good afternoon, I believe it is,
11 Dr. Buller, where you are. How are you?
12 A. I'm very well. Thank you.
13 Q. Okay. I've asked my colleague,
14 Mr. Katz, to display and Exhibit 1017, which is
15 Cheung.
16 Okay. Dr. Buller, I trust you remember
17 the Cheung reference?
18 A. I do.
19 MR. LOWENSTEIN: Okay. Could we go to
20 the second page, please.
21 Okay. Let's zoom in on Figure 2 of
22 Cheung.
23 Okay. Now, let's see if we can see the
24 whole figure, if possible. Just bring it down a
25 little bit.

1 Okay. Perfect.
2 Q. Dr. Buller, can you see Cheung's
3 Figure 2 in front of you?
4 A. I can.
5 Q. Now, this is not quite a bird's-eye
6 view, but it's a sort of tilted bird's-eye view;
7 is that fair to say?
8 A. Yeah.
9 Q. Okay. And let's imagine that Cheung is
10 like a clock face. I want to direct your
11 attention to the interior diamond that is
12 roughly around 3:00 o'clock.
13 Do you see that?
14 A. [Garbled.]
15 THE REPORTER: I can't hear the doctor.
16 He's very muffled.
17 THE WITNESS: I see diamonds around the
18 3:00 o'clock mark. I can see -- which one do
19 you mean?
20 MR. LOWENSTEIN: Perhaps, Will, you can
21 zoom in a bit.
22 Q. Okay. Can you see right around
23 3:00 o'clock there's an interior diamond?
24 Perhaps you can highlight it for us,
25 Will.

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

1 diamond, we see a diamond of the outer frame in
2 shot, or at least part of a diamond; is that
3 fair to say?
4 A. We see part of a diamond of the
5 metallic brain in Cheung, yes.
6 Q. Okay. And on the outer surface of the
7 frame, we see an outer cloth; is that fair to
8 say?
9 A. There's a cloth wrapped around. So
10 yes, you can see a little bit of a cloth through
11 the space in the diamond.
12 Q. And the space in the diamond, are we
13 seeing the inner surface of the outer cloth?
14 A. Yes, you will be seeing a little bit of
15 the inner surface of the outer cloth in that
16 space in the shade.
17 Q. Does the inner surface of Cheung's
18 outer cloth appear smooth to you?
19 A. No, because I can see definite bubbles
20 on it. I mean, looking at the lower strut that
21 you can see, you can see darker areas where I
22 think it is that little gaps between the cloth
23 and the strut, if you can see what I mean.
24 Q. Well, let me ask you a different
25 question.

1 Do you see any stray, outwardly
2 extending fibers on the inner surface of
3 Cheung's outer cloth?
4 A. In that little part, no, I can't.
5 Q. And aside from the -- I think you're
6 referring to these two darker spots on the
7 bottom edge of the frame.
8 Is that what you're referring to?
9 A. They're not on the frame. They
10 appear -- it appears to be shadows. So it's not
11 a smooth surface.
12 I think your first question for me was,
13 was it a smooth surface. I'm saying it's not
14 smooth, because my eye is seeing two sort of --
15 they look like sort of indentations, which give
16 rise to darker shadow on the cloth.
17 Q. You agree that the inner surface of
18 Cheung's outer cloth, to the extent there's any
19 indentation, does not go past the full width of
20 the bar of the outer frame; is that fair to say?
21 A. No, I can't tell that. Because I can
22 see such a little bit, I can't see.
23 Q. You can see clearly the bar of the
24 outer frame both at the top and the bottom; is
25 that fair to say?

1 A. No, because parts of them are covered
2 in sutures. I can see white material that I
3 take to be sutures, which are being used, I
4 presume, to attach the outer cloth to the frame,
5 and the lower one may be partly to attach the
6 inner cover to the frame, which occurs at a
7 lower level than the outer cloth.
8 Q. Okay. That's fair. Perhaps my
9 question wasn't very clear, so that's a fair
10 distinction.
11 You agree that the -- we can clearly
12 see the bars of the outer frame in this diamond,
13 and you agree that the bars of the outer frame
14 is not completely covered by the inner surface
15 of the outer cloth; is that fair to say?
16 A. Correct. It's not -- it's definitely
17 not completed covered. I can see chunks of the
18 frame quite well.
19 Q. Okay. Now, I want to point to the
20 sutures -- the suture which you just looked at.
21 And you see there's a suture -- or two sutures,
22 perhaps. I'm not sure how you would refer to
23 it.
24 You see there's either one or a pair of
25 sutures on the top of the bar for Mr. Katz's --

1 for the mouse.
2 Do you see that, sir?
3 A. Yes. It looks like two sutures to me
4 there around the bar.
5 Q. Okay. And do you see that there's a
6 bit of white that comes off of the suture
7 perhaps?
8 Do you know what that is?
9 A. I really can't tell from this photo. I
10 mean, it could be -- it could be light onto the
11 pericardium, or it could be part of a suture or
12 part of a knot for the sutures that are coming
13 through the pericardium.
14 Q. Okay.
15 A. Because that's against the pericardium.
16 That side appearance that I think you're asking
17 me about is against the pericardium. It's
18 wrapped around one of the internal bifold bars.
19 Q. Now, I want you to go back to the inner
20 surface of the outer cloth.
21 Do you see any openings in the inner
22 surface of the outer cloth?
23 A. Well, yes. These triangular shadows,
24 these things that I've spoken about, look like,
25 to me, to be indentations into the cloth.

1 Q. Do you believe an indentation is an
2 opening?
3 A. Well, it can be classed as an opening.
4 I mean, it can be like a little cave going in
5 there.
6 I can see two dark shadows, but the
7 resolution of the photograph might require that
8 light. This isn't enough to give any detail.
9 But it's certainly not smooth, and there's two
10 shadows, suggesting that there is an indentation
11 at least -- there may be more than that -- in
12 that position.
13 Q. Now, the indentation, that would be
14 caused by the bar; correct?
15 A. No. I mean, it's in the vicinity of
16 the bar, but I have no idea what it's caused by.
17 Q. You would agree -- well, first of all,
18 you don't know what those darker areas are; is
19 that fair to say?
20 A. They look to me to be indentations.
21 That's my opinion.
22 Q. But they could be a shadow; is that
23 fair to say?
24 A. Well, the same: Because they're an
25 indentation, there is less light in there, and

1 that is shadow.
2 So I don't think that the two are
3 mutually exclusive. It's a shadow there because
4 there's an indentation.
5 Q. But there could also be a shadow with
6 no indentation; isn't that fair to say?
7 A. Well, there would have to be something
8 to cast the shadow, and I don't see anything
9 there to cast those very low-fly shadows. I
10 think that is a shadow in an indentation.
11 Q. You agree, however, that the -- it's
12 difficult to tell what those dark spots are; is
13 that fair to say?
14 A. No. My opinion is it's not smooth, and
15 there are indentations, and within them there's
16 shadow, and that is why you can see them.
17 Q. To the extent that there is an
18 indentation, would you agree that the
19 indentation could be caused by pressure from the
20 outer frame?
21 A. No.
22 Q. By pressing against the outer frame?
23 A. No.
24 Q. You don't think it's possible that the
25 indentation which is just above the outer frame

1 could be caused by pressing against the outer
2 frame?
3 A. No.
4 Q. You're aware that if you have a metal
5 surface that presses against a fabric, the metal
6 surface could cause an indentation of the
7 fabric, of course; correct?
8 A. It could. But that would be along the
9 direction of the strut. These are not. These
10 are extending upwards from the strut, sort of
11 fanning away from the top edge of the strut.
12 Q. Well, as a matter of fact, the two dark
13 spots that you're referring to are just above
14 the metal frame; isn't that correct?
15 A. They're extending up from the metal
16 frame. They may be underneath the metal --
17 underneath the fabric adjacent to the frame, but
18 where I can see them is extending up from the
19 metal frame.
20 And they're two separate areas.
21 They're not joined together; they're two areas.
22 Q. So I just want to make sure I
23 understand your testimony.
24 Your testimony is we can see what
25 appears to be two dark spots just above the

1 metal frame, and you know to a certainty that
2 that is an indentation, and it's not an
3 indentation caused by the metal frame; is that
4 correct?
5 A. No.
6 Q. In what way does that misstate your
7 testimony?
8 A. Because there are two dark spots there.
9 It's not -- I mean, I'm looking at them. There
10 are two dark spots there. They are certainly
11 there.
12 They are caused by the fact that the
13 fabric is not flat, is not smooth inside. My
14 opinion is that they are shadow because the
15 fabric is not smooth on the inside surface.
16 Q. Now, aside from those two dark spots
17 that you're referring to, do you see any other
18 openings in the inner surface of the outer
19 cloth?
20 A. Well, I can only see a tiny bit of
21 cloth there. They're the two main ones where
22 it's darker. There are other areas where the
23 light and dark is changing so that there are
24 other areas that there are small -- two main
25 areas where I can see that --

1 Q. Well, let's be precise: Is there any
2 other opening that you can see in the inner
3 surface of the outer frame aside from these two
4 dark spots that you're referring to?
5 A. The two large dark areas are the two
6 main ones I can see. There's some other light
7 variation over the surface, which again tells me
8 the surface is not smooth.
9 Q. What light variation are you referring
10 to?
11 A. I can't point to it. I have no -- the
12 surface is not a completely uniform color. It
13 varies in grayness.
14 Q. Have you ever physically examined the
15 valve shown in Cheung?
16 A. No.
17 Q. Have you ever asked anyone at Edwards
18 Lifesciences about the valve shown in Cheung?
19 A. No.
20 Q. So is it fair to say that all of your
21 opinions about what we see on the inner surface
22 of the outer cloth of Cheung in Figure 2 is
23 based upon your visual inspection?
24 A. Right. It's on my review of the paper,
25 reading it. I'm looking at the figures from

1 that time. Because it's a prior art document, I
2 have looked at it as it would have been
3 published at the time and as I would have seen
4 it through the eyes of a person looking at it at
5 that time.
6 Q. Can we agree that Cheung says
7 absolutely nothing whatsoever about indentations
8 appearing on the inner surface of its outer
9 cloth?
10 A. I don't remember anything being said
11 about indentations on the inner surface of the
12 outer cloth; that's true.
13 Q. Can we agree that the dark spots that
14 you're referring to in Cheung's Figure 2 do not
15 extend through a thickness of the cloth?
16 A. I don't know. I mean, you can see that
17 dark, and it could well extend through the
18 thickness. I can't tell from this
19 two-dimensional, rather low-quality image.
20 Q. How deep is this indentation, based
21 upon your visual examination?
22 A. I cannot tell. You can see the
23 beginning of it. It could go through the
24 fabric, as you've just said. I can't tell.
25 I can see the area which is not smooth.

1 I can see that it causes shadow and -- because
2 it's going in, and this light is getting into
3 it, and that could be an opening that goes
4 through the cloth.
5 Q. Do you believe that the shadow we see
6 in Cheung's Figure 2 will be -- what you
7 identify as an indentation, you believe that
8 could be a hole that goes all the way through
9 Cheung's outer cloth?
10 A. There could be an opening. I'm not
11 saying that I believe, because I'm saying it
12 could be part of an opening that goes through
13 it. It's a fibrous cloth, and there may well be
14 openings between the fibers that go all the way
15 through to the exterior.
16 MR. LOWENSTEIN: Okay. Let's go down a
17 little bit, Will. Let's look at the outer cloth
18 of Cheung.
19 Q. Do you see any openings in Cheung's
20 outer cloth?
21 A. No, because it's fairly brightly lit.
22 But what I do see -- again, if you look
23 at the lower edge, and now that you've changed
24 the zone of the image I'm looking at, you see
25 the outer edge, which you can clearly see has

1 both got fibers on it and is not smooth. It is
2 waving in and out. It's undulating in and out,
3 and that's the sort of appearance that I think
4 you were seeing in that tiny segment of the
5 inner surface.
6 Q. Now, if I were looking at a big, puffy
7 cumulus cloud -- do you know what a cumulus
8 cloud is?
9 A. I do.
10 Q. Okay. And I was looking at a big,
11 puffy cumulus cloud.
12 Now, in your experience, do cumulus
13 clouds -- are they -- conform to generic
14 geometric shapes, like a square or a rectangle,
15 or are they uneven in their surfaces?
16 A. Well, they certainly don't conform
17 closely to geometric shapes, but you can often
18 look at them and see things, like trains and
19 things. I mean, I have enjoyed watching clouds
20 pass by, and you can often see lots of
21 interesting shapes in them, but it is completely
22 random.
23 THE REPORTER: I cannot hear the
24 doctor.
25 (Discussion held off the record.)

1 BY MR. LOWENSTEIN:
2 Q. So I think the last question and answer
3 may have been a bit muffled, but I think it's
4 fair to say that a cumulus cloud has an uneven
5 surface.
6 Is that fair to say?
7 A. Yes. I'm not sure it has a surface, so
8 I would rather talk about the photograph in
9 front of me, because, obviously, if we talk
10 about a cloud, it's very abstract.
11 I'm not really sure it has a surface.
12 From a distance it looks as though it does, but
13 if you get up there, it's just steamy air that
14 you sort of slowly get into more and more and
15 more of it. You know, there isn't -- you don't
16 suddenly hit a surface when you fly in an
17 airplane through a cloud.
18 Q. So if you were looking at a cumulus
19 cloud and you saw the uneven surface -- the
20 visually uneven surface, would you characterize
21 the parts of the cumulus cloud that are a little
22 bit closer to the center relative to other
23 portions of the crowd as being an opening in the
24 cloud?
25 MR. SUMMERS: Objection. Form.

1 THE WITNESS: No, I'm not really -- I'm
2 not loving your analogy -- if that's what it
3 is -- with a cumulus cloud, because it's gas.
4 It's -- you're looking at something --
5 BY MR. LOWENSTEIN:
6 Q. Okay. We'll go to something else:
7 cotton candy.
8 Have you ever been to -- you're
9 familiar with cotton candy?
10 A. Yeah. Candyfloss we call it, yeah. I
11 think cotton candy is candyfloss.
12 Q. So you've got a big, puffy stick of
13 cotton candy, and we can agree that not all the
14 fibers are exactly -- there may be some
15 unevenness in the surface of the cotton candy;
16 is that fair to say?
17 A. Yes.
18 Q. But let's assume you've got a big,
19 puffy piece of cotton candy. You haven't taken
20 any bites out of it. It's relatively circular,
21 or spherical perhaps, as the case may be.
22 If there was a slight indentation on
23 the outer surface of the cotton candy, would you
24 refer to that as an opening?
25 A. Well, that's -- lots of cotton candy

1 has lots of openings into it and through it,
2 because it's the fibers of sugar, spun sugar,
3 heading in all directions, and there's lots of
4 openings between the fibers of sugar.
5 Is that what you're asking me?
6 Q. So you've got a big, puffy piece of
7 cotton candy, and it's maybe 20 inches in
8 diameter. It's -- visually you don't see any
9 holes.
10 You would look at that and you would
11 say, "I see an opening"?
12 A. Without you showing me it, I can't tell
13 you what I would say.
14 There are lots of openings between all
15 the strands of sugar. It's covered in openings,
16 and there'll be an unevenness all over the
17 surface. It's not a smooth surface. It is a
18 spun sugar, and there's lots of openings all
19 over it.
20 Q. Would you agree that if I had a glass
21 of water, that there could be some
22 intermolecular space between water molecules?
23 MR. SUMMERS: Objection. Form.
24 THE WITNESS: Okay. You're now talking
25 about intermolecular space.

1 Yes, there would be some space, but you
2 can't see it.
3 BY MR. LOWENSTEIN:
4 Q. Are those openings?
5 A. No.
6 Q. Why not?
7 A. Well, because we're talking about a
8 completely different scale. You can get down to
9 there's space between the electrons and the
10 protons when you get into an individual atom.
11 But we're not talking about that.
12 We're talking about openings in the surface of
13 fabrics on a stand, I hope.
14 Q. Well, actually, we're talking about
15 cotton candy.
16 A. Yes. I answered about cotton candy as
17 best I can.
18 Q. Okay. And I think we're talking about
19 cumulus clouds.
20 A. Well, we were talking about water and
21 intermolecular distances a minute ago.
22 Q. Okay. So an intermolecular opening is
23 not an -- or space is not an opening.
24 So how large does something have to be
25 to be an opening?

1 MR. SUMMERS: Objection. Form.
2 THE WITNESS: I don't know. You need
3 to -- you need to, you know, quantitate it to
4 what we're actually talking about.
5 And you'd have a very good idea with
6 the cotton candy if you showed me a photo of the
7 distance between the strands of the candy, which
8 will lead to the sort of openings which are
9 going into cotton candy. And you've got an
10 idea, when you've got fabrics, about what the
11 openings are, depending on the fabric.
12 BY MR. LOWENSTEIN:
13 Q. Now, when we look at Cheung, you
14 pointed me to the bottom of the outer cloth, and
15 you said you see openings there.
16 Aside from the bottom of the outer
17 cloth, do you see any openings elsewhere in
18 Cheung's outer cloth?
19 A. Yes. On the inside. Because if you
20 look -- how you've got the photo now, I'm seeing
21 part of the photo on my screen -- not all of it,
22 but part of it. But you're seeing the outside
23 of the bottom edge, but you're also seeing,
24 because of the angle it's taken at, the inside
25 of the top edge.

1 And you can see that that is not
2 smooth. It is going along, undulating in a very
3 similar way to the bottom. So you can see the
4 inside is undulating to a much greater degree
5 than I can see in that tiny, little diamond
6 opening previously.
7 So you can see that the inside is not
8 smooth. You can also see various fibers going
9 in at various places and tufts actually
10 extending off the fabric and going in between
11 the struts --
12 Q. So when you --
13 A. -- very similar to what you see in
14 Walther.
15 Q. So you said there's an undulating in
16 surface in Cheung; is that fair to say?
17 A. Yes. On the inside, looking on the
18 top, you can only see the outside of the bottom
19 of the outer covering, but you can get a good
20 idea of the inside profile along the top because
21 of the angle the photograph is taken at.
22 Q. So to determine what the inside of
23 Cheung's outer cloth look like, you would look
24 to the top of the outer cloth and not an image
25 of the inside of the outer cloth?

1 A. Because of the angle that this
2 photograph -- we're looking at one photograph.
3 This photograph is taken at something at more
4 than a 45-degree angle, looking downwards, and,
5 therefore, you're able to get an idea of the
6 inside texture of the cloth at the top and the
7 outside texture of the cloth at the bottom
8 because they're against different, contrasting
9 color and structure.
10 And you see that there is an
11 undulating, very uneven surface with tufts and
12 fibers extending inwards on the top, and at the
13 bottom you see there is a very unsmooth surface
14 running around the outside. So it looks as
15 though the inner and outer surface are the same,
16 and they are far from smooth and have tufts,
17 fibers and undulations.
18 Q. So if I wanted to get a sense for what
19 the inner surface of the outer cloth looked
20 like, would it be better to look at the top of
21 the outer cloth, or would it be better to look
22 at the inner surface that we can see through the
23 diamond at roughly 3:00 o'clock?
24 A. Well, the trouble is, you can only see
25 a tiny little bit through the diamond at

1 3:00 o'clock. You can see a lot more of the
2 circumference looking at the front photo.
3 I would look at all of it in the front
4 photo, I mean, look at the different parts, but
5 from everywhere I look in the diamond and
6 looking at the front of the device, you can see
7 that the inner surface is far from smooth. It's
8 got toughs, fibers, and it's undulating, as is
9 the outer surface.
10 Q. You would agree that if we're looking
11 at 6:00 p.m., let's say from -- not p.m.
12 If we're looking from, say, 5:00 to
13 7:00 o'clock on Cheung's Figure 2 -- are you
14 with me?
15 A. I think so. Someone's putting a cursor
16 on it.
17 So you're looking between -- from one
18 narrow bar -- not the bar with the stitch, but
19 you're looking from one narrow bar round to the
20 narrow bar at the other side of the initial --
21 Q. Yeah, so let's do this -- can you just
22 zoom back a little bit.
23 Okay. Go down, please.
24 Okay. So you see roughly at
25 6:00 o'clock there's a commissure; correct?

1 Dr. Buller?
2 A. Yes?
3 Q. You can see there's a commissure at
4 6:00 o'clock?
5 A. At 6:00 o'clock there's a commissural
6 post and the commissure of a valve in front of
7 it.
8 Q. Okay. And then we can see two columns
9 of the inner frame, for lack of a better term,
10 on either side of the commissure; is that fair
11 to say?
12 A. Yes. You see a zigzag each side
13 connecting to the vertical bar on each side.
14 Q. You would agree from this angle,
15 looking at this section, the commissure at
16 6:00 o'clock and the two columns on either side,
17 that we cannot see the inner surface of the
18 outer cloth; is that fair to say?
19 A. No. I think you can see the edge of
20 the inner surface of the outer cloth between
21 those two points.
22 Q. And you believe it is better, to get a
23 sense for the outer cloth -- the surface of the
24 inner -- sorry. Let me start over.
25 If I were to compare the top of the

1 outer cloth that we see at the commissure and
2 the columns on either side of it versus the
3 inner surface of the cloth that we see at the
4 3:00 o'clock diamond, which of those sections
5 will give me greater insight into what the inner
6 surface of the outer cloth is like?
7 A. I think I would look at both, because
8 they're different parts of the same photograph,
9 and I think they're in agreement.
10 What I'm saying with the two shadows we
11 talked about within the diamond at 3:00 o'clock
12 is very much in agreement with the undulating
13 appearance you get on the inner cloth looking at
14 the segment between 5:00 o'clock and
15 7:00 o'clock.
16 Q. You see at the commissure at
17 6:00 o'clock -- and I'm looking at the top of
18 the outer cloth. I'm looking at the area
19 encompassed by the two columns on either side of
20 it.
21 We can see little pieces -- perhaps we
22 can see little pieces of cloth sticking out; is
23 that fair to say?
24 A. Yeah, I see it as undula- -- I mean,
25 the surface is far from smooth, it is undulating

1 in and out, and there are little tufts of
2 fabric, perhaps more so if you move around to
3 8:00 o'clock, where, because you're seeing that
4 section more clearly because you're not looking
5 front-on on it, you're looking more side-on on
6 it, you see tufts and fibers extended inwards
7 between the two vertical struts, the first being
8 at 7:00 and the next being at 8:00 o'clock.
9 Q. You agree, however, that there are no
10 tufts of fibers that can be seen in the diamond
11 at 3:00 o'clock; correct?
12 A. No. I can see tufts that I think are
13 fibers sticking inwards from the surface.
14 Q. Show me what tuft of fiber you see
15 within the diamond at 3:00 o'clock.
16 A. How exactly do I show you?
17 Q. Describe where it is.
18 A. At the 3:00 o'clock one?
19 Q. Yes.
20 A. No, I couldn't see any. I think I
21 already answered you at 3:00 o'clock I
22 couldn't --
23 Q. Okay. So I just want to be totally
24 clear, because you just said the opposite.
25 We don't see any tufts of fibers on the

1 inner surface of the diamond at 3:00 o' clock;
2 correct?
3 A. I can't see any in that tiny bit. I
4 can only see less than half of the diamond, but
5 I can't see any in that little segment, no.
6 Q. Okay. Now, is it possible that -- if
7 you have a fabric and you cut one edge of it, is
8 it possible that you could have little tufts
9 sticking up where you cut the fabric?
10 A. No, I don't think this is an artifact
11 caused by cutting it. Because what I see, I see
12 in --
13 Q. I don't think you're answering my
14 question, because I didn't ask you about Cheung.
15 I asked you if you have a fabric and
16 you cut one edge, is it possible to have tufts
17 of fibers that stick up where you cut?
18 MR. SUMMERS: Objection. Form.
19 THE WITNESS: Yes. Depending on what
20 it is and how you cut it and everything else,
21 all the provisos. But I don't know what the
22 fabric is or how you're cutting it or what
23 [garbled] or how it's made up. The answer is
24 definitely, yes, but I know so little about it.
25 MR. LOWENSTEIN: Okay. I can tell the

1 court reporter would like to take a break, so
2 let's take a break.
3 (Recess from 9:36 a.m. to
4 9:41 a.m. PST.)
5 BY MR. LOWENSTEIN:
6 Q. Dr. Buller, if I were to cut -- let's
7 say I have a woven PET fabric, and I were to cut
8 lengthwise and separated two -- and turned it
9 into two pieces of woven PET fabric: Might I
10 see frayed edges where the cut occurs?
11 A. You might.
12 Q. Is it possible to have a graft covering
13 where the surface on one side of the covering
14 is -- has outwardly extending fibers but the
15 inner surface of the covering is smooth and does
16 not have inwardly facing fibers?
17 A. Not to my knowledge, no.
18 Q. You're not aware of any fabric that has
19 outwardly facing fibers on one side of the cloth
20 but no inwardly facing fibers on the other side
21 of the cloth?
22 MR. SUMMERS: Objection. Form.
23 THE WITNESS: I'm not aware of a PET
24 medical cloth -- talking about these sort of
25 cloths -- that is like that, no.

1 BY MR. LOWENSTEIN:
2 Q. Are you familiar with velour woven PET?
3 A. Yes.
4 Q. Okay. And is it possible to have a
5 velour woven PET with a woven base and loose
6 structures on one side of the cloth but not the
7 other?
8 A. Yes. But it still won't be smooth on
9 the inside, because it will be -- it'll have a
10 weave that'll undulate up and down, and it will
11 undoubtedly have some fibers, but it's still
12 going to be a woven PET cloth.
13 Q. But you could have the loose structures
14 on one side of the velour woven PET cloth but
15 not on the other; is that fair to say?
16 A. You can have them dominantly on one
17 side, yes, or you can have them on both.
18 Q. Are there medical-grade, velour woven
19 PET cloths with loose fibers on one side of the
20 cloth but not the other?
21 A. I don't know.
22 Q. There could be, though?
23 A. I don't know. That's my answer: I
24 don't know.
25 Q. Can there be medically available,

1 velour woven PET cloths with loose fibers on one
2 side of the cloth but a weave on the other side
3 of the cloth?
4 A. There could be, yes.
5 Q. So if you see one side of the cloth,
6 that would not necessarily tell you anything
7 about the other side of the cloth; is that fair
8 to say?
9 A. That's true. If you can only see one
10 side of the cloth, you wouldn't know what's
11 going on on the other side of the cloth. I
12 mean, I think that is -- that is
13 straightforward.
14 MR. LOWENSTEIN: Okay. Let's show
15 Exhibit 2087.
16 Q. Dr. Buller, as you can see -- or I'll
17 represent to you that this document contains
18 portions of Edwards Lifesciences' invalidity
19 contentions in the district court case.
20 Do you understand my representation?
21 A. No. I'm sorry. It contains portions
22 of Edwards' representations in --
23 Q. No. Maybe I misspoke. Let me clarify.
24 I'm going to represent to you that
25 Exhibit 2087 is portions of Edwards

1 Lifesciences' preliminary invalidity contentions
2 in the district court action.
3 Do you understand my representation?
4 A. I think so.
5 Q. Okay.
6 A. I've never seen this before.
7 MR. LOWENSTEIN: Let's go to page 7 of
8 the PDF, which has "Page 50" at the bottom.
9 Q. And, Dr. Buller, do you see there's a
10 figure, and underneath it, it says "Apogee
11 [garbled]"?
12 A. I see it, yes.
13 Q. Let's look at this like a clock face,
14 just like we did with Cheung.
15 And if we look at the commissure at
16 6:00 o'clock and the two columns on either side
17 of it, if we look at that section, we can see
18 outwardly extending fibers both on the top and
19 on the outer surface; is that fair to say?
20 A. Yes, I think that's fair to say.
21 MR. LOWENSTEIN: Okay. And I want to
22 now zoom into the cell at 3:00 o'clock.
23 Q. Okay. Can you see what I'm referring
24 to?
25 A. I do. I see the cell you're talking

1 about.
2 Q. Now, this is the inner surface of the
3 outer cloth; is it not?
4 A. Yes. This -- again, just like we
5 looked at before, this will be a little bit of
6 the inner surface of the outer cloth seen
7 through the diamond-shaped cell.
8 Q. We do not see any inwardly facing
9 fibers in the inner surface of the outer cloth;
10 is that fair to say?
11 A. This resolution, this photograph, I
12 can't see any. But again, I see some shadow, I
13 see some bubbling, it doesn't look smooth to me,
14 and I see a shadow coming off the strut.
15 Q. Does the inner surface of the outer
16 cloth look just like the outer surface of the
17 outer cloth?
18 A. Yes.
19 Q. It looks exactly the same?
20 A. No, it doesn't look exactly the same,
21 because it's in the shadow. So, I mean, it
22 looks several shades darker because it's in the
23 interstices of the cell, and you've got the
24 valve leaflet. So it isn't as well lit.
25 And because it's not as well lit, it

1 looks to be a darker shade of gray, and the
2 clarity you get of the surface is not as good
3 because you haven't got the high contrast on it
4 because it's not lit in there.
5 Q. So you believe that the figure that
6 we're looking at in the cell at 3:00 o'clock,
7 that image is too dark and unclear for you to
8 clearly assess the state of the inner surface of
9 the outer cloth; is that your testimony?
10 A. I'm saying it's not very well lit.
11 So if you're saying does it look
12 exactly the same, no, it doesn't look exactly
13 the same. It looks several shades darker, and
14 you're not seeing the clarity because it's not
15 well litigation. It's not been taken, the
16 photograph, to best show that area of cloth.
17 Q. But you can see on the outer surface of
18 the outer cloth outwardly extending fibers,
19 can't you?
20 A. I can. And I see them best when
21 they're against the blue background. So there
22 is a very -- a coarsely woven sort of fabric
23 that the device is standing on, and where you
24 see the fibers best is where they're contrasted
25 against the blue background.

1 So I can see fibers very clearly at --
2 running around sort of 4:00 o'clock and
3 5:00 o'clock on that side and on the other side
4 against the blue background, but you haven't got
5 that contrast when you're looking inside through
6 an internal cell in the shadow of the valve
7 leaflets.
8 Q. But we can agree that there's no
9 visible, inwardly facing fibers on the inner
10 surface of the Apogee outer cloth; correct?
11 A. No, we can't agree, because I'm saying
12 I can't see them.
13 Where I can see the fibers best is
14 where you're seeing them against a contrasting
15 color and surface. I can't see the fibers
16 clearly looking directly at a little section of
17 the white cloth, even on the front of the
18 material.
19 If we take a little equivalent section
20 right on the front of the device, I can't see
21 the fibers nearly as clearly as when they're
22 against a contrasting background and where they
23 are well lit.
24 MR. LOWENSTEIN: Let's zoom in a bit on
25 the cell at 3:00 o'clock.

1 Q. Okay. We've zoomed in further.
2 Can we agree that you cannot see any
3 inwardly facing fibers on the inner surface of
4 the outer cloth?
5 A. I cannot see individual fibers. The
6 surface looks bubbly and is not smooth.
7 Q. Your testimony is that the inner
8 surface that we see in Apogee is not smooth; is
9 that your testimony?
10 MR. SUMMERS: Objection. Form.
11 THE WITNESS: No. You're just looking
12 at a little bit at 3:00 o'clock or a little part
13 of the fabric you can see in the cell, and in
14 that I can see that it is bubbly and not smooth.
15 But it is not well lit, and you're not seeing it
16 against a contrasting surface to actually be
17 able to pick out individual fibers.
18 BY MR. LOWENSTEIN:
19 Q. You would agree that just above the
20 inner surface of the outer cloth in Apogee, the
21 blue carpet -- the blue material is just above
22 it; correct?
23 A. Where are you looking? Just above the
24 3:00 o'clock diamond?
25 Q. Yes.

1 A. Yes, there's blue cloth there.
2 Q. Providing a clear contrast for you;
3 correct?
4 A. No, because it's not well lit in there.
5 You can see the color of the cloth
6 compared with the front of it is not -- it's in
7 the shade of a much taller leaflet, so it is
8 darker. And again, I can see that it's not
9 smooth, but it's very difficult to make out
10 individual fibers there because it's in the
11 shadows, even on the outside.
12 Q. All right. So I want you to look -- we
13 see the -- inside the valve we see some
14 stitching. There's some white stitching.
15 There's a bluish-green stitch.
16 Do you see that, sir?
17 A. Yes. Inside -- you're looking down --
18 Q. Inside the valve.
19 A. Yes.
20 Q. Okay. And you see there's a white
21 strip at the bottom?
22 A. I do.
23 Q. And you see that there are blue-green
24 stitches spaced apart in a somewhat irregular
25 fashion?

1 Do you see that?
2 A. Yes. Like a sort of cone -- like teeth
3 running around, yeah, if that's what you mean.
4 Q. Yes.
5 A. There's -- below the valve there is
6 appearance of a sort of almost alternating white
7 and greeny-blue, as you say, slightly irregular.
8 Q. Do you see any inward-facing fibers on
9 that white strip at the bottom?
10 A. No. It's too -- it's right down in the
11 shadow. I can't. It's not well lit, and that
12 is right down at the bottom end of the valve and
13 inside, and you can see even the resolution on
14 the blue fabric is different. It's sort of
15 blurred compared with seeing where it's lit, and
16 you can see the weave much more clearly.
17 Q. Now, let's go back to the diamond at
18 3:00 o'clock.
19 A. Yes?
20 Q. Do we see any openings on the inner
21 surface of the outer cloth?
22 A. Again, I can see a shadow a bit. I can
23 only see one this time. But just above/below
24 stitching I can see perhaps four -- definitely
25 three, perhaps four stitches running along the

1 strut, and then just above that I can see the
2 same sort of shadow appearance, suggesting that
3 the cloth is not smooth and is not lying in all
4 places as close or against the strut.
5 Q. How do you know the shadow isn't cast
6 by some other intervening object, perhaps part
7 of the frame?
8 A. I can't see anything that would cast
9 that shadow down in that position. I can see,
10 you know, a fairly dark shadow just above the
11 upper of the three/four sutures.
12 MR. LOWENSTEIN: Let's go up one page.
13 So we're going to go to page 6 of the
14 PDF, which has the "Page 31" at the bottom, and
15 I want you to move a little bit -- okay.
16 Q. Do you see it says "valve 33 French"?
17 A. Yes, "valve 33 French."
18 Q. Do you have any reason to believe that
19 does not accurately reflect --
20 A. I've never seen this document nor read
21 it. I really have no opinion about it. This is
22 completely new to me. I have no reason to
23 disbelieve anything in it. I've never seen it.
24 Q. So in other words, the representation
25 is the crimp profile is 33 French, and you have

1 no reason to disagree with that; is that fair to
2 say?
3 A. I've never seen this document. I
4 haven't analyzed it. I haven't read it. I've
5 got no reason to disagree with anything. It
6 says "crimped valve 33 French," but I --
7 that's -- all I know is what it says there. I
8 have not looked at the document.
9 MR. LOWENSTEIN: Okay. Let's pull up
10 Exhibit 1012.
11 Okay. And let's go down a little bit.
12 Okay. Yes. Right here.
13 Q. All right. Dr. Buller, do you have the
14 Exhibit 1012 in front of you?
15 A. I can't see an exhibit number or
16 anything, but I can see it's the Cribier
17 article, and what you've got is the photograph
18 of the Sapien valve in front of me. I can't see
19 an exhibit number.
20 Q. Well, we see, actually, at the top the
21 filename, Exhibit 1012, and then --
22 A. I see the filename, but I can't see
23 anything on the --
24 MR. LOWENSTEIN: Let's go down just a
25 little bit.

1 Do we not have this marked?
2 THE WITNESS: It's the Cribier article
3 from 2009, and the page you're on has a picture
4 of the Edwards Sapien THV.
5 BY MR. LOWENSTEIN:
6 Q. Well, okay. Actually, I believe this
7 is Petitioners' -- go to the first page.
8 Okay. Go down.
9 So we can see we're looking at
10 Exhibit 1012?
11 A. I've got it, yeah.
12 MR. LOWENSTEIN: Okay. Let's go to the
13 second page, which is 348 at the bottom.
14 Q. And we're looking at a picture of a
15 Sapien valve; is that fair to say?
16 A. Yes.
17 Q. Okay. And you see that there is
18 stitching connecting the inner skirt to the
19 outer frame?
20 A. Yes.
21 Q. And would you agree that the inner
22 skirt is attached to the -- or is connected to
23 the inner surface of the outer frame?
24 A. Yes, the skirt is up against the inner
25 surface of the outer frame, or part of it, and

1 is stitched to it with, you know, three or four
2 sutures on each strut that go around the strut
3 to the outside.
4 Q. Okay. So I'm wondering: Is it
5 possible to open up Walther, and I want to have
6 both Walther and Cribier side by side.
7 A. I now have Walther. I'm now back to
8 Cribier. But I don't have both. I had Walther
9 a bit ago, and now I've just go Cribier again.
10 Okay. I've got both.
11 MR. LOWENSTEIN: Okay. Will, I would
12 like you to zoom in on Walther's bird's-eye view
13 in Figure 1, and then zoom in on Cribier's
14 picture of Sapien.
15 Q. Okay. So, Dr. Buller, do you agree
16 that we are looking at a split screen, and on
17 the left side we have a picture of Sapien, and
18 on the right side we have a picture of the
19 bird's-eye view from Walther's Figure 1?
20 Is that fair to say?
21 A. Yes, that whats I'm seeing.
22 Q. Okay. And you would agree Walther is a
23 Sapien with an outer PET cloth on the outer
24 surface of the outer frame; correct?
25 A. That's what Walther says it is, yes.

1 Q. Can -- now, we're looking down at the
2 valve.
3 Can we see the stitches from -- that we
4 see in Cribier in this bird's-eye view of
5 Walther?
6 A. I think you may be able to see some of
7 them, yes. But there's other material, because
8 you're seeing some of the cloth poking through.
9 Because, obviously, Walther has the
10 exterior cloth that comes higher than the
11 internal skirt, you are seeing some of the
12 Walther's cloth and some of the fibers poking
13 through. And so it's difficult to make out
14 exactly what is what.
15 Q. It's difficult for you to distinguish
16 the sutures for the inner skirt from the fibers
17 in the outer cloth; is that your testimony?
18 A. I think I can see some of them, because
19 you know there are only three or four on a
20 strut, as is shown in the Cribier photo in front
21 of me on the left-hand side of the screen. You
22 know there are only three or four a strut, and
23 you know where the struts are, and you can
24 see -- lower than the cloth of the outer skirt
25 is poking through, you can see discretely three

1 or four per strut sutures, and I take it that
2 they are the ones attaching the inner skirt to
3 the frame.
4 You'll see them best -- I mean, because
5 Walther is not quite central -- so the lens of
6 the camera taking this bird's-eye view is more
7 towards the bottom of the frame at 6:00 o'clock
8 and that's why you're seeing less of the inside.
9 On the upper part between 9:00 o'clock
10 and 3:00 o'clock -- so the upper half of the
11 device -- you're seeing more of the inside wall
12 because this is -- this is looked at not
13 completely true down the center, and it is in
14 the upper part where you can see these discrete
15 three or four stitches below the Walther's
16 cloth, which is also bulging in through some of
17 the cells.
18 MR. LOWENSTEIN: Okay. So let's -- I
19 want to zoom in to the lower right quadrant of
20 Walther's bird's-eye view.
21 THE WITNESS: I see.
22 BY MR. LOWENSTEIN:
23 Q. All right. So we're looking -- let's
24 go up a little bit. Let's try to get exactly
25 the lower right quadrant of Figure 2 if we can.

1 I'm sorry. Figure 1.
2 No, no, no.
3 THE WITNESS: I can see the lower
4 right, but I can also see some parts of the
5 upper right. But you'll see it really
6 emphasizes the fact that we're not looking truly
7 in the center of the stent. We're seeing more
8 of the internal surface on the upper half than
9 we do on the lower half, where you see far less
10 of the internal surface on the lower half.
11 BY MR. LOWENSTEIN:
12 Q. Okay. So do you believe right now we
13 are looking at approximately the lower
14 right-hand quadrant of Walther's Figure 1
15 bird's-eye view?
16 A. Approximately, yes. Not completely.
17 Q. Okay. And I want you to start at about
18 4:00 o'clock.
19 You'll see there's an attachment for
20 the valve?
21 A. Yes. That's one of the commissures.
22 You see the pericardium in this sort of
23 McDonald's shape, the M somewhat upside down
24 side-on. You can see the initial attachment
25 that'll be to one of the commissural posts, and

1 you've got that M-shaped structure where it's
2 wrapped around the bifold bars.
3 Q. Okay. And I want you to go down from
4 there. So let's say that's at about
5 4:00 o'clock, and I want you to focus on the
6 4:00 to 5:00 o'clock space.
7 A. Okay. We're starting at the
8 commissure, and we're looking at the space
9 heading downwards from there?
10 Q. Yeah, down and to the left.
11 A. Yeah.
12 Q. Okay. And we can see -- on one side of
13 the outer frame, we can clearly see fibers from
14 the outer cloth; correct?
15 A. Yes. On both sides I think you can.
16 Q. Well, on the other side of the outer
17 frame, is it possible that we are looking at --
18 on the inward side of the outer frame, is it
19 possible that the fibers we're looking at are
20 the sutures for the Sapien inner skirt?
21 A. No.
22 Q. It's not possible?
23 It's not possible that we're looking at
24 the sutures for the inner skirt?
25 A. No.

1 Q. There's no possibility that we can see
2 the sutures for the inner skirt; is that your
3 testimony?
4 A. You can --
5 MR. SUMMERS: Objection. Form.
6 THE WITNESS: You can see, as I've
7 said, at the top where you're saying it, but the
8 fibers that you're looking at that you're asking
9 me about on the inside and outside are the
10 fibers from the outer skirt poking in through
11 the openings of the stent frame.
12 BY MR. LOWENSTEIN:
13 Q. How do you know that?
14 A. Well, I can see they are.
15 Q. Explain to me how you know that the
16 fibers we're looking at on the inside of the
17 outer frame are not the sutures for the Sapien
18 inner skirt?
19 A. They're much smaller than the sutures.
20 They are small, little fibers like on the
21 outside. The sutures are relatively big, as you
22 can see on the Edwards Sapien valve.
23 Q. So it's your testimony that in this
24 section we can't see the sutures for the inner
25 skirt at all?

1 A. In that section I can't make them out
2 to simply -- where you're seeing more on the top
3 half -- because, as I've explained, this
4 photograph isn't truly down the center; it's
5 more towards the bottom -- you can see less
6 detail of the inside on this lower quadrant than
7 you can on either of the upper quadrants, where
8 I think I can make out the sutures for the inner
9 skirt of the Sapien.
10 Q. So I don't think you answered my
11 question, and I'm going to ask it again. I want
12 to be very clear. So please answer the question
13 that I ask exactly.
14 Do you know to a certainty that we
15 cannot see sutures for the Sapien inner skirt
16 when we look on the inside of the outer frame in
17 Walther's bird's-eye view at 4:00 to
18 5:00 o'clock?
19 A. I cannot clearly see them in this
20 segment. As I said, I can see them in the upper
21 segments, where you'll see more detail of the
22 inside.
23 What I am seeing in this --
24 Q. I'm sorry. You're not answering my
25 question. I need you to answer my question.

1 I started my question "Do you know with
2 a certainty" -- "to a certainty?" I'm going to
3 ask it again. I need you to answer that
4 question. So let me -- I'm going to ask it
5 again, and you need to answer that question.
6 Do you know to a certainty that the
7 fibers we see on the inner side of the outer
8 frame in Walther's bird's-eye view at 4:00 to
9 5:00 o'clock are not fibers associated with the
10 sutures for Sapien's inner skirt?
11 A. Yes.
12 Q. You know to a certainty?
13 A. Yes.
14 Q. How do you know that?
15 A. Because there aren't fibers that appear
16 like that from the sutures of the Sapien inner
17 skirt.
18 Q. Now, let's just remove the word
19 "fibers," and let's just say "the white
20 material." Okay?
21 Do you know to a certainty that the
22 white material that we see on the inner side of
23 the outer frame in Walther's bird's-eye view at
24 4:00 to 5:00 o'clock do not, at least in part,
25 include the sutures for the Sapien inner skirt?

1 A. I cannot see any of the sutures clear
2 enough to say that they are visible.
3 Q. So you cannot say to a certainty that
4 we can't see sutures in the segment that we're
5 talking about; correct?
6 A. You keep saying "we," and this is why
7 I'm having a trouble answer.
8 I'm telling you I cannot see the -- I
9 certainly cannot see the sutures in this --
10 Q. I'm not saying "certainly." I'm saying
11 "to a certainty."
12 A. No, you're saying "we."
13 Q. Can you see to a certainty, 100 percent
14 certainty, that we cannot see -- that you
15 cannot -- let me reask it. I'll revise the
16 question.
17 Can you say to a certainty, under oath,
18 that we cannot -- new question.
19 Can you saw to a certainty, under oath,
20 that in the white material that is visible on
21 the inside of Walther's outer frame in the
22 bird's-eye view between 4:00 to 5:00, can you
23 say to a certainty that that white material does
24 not include, at least in part, sutures for the
25 Sapien inner skirt?

1 A. I cannot see the sutures in the segment
2 from 4:00 to 5:00 o'clock.
3 Q. That's not answering my question.
4 Okay?
5 Can you say to a certainty that the
6 white material we see on the inside of the outer
7 frame in Walther at 4:00 to 5:00 o'clock does
8 not include the sutures of the Sapien inner
9 skirt?
10 MR. SUMMERS: Objection. Form.
11 THE WITNESS: I think I've answered to
12 the best of my ability. I cannot see anything,
13 which is the suture --
14 BY MR. LOWENSTEIN:
15 Q. That's not answering my question.
16 It's one thing to say you can't see it.
17 It's another thing to categorically exclude it.
18 Would you agree?
19 A. Yes. But I can only tell you what I
20 can see or can't see. I mean --
21 Q. Okay. And I'm asking what you -- I'm
22 not asking you what you can see. I'm asking
23 what you can categorically exclude, and I'm
24 asking what you know to a certainty, which is,
25 you understand, different from "what I think I

1 see."
2 I'm not asking about a guess. I'm not
3 asking about what you think you see. I'm asking
4 about what is and what you know to a certainty
5 and what you don't know to a certainty.
6 You understand?
7 MR. SUMMERS: Objection. Form.
8 THE WITNESS: Okay. I think I'm
9 beginning to understand.
10 BY MR. LOWENSTEIN:
11 Q. Okay. So let me ask the question
12 again.
13 Do you know to a certainty that the
14 white material visible on the inner side of
15 Walther's outer frame in the bird's-eye view at
16 4:00 to 5:00 o'clock does not include the
17 sutures for the Sapien inner skirt?
18 A. I certainly cannot see the sutures.
19 Q. That's not answering my question.
20 Okay?
21 We just went over the distinction
22 between what you certainly can't see and what is
23 to a certainty. If you can't answer my
24 question, just say, "I don't know the answer,"
25 but you need to answer my question.

1 I'm going to ask it again: Do you know
2 to a certainty that the white material on the
3 inner side of the outer frame of Walther's
4 bird's-eye view between 4:00 and 5:00 o'clock
5 does not include the sutures for the Sapien
6 inner skirt?
7 A. I don't know for a certainty that it
8 doesn't contain the sutures, but I can't see
9 them.
10 Q. Thank you for answering my question.
11 Now, let's focus on this same section.
12 You see there's white material on the
13 inner side of the outer frame, correct, that
14 we've been talking about?
15 A. Yes.
16 Q. Do you know to a certainty -- well, let
17 me ask you this: Do you believe that any of
18 that white material that we see is associated
19 with either the inner skirt or the sutures for
20 the inner skirt?
21 A. Parts of it may be, but part of it is
22 certainly the outer cloth poking through.
23 Q. What part of the white material at 4:00
24 to 5:00 o'clock is associated with the inner
25 skirt?

1 A. I can't divide it up like that because
2 you haven't got the resolution there.
3 But the fibers that are sticking in are
4 from the outer skirt, where you can see
5 individual wispy fibers, and the majority of the
6 material, because you're looking down on it,
7 close to straight down on it, is mostly material
8 that's poking in from outside, in my opinion.
9 Q. So in your opinion, most of the
10 material that we see is from the outer cloth.
11 That's your testimony?
12 A. Correct. At 4:00 to 5:00 o'clock.
13 Q. Is it possible that what we see in the
14 white material at 4:00 to 5:00 o'clock is
15 predominantly material associated with Levi's --
16 sorry, not Levi's -- Sapien's inner skirt and
17 the sutures there to?
18 MR. SUMMERS: Objection. Form.
19 THE WITNESS: No. It's too rough, too
20 wispy, too irregular to be the more dense inner
21 skirt.
22 BY MR. LOWENSTEIN:
23 Q. So you know to a certainty that the
24 white material we see on the inside of the outer
25 frame is not associated with the inner skirt of

1 the Sapien or the sutures thereto; is that your
2 testimony?
3 MR. SUMMERS: Objection. Form.
4 THE WITNESS: My opinion is that the
5 majority of what you're seeing at 4:00 to
6 5:00 o'clock in this particular zone is related
7 to the outer cloth poking through the holes in
8 the frame -- the openings in the frame.
9 BY MR. LOWENSTEIN:
10 Q. Now, have you ever handled Walther's
11 valve?
12 A. No.
13 Q. Did you ask anyone at Edwards
14 Lifesciences about Walther's valve?
15 A. No.
16 Q. Did you contact any of the five authors
17 of Walther's paper who are from Edwards
18 Lifesciences to ask them about Walther's valve?
19 A. No. I wanted to analyze it as it was
20 published -- as it was available at the time
21 that it was published. I didn't want
22 information from now. I wanted to look at it as
23 I would have understood it at the time.
24 Q. And you agree that if you wanted to get
25 the answer to what we actually -- if you wanted

1 to actually know what the inner surface of
2 Walther's outer cloth was like, would you agree
3 that the authors of this paper would have more
4 insight into that question beyond what we see in
5 this pixilated image?
6 MR. SUMMERS: Objection. Form.
7 THE WITNESS: They may have. This was
8 published a long time ago. If you're talking
9 now -- at the time I think they would have known
10 a lot, but I don't know what -- I have no idea
11 what they would know now or remember. They'd be
12 looking at the images that I'm looking at and
13 giving their opinions.
14 BY MR. LOWENSTEIN:
15 Q. You agree that the author does not
16 discuss the inner surface of its outer cloth?
17 A. Sitting here, and without going through
18 it, I can't remember any particular discussion
19 about -- specifically about the inner surface.
20 It's generally about the cloth.
21 Q. Beyond this specific image that we're
22 looking at right now, do you have -- is there
23 any other evidence in Walther that bears upon
24 the inner surface of its outer cloth?
25 A. Yes. There are other images where I

1 think you can see little pieces of cloth. A bit
2 like you've shown me on other devices where
3 you're looking into the image, there are other
4 photographs where you can look in and you can
5 see bits about the cloth.
6 Q. I'm talking about the inner surface of
7 the outer cloth.
8 A. Yes, I'm talking about the inner
9 surface of the outer cloth.
10 Q. Direct me to -- make it bigger. Let's
11 zoom out.
12 Which figure would you like to look at?
13 A. I'm not seeing them all yet. I think
14 it's Figure 2. If you could zoom out so I can
15 see all the figures.
16 Yes, it's Figure 2.
17 Q. And you agree that you did not cite
18 Figure 2 for this proposition in your
19 declaration; correct?
20 A. That's true. You're asking me now, and
21 I'm answering your question.
22 Q. And you agree that the outer cloth in
23 Figure 2 -- I'm asking you about the top left
24 image in Figure 2.
25 Are you with me?

1 A. Top left image now, yeah. Yes.
2 Q. You agree that the outer cloth of
3 Walther is wrapping around the apices at the
4 proximal end of the valve; correct?
5 A. Yes, it's wrapping around the apices at
6 the proximal -- the inflow end of the valve.
7 Q. And yet that's the exact opposite of
8 your testimony in the '549 case, wasn't it?
9 A. No.
10 Q. Where you testified that the apices
11 were uncovered, wasn't it?
12 A. Sorry. Are you talking about the lower
13 apices or the upper apices? I'm confused now.
14 Because I'm looking at the --
15 Q. No. No. Nope, nope, nope. I said
16 very clearly we were talking about the top left
17 figure in Figure 2, and I clarified that we're
18 looking at the proximal end.
19 So --
20 A. By "proximal," do you mean the inflow?
21 Q. I'm referring to the top left image of
22 Walther's Figure 2.
23 A. Yes, but which --
24 Q. And you agree that the outer cloth
25 wraps around the apices, don't you?

1 A. Yes. That's what I just said. It
2 wraps around the lower apices.
3 Q. Okay. Does it wrap around from the
4 outside of the outer frame or the inside of the
5 outer frame?
6 A. It doesn't wrap around internally.
7 It's wrapping around the external -- I think
8 you -- it may be that I'm confused by your
9 question.
10 It wrapping around the outer surface.
11 It's not wrapping up inside the --
12 Q. So what we are seeing in Figure 2 is
13 just the outer surface of the outer cloth as
14 it's wrapping around, isn't it?
15 A. Wrapping around circumferentially.
16 It's wrapping around the outside of the device,
17 as the author says.
18 Q. So that wouldn't give you any insight
19 into the inner surface of the outer cloth, would
20 it?
21 A. No, that photo, the upper photo, does
22 not give you any insight into the inner surface,
23 because you're looking at it fairly straight on,
24 so you're only seeing the outer surface.
25 Q. Okay. So that gives you no insight

1 whatsoever into the inner surface of the outer
2 cloth; correct?
3 A. Well --
4 MR. SUMMERS: Objection. Form.
5 THE WITNESS: It only shows the outer
6 surface, so that you're looking at the outer
7 surface.
8 BY MR. LOWENSTEIN:
9 Q. So the answer to my question is yes, it
10 gives you no insight whatsoever into the inner
11 surface of the outer cloth; correct?
12 A. You're only seeing the outer surface.
13 Is that not answering your question?
14 Q. What I asked you was for evidence --
15 any other evidence aside from the bird's-eye
16 view in Figure 1 from Walther that tells us
17 anything about the inner surface of the outer
18 cloth.
19 Is there anything else in Walther --
20 A. Yes. I --
21 Q. -- that tells us about the inner
22 surface of the outer cloth beyond the bird's-eye
23 view in Figure 1?
24 A. Yes. Figure 2, looking at -- I gave
25 you that answer. You said that was not in your

1 report, and I agreed. And I'm saying now I've
2 looked at it more closely, and I can see a bit
3 of the cloth at around 9:00 o'clock between the
4 valve and the frame, and you can see a bit of
5 the inner surface.
6 It's a bit like looking into the cells,
7 as you had me doing on the previous
8 photographs -- not that figure. Figure 2, the
9 lower one.
10 Yes, there. Yes, there.
11 If you look into the -- so looking in
12 at 9:00 o'clock between the leaflet on the
13 inside and the leaflet on the outside -- there
14 are two pericardial leaflets, and it's the outer
15 one that belongs to the surgical valve, which is
16 darker in color. And between those two you can
17 see part of the frame, and you can see a small
18 piece of the cloth wrapping around.
19 I have no way of pointing it to you,
20 but you can see it's a small piece of the cloth,
21 and you can see part of the inside of it.
22 Yes, that there. You're zooming in on
23 it now, but it's become very pixilated. But you
24 can see it has a rough surface on the inside.
25 Q. So you're looking at this dark brown

1 coloration; is that correct?
2 A. Yes. It's in the shadows, so it's a
3 bit like the photos --
4 Q. So you agree that we don't see anything
5 that's white --
6 A. We don't see --
7 Q. -- in that section; correct?
8 A. We don't see anything that's white.
9 It's in the shadows. It's several tones down,
10 as we talked about in previous photographs, but
11 in there you can see it has a rough surface.
12 Q. Would you agree that the color that
13 we're looking at substantially matches the color
14 of the existing valve that Walther is replacing?
15 A. Well, no, it doesn't, because you can
16 make it out, and you can see that it's a rough
17 surface.
18 So it's a different color, but it is in
19 the shadow, so it is much darker than the other
20 photos, where you're seeing brightly lit outer
21 fibrous cloth.
22 Q. So I want to make sure I understand.
23 This image provides insight into the
24 inner surface of the outer frame more so than
25 the 3:00 o'clock diamond that we saw in Cheung

1 and Apogee; is that your testimony?
2 A. No.
3 And I think you misspoke. It's not
4 about the frame. I'm looking at the fabric
5 covering, Walther's outer cloth, which is
6 wrapped around. And this certainly doesn't give
7 you more image. It's very similar to the sort
8 of quality that you're getting on your diamonds
9 that you had me look at a few minutes ago.
10 Q. You believe that -- you would agree,
11 though, that there's nothing in this section
12 that is necessarily a white material, whether
13 it's shadowed or not?
14 A. Well, it's in the shadow, and,
15 therefore, it doesn't appear as white. It
16 appears several shades darker.
17 But you can see the rough inner surface
18 in that little segment, very much like you were
19 showing me in the diamonds in the previous
20 photographs.
21 Q. I don't see any white at all, and I
22 don't see any cloth at all.
23 A. Okay.
24 Q. So how do you know that this is just --
25 not just more of the inner surface of the valve

1 that is being replaced?
2 A. Because it's in the position of the
3 cloth. It's coming halfway around the
4 vertical -- halfway up the vertical bar. And if
5 you compare that with the front-on image, you'll
6 see it's in position where the cloth is placed
7 on Walther.
8 Q. So your testimony is that this provides
9 more insight -- let me start over.
10 Your testimony is that the bottom image
11 of Walther's Figure 2, which you did not
12 reference in the petition or in your declaration
13 thereto, provides more insight into the inner
14 surface of Walther's outer cloth than the image
15 at 3:00 o'clock in Cheung provides as to
16 Cheung's inner surface of its outer cloth.
17 Is that your testimony?
18 A. They're about the same. It's not more.
19 I'm saying that this is in the shadows. I
20 didn't rely on it. I've spotted it since that
21 it is there.
22 It's not in my report, as I said to you
23 when you first asked that, but it is further
24 information, which -- you asked me whether there
25 was anything else, and so I'm answering that

1 yes, this agrees with my opinions about the
2 surface -- the inner surface of the outer cloth.
3 I don't see any dents in the surface
4 like Brecker sees, and the white line that
5 Brecker refers to I think is just white light
6 reflected off the frame.
7 Q. Did you ever see inwardly facing fibers
8 in a Rorschach test?
9 A. Sorry. Ask that question -- I
10 didn't --
11 Q. Have you ever seen inwardly facing
12 fibers in a Rorschach test?
13 A. I don't understand the test. What's
14 the term you're using? "Rorschach"?
15 Q. Rorschach.
16 A. I don't understand that. I'm sorry.
17 Q. You would agree that even if --
18 I'm getting a feedback or something.
19 (Discussion held off the record.)
20 MR. LOWENSTEIN: Well, we've been going
21 for a bit, so why don't we take a break. And I
22 think what I'm going to do is I'm going to log
23 off and reconnect, and then hopefully that will
24 address the issue.
25

1 (Recess from 10:32 a.m. to
2 10:40 a.m. PST.)
3 BY MR. LOWENSTEIN:
4 Q. Looking back at this same image where
5 we left off, can you say to a certainty that the
6 brownish portion that you have been directing us
7 to in the bottom image in Walther's Figure 2 is
8 not the artificial leaflet material for the
9 valve that is being replaced?
10 A. Yes.
11 Q. You can say that to a certainty?
12 A. Yes.
13 Q. If interventional cardiologists said,
14 "That's crazy. We're obviously looking at the
15 native leaflets," they would be lying; is that
16 your testimony?
17 MR. SUMMERS: Objection. Form.
18 THE WITNESS: They can have a
19 difference of opinion. I'm giving you my
20 opinion. I'm not accusing anyone of lying. I
21 haven't heard anyone else give an opinion on it.
22 I'm telling you that I'm certain that
23 that is part of the Walther's cloth because of
24 the position and the height it comes up the
25 vertical strut that you can see at a bit after

1 6:00 o'clock.
2 BY MR. LOWENSTEIN:
3 Q. Can you state to a certainty that this
4 cloth that you imagine seeing, this brown --
5 this brown material which you identify as
6 Walther's white cloth, can you say to a
7 certainty that this image displays inward-facing
8 fibers?
9 A. No. I can see it's a rough surface,
10 but there's not the resolution there in the
11 shadows down there to see fibers.
12 I wouldn't expect to see fibers, but I
13 can see that it is a rough -- it's not a smooth
14 inner surface, and I can see that it's fairly
15 uniform across its thickness. It doesn't appear
16 to have a brighter white inner layer of dense
17 material as Brecker was suggesting from the
18 other image.
19 Q. In this image that you're looking at in
20 the white cloth that you imagine seeing that is
21 actually brown, do you see openings?
22 A. No. I can see that it's not smooth,
23 and, therefore, there are depressions and --
24 it's not smooth, and, therefore, it's got
25 depressions in it by virtue of the fact it's not

1 smooth.
2 But again, there isn't any great
3 resolution, and I certainly can't see fibers,
4 and I can't see individual things that I can say
5 are openings, but it is -- it is rough.
6 MR. LOWENSTEIN: Let's go back to
7 Walther's Figure 1. I want to look at the top
8 image this time.
9 Q. Do you see -- okay. So you agree we're
10 looking at Walther's Figure 1, the head-on
11 image, not the bird's-eye view, but the top
12 image in Figure 1.
13 Do you see that?
14 A. The side-on image. The upper figure --
15 the upper photograph of Figure 1.
16 Q. Okay. Do you see any openings in this
17 image?
18 A. Yes, I can see -- because it's brightly
19 lit, I can see the fibers, and I can see, you
20 know, shadows between them, and I can see that
21 they -- between the fibers there are openings
22 that go deep into the cloth.
23 Q. Do you see -- can you see the frame
24 through the outer cloth?
25 A. No, I cannot see the -- in this picture

1 with this lighting, I can't see the frame
2 through the outer cloth. If it was backlit,
3 perhaps I could, but in this image I cannot see
4 the frame through the cloth.
5 Q. Do you believe Walther's outer cloth is
6 impermeable?
7 A. I think it's very unlikely to be
8 impermeable until its squashed and blood clots
9 in it. I think fluid would probably pour fairly
10 easily through it, because it's a very loose --
11 very loose cloth with big gaps between the
12 fibers, and, therefore, I think it would --
13 fluid would pour through it.
14 Q. You agree that woven PET -- I'm sorry.
15 It's your testimony that fluid would
16 pour through Walther's outer cloth?
17 A. Yes. I think if you poured water on
18 it, it would pour through it. That is my
19 opinion of this cloth.
20 Q. Do you believe that woven PET is a
21 gravity material?
22 A. Woven PET can be a graft material, but
23 one thing I'm in agreement with Brecker is that
24 it needs to be dense and nonporous to fulfill
25 the graft material of the '236 patent and,

1 indeed, the other patents.
2 Q. You agree that you did not proffer any
3 claim constructions in your declaration;
4 correct?
5 A. Using plain and ordinary meaning.
6 Q. And you agree that you did not provide
7 any testimony concerning whether Walther's outer
8 cloth is porous or not; correct?
9 A. Sorry. Could you ask that -- I
10 missed --
11 Q. You did not provide any testimony in
12 your initial declaration concerning whether
13 Walther's outer cloth is porous or not; correct?
14 A. I don't remember. I was just answering
15 the question you just asked me.
16 Q. And you agree that you did not provide
17 any testimony suggesting -- indicating that
18 Walther lacked in outer cloth based upon its
19 porosity or permeability; correct?
20 A. I don't remember saying anything like
21 that. I said it's a very loose, compressible,
22 voluminous cloth.
23 Q. You agree that Walther's outer cloth is
24 added talk to address PVL between Walther's
25 valve and the existing valve; correct?

1 A. Correct. That's why it's put there.
2 Q. Walther does not say that it is
3 directed towards addressing PVL between its
4 outer cloth and its outer frame; correct?
5 A. Sorry. Walther does not say...
6 Q. That it is directed towards addressing
7 PVL between its outer cloth and its outer frame;
8 correct?
9 A. Yes, it does. Walther specifically
10 says on the first page, I think, that it forms a
11 seal between the two valves and the --
12 Q. I'm not asking about the two valves.
13 I'm asking about Walther's outer cloth and
14 Walther's outer frame.
15 A. Yes. That is the frame -- one of the
16 valves is the Sapien on which it's put, and the
17 outside of the Sapien is the frame. And Walther
18 teaches that there is a seal created between the
19 two valves, one valve being the Sapien and its
20 frame and the other valve being the surgical
21 valve into which it's placed.
22 I --
23 Q. You're aware that Walther already has
24 an inner skirt; correct?
25 A. The Sapien has an inner skirt, but it

1 doesn't come to the --
2 Q. I just -- you answered my question.
3 That's it.
4 And we've already established that
5 Walther's outer cloth wraps around the bottom
6 apices at the proximal end; correct?
7 A. Not internally wraps around, which I
8 think was where you were confusing my testimony.
9 It's wrapping circumferentially around the
10 outside.
11 Q. That's exactly what I said earlier.
12 So there's no indication in Walther
13 that it is creating a PVL seal between the inner
14 surface of its outer cloth and the outer surface
15 of its inner skirt; correct?
16 A. Yes. Because you need to seal the gap,
17 and the gap --
18 Q. There's no teaching in Walther that
19 you're creating a seal between the inner surface
20 of the outer cloth and the outer surface of the
21 inner skirt; correct?
22 MR. SUMMERS: Objection. Form.
23 Please let the witness finish his --
24 MR. LOWENSTEIN: Don't interrupt my
25 deposition.

1 MR. SUMMERS: Stop interrupting the --
2 BY MR. LOWENSTEIN:
3 Q. Answer my question.
4 MR. SUMMERS: Stop interrupting --
5 BY MR. LOWENSTEIN:
6 Q. Answer my question.
7 MR. SUMMERS: -- the witness.
8 BY MR. LOWENSTEIN:
9 Q. Answer my question.
10 MR. SUMMERS: He is.
11 BY MR. LOWENSTEIN:
12 Q. You said there's no teaching.
13 You answered yes; correct?
14 A. No. There is teaching that you seal
15 against the Sapien valve, and against the Sapien
16 valve includes the outer surface of the --
17 Q. Show me exactly what sentence you're
18 talking about. I want to see exactly the
19 disclosure you're referring to. Let's see it.
20 You want to look at page 1?
21 A. Yes, can you go to page 1, please,
22 front page.
23 Right. On the right-hand column -- let
24 me just put my glasses back on.
25 On the right-hand column in the

1 introduction, it says, "The addition of an outer
2 cloth to the Sapien cloth valve is designed to
3 reduce paravalvular leak by creating a seal
4 between the two valves."
5 And that is telling you that it's
6 creating a seal on one surface against the valve
7 into which it's put, the surgical valve, and on
8 the other surface, on the inside, against the
9 Sapien valve. They are the two valves.
10 Q. If you were to refer to "Walther's
11 valve," could that refer to -- could that
12 encompass Walther's outer cloth as well?
13 A. No, because the two valves -- one of
14 them -- it's just above it -- is the Sapien.
15 The addition of an outer cloth to the Sapien
16 cloth valve is designed to reduce paravalvular
17 leak by creating a seal between the two valves.
18 Q. So Walther's valve -- if I refer to
19 "Walther's valve," you would understand me to be
20 excluding the outer cloth?
21 A. No, "Walther's valve," I would include
22 the cloth. But when you talk about the Sapien
23 valve, which is what it's built on, that is the
24 second valve between the two valves.
25 Q. So in Levi -- if I refer to "Levi's

1 valve," I would be excluding its outer skirt; is
2 that correct?
3 A. No. Because Walther is built on a
4 known, used, marketed valve called the Sapien.
5 That is the valve on which it is put. With
6 Levi -- I think we're talking about the Levi
7 patent, and we're talking about -- and you'd
8 have to say which one, because there are lots of
9 ones.
10 But Levi teaches lots of valves, and if
11 you say what aspect of Levi you're talking
12 about, I would know which valve. There's no one
13 Levi valve that -- it's a patent disclosure with
14 lots of different ideas and embodiments in it.
15 Q. But you would agree, though, that
16 persons of ordinary skill in the art -- if
17 there's a TAVR with a powder covering of some
18 sort, you would agree that a person of ordinary
19 skill in the art may refer to -- as the valve to
20 include whatever the outer covering is; correct?
21 MR. SUMMERS: Objection. Form.
22 THE WITNESS: Well, different people
23 saying different things may -- "may," as your
24 question says -- be referring to different
25 things. But this makes it very clear that it's

1 talking about, one, the Sapien valve and, two,
2 the valve into which it's put, the surgical one,
3 and is creating a seal between the two. And I
4 think it is obvious to a person of ordinary
5 skill in the art that that's what it's there for
6 is to create a seal between the two valves.
7 BY MR. LOWENSTEIN:
8 Q. Is there any other statement in Walther
9 that supports your understanding?
10 A. Well, all of it does, but that
11 statement is very specific --
12 Q. I want you to point some me to any
13 specific statement that you believe supports
14 your position?
15 A. No. It would be a person's -- a person
16 of ordinary skill in the art's understanding of
17 the purpose. It's to stop paravalvular leak
18 occurring between the two valves. You've added
19 something to the Sapien to stop leaking between
20 the two, and, therefore, you've got to seal to
21 both surfaces. You've got a seal to the surface
22 into which you've placed the device, and you've
23 got a seal against the existing surface of the
24 device onto which you've added Walther's fabric.
25 Q. So Walther, just again, that was

1 published in 2011; is that correct?
2 A. I can look and see.
3 It was published -- available online
4 3rd of April, 2011. Yes. It was published in
5 2011.
6 Q. And that was three years after you
7 retired?
8 A. No, I hadn't retired by then. I'd
9 stopped doing procedures. I'd stopped --
10 Q. Okay. And we know well that you've
11 never implanted a TAVR; correct?
12 A. Correct, I've never implanted a TAVR
13 device.
14 Q. And you've never handled a TAVR with an
15 outer covering of any kind; correct?
16 A. No. I've handled lots of TAVRs without
17 a covering.
18 Q. In the context of litigation; correct?
19 A. No. I've at meetings and things seen
20 devices and handled devices, and in the context
21 of litigation, I've handled devices without
22 covers, like, you know, Sapien 3, Sapien 3
23 Ultra, and other manufacturers' devices.
24 Q. And you've never spoken to any of the
25 authors of Walther about the nature of a TAVR

1 cloth; correct?
2 A. Correct. I mean, I've -- to my
3 knowledge, I've never met any of them, and I've
4 certainly never spoken to them.
5 I didn't wish to speak to any of them.
6 I wished to rely just on the publication at the
7 day it was published in 2011.
8 Q. And you can see that five of the six
9 authors of Walther were at Edwards Lifesciences;
10 correct?
11 A. Correct.
12 Q. And you did nothing whatsoever to
13 verify your understanding of what Walther
14 discloses outside of the four corners of
15 Walther; correct?
16 A. I deliberately have not, because I
17 don't want to know extraneous things. I want to
18 know what is available in the prior art, and,
19 therefore, I wanted to know what the
20 interpretation would be of a person of ordinary
21 skill reading the publication.
22 I don't want to know the opinions of
23 the --
24 Q. Are you an expert in analyzing
25 photographs?

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

1 field of stents. And I'm very familiar with
2 looking at photographs to see shadows, lighting,
3 and ascertain the structure that I'm looking at
4 in this field.
5 BY MR. LOWENSTEIN:
6 Q. Would you agree that Dr. Brecker has
7 substantially more expertise than you in the
8 field of TAVRs?
9 A. In clinically using them or placing
10 them, yes, he has much more. I don't know that
11 he has more experience in analyzing photographs
12 or looking at devices, analyzing devices.
13 Q. Dr. Brecker, to my recollection, has
14 implanted over a thousand -- I think it was on
15 the order of 1300 TAVRs.
16 Do you have any reason to believe
17 that's not true?
18 A. No, I have no reason to believe that's
19 not true.
20 Q. And you have implanted zero TAVRs;
21 correct?
22 A. Absolutely correct. And as I've said
23 many times, I've never implanted a TAVR.
24 Q. And Dr. Brecker has published dozens of
25 articles relating to TAVRs; is that correct?

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

1 can't just pick up the phone and call just
2 anyone at Edwards Lifesciences; correct?
3 A. Well, he could, but I'm absolutely he
4 sure he wouldn't have. And --
5 Q. You understand that would be ethically
6 improper; correct?
7 A. Yes. In the context of the
8 litigation --
9 Q. Okay.
10 A. -- he wouldn't be doing it to obtain
11 anything. But, you know, he is as capable as I
12 am of ringing up a company outside litigation
13 and asking for information.
14 Q. You got to just answer the questions I
15 ask. I think you answered my question. Let's
16 move on.
17 Now, you'll see Walther references a
18 Model 9000 MIS; correct?
19 A. Yes. He does in the abstract, yes.
20 Q. And did you ask Edwards for samples of
21 the Model 9000 MIS?
22 A. No.
23 Q. Do you believe that Dr. Brecker had
24 asked Edwards for samples of the Model 9000 MIS?
25 MR. SUMMERS: Objection. Form.

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

1 frame?
2 A. Yes.
3 Q. Show me.
4 A. If you look at say -- if we go up to
5 the top image, where you can see more of the
6 inside, as I've said. So you go up to the upper
7 quadrants, and if you look, for instance, at
8 11:00 o'clock, if you see the bright reflection
9 of the frame where there's sort of five lines --
10 or what I see as five lines up it, immediately
11 to the right of that there is a gap which is
12 extending into the frame.
13 Yeah, someone's putting a cursor -- or
14 was putting a -- they've moved it down, but
15 quite close to where I see a gap. I see fuzzy
16 bits coming in, and then a gap, and then more
17 fuzzy bits coming in.
18 Q. Can you see the outer frame through
19 this white material?
20 A. I can see the outer frame at the top.
21 The outer frame looks variously bright light or
22 dark black, depending on the light reflecting
23 off it. So I can see the frame all the way
24 around, around the --
25 Q. Do you see the frame through the cloth?

1 A. No, you can't see the frame through the
2 cloth.
3 Q. Okay. Now, I want to go to the area
4 between 12:00 o'clock and -- I'm not sure. I
5 guess that would be between 1:00 and
6 2:00 o'clock. And you see there there's the
7 attachment for the pericardium, and then there's
8 two apices to the right.
9 Do you see the two apices to the right?
10 A. The apices -- so now where there's
11 almost a sort of little oval, like, bright white
12 reflection, yes, they're the two apices.
13 Q. Okay.
14 A. It goes apex, trough, apex. So I'm
15 saying if you look at the commissural bar --
16 Q. Yeah, so I think there's an apex and a
17 trough.
18 So could you highlight what we're --
19 THE WITNESS: Yes, there's a trough and
20 an apex.
21 MR. LOWENSTEIN: Can you highlight from
22 here to here.
23 Q. Okay. You see this section that I'm
24 highlighting?
25 A. Yes. That goes apex, trough, apex. So

1 that --
2 Q. Okay. Very good.
3 So we're starting with the first apex
4 to the right of 12:00 o'clock.
5 A. Yes.
6 Q. I'm going to ask you about the white
7 material on the inside of the outer frame
8 between those two apices.
9 Are you with me so far?
10 A. I am.
11 Q. Can we see the sutures from the Sapien
12 inner skirt on the inside of the outer frame?
13 A. Yes, I think you can see the three
14 sutures -- so if you look down into the gap
15 between the valve leaflet, the pericardium, and
16 the white material, you can see three very
17 uniform bubbles between the apex and the trough,
18 and I think they are three of the stitches that
19 attach the inner material, the inner skirt, to
20 the frame.
21 Do you see -- they're very clear, I
22 think.
23 Q. Well, let's be more specific, because
24 I'm not sure exactly what you're referring to.
25 I want to start with the first apex

1 just to the right of 12:00 o'clock.
2 A. Got it.
3 Q. Let's just focus on the area -- let's
4 follow the bar frame down towards the troughs.
5 I just want you to highlight, Will,
6 this area.
7 THE WITNESS: Yes.
8 BY MR. LOWENSTEIN:
9 Q. Do you see this area that I've
10 highlighted -- or Will has highlighted?
11 A. Yes. That area -- so exactly in that
12 area I can see three stitches, which I am
13 certain are the attachment of the inner cloth to
14 the frame, and they are -- they're not the top,
15 much larger number of things sticking in; they
16 are further down. They are three stitches that
17 you can see exactly in that square you
18 highlighted briefly, and they are attachments of
19 the inner skirt to the frame.
20 Q. And just to be sure, you'll recall that
21 the cells resemble diamonds, and we're looking
22 at a bar that's going downwards diagonally.
23 Are we referring to sutures that are
24 attached to that bar?
25 A. Yes, you're saying sutures attached to

1 that bar -- you're saying the sutures which are
2 attaching the inner skirt to the frame to that
3 bar you're speaking about.
4 Q. Now, if we go downwards from the
5 sutures, are we looking at the Sapien inner
6 skirt?
7 A. Yes, there you are.
8 Q. Okay.
9 A. And the reason you can see it up here
10 on the top is because, as I've explained, the
11 view is off center. You are seeing far more of
12 the inside than you are when you look at the
13 lower quadrants, where the camera lens is almost
14 lined up with the frame down at 6:00 o'clock so
15 you're looking straight down the frame.
16 Here you're looking slightly in, and
17 that's why you can see the material of Walther's
18 cloth. And then you're looking down, and you
19 can see the stitches, and you can see what I'm
20 certain is part of the inner skirt.
21 Q. Now, focusing just upon the inside of
22 the outer frame, the white material between the
23 first and second apices to the right of
24 12:00 o'clock, is all of the whitish material
25 that we see the sutures for the Sapien inner

1 skirt and the inner skirt material?
2 A. I'm sorry. I'm lost with what you're
3 asking me. Can you repeat that again.
4 Q. So you see there's a --
5 A. Which segment are we looking at first,
6 so I'm looking at the same bit.
7 Q. We're looking at the same section we
8 were talking about.
9 A. Okay.
10 Q. We're talking about --
11 A. Got it. Now I forget --
12 Q. -- starting at 12:00 o'clock, we're
13 talking about the first two apices that we --
14 A. Sorry. This is confusing.
15 Starting at 12:00 o'clock, you would be
16 much further over. That's where the -- at
17 12:00 o'clock, that's where the commissure is.
18 Q. Yeah. I'm talking about the first two
19 apices to the right.
20 A. Yes. But you said "starting at
21 12:00 o'clock." If someone just highlighted
22 the --
23 Q. What I'm trying to say is I'm starting
24 at 12:00 o'clock to orient you, and then I'm
25 talking about the two apices to the right.

1 A. Okay.
2 Q. So I'm not asking you about
3 12:00 o'clock. I'm trying to identify the
4 apices relative --
5 A. So we're talking about 1:00 o'clock to
6 2:00 o'clock?
7 Q. Roughly. Roughly.
8 A. Roughly, I mean.
9 Q. Okay. I think that's a fair
10 description. I think that's where we've been
11 talking about in the last several questions, I
12 think.
13 Is that fair to say?
14 A. Okay.
15 Q. Okay. So starting now with the apices
16 at 1:00 and 2:00 o'clock, and I'm asking you
17 about the white material that is on the inside
18 of the outer frame.
19 Are you with me?
20 A. On the inside of the frame, yes.
21 Q. Okay. And we see both Sapien's inner
22 skirt --
23 A. Yes.
24 Q. -- and the sutures for the inner skirt
25 attaching it to the outer frame; correct?

1 A. Yes.
2 Q. Do we see any fibers from the outer
3 cloth on the inside of the outer frame in this
4 section?
5 A. You undoubtedly do, but I don't think
6 that poking in is as clearly seen as when you
7 get down to sort of closer round to
8 3:00 o'clock, because they're --
9 Q. You're seeing the sutures fairly
10 clearly here; correct?
11 A. You can see the sutures because sutures
12 are much larger than -- I mean, sutures are way
13 bigger than fibers.
14 And you are seeing what I take to be
15 some of the material, but it is poking in under
16 the strut, where you see it very white. It
17 looks fairly bright white above the internal
18 skirt.
19 Q. Now, you agree that the outer cloth
20 extends vertically higher than the sutures for
21 the inner skirt; correct?
22 A. It does, yes. And so there's a bare
23 space in which Walther's outer cloth can poke
24 through because there is no inner cloth there.
25 Q. And yet you agree that we can see the

1 sutures clear as day without any -- without
2 being blocked out by inwardly facing fibers made
3 out of cloth; is that correct?
4 A. Well, the stent is coming -- because
5 you're at this angle --
6 Q. Wait, wait, wait. Just answer my
7 question.
8 Simple question: You agree that we can
9 see the sutures for the Sapien inner skirt clear
10 as day between the apices at 1:00 and
11 2:00 o'clock without being obscured by fibers
12 from the outer cloth; correct?
13 A. Yes. And that's --
14 Q. That's it. That's it.
15 A. I think I'm --
16 Q. No, no. That's --
17 A. You're not letting me finish answering
18 your question.
19 Q. I asked you a yes-or-no question. You
20 answered it.
21 A. It is not a yes-or-no question.
22 Q. Yes, it is. If you want to do
23 redirect, you can do redirect with your counsel
24 later, which will allow me to cross -- will
25 allow our discussion to continue even further.

1 A. Excellent.
2 MR. LOWENSTEIN: Let's show
3 Exhibit 2100.
4 Okay. Let's just go down a little bit.
5 Q. Okay. Do you see in front of you
6 there's a document that we've marked as
7 Exhibit 2100?
8 A. I see.
9 MR. LOWENSTEIN: Okay. Let's go to the
10 first image, please.
11 Q. Do you recognize the valve that we're
12 looking at?
13 A. Do I?
14 Q. Do you recognize the valve that we're
15 looking at?
16 A. It looks like an Ultra. It looks like
17 a Sapien Ultra.
18 Q. Would you agree that the outer covering
19 that we see here is free of an outer graft
20 covering?
21 Let me ask you this: Do you see that
22 the material on the outside, the white material,
23 is free of an outer graft covering?
24 MR. SUMMERS: Objection. Form.
25 THE WITNESS: I haven't looked at it or

1 analyzed it. The Sapien 3 Ultra is not part of
2 this case, as far as I know.
3 BY MR. LOWENSTEIN:
4 Q. I'm asking you to do it right now.
5 A. I can't. This is a photograph of it.
6 I've not examined it or looked at it --
7 MR. LOWENSTEIN: Let's zoom in?
8 THE WITNESS: -- to be able to answer
9 these questions.
10 MR. LOWENSTEIN: Let's zoom in -- let's
11 be helpful. Let's zoom in.
12 Q. Can you see it better now?
13 A. I can see it better, yeah.
14 Q. Okay. Can you determine from the image
15 that we're looking at whether the white material
16 is free of an outer graft covering?
17 A. No.
18 Q. Why not?
19 A. Because I can't. You can't do it from
20 just looking at that photograph.
21 Q. So it might be free of an outer graft
22 covering; correct?
23 MR. SUMMERS: Objection. Form.
24 THE WITNESS: I said I can't tell from
25 the photograph. It might; it might not.

1 I haven't done this analysis. I
2 haven't examined any Sapien 3 Ultras for a long
3 time, I haven't examined them for any purpose
4 for this case, and I haven't got an opinion
5 about it.
6 Q. So I'm just asking: Based upon your
7 looking at this photograph, you can't tell one
8 way or the other whether the white material is
9 free of an outer graft covering; correct?
10 A. Right. I've said I can't tell from
11 this photograph.
12 Q. You would agree that the white material
13 is translucent; correct?
14 MR. SUMMERS: Objection. Form.
15 THE WITNESS: No. I mean --
16 BY MR. LOWENSTEIN:
17 Q. You don't see the bars through the
18 white material?
19 A. Bars? You can see something I can't on
20 this image. No, I can't.
21 Q. It's amazing how your vision comes and
22 goes, because I can clearly see the bars of the
23 stent.
24 You can't?
25 A. I can't clearly see them. I can see

1 some areas that probably has darkness for bars.
2 So I can't clearly see the design of the stent.
3 Q. It's amazing, because I thought you
4 could see parts of visual spectrum that were not
5 available to normal humans when you sussed out
6 the outer graft covering in Walther's Figure 2.
7 And yet you can't see the clear bars
8 that are clear as day to everyone on this call?
9 MR. SUMMERS: Objection. Form.
10 THE WITNESS: Perhaps my monitor's not
11 as good as yours here.
12 But no, I'm answering your questions.
13 I can't.
14 MR. LOWENSTEIN: Okay. Let's help the
15 good doctor again. Let's zoom in towards the
16 middle between --
17 Q. You'll see that this is a Sapien 3
18 Ultra valve that's being held between two human
19 fingers?
20 A. I can see the fingers.
21 Q. Okay. Now, I've zoomed in to just
22 about the middle.
23 A. Yeah.
24 Q. You don't see the bars of the outer
25 frame through the white material?

1 A. No. I mean, there may be odd places
2 where I can see darkness, where it's darker, but
3 I can't clearly see the bars of the frame
4 through it.
5 MR. LOWENSTEIN: Okay. Let's zoom back
6 just a little bit, just to the last image that
7 we had.
8 Q. Okay. Does the outer surface of the
9 Sapien 3 Ultra outer cloth have openings?
10 A. Sorry --
11 Q. Openings.
12 MR. SUMMERS: Objection. Form.
13 THE WITNESS: Yes. It's a bubbly outer
14 surface. I mean, the image you're showing me
15 doesn't even seem to be fully focused, but the
16 outer surface is clearly not smooth.
17 BY MR. LOWENSTEIN:
18 Q. So it has openings?
19 A. Yeah.
20 Q. Okay.
21 A. It has indentations, as I said before.
22 But it's not very finally focused. I can't see
23 individual fibers. It's clearly not a smooth
24 surface. But it really doesn't seem to be a
25 very sharply focused image.

1 Even the frame above doesn't seem to be
2 in focus on what I'm looking at. It looks as
3 though the frame's out of focus.
4 Q. Does the outer edge of this white
5 material that we see in the Sapien 3 Ultra, are
6 the openings -- do they extend through the
7 thickness of the outer surface?
8 MR. SUMMERS: Objection. Form.
9 THE WITNESS: If they're undulations,
10 yes, they -- absolutely they extend. I can't
11 tell from this photograph, and I can't give you
12 dimensions, as you'll understand, but there are
13 depressions, which you can call openings, and
14 they extend a distance.
15 It's a rough surface. I can see there
16 is a rough surface even though it's somewhat out
17 of focus.
18 BY MR. LOWENSTEIN:
19 Q. Do the fibers define an opening that is
20 created by spacing formed between adjacent
21 fibers?
22 A. I don't know. As I said, I can't see
23 the fibers. So I can't see individual fibers,
24 so I can't see adjacent fibers.
25 Q. So you can can't tell in the image that

1 we're looking at whether the fibers define an
2 opening that is created by spacing formed
3 between adjacent fibers?
4 A. As I can't see individual fibers, I
5 cannot answer anything about the adjacent
6 fibers, because you would have to be able to see
7 the fibers and adjacent fibers to answer that
8 question.
9 Q. Okay. We're zoomed in at 300 percent
10 here.
11 Would you like us to zoom out or zoom
12 in?
13 A. As I've said, what I'm looking at, the
14 image quality is not great, it's not very in
15 focus, even the frame is not very clear above,
16 and I can't see individual fibers. So I can't
17 answer questions about what's happening between
18 adjacent fibers, because I can't see even one
19 fiber.
20 Q. Well, I want to make sure we get your
21 clearest possible testimony about what this
22 image shows.
23 Would you like us to zoom in or zoom
24 out?
25 A. I don't think it's going to help, but

1 you can zoom any way you think.
2 You're asking the questions. I will do
3 my best to answer your questions whether you
4 zoom in or zoom out.
5 MR. LOWENSTEIN: Well, let's zoom out.
6 Let's try it both ways.
7 Q. Okay. So now we're looking at it at
8 150 percent, according to Adobe at least.
9 Okay. At this level of zoom do the
10 fibers in the Sapien 3 Ultra define an opening
11 that is created by spacing formed between
12 adjacent fibers?
13 MR. SUMMERS: Objection. Form.
14 THE WITNESS: I can't see individual
15 fibers. I can't discern adjacent fibers. I
16 can't answer the question.
17 BY MR. LOWENSTEIN:
18 Q. Okay.
19 A. It looks as though it's very wet, too.
20 It's going to be -- I mean, part of the reason
21 why it appears like it does is because it looks
22 as though it's a very, very wet device. I'm
23 judging that, really, from the reflection of the
24 person's gloves.
25 Q. Do you see a inner surface of white

1 material?
2 MR. SUMMERS: Objection. Form.
3 THE WITNESS: On this photograph?
4 BY MR. LOWENSTEIN:
5 Q. Yes.
6 A. No, I can't see it. Because this is
7 looked at essentially straight, side-on, I can't
8 see easily an inner surface. It hasn't got
9 enough angulation to judge the inner surface,
10 either the top or the bottom.
11 Q. Do the fibers on the inner surface on
12 the white material -- and by "inner surface," I
13 mean the surface facing the outer frame.
14 Do those fibers define an opening
15 extending through a thickness of the white
16 material?
17 MR. SUMMERS: Objection. Form.
18 THE WITNESS: I can't see them. I
19 haven't analyzed this. I've never seen this
20 photograph before. It's not a good enough
21 quality to even see individual fibers. I cannot
22 see any individual fibers.
23 BY MR. LOWENSTEIN:
24 Q. Do the fibers on the inner surface of
25 the white material have openings that extend to

1 the outer frame?
2 MR. SUMMERS: Objection. Form.
3 THE WITNESS: I can't answer that. I
4 can't see any individual fibers, and I can't see
5 any of the inner surface.
6 MR. LOWENSTEIN: Okay. So let's zoom
7 in.
8 Where were we at before? 300? Let's
9 go to 400.
10 Q. Okay. So we're now at a 400
11 magnification. Previously we had done 300 and
12 also 150.
13 Do any of your answers to any of my
14 previous questions change?
15 A. No. The image quality is now awful.
16 It's completely out of focus, even the person's
17 fingers. Like, in the frame there's -- and it
18 doesn't help at all.
19 I can't discern -- it's the underlying
20 quality of the photograph, not the
21 magnification, that's helping. So this doesn't
22 alter anything that I have said to you.
23 MR. LOWENSTEIN: Let's go back to 100.
24 Q. So your testimony is the photograph we
25 see on Exhibit 2100 has insufficient resolution

1 for you to testify knowledgeably about the white
2 material we see around the valve?
3 A. No, I just -- all the answers I've
4 given you I stick to. I can see that it's a
5 rough surface. I can see there are indentations
6 on it. I can't see individual fibers. It looks
7 as though it's very wet. So the fibers, even if
8 they are there, may be stuck down.
9 But the resolution of the photograph is
10 such that I doubt, even if it was dry, I would
11 be able to see individual fibers.
12 MR. LOWENSTEIN: Let's go to the next
13 page.
14 Q. Dr. Buller, we're now on page 2 of
15 Exhibit 2100.
16 Is this a separate image of the
17 Sapien 3 Ultra?
18 A. I think it's more out of focus than the
19 last one. But yes, it's now on the palm of
20 someone's hand, so it's a separate image, and it
21 looks to me to be a Ultra.
22 But again, I have no knowledge of this.
23 I haven't seen these photographs before. I've
24 not analyzed the Ultra. I have not thought
25 about the Ultra in the context of this IPR.

1 Q. Could we agree that this Ultra does not
2 appear to be wet?
3 MR. SUMMERS: Objection. Form.
4 THE WITNESS: I can't tell. It's
5 not -- I mean, the person's hand, it does not
6 appear to be wet. But if it actually is an
7 Ultra, it's probably come out of a bottle and
8 was wet. But I can't tell from this image.
9 But certainly the last one I could see
10 glistening on the person's gloves. This is on
11 someone's hand with no glove. I don't see any
12 evidence of fluid on it, but that's about as far
13 as I can say.
14 BY MR. LOWENSTEIN:
15 Q. Can we agree that the white material in
16 this second image on page 2 of -- the image on
17 page 2 of Exhibit 2100, can we agree that the
18 white material is translucent?
19 A. I can --
20 MR. SUMMERS: Objection. Form.
21 THE WITNESS: I can see through it a
22 little bit more of the image of the frame, more
23 than I could on the last image, but still it's
24 not -- it's not clear. I wouldn't like to trace
25 out the geometry of the frame if I didn't have

1 fairly good knowledge already of the geometry of
2 the underlying frame, which is the same as
3 Sapien 3, the same frame.
4 BY MR. LOWENSTEIN:
5 Q. We can agree, however, that it would be
6 inaccurate to describe the white material on
7 this valve as opaque?
8 MR. SUMMERS: Objection. Form.
9 THE WITNESS: Well, no. I think it
10 is -- I still think opaque is -- you're not
11 seeing clearly through it. I mean, it's not
12 like looking through glass. It is significantly
13 opaque.
14 BY MR. LOWENSTEIN:
15 Q. Would it be more accurate to say it's
16 translucent?
17 MR. SUMMERS: Objection. Form.
18 THE WITNESS: To a degree. But with
19 all these things, there's -- you've got to sort
20 of quantify it. I can't see anything clearly
21 through it.
22 BY MR. LOWENSTEIN:
23 Q. You know, when you say "significantly
24 opaque," it's like when I hear young people say
25 "significantly unique." It's either one of a

1 kind, or it's not.
2 And "opaque" means you can't see
3 through it; correct?
4 A. "Completely opaque" means you can't see
5 through it. I can't see --
6 Q. No, no, no, no. "Completely opaque" --
7 MR. SUMMERS: Objection --
8 BY MR. LOWENSTEIN:
9 Q. -- means you can't see through it;
10 correct?
11 A. Yes.
12 Q. And "translucent" means you can see
13 through it, but it's not with clear visibility,
14 let's say; correct?
15 A. I think that's not unreasonable.
16 Q. Okay. And "transparent" is you can see
17 through it; correct?
18 A. Yes. Again, you know, there are
19 degrees of even transparency, but yes.
20 Q. Okay. And as between transparent,
21 translucent and opaque, which of those three
22 terms most accurately describes the white
23 material on page 2 of Exhibit 2100?
24 MR. SUMMERS: Objection. Form.
25 THE WITNESS: I can see something

1 through it, an outline, but it is not clear at
2 all and not in any detail, and I can only see it
3 on the sort of front surface facing me.
4 BY MR. LOWENSTEIN:
5 Q. You're not able to answer my question?
6 A. No.
7 Q. So you can't tell me whether the image
8 we see on page 2 of Exhibit 2100, whether that
9 is best described as transparent, translucent or
10 opaque; is that fair to say?
11 A. No. I mean, of the three, the middle
12 one is better. I mean, it's not completely
13 opaque, as we've already established, and it's
14 certainly not completely see-through. It is
15 somewhere in the middle, but the -- what I'm
16 seeing through it is extremely fuzzy.
17 Q. So I'm not sure I quite understood your
18 answer.
19 Is it fair to say that "translucent" is
20 a better descriptor than "opaque"?
21 A. Yes.
22 Q. Okay. Good.
23 A. But I never looked at this document,
24 never looked at these images. I don't know how
25 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

1 formed between adjacent fibers?
2 A. I can't see individual fibers, so I
3 can't --
4 Q. Would you like us to zoom in further?
5 A. It's not going to help. I cannot see
6 individual fibers on the image I've got on the
7 monitor in front of me.
8 Q. Would you like me to zoom out?
9 A. No. I'm not going to -- I don't think
10 it's going to help. You can try if you wish
11 to -- you're asking the questions -- but I don't
12 think I'm going to be able to see individual
13 fibers and answer questions about what's
14 happening between adjacent fibers.
15 Q. Now, looking at this image, and with
16 reference to the side of this white material
17 that's facing the frame, are there openings on
18 that side of this material?
19 MR. SUMMERS: Objection. Form.
20 THE WITNESS: I may not be
21 understanding your question, but, I mean, the
22 openings I'm talking about are on the outer
23 surface, because this is --
24 BY MR. LOWENSTEIN:
25 Q. Yeah, I'm asking about the openings on

1 the inner surface.
2 A. I can't see the inner surface.
3 Q. Do you know whether there are openings
4 on the inner surface?
5 A. No. I mean, I can't see any of the
6 inner surface. So this photograph doesn't help
7 me.
8 Q. Why can't you tell whether there are
9 openings on the inner surface?
10 A. Because I can't see any inner surface.
11 Q. So you would need to be able to see
12 openings in the inner surface to determine
13 whether there are openings; correct?
14 A. Well, as I haven't done any analysis of
15 this document or this device and I don't know
16 for certainty what it is, where it comes from,
17 how it's treated, I can't give you -- I can't
18 even see any of the inner surface, and I haven't
19 done any analysis of Ultra.
20 Q. The openings that may or may not exist
21 on the inner surface of this white material, do
22 they extend through a thickness of the material
23 to the outer frame?
24 MR. SUMMERS: Objection. Form.
25 THE WITNESS: Since I can't see any, I

1 can't answer. If you're asking me to answer
2 these questions off this image, I cannot.
3 BY MR. LOWENSTEIN:
4 Q. Because the image is not clear enough?
5 A. Well, because even if it was clearer, I
6 wouldn't be able to see the inner surface. I
7 can't answer questions about the inner surface
8 off an image that doesn't show any of the inner
9 surface.
10 MR. LOWENSTEIN: All right. Let's
11 bring up Exhibit 1011, and let's go to
12 Figure 22.
13 Q. Dr. Buller, I'm sure you're very
14 familiar with this image, and you can see that
15 we're looking at Figure 22 of Spenser II; is
16 that fair to say?
17 A. Yes.
18 Q. You agree that from this image you
19 cannot see the inside surface of layer 256;
20 correct?
21 A. From the image, no, you can't. You can
22 just see a top edge of it. I mean, you can see
23 the inner circle. So you can see that just tiny
24 bit of the top, which appears just to be a
25 concentric circle.

1 Q. Does that bit that you see at the top,
2 does that provide any insight to you about
3 the --
4 A. Because this is a patent -- we're not
5 talking about a photograph now. This is a
6 patent. All it's representing is the position
7 of the compressible material that Spenser
8 teaches -- Spenser II teaches.
9 Q. Would you agree that Spenser II does
10 not describe fibers on the inner surface of
11 layer 256?
12 A. No. Spenser does describe fibers on
13 the inner surface of this material, this
14 compressible --
15 Q. You would agree that it refers to
16 fibers on the surface, but it doesn't refer to
17 the inner surface; correct?
18 A. No. But when it wants to refer to an
19 individual surface, it does. In the same
20 paragraph that it says "fibers on the surface,"
21 later when its talking about adding a growth
22 factor, it talks about the outer surface.
23 So it is very clear that when Spenser
24 says "fibers on the surface," he is not limiting
25 it to one surface. He's talking about both

1 surfaces. Because when he wants to limit it to
2 one surface, he does so. It's in the same
3 paragraph as the disclosure about...
4 Q. Oh, I'm very familiar with that
5 paragraph.
6 A. I'm sure you are.
7 So Spenser, when he wants to talk about
8 one surface, does so. When he's talking about
9 the surface, I mean, everybody, including myself
10 as a person of ordinary skill in the art, would
11 know that there's an inner and an outer surface,
12 and there'll be fibers on both.
13 And, I mean, obviously with Figure 22,
14 if the material wraps all the way around the
15 back, you'd expect there to be fibers on the
16 back as well that you can't see on the image --
17 on the patent drawing.
18 Q. So if I were to reference the surface
19 of my car, you would understand me, for example,
20 to not just refer to the exterior surface of my
21 hood but also the interior surface; is that
22 correct?
23 A. I'm not talking about cars. I don't --
24 Q. Well, I am. I just want to -- I want
25 to understand.

1 So if I referred you to the surface of
2 my car, you would understand me to refer, for
3 instance, not only to the outer surface of my
4 hood but also the inner surface?
5 A. It would depend on the context.
6 Q. Because when people refer to "the
7 surface," you would agree sometimes they mean
8 the outer-facing surface; correct?
9 MR. SUMMERS: Objection. Form.
10 THE WITNESS: Depending on the context,
11 they might. But Spenser makes it absolutely
12 clear that he differentiates between -- if he
13 wants to say the outer surface, he says so, as
14 he says a couple of lines lower, than saying
15 "the surface."
16 He's not limiting the fibers to being
17 on the outer surface. He's teaching that they
18 are on the surface of the compressible material,
19 and clearly it has inner and outer surfaces.
20 BY MR. LOWENSTEIN:
21 Q. Would you agree that outwardly
22 extending fibers may facilitate attachment to
23 native leaflets?
24 A. Yes. They may encourage sort of blood
25 coagulation and tissue ingrowth, which help to

1 attach things. Blood clotting and tissue
2 ingrowth help to attach things.
3 Q. Now, is there human tissue between --
4 well, let me ask you this: Are the native
5 leaflets touching the outer surface of
6 Spenser II's outer cloth?
7 A. There are no -- this diagram is just of
8 the device. There are no --
9 Q. Okay. Let me rephrase it.
10 Would you agree that the outer surface
11 of layer 256 is intended to contact either the
12 leaflets or the annulus?
13 A. Well, the annulus extend -- the
14 leaflets extend from the annulus. So yes, it
15 will undoubtedly -- if it's put into a human
16 valve, it will touch human tissue in the form of
17 leaflet material.
18 Q. Would you agree that the inner surface
19 of Spenser II's 256 -- that the leaflets or
20 annulus are not interposed between the inner
21 surface of the outer cloth and the outer frame?
22 A. The native leaflets are not interposed
23 between the frame and the outer cloth, correct.
24 Q. And would you agree that a person of
25 ordinary skill in the art may find a surface

1 advantageous when attaching to native tissue but
2 less advantageous or not advantageous when
3 connecting to a metal frame?
4 MR. SUMMERS: Objection. Form.
5 THE WITNESS: No. Because one of the
6 main purposes for having the increased surface
7 area with all the fibers is the blood clotting,
8 which helps to seal up paravalvular leaks. And
9 this is specifically put there, just like in
10 Walther, to prevent paravalvular leaks.
11 [Garbled.]
12 (The reporter requested clarification.)
13 THE WITNESS: The reason for having the
14 increased surface area with all the fibers is to
15 get blood clotting through the thickness of the
16 cloth to help prevent paravalvular leakage, so
17 that the increased surface areas with all the
18 fibers matters all the way through to the frame.
19 BY MR. LOWENSTEIN:
20 Q. You would agree that a plausible
21 interpretation of Spenser II is that the
22 compressible material includes a plurality of
23 fibers extending outward from the outer surface?
24 A. It does. It doesn't have to have. He
25 teaches the fibers as being, you know, one of

1 the options for the compressible material having
2 them, but it teaches fibers on the surface that
3 would be the inner and outer.
4 Q. Okay. I want to direct you to claim 29
5 of Spenser II.
6 A. Yes.
7 Q. And we can see --
8 A. Can I see claim 29? Because I --
9 MR. LOWENSTEIN: It's 44 and 45 of the
10 PDF.
11 Q. Okay. So we agree in claim 29 it's
12 claimed that the compressible material includes
13 a plurality of fibers extending outward from the
14 outer surface; correct?
15 A. Yes.
16 Q. Is there a claim that refers to fibers
17 extending from the inner surface.
18 A. No, because this is talking about the
19 grace factor and saying the grace factor --
20 Q. I'm just asking a yes-or-no question:
21 We can agree there's no claim that says the
22 fibers extend from the inner surface?
23 A. I haven't looked at all the claims.
24 You're asking me to look at something -- I can
25 only see -- on the screen you put in front of

1 me, I can only see claim 28 and 29. Those
2 clearly --
3 Q. Okay. Let's help you out.
4 Will, can you do a Control-F for the
5 word "inner."
6 A. I'll take your word for it if you say.
7 What I'm saying is I just can't see the claims,
8 and you're asking me a question about all of
9 them.
10 Q. Okay. So you're not aware of any
11 express disclosures -- I'm not talking about
12 your inference.
13 You're not aware of any express
14 disclosure concerning fibers extending from the
15 inner surface of the compressible material; is
16 that fair to say?
17 MR. SUMMERS: Objection. Form.
18 THE WITNESS: I consider the disclosure
19 of them extending from the surface to cover the
20 inner surface. So it isn't --
21 BY MR. LOWENSTEIN:
22 Q. No, no, no, no, no. I'm not asking for
23 your inference. I said "express disclosure."
24 Is there any express disclosure that
25 says that?

1 Because we see in claim 29 it refers to
2 the compressible material, including a plurality
3 of fibers extending from the outer surface.
4 It doesn't say the inner surface, you
5 would agree; correct?
6 A. Correct.
7 Q. Okay. And the only thing you're
8 pointing to is something about the surface, but
9 there's no express disclosure about the inner
10 surface; correct?
11 A. Right, there is no -- if by that you
12 mean a specific statement that fibers are on the
13 inner surface, there is a statement that covers
14 the inner surface about fibers being on the
15 surface.
16 Q. I'm not asking for your interpretation.
17 I'm just asking you about an express disclosure.
18 So let me ask it again: You would
19 agree there is no express disclosure about
20 fibers extending from the inner surface of
21 compressible material 256; correct?
22 A. No, because my opinion is that the
23 disclosure is an express disclosure.
24 Q. Okay. No, no. Because you're making
25 an inference. You're making your inference as

1 to what you understand it to mean.
2 I'm not asking about what you believe.
3 I'm asking about what it expressly says
4 unmistakably, without editorialization.
5 A. I don't think --
6 Q. I think you've already answered the
7 question, but I'd like you to just answer it
8 cleanly without putting in what you think is
9 helpful, because you need to answer my
10 questions.
11 MR. SUMMERS: Objection. Form.
12 BY MR. LOWENSTEIN:
13 Q. So just answer my question.
14 You admit that there is no express
15 disclosure of fibers extending from the inner
16 surface of the compressible material; correct?
17 MR. SUMMERS: Objection --
18 THE WITNESS: No. I regard the
19 disclosure of fibers from the surface to include
20 the inner surface. That is my opinion.
21 BY MR. LOWENSTEIN:
22 Q. So if I refer to the surface of my car,
23 that necessarily refers to both the outside of
24 the hood and the inside of the hood; correct?
25 A. So it depends on context. I'm not

1 talking about your car. I'm talking about this
2 disclosure about a medical device and about the
3 characteristics of the --
4 Q. So let's say I get a wax job on my car,
5 and they say, "We're going to cover the surface
6 of your car." I should get angry because "Wait
7 a minute. You didn't wax the inside of my hood.
8 What's going on? I've been cheated."
9 Is that what I should -- is that how I
10 should react?
11 MR. SUMMERS: Objection. Form.
12 THE WITNESS: No.
13 BY MR. LOWENSTEIN:
14 Q. Because that's absurd; right?
15 Everyone knows the surface, at least in
16 that context, refers to the exterior surface;
17 correct?
18 A. It depends on context. I'm not talking
19 about or giving an opinion about your car. I'm
20 giving an opinion about a patent disclosure
21 about having fibers on the surface, and that is
22 an express disclosure of fibers on the outer and
23 inner surface of the material that Spenser II is
24 talking about, to my knowledge.
25 Q. How about in the context of a patent

1 with a claim that expressly says "a plurality of
2 fibers extending outward from the outer
3 surface," where I can see those outward fibers
4 in Figure 22 and yet I see no express
5 description of fibers from the inner surface and
6 I don't see the inner surface?
7 Could a reasonable interventional
8 cardiologist conclude that Spenser II doesn't
9 say anything about the inner surface of
10 compressible layer 256?
11 MR. SUMMERS: Objection. Form.
12 THE WITNESS: No.
13 BY MR. LOWENSTEIN:
14 Q. No interventional cardiologist could
15 honestly disagree with you?
16 MR. SUMMERS: Objection. Form.
17 THE WITNESS: I don't think so, no.
18 The express disclosure of having fibers on the
19 surface covers the inner and outer. They are
20 the surface.
21 BY MR. LOWENSTEIN:
22 Q. Just like the inner and outer surface
23 of the hood of my car.
24 That's the surface; correct?
25 A. No. Because it's to do with context.

1 Q. So I just want to make sure: If
2 Dr. Brecker says, "I've looked at Figure 22. I
3 see fibers on the exterior. I know that fibers
4 are used in contact with native tissue, and I
5 know that Figure 29 of Spenser II specifically
6 refers to outwardly extending fibers on the
7 outer surface," and if he were to conclude,
8 based upon that evidence, that Spenser II
9 doesn't say or show anything about the inner
10 surface of compressible material, you would
11 conclude that he's lying?
12 A. I'm not concluding anything about
13 Stephen Brecker lying. I do not believe he
14 would lie. I hope he wouldn't lie.
15 What I am doing is giving you my
16 opinion, having --
17 Q. I'm not asking about your opinion. I
18 asked you if a reasonable interventional
19 cardiologist could reach a different conclusion
20 based upon the evidence we just discussed.
21 A. I don't think an objective
22 interventional cardiologist who's skilled in
23 this art would have a different opinion.
24 Spenser clearly teaches that you can have fibers
25 on the surface, and that includes both the outer

1 and inner.
2 Q. Are you aware of any aspect of
3 Dr. Brecker's testimony in any of these cases
4 where he has said anything that you think is
5 dishonest?
6 A. No. He's got --
7 Q. Okay. You answered the question.
8 Have you seen anything from
9 Dr. Brecker's analysis that you believe was not
10 careful and well thought through even if you
11 ultimately disagree with him?
12 A. Yes.
13 Q. What?
14 A. The reflection of light off the frame.
15 As I've already mentioned, because you were
16 showing me various similar images to the ones he
17 relied on, he has an analysis of Walther, and
18 his analysis concludes that there is a dense
19 inner layer on the fabric, and I think he's
20 completely wrong.
21 I think it is quite clear that it is
22 light reflected off the edge of the frame. My
23 opinion is entirely different. I think he is
24 completely mistaken on that, and I hope he will
25 have another look at it.

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

1 I don't know if you guys can eat a
2 little faster, because, you know, it's kind of
3 getting late in the day --
4 MR. LOWENSTEIN: We can go off the
5 record, Audra.
6 (Recess from 11:51 a.m. to
7 12:08 p.m. PST.)
8 MR. LOWENSTEIN: Let's put up
9 Exhibit 2026.
10 Q. Okay. Dr. Buller, do you see a
11 document that's been marked Exhibit 2026?
12 A. Yes. Again, I can't see the exhibit
13 number, but yes, I'm familiar with it.
14 Q. Do you see it at the bottom in the
15 footer.
16 A. No. I can't see the bottom.
17 Yes, now I can.
18 Q. Okay. So let's go to page -- well, you
19 see the document is titled "Sapien 3 Ultra Valve
20 First-in-Human Experience"?
21 A. I do.
22 MR. LOWENSTEIN: Okay. Let's go to
23 page 8.
24 Q. Okay. Do you see that there's an image
25 of the Sapien 3 fabric skirt on one side and the

1 Sapien 3 Ultra skirt on the other?
2 A. I do.
3 Q. Okay. And how were these images taken?
4 A. I don't know. They're some form of
5 photography, I'm guessing. I don't know whether
6 they're CGI or that.
7 But, I mean, again, I haven't studied
8 this, because I've had no reason to study the
9 Sapien 3 Ultra. But they may be photographs,
10 they may be CGI, and just -- I can't tell.
11 Q. Does -- looking at the Sapien 3 Ultra
12 image, do you see a graft covering?
13 A. Do I see a...
14 Q. Graft covering.
15 MR. SUMMERS: Objection. Form.
16 THE WITNESS: Well, of the two images
17 there, one will be much less porous than the
18 other, perhaps to a certainty, but how nonporous
19 it is I don't know. The one -- I'm talking
20 about the image on the left.
21 BY MR. LOWENSTEIN:
22 Q. You can't say whether the Sapien 3
23 Ultra discloses or doesn't disclose a graft
24 covering?
25 A. I haven't analyzed -- as I said a

1 number of times, I just haven't analyzed or
2 looked at or thought about or inspected or
3 anything the Sapien 3 Ultra. I didn't know it
4 was relevant to the IPR.
5 Q. Just looking at the image, you'll see
6 there are many openings in the Sapien 3 Ultra
7 fibers; is that fair to say?
8 A. You're talking about the right-hand
9 image now?
10 Q. Yes.
11 A. Yeah, on the right-hand image there are
12 openings between the fibers.
13 Q. And would you believe that Sapien 3
14 Ultra, based upon this image, is leaking?
15 MR. SUMMERS: Objection. Form.
16 THE WITNESS: It depends what you mean
17 by -- the fabric would not be nonporous on the
18 right for certainty. I mean, it's not nonporous
19 fabric.
20 BY MR. LOWENSTEIN:
21 Q. You said "would not be nonporous."
22 That was a double negative.
23 A. Sorry.
24 Q. Do you mean to say --
25 A. Would not be nonporous. No, I said it

1 right.
2 Q. Yeah. So is another way to say that
3 "would be porous"?
4 A. Yeah, it would be a porous fabric on
5 the right for certainty. Because this isn't a
6 very -- this is a -- I'm looking at the little
7 thing that says "Lens times 20," so this
8 suggests to me it's a 20 magnification. You've
9 blown it up on the screen, so there may be more,
10 so I can't judge.
11 But again, I just don't know the
12 quality of this image, who took it, how it's
13 taken. I haven't looked through this. I
14 haven't analyzed the Sapien 3 Ultra. But what
15 you're showing me is clearly a loose fabric, and
16 there are clearly holes between the fibers. And
17 if the black is behind it, it looks as though on
18 this image holes are going all the way through
19 it.
20 Q. So do you see a graft covering in the
21 Sapien 3 Ultra image?
22 MR. SUMMERS: Objection. Form.
23 THE WITNESS: The left-hand image may
24 be a graft --
25

1 BY MR. LOWENSTEIN:
2 Q. No, no, no, no. I'm asking about
3 Ultra.
4 Do you see a graft covering in the
5 Sapien 3 Ultra image?
6 MR. SUMMERS: Objection. Form.
7 THE WITNESS: Well, I see -- because I
8 don't know which material is on the inside. So
9 no, I don't think that that would constitute a
10 graft covering, because it would be porous.
11 BY MR. LOWENSTEIN:
12 Q. Do you see in the Sapien 3 Ultra image
13 openings that extend through a thickness of the
14 fibers?
15 MR. SUMMERS: Objection. Form.
16 THE WITNESS: Again, I know nothing
17 about the provenance of the image, and I haven't
18 analyzed it, but the image in front of me has
19 openings that appear to be going all the way
20 through the fabric. But I don't know how this
21 was taken or where it comes from.
22 BY MR. LOWENSTEIN:
23 Q. Now, the Sapien 3 on the left, would
24 that be a graft covering?
25 A. Could be.

1 Q. You're not sure?
2 A. Well, no. I mean, it's obviously much
3 tighter weave, it's got a density to it which
4 there isn't on the Sapien 3 Ultra, and it may
5 well be nonporous. But I can't -- I mean, you
6 know, porosity is something that one judges
7 better by measuring porosity rather than the
8 image.
9 And again, I haven't done -- I haven't
10 done an analysis of Sapien 3. I haven't done an
11 analysis of Sapien 3 Ultra nor Sapien 3.
12 They're not prior art, and they weren't
13 important to me for the purposes of the IPR.
14 Q. In the Sapien 3 image that we're
15 looking at, do you see openings that extend
16 through a thickness of the fibers?
17 A. There are openings, because you can see
18 it's not a flat -- it's a woven surface. You
19 can see it's woven with fibers running up and
20 down, vertically and crosswise. There are
21 dimples between them. So that's saying there
22 are openings.
23 Q. So can you say whether this is a graft
24 covering in view of those openings?
25 A. No, because I don't think that makes a

1 difference as to whether it's a graft covering
2 or not. I'm not sure that's relevant to whether
3 it's a graft covering or not.
4 Q. So you can have a graft covering with
5 openings in it; is that your understanding?
6 A. They're not openings that make it -- if
7 the openings are large enough that it's then
8 porous, then it's not a graft covering. Because
9 on thing that I think one thing Brecker and I
10 are in agreement on is that the graft covering
11 needs to be dense and nonporous, as taught in
12 the specification.
13 And this is dense in comparison with
14 the image on the right-hand side. It has a
15 higher density. I think one can see that from
16 the photograph. They're both at the same
17 magnification, as far as I can tell: times 20,
18 times 20. So it is more dense, and it may well
19 be nonporous.
20 But I would need to do more analysis
21 and check these really are true images and these
22 haven't been CGI'd or altered. Because this
23 looks like a marketing document, and very often
24 the images are not exactly what they appear to
25 be.

1 MR. SUMMERS: Nathan, while you're
2 thinking of your next question, one of my
3 colleagues on the phone says they're getting a
4 little bit of feedback when you start your
5 questions, and I'm wondering if Will's
6 microphone might be on or something that he can
7 use to address that possibly.
8 (Discussion held off the record.)
9 BY MR. LOWENSTEIN:
10 Q. Now, Dr. Buller, I believe earlier you
11 referred to Walther as leaky or porous, if
12 memory serves.
13 Do you recall that?
14 A. Yes. Because it's -- we like -- well,
15 not dissimilar from what we were saying with
16 Sapien 3 Ultra in front of me.
17 Q. But you agree with me that Walther is
18 opaque, at least from the photograph we saw,
19 whereas Sapien 3 Ultra is translucent, at least
20 from the images we saw; correct?
21 A. Yes. But as I said when I was talking
22 about Walther, in fact, before you showed me the
23 images, wherever they were from and whoever they
24 were with, of Sapien 3 Ultra, it wasn't backlit.
25 I mean, you can change -- depending on lighting,

1 you could achieve different things, and I don't
2 know that Walther, taken in a different way,
3 wouldn't be a bit more translucent.
4 Q. What methodology did you use to
5 determine how leaky Walther's cloth is?
6 A. My knowledge about the material that
7 he's talking about and the appearance of it, the
8 very light, fluffy, fibrous appearance of it.
9 Q. You agree that Walther just refers to
10 its outer covering as a PET cloth; correct?
11 A. Yes, a PET cloth. But just like I've
12 been able to look at the Sapien 3 Ultra, which,
13 as I said, I don't know a lot of things about
14 it, but I can look at that, and I've told you
15 that would definitely leak.
16 There are images you could look at and
17 you could say it would be leaky, as I've just
18 done for you with the Sapien 3 Ultra cloth in
19 front of me.
20 Q. Now, you agree that Sapien 3, Sapien 3
21 Ultra and Walther all have PET coverings;
22 correct?
23 A. As far as I know, they're all made of
24 PET. As I say, I haven't -- this photograph in
25 front of me doesn't say it's PET, but as far --

1 I mean, I've got a distant memory of it that it
2 is PET.
3 And I'll take your -- and as I keep
4 saying, I haven't analyzed Sapien 3 Ultra. I
5 haven't looked at it. The image in front of me
6 doesn't tell me it's PET. So I would much
7 rather look at a document and read things and
8 analyze it if I have to answer questions about
9 Sapien 3.
10 Q. Now, do you have a sense for whether
11 Sapien 3 -- whether its skirt is opaque or
12 translucent?
13 A. Again, it would likely depend on the
14 lighting and whether it's wet. Things tend to
15 become more translucent when they're wet. And
16 it depends on the lighting. If it's backlit,
17 you may -- I've never looked at -- again, I
18 haven't analyzed Sapien 3 as any part of this
19 case, and I certainly haven't looked at it from
20 the point of view can I see any of the frame
21 through it.
22 I haven't looked at it. I didn't know
23 it was relevant.
24 MR. LOWENSTEIN: Okay. Let's pull up
25 Exhibit 2083.

1 Q. Now, you'll see we have Exhibit 2083.
2 It's a little bit obscure, but I think you'll
3 see the footer.
4 A. Yeah.
5 MR. LOWENSTEIN: Okay. Let's go to
6 page 54, please.
7 Q. I want you to look at the statement at
8 the beginning of this first paragraph. It says,
9 "In fact, Levi teaches against a tight-fitting
10 outer skirt."
11 You see that?
12 A. I do.
13 Q. Is that statement true?
14 A. No -- I mean yes. It's not the only
15 thing he teaches. He teaches a tight-fitting
16 outer skirt as well, but one embodiment and part
17 of his teaching is a bulging, loose-fitting
18 outer skirt. But it can't -- that is one of his
19 aspects of his teaching.
20 Q. Well, I don't think you answered my
21 question, because this statement says, "Levi
22 teaches against a tight-fitting outer skirt."
23 And the question is do you believe that
24 statement is correct?
25 A. No. I think Levi teaches various

1 things, and one of his embodiments is a very
2 loose-fitting, baggy skirt. But that's only one
3 of the embodiments.
4 If that -- I'm not a lawyer, so I don't
5 know. I mean, "teaching against" -- I mean,
6 he's got an embodiment which is definitely not a
7 tight-fitting skirt, but I wouldn't regard that
8 as teaching against -- as just a cardiologist, a
9 person of ordinary skill, it sounds as though he
10 would be telling you under no circumstances
11 should you, could you, can you have a
12 tight-fitting skirt, and that's not my reading
13 of Levi.
14 But I'm not a lawyer, and it may be
15 that "teaches against" has a specific legal
16 meaning.
17 I'm not sure -- what document is this?
18 Is this a legal document?
19 Q. Yes. This is Edwards' statements to
20 the patent office.
21 A. Right. Well, then --
22 Q. My question is do you believe Edwards
23 should correct its misstatement to the patent
24 office that Levi teaches against a tight-fitting
25 outer skirt?

1 A. I'm not a lawyer, so I can't give
2 you -- I don't know a definition of "teaches
3 against."
4 As I've said, Levi has an embodiment
5 that has a baggy, loose skirt, but I don't read
6 it as he's in any sense teaching against saying
7 there's no possibility of having a tight-fitting
8 skirt. But I'm not a lawyer.
9 Q. Well -- okay. So we can agree that the
10 reference to Levi that you rely upon is an
11 Edwards patent; correct?
12 A. The Levi patent, that's -- you've
13 raised another good point. I don't know which
14 one that -- there may -- for all I know, there
15 are other Levi patents.
16 Q. Yes. This is a related patent with
17 almost all of the figures in common.
18 And so the question is do you
19 believe --
20 A. I assume because we've got --
21 Q. Hold on a second. I didn't finish my
22 question. I was getting a lot of feedback, so I
23 wasn't sure I was being clear. Let me try
24 again, and hopefully it'll be clearer.
25 Is it fair to say that Edwards would

1 not knowingly make a false statement to the
2 United States Patent Office, particularly
3 concerning one of its own references?
4 A. I think that's fair. I mean, I don't
5 know internal workings, but I know them to be a
6 very reputable company, and I don't believe they
7 would knowingly make anything.
8 And also, on my previous question I
9 thought we were talking about the Levi that I
10 know. You've now told me you're talking about
11 some other one that I've never been shown, and I
12 feel that's a bit unfair. I would like to be
13 shown what Levi we're talking about, because if
14 it's talking about a different one --
15 Q. Well, I'm asking if this statement is
16 true as it applies to the Levi that you
17 analyzed.
18 A. If it's not -- you just told me it's
19 not about that one.
20 Q. I understand.
21 Let's say the statement did concern the
22 Levi you are familiar with, the one that shares
23 40-some-odd figures with the Levi that's being
24 discussed here and that shares many of the same
25 disclosures.

1 And the question is, as to the Levi
2 that you're familiar with, is it a correct
3 statement to say Levi teaches against a
4 tight-fitting outer skirt?
5 MR. SUMMERS: Objection. Form.
6 THE WITNESS: No. I think I've
7 answered that, because I thought you were asking
8 me about the Levi that I'm familiar with, which
9 is in this case.
10 I mean, it seems very unfair to me to
11 suddenly put something in front of me about Levi
12 which is a different Levi. I have no knowledge
13 of a different Levi.
14 BY MR. LOWENSTEIN:
15 Q. Okay. I want to go down to the
16 sentence starting, "This allows the skirt to lie
17 flat against the outer surface of the frame when
18 it is readily compressed. As the frame is
19 expanding, the portion of the frame between the
20 attachment locations of the skirt foreshortens,
21 thereby creating excess material in the skirt
22 that can buckle outwardly away from the frame."
23 Do you see that?
24 A. I see it.
25 Q. Do you believe that the Levi that you

1 analyzed has teachings to that effect?
2 A. Yes. I mean, clearly Levi teaches what
3 it teaches. But as I've said to you in my
4 previous answers, Levi has an embodiment that
5 has a bulging skirt that has excess material.
6 But I have no knowledge of this other
7 Levi patent, and, therefore, I am -- you know, I
8 would love to see it and be -- know what I'm
9 talking about. Because if this is about
10 something different, I have no knowledge of it.
11 Q. Sorry. I was on mute. Let me start
12 again.
13 You see the paragraph on page 52 of the
14 PDF in Exhibit 2083 there's -- at the end of
15 that page there's a paragraph starting "the
16 skirt 18."
17 Do you see that?
18 A. I do.
19 Q. Okay. So that reads, "The skirt 18 in
20 Levi is designed to have excess material between
21 the upper and lower edges of the skirt that does
22 not lie flat against the frame when the
23 prosthetic valve is radially expanded. This
24 allows the skirt to bulge or buckle outwardly
25 away from the frame of the prosthetic valve."

1 Do you believe those statements would
2 accurately describe your Levi's disclosure?
3 A. Yes. Again, I'm very confused about
4 this, because it's not talking about my
5 disclosure.
6 But yes, the Levi that I'm familiar
7 with has an embodiment -- it's not limited to
8 it, but it has an embodiment in which it has a
9 skirt that can bulge out. It doesn't,
10 obviously, always bulge out everywhere and stay
11 away from the frame everywhere. It can, but it
12 depends on the circumstances.
13 It is -- there's excess material, which
14 allows it to bulge out in places.
15 Q. Now, let's go to the last sentence on
16 this same page within the same paragraph,
17 starting -- there's a typo, but I think we know
18 what that word means.
19 So it says, "By buckling outwardly, the
20 skirt" --
21 A. Where are you reading from?
22 Q. At the very last sentence.
23 A. "Levi further discloses"?
24 Q. No. "By buckling outwardly."
25 A. But that's not the beginning of a

1 sentence. That's -- oh, I see. The very
2 last -- on the bottom, "By buckling outwardly,
3 the skirt can" --
4 Q. Okay. So what this reads is "By
5 buckling outwardly, the skirt can fill in gaps
6 between the frame and the native annulus to
7 assist in forming a seal with the surrounding
8 anatomy."
9 Do you believe that would be a fair
10 statement if describing your Levi?
11 A. The word "buckling" is not -- I mean,
12 "bulge" is Levi, "bulges out." You seem to have
13 missed a sentence which talks about fibers.
14 I just have no knowledge. You're
15 asking me about a patent and disclosure I have
16 no knowledge of.
17 I wouldn't have described the Levi I
18 know -- because I know the word as "bulge." I'm
19 not familiar with it being "buckling" in there.
20 I'm not exactly sure what it means by that. But
21 I would need to read and analyze the patent. I
22 have no knowledge of this other Levi patent.
23 Q. Well, I'm not asking you about this
24 other Levi patent.
25 I'm asking you whether -- and I thought

1 this was clear. But I'm asking the extent to
2 which these statements are applicable to your
3 Levi, not this other Levi.
4 A. I wouldn't use the work "buckling."
5 Q. I'm sorry?
6 A. I wouldn't have using the word
7 "buckling."
8 Q. Okay. Yeah, I think that was the
9 question I was about to ask.
10 Supposing instead of the sentence that
11 we just read, supposing it said "bulging"
12 instead of "buckling" --
13 A. Yeah.
14 Q. -- would that correctly characterize
15 your Levi?
16 A. Yes, I think that's fair.
17 Q. Okay.
18 A. Because that's the word I remember. I
19 mean, again, you've not even shown me my Levi,
20 but I remember it teaching about bulging out. I
21 just don't know what they mean by the word
22 "buckling," really. It's --
23 Q. No, fair enough. Fair enough.
24 Just one second.
25 So you agree that Walther discloses

1 using a 33 French delivery sheath?
2 A. I think that's right. I mean, I
3 haven't got it in front of me, and I haven't
4 focused, but I think both Walther and Cheung use
5 a 33.
6 But that was an available catheter to
7 use in patients, and I think Walther used what
8 was -- Walther is clearly a in vitro experiment,
9 but I think he used what was available as a --
10 Q. You're well aware, of course, that
11 narrower sheaths were also available to deliver,
12 for instance, a Sapien valve at that time;
13 correct?
14 A. Narrower sheaths were available, but
15 this was a sheath that was used or transapical
16 in that timeframe.
17 Q. Now, do you recall that you were
18 looking at -- I can show it to you again if
19 you'd like.
20 You recall in Exhibit 2087 we were
21 looking at a valve that was referred to as
22 Apogee, and do you recall that that valve also
23 had a 33 French crimp?
24 A. You showed me a photograph that had
25 "33 French" next to it, yes.

1 Q. Okay.
2 A. Again, I don't know what that is.
3 Q. Now, each of these -- each of these
4 references describe a 9000 MIS model number;
5 correct?
6 A. I don't know. I don't remember seeing
7 that in the Apogee document.
8 Q. You can take my representation. You
9 can verify it if you'd like, but it's there.
10 A. Well, I'd like to see the document
11 before I say -- I mean, you know, I'll take your
12 representation if that's saying that they do,
13 yeah.
14 Q. Are you aware of any 9000 MIS model
15 TAVR that was delivered using anything other
16 than a 33 French delivery sheath?
17 A. I don't know. I've never -- I've never
18 looked at that. And I haven't taken these code
19 numbers, which I'm sure mean something to
20 Edwards; don't mean a great deal to me.
21 I think in the last deposition you
22 asked me whether I was familiar with that. I
23 think I said no then, and I'm no more familiar
24 with it now. It's clearly a code number for
25 something to do with these devices, but I don't

1 know what it codes for.
2 Q. Do you agree that if you're implanting
3 a TAVR into a person, that you would not use a
4 wider delivery sheet than was necessary?
5 MR. SUMMERS: Objection. Form.
6 THE WITNESS: I think as a general
7 statement, that is entirely reasonable, but I
8 don't know that you never would. Because if
9 things are being done operatively, sometimes
10 bigger is better.
11 You know, if you're talking about doing
12 things percutaneously, you always want as small
13 as possible. But if you've actually got a
14 surgeon opening up things and exposing the apex
15 of the heart, for instance, I don't know that
16 the same is true. You just want to make it
17 easy. They're in control, they have purse
18 strings around that, and they may choose size
19 because they're the surgically in control of it.
20 So I can't answer the completely
21 general question, but for percutaneous
22 deliveries you always want to use the smallest
23 you could.
24 BY MR. LOWENSTEIN:
25 Q. For a transapical approach -- if you're

1 implanting a TAVR via transapical approach,
2 would you use a 33 French sheath if the valve
3 could be delivered via a 24 French sheath?
4 A. I don't know. Because obviously more
5 space allows for more movement, more freedom of
6 movement, and you could be measuring things with
7 a sidearm. I just don't know.
8 Q. Have you ever heard of any
9 transapically delivered TAVR using a larger
10 sheath than what was necessary to deliver the
11 TAVR?
12 A. I don't know. I can't answer that I'm
13 afraid. I just don't know.
14 Q. When using a larger sheath -- I have
15 another question. Let me withdraw that.
16 Are you aware that Edwards had approved
17 the 26 French transapical delivery sheath at the
18 time of Walther?
19 A. No. I'm not familiar with the approval
20 dates of the transapical devices. I do not have
21 any knowledge about the dates for approval on
22 the sizes.
23 Q. We can agree that if a 26F Edwards
24 sheath had been approved at the time, it would
25 have been available to the authors Walther and

1 Cheung; correct?
2 A. I just don't know. I have no idea.
3 Q. We can reasonably infer that if a 26
4 French Edwards delivery sheath was publicly
5 approved, that it would have been available to
6 the authors of Walther, given that five of the
7 six Walther authors were at Edwards
8 Lifesciences; correct?
9 A. I don't know.
10 Q. That seems like a reasonable inference,
11 though, doesn't it?
12 A. Well, no. Because this is a French --
13 this isn't in a patient and things, and they may
14 have been using up old product deliberately.
15 I mean, it doesn't seem there was
16 anything about the experiments that Walther did
17 that was the critical thing about the sizes of
18 sheath, and, therefore, they may have been using
19 up available old stock to do the experiment and
20 keep the costs down.
21 It's a benchtop experiment. It wasn't
22 in a patient.
23 Q. So you believe that Edwards
24 Lifesciences in a paper with five different
25 authors from their company, they could not spare

1 a 26 French delivery sheath; that that was just
2 the only one they had available?
3 That's your -- what you surmise?
4 A. That wasn't what I said at all. I'm
5 not saying they couldn't spare it. I'm saying
6 there was no necessity.
7 If they had a 33 available to do a
8 benchtop experiment on the thing, I don't see
9 any disadvantage of using it.
10 Q. Can you think of any plausible universe
11 in which they also wouldn't have had a 26 French
12 sheath available, assuming it was approved at
13 the time?
14 A. I really don't understand the question.
15 I've told you that in a benchtop
16 experiment I don't think the sheath size is of
17 any real consequence, and, therefore, I have no
18 knowledge of why they chose to use the 33,
19 assuming something else was available. I have
20 no knowledge that something else was available,
21 but I have no knowledge about their choice.
22 Q. You understand that Cheung was
23 delivered in a human being; correct?
24 A. Right. Cheung was much earlier. I
25 think it was in 2008 that the Cheung device was

1 delivered. This was to treat a patient.
2 Q. That was not a bench test; correct?
3 A. Correct. It was to treat a patient.
4 Q. And if you were to have a TAVR that
5 could be delivered by a 33 French or 26 French
6 and it was a transapical approach, an
7 interventional cardiologist of skill in the art
8 with experience with TAVRs would have opted for
9 the 26 French; correct?
10 Because that has the higher likelihood
11 of avoiding complications; isn't that fair to
12 say?
13 A. They may. I don't know. Because this
14 is done surgically through the apex, and I just
15 don't know.
16 As I've said to you, I don't know what
17 the decision-making is. I certainly don't know
18 whether a smaller device was available in 2008,
19 a smaller sheath was available. I don't know
20 the familiarity of the surgeon, Cheung, with it.
21 I don't know.
22 Q. And you have no evidence that suggests
23 that a 9000 MIS was ever crimped down to a 26
24 French diminution; correct?
25 A. Correct. And as I've said to you, I'm

1 not really familiar -- I don't know what devices
2 the 9000 MIS applied to and whether it applied
3 to other devices or whether -- I don't know what
4 the code stands for, the 9000 MIS.
5 MR. LOWENSTEIN: Okay. Why don't we
6 take a short break, and then I'll determine
7 whether they need a long break.
8 Is that reasonable to everyone?
9 MR. SUMMERS: Sure.
10 (Recess from 12:46 p.m. to
11 12:52 p.m. PST.)
12 BY MR. LOWENSTEIN:
13 Q. Dr. Buller, you were an expert for
14 Edwards Lifesciences in a litigation with Boston
15 Scientific; is that correct?
16 A. I was.
17 Q. And was the accused product -- or was
18 an accused product in that case the Sapien 3
19 valve?
20 A. Yes.
21 Q. And through your work in that case, did
22 you become very familiar with Sapien 3?
23 A. Yes, I think that's fair. I am very
24 familiar with Sapien 3.
25 But that case was a long time ago. I

1 mean, many years ago. So -- but yes.
2 Q. You're aware that there's a district
3 court litigation between Aortic and Edwards
4 Lifesciences that is ongoing; is that fair to
5 say?
6 A. As far as I know, I'm aware, as I think
7 I told you last time, that there is one that
8 Aortic has sued, but that's the extent of my
9 knowledge.
10 Q. Okay.
11 A. I don't have any other knowledge than
12 that.
13 Q. Are you aware that Sapien 3 Ultra is an
14 accused device in that litigation?
15 A. Yes, I was aware of Sapien. I think
16 fairly obvious, yeah. I think I was -- I don't
17 know whether I was actually told that, but I
18 kind of worked that out for myself.
19 Q. Are you now or have you ever been an
20 expert witness or consultant in the district
21 court case?
22 A. No. I haven't been asked to give
23 any -- I've not seen anything, not been talked
24 to about, other than to tell that Aortic had
25 sued Edwards. They told me that some time ago,

1 but that didn't come as a surprise.
2 I can't remember if they told me that
3 it was Ultra, but as I say, I think I worked
4 that out for myself. And I've not been
5 instructed in it or asked to give any advice or
6 look at anything.
7 MR. LOWENSTEIN: Okay. Unless there is
8 redirect, I have concluded my examination. I
9 thank you for your time, Dr. Buller, and I pass
10 the baton.
11 THE WITNESS: Thank you very much.
12 MR. SUMMERS: I have no questions.
13 Thank you, Dr. Buller.
14 MR. LOWENSTEIN: Thank you all.
15 And, Audra, should we hold on?
16 THE REPORTER: I just need your orders.
17 Do you need this expedited?
18 MR. LOWENSTEIN: I would like it
19 expedited, if that's okay.
20 (Discussion held off the record.)
21 MR. LOWENSTEIN: Would Monday be okay?
22 THE REPORTER: Yes.
23 MR. LOWENSTEIN: Okay. Let's do
24 Monday.
25 MR. SUMMERS: We'd like a copy.

1 THE REPORTER: And do you want your
2 transcript on Monday as well, Mr. Summers?
3 MR. SUMMERS: No, I don't think we need
4 it on Monday. I think we're good with getting
5 it a little later.
6 (At 12:55 p.m. PST the
7 deposition of NIGEL P. BULLER,
8 MD, was adjourned.)
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1 STATE OF CALIFORNIA)
2 COUNTY OF LOS ANGELES) SS.
3
4
5 I, NIGEL P. BULLER, hereby certify under
6 penalty of perjury under the laws of the State of
7 California that the foregoing is true and correct.
8 Executed this _____ day of
9 _____, 2022, at
10 _____, California.
11
12
13 _____
14 NIGEL P. BULLER, MD
15
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1 STATE OF CALIFORNIA)
2 COUNTY OF LOS ANGELES) SS.
3
4 I, AUDRA E. CRAMER, CSR No. 9901, in and for the
5 State of California, do hereby certify:
6 That, prior to being examined, the witness named
7 in the foregoing deposition was by me duly sworn to
8 testify the truth, the whole truth and nothing but the
9 truth;
10 That said deposition was taken down by me in
11 shorthand at the time and place therein named, and
12 thereafter reduced to typewriting under my direction,
13 and the same is a true, correct and complete transcript
14 of said proceedings;
15 I further certify that I am not interested in the
16 event of the action.
17 Witness my hand this ____ day of _____,
18 2022.
19
20
21
22 Audra Cramer
23 Certified Shorthand
24 Reporter for the
25 State of California

ERRATA SHEET

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Signature of Deponent

SUBSCRIBED AND SWORN BEFORE ME

THIS____DAY OF_____, 2022.

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(Notary Public) MY COMMISSION EXPIRES:_____

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