UNITED STATES PATENT AND TRADE COMMISSION
BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION AND EDWARDS LIFESCIENCES LLC,	)
Petitioners,	) IPR2022-00556
-v-	) Patent No. 10,987,236
AORTIC INNOVATIONS, LLC,	)
Patent Owner.	)

ORAL DEPOSITION TAKEN REMOTELY VIA
VIDEOCONFERENCE
OF
STEPHEN J.D. BRECKER
FEBRUARY 8, 2023
9:20 A.M. (PST)

REPORTED BY:
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Edwards v. Aortic Innovations
IPR2023-01325
Edwards Ex. 1146

1 February 8, 2023

2 Oral deposition, taken remotely via

3 videoconference, of Stephen J.D. Brecker,

4 reported remotely via Zoom Videoconference by

5 Debra Sapio Lyons, a Registered Diplomat

6 Reporter, a Certified Realtime Reporter, a

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9 United States District Court for the Eastern

10 District of Pennsylvania, a Certified Court

11 Reporter and Notary Public of the State of New

12 Jersey.

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1 I N D E X

2 WITNESS PAGE

3 STEPHEN J.D. BRECKER

4 BY MR. STOWELL 8

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6 BY MR. STOWELL 217

7

8 PREVIOUSLY MARKED EXHIBITS

9 NUMBER DESCRIPTION PAGE

10 Exhibit 1001, U.S. Patent 20

11 Number 10,987,236

12

13 Exhibit 2103, Second Declaration of 44

14 Dr. Stephen J.D. Brecker

15

16 Exhibit 1003, Declaration of Nigel 99

17 Buller, M.D.

18

19 Exhibit 1007, Walther article 106

20

21 Exhibit 1008, United States Patent 161

22 No. 9, 393,110 B2

1 PREVIOUSLY MARKED EXHIBITS, CON'T

NUMBER	DESCRIPTION	PAGE
Exhibit 2026, multipage document titled SAPIEN 3 Ultra Valve, First-In-Human Experience		214

1 THE REPORTER: Good afternoon. My
2 name is Debra Lyons. I am a certified
3 court reporter.
4 Today's date is February 8, 2023
5 and the time is approximately 12:19 p.m.
6 This is the deposition of Dr.
7 Stephen Brecker in the matter of Edwards
8 Lifesciences versus Aortic Innovations.
9 At this time I will ask counsel to
10 identify yourself and whom you represent,
11 and agree on the record that there is no
12 objection to this deposition officer
13 administering a binding oath to the
14 Witness via Zoom video conference.
15 Please state your agreement on the
16 record starting with the noticing
17 attorney.
18 MR. STOWELL: This is Joshua
19 Stowell for Petitioner, Edwards
20 Lifesciences. No objections.
21 MR. LOWENSTEIN: This is Nathan
22 Lowenstein. I believe -- I'm not sure,

1 Josh, we need to identify all attorneys if
2 you want to -- on your end.
3 MR. STOWELL: I think it's fine,
4 Nathan, if you just introduce yourself.
5 MR. LOWENSTEIN: I don't believe
6 that's typically the way it's done. I
7 believe I saw Brian Barnes from Knobbe,
8 Martens on your end as well.
9 On -- for us, we have -- I'm Nathan
10 Lowenstein of Lowenstein & Weatherwax for
11 Aortic Innovations. There's also William
12 Katz from my law firm and a litigation
13 clerk, Gwynneth Orlino. And we are also
14 joined by Justin Nifong of NK Patent Law.
15 And the CEO of Aortic Innovations, Dr. Ali
16 Shahriari.
17 THE REPORTER: Could I please have
18 that last name again.
19 MR. LOWENSTEIN: Shahriari,
20 S-H-A-H-R-I-A-R-I.
21 THE REPORTER: Thank you.
22 MR. STOWELL: And for completeness,

1 also joining me today, this is Josh
2 Stowell, is Craig Summers, that's
3 C-R-A-I-G, S-U-M-M-E-R-S.
4 THE REPORTER: Thank you.
5 Dr. Brecker, would you raise your
6 right hand, please.
7 DR. STEPHEN J.D. BRECKER, having
8 been first duly sworn, was examined and
9 testified as follows:
10 THE REPORTER: One moment. Thank
11 you.
12 You may proceed.
13 EXAMINATION
14 BY MR. STOWELL:
15 Q. Good morning, Mr. Brecker -- or
16 Dr. Brecker. Nice to see you again.
17 You understand that you are under
18 oath today just as if you were testifying in a
19 Court of Law and you are required to tell the
20 truth?
21 A. I do.
22 Q. And the court reporter is writing

1 down everything we say. So just as -- as our
2 last deposition, all of your answers will need
3 to be verbal.
4 Do you understand?
5 A. I do.
6 Q. As the court reporter informed us,
7 it's really important that we don't talk over
8 each other today. So, please, try to wait to
9 answer until I finish my question.
10 Is that fair?
11 A. Yes, that is.
12 Q. If at any point today you don't
13 understand one of my questions, please let me
14 know. If you don't speak up, our assumption
15 will be that you have understood the question.
16 Is that fair?
17 A. That is fair.
18 Q. Mr. Lowenstein may make short
19 objections during the deposition. However, you
20 will need to answer all of my questions unless
21 you are specifically instructed not to answer by
22 Mr. Lowenstein.

1 Do you understand?
2 A. I understand.
3 Q. If at any point during the
4 deposition you need to take a break, please let
5 me know. I will just ask that we finish the
6 line of questioning we're on before we take the
7 break.
8 Do you understand?
9 A. I do.
10 Q. We're doing this deposition
11 remotely today, so if at any point you encounter
12 technical difficulties, please speak up and let
13 us know. Again, if you don't speak up, we will
14 assume that the technology is working okay.
15 Is that fair?
16 A. Yes, that's fair.
17 Q. Is there any reason you can't
18 provide truthful and accurate testimony today?
19 A. There is no reason that I cannot
20 provide truthful and accurate testimony.
21 Q. Are you taking the deposition from
22 Los Angeles today?

1 A. I am.
2 Q. And are you at the offices of the
3 Lowenstein law firm?
4 A. I am.
5 MR. LOWENSTEIN: Objection to form.
6 THE WITNESS: I am.
7 BY MR. STOWELL:
8 Q. And I understand you have multiple
9 monitors set up today to help you track
10 everything going on in the deposition; is that
11 correct?
12 A. Well, I'm now on a laptop with you.
13 And I have one other monitor that is currently
14 showing Brecker marked exhibits, yeah. So just
15 these two.
16 The -- the monitor that we had
17 tried to do the deposition on is connected -- is
18 not linking to the Internet well, so this is a
19 much more stable connection.
20 Q. And I understand that
21 Mr. Lowenstein and Mr. Katz are in the room with
22 you today; is that correct?

1 A. That is correct.
2 Q. And Ms. Orlino is also in the room
3 with you today?
4 A. She is.
5 Q. Is anyone else present with you
6 today at today's deposition?
7 A. There is nobody else in the room.
8 Q. Do you have any materials with you
9 today at the deposition?
10 A. I do.
11 Q. What did you bring with you today?
12 A. I didn't bring these. These are
13 materials that are -- have been provided to me.
14 Q. And what materials have been
15 provided to you?
16 A. So I have a folder with clean
17 copies of the following documents:
18 Patent Owner Aortic Innovations,
19 LLC's Response.
20 The '236 Patent.
21 These are all clean copies, I
22 believe you asked.

1 Declaration of Nigel Buller.
2 That's Exhibit 1003.
3 I have Exhibit 1007, Walther.
4 So these are what I have in paper
5 form, is what I'm basically saying.
6 I have the Levi patent,
7 Exhibit 1008.
8 I have 1011, Spenser II.
9 I have Cribier, Exhibit 1012.
10 I have Exhibit 1017, Cheung.
11 I have Exhibit 2426, Thomas.
12 I have a clean paper copy of
13 Exhibit 2051, my declaration.
14 I have Exhibit 2056, Hartley.
15 2057, Chu.
16 2064, Leibig.
17 2087, Defendant's Preliminary
18 Invalidity Contentions labeled Apogee.
19 I have Exhibit 2100.
20 I have Exhibit 2101 marked
21 Dehdashtian.
22 I have exhibit -- yeah, that's

1 labeled -- it says Exhibit 2102 '442
2 application, that's Spenser.
3 Then I have Exhibit 2103, second --
4 my second declaration.
5 And then finally in the folder I
6 have Exhibit 2106.
7 And then I have those documents on
8 a clean electronic folder matching the paper
9 folder.
10 Q. And you said these exhibits were
11 provided to you, provided by whom?
12 A. By Lowenstein & Weatherwax.
13 Q. And how were the documents that
14 were provided to you selected?
15 A. I don't have the -- I -- I don't
16 have information about why that -- why those
17 documents are there and maybe others are not. I
18 don't -- I -- I have those documents in paper
19 format.
20 Q. Did you request hard copies of
21 those specific exhibits?
22 A. I request -- I -- I wanted to be

1 sure that I had hard copies of the patent and my
2 declaration and a few of the others. I can't
3 remember which ones I said I wanted as hard
4 copies. I find it easier to answer questions on
5 my declaration from a paper copy.
6 Q. And all of the hard copy materials
7 you have today are clean copies that are free of
8 any notes, markings, or sticky tabs; is that
9 correct?
10 A. That is correct.
11 Q. Do you have any devices set up to
12 communicate with anyone else during today's
13 deposition such as chat windows or text chains?
14 MR. LOWENSTEIN: Objection; form.
15 THE WITNESS: I do not.
16 BY MR. STOWELL:
17 Q. And now that the deposition is
18 started, are you aware that you are prohibited
19 from speaking to anyone about the subject matter
20 of your deposition while the deposition is
21 pending?
22 A. I'm aware of that.

1 MR. STOWELL: I will ask our hot
2 seat operator to pull up Exhibit 1001.
3 THE WITNESS: Just before we start,
4 I have a couple of things I'd like to say.
5 BY MR. STOWELL:
6 Q. Okay.
7 A. So with respect to Exhibit 2103, my
8 second declaration, there -- there are some type
9 -- there is a typographical error and it relates
10 to the word "set" or "sets," which should be
11 replaced by the word "portion" or "portions."
12 I'll point out the paragraphs that that is
13 relevant.
14 So in Paragraph 100, where I state
15 that, "I note that in Grounds 1-2, and 6,
16 Petitioner and Dr. Buller contend that Walther's
17 outer cloth satisfies the open vert on the
18 second set of fibers limitations," the word
19 "set" should be replaced with "portion." I
20 think that's the only reference to it in that
21 paragraph.
22 There are two further paragraphs

1 where the same correction needs to be made.
2 Paragraph 139, there are two words of "set," one
3 in the text and one in the annotation. Again,
4 those should be replaced by the word "portion."
5 And the same in Paragraph 140, the
6 word "set" should be replaced by "portion." And
7 I think there are two references to it.
8 The second point I'm -- you asked
9 me at the start is there any reason why I cannot
10 give truthful and honest testimony, and there's
11 no reason.
12 I should point out that last night,
13 however, I did have a medical issue and I am,
14 therefore, taking some regular painkillers.
15 They are not sedating painkillers and some
16 antibiotics. I will say -- yeah, so I wasn't
17 terribly well in the night. I don't believe
18 that affects my abilities.
19 Q. And do you feel that you are
20 healthy enough to sit for today's deposition?
21 A. I do.
22 Q. Okay.

1 MR. STOWELL: And, Mr. Lowenstein,
2 do you have any objection to continuing
3 with Dr. Brecker's deposition today based
4 on his disclosure about his medical issue?
5 MR. LOWENSTEIN: Not unless his
6 condition materially worsens, but our plan
7 is to go forward with the deposition.
8 BY MR. STOWELL:
9 Q. And, Dr. Brecker, will you let us
10 know during today's deposition if your condition
11 materially worsens so that we can make proper
12 accommodations or reschedule the deposition?
13 A. Yes, I will.
14 Q. Okay. In terms of the
15 typographical errors, when did you discover the
16 errors that you just discussed in Exhibit 2103?
17 A. So that would have been over the
18 weekend on reading it through and discussing it
19 with counsel.
20 Q. And was it you who discovered the
21 errors?
22 A. It was in discussion.

1 Q. And when you say "in discussion" --
2 A. I didn't --
3 Q. -- is this discussion with counsel?
4 A. Correct.
5 Q. And is it your position that "sets"
6 of fibers are different than "portions" of
7 fibers?
8 A. I haven't made any opinion on the
9 definition. I've simply used the term
10 "portion." It's correct that the term "portion"
11 should be used to reflect the claim language.
12 Q. So Claim 1 uses the term "portions
13 of fibers" in the '236 Patent; correct?
14 A. Claim 1 uses the term "portion."
15 Claim -- Claim 3 and 4 use the term
16 "portion."
17 Claim 2 does not include the word
18 "portion."
19 Q. And so you have made this
20 correction to Exhibit 2103 to replace the term
21 "set" with the term "portion" that is used in
22 Claims 1, 3, and 4 of the '236 Patent; is that

1 accurate?
2 A. That is accurate.
3 Q. Okay.
4 MR. STOWELL: I will ask the hot
5 seat operator to pull back up
6 Exhibit 1001.
7 (Exhibit 1001, U.S. Patent
8 Number 10,987,236, was previously marked
9 for identification.)
10 BY MR. STOWELL:
11 Q. Exhibit 1001 is U.S. Patent
12 Number 10,987,236.
13 Do you see that, Dr. Brecker?
14 A. Yes.
15 Q. And are you familiar with this
16 patent?
17 A. I am.
18 I just want to refresh -- I think I
19 have to refresh the -- the Box. It hasn't come
20 up, actually, in the exhibit Box.
21 I have it. I have the '236 Patent
22 as paper, but my suspicion is that because the

1 Dropbox is on this --
2 MR. LOWENSTEIN: I think we have an
3 electronic version --
4 THE REPORTER: I can't hear you.
5 Mr. Lowenstein, I can't hear you.
6 MR. LOWENSTEIN: I was just
7 reminding Dr. Brecker that I think there's
8 an electronic version, too.
9 THE WITNESS: Yes, the -- so I have
10 a paper version of '236 and I have a clean
11 electronic version.
12 With respect to the Dropbox,
13 however, and this might become relevant if
14 you have exhibits that I haven't seen
15 before, this Dropbox is on a screen which
16 is connected to the same computer that the
17 Internet had dropped out of. And -- and
18 I'm refreshing the screen, but it's not --
19 it's not pulling up the --
20 MR. LOWENSTEIN: I hope you don't
21 mind, Josh, my making a suggestion?
22 So, basically, he can't get the

1 document from the Dropbox. It may be
2 because of the connectivity issue.
3 I think if it's a document he
4 already has, we could probably manage
5 without it. But if it's a document that
6 we don't have, perhaps what you could do
7 is you could, in addition to uploading it
8 to the Dropbox, e-mail it to Will and me
9 and, therefore, we'll probably get --
10 access it some other way if that works.
11 MR. STOWELL: Okay. We can proceed
12 along those lines.
13 And, Mr. Lowenstein, you don't have
14 an objection to continuing with the
15 deposition, given that Dr. Brecker is
16 unable to access the Box so long as we
17 proceed, again, along the lines you just
18 outlined?
19 MR. LOWENSTEIN: So long as he can
20 look at the documents that you're asking
21 about in its entirety, I'm good.
22 BY MR. STOWELL:

1 Q. So, Dr. Brecker, you have a hard
2 copy of the '236 Patent with you today; correct?
3 A. I have a hard copy and I also have
4 the electronic copy.
5 Q. Okay. I can --
6 MR. LOWENSTEIN: We're good. Let's
7 go.
8 BY MR. STOWELL:
9 Q. You are familiar with Exhibit 1001,
10 the '236 Patent; correct?
11 A. Correct.
12 Q. And you have reviewed this patent
13 many times; is that correct?
14 A. I have reviewed this patent. I
15 can't say how many times, a few times.
16 Q. And have you studied the patent
17 recently in preparation for your deposition?
18 A. I have.
19 Q. If we look at Claim 1 of the
20 '236 Patent, it recites a "cylindrically
21 extending polymeric inner graft covering."
22 Do you see that?

1 A. Yes.
2 Q. Now, the term "graft covering" is
3 not in the specification of the '236 Patent;
4 correct?
5 A. So I would have to -- I would have
6 to check through.
7 Q. Do you ever recall during your
8 review seeing the term "graft covering" in the
9 specification?
10 A. I can't immediately.
11 Q. If as we go through the '236 Patent
12 today, you see "graft covering" in the
13 specification, please let me know so we can
14 discuss it at that time. Okay?
15 A. I will.
16 Q. What does graft covering in Claim 1
17 of the '236 Patent mean?
18 MR. LOWENSTEIN: Objection; form.
19 THE WITNESS: So I have not defined
20 graft cover for the purposes of this IPR.
21 BY MR. STOWELL:
22 Q. So is it fair that you do not have

1 an opinion regarding the meaning of graft
2 covering in Claim 1 of the '236 Patent?
3 MR. LOWENSTEIN: Objection; form.
4 THE WITNESS: No, it's not fair.
5 BY MR. STOWELL:
6 Q. And so what is your opinion --
7 A. Sorry. I hadn't finished.
8 Q. Okay.
9 A. Sorry. Could you just ask the
10 question again that you asked?
11 Q. Is it fair that you do not have an
12 opinion regarding the meaning of graft covering
13 in Claim 1 of the '236 Patent?
14 A. No, I don't think that's fair.
15 Q. What is your opinion regarding the
16 meaning of graft covering in Claim 1 of the
17 '236 Patent?
18 A. So I am not reading it in any way
19 other than the words themselves for the purposes
20 of this IPR. So the way I would understand
21 graft cover is a covering made of graft
22 material.

1 Q. What is graft material?
2 A. So I haven't defined graft
3 material.
4 Q. Do you believe the '236 Patent
5 defines graft material?
6 A. I don't think I've expressed an
7 opinion on that.
8 I'd just like to look at my
9 declaration, but I don't think the definition of
10 graft material, which may be of relevance
11 outside of the issues around this IPR, I don't
12 think I have made any definition of it.
13 I can tell you that woven PET can
14 be a graft cover, but I haven't made any
15 definition of it for the purposes of today.
16 Q. Does -- so you used the term "graft
17 material" in your response. What did you mean
18 when you used that term?
19 A. Any material that can be a graft.
20 Q. And what is a graft?
21 A. So --
22 MR. LOWENSTEIN: Objection; form.

1 THE WITNESS: So I haven't made an
2 opinion or made a definition of the term
3 "graft" for the purposes of this IPR.
4 BY MR. STOWELL:
5 Q. When you used the term "graft" in
6 your answer, what did you mean by graft?
7 A. I'm simply reading the term "graft
8 cover" to say a cover which is composed of a
9 graft. I haven't defined graft for the purposes
10 of this claim or this IPR. I haven't applied
11 any definition, nor have I applied any specific
12 limits to it.
13 I've said, and I don't think there
14 is any dispute about this between the parties or
15 the experts, that woven PET can be a graft
16 cover.
17 Q. Did the term "graft" have a plain
18 and ordinary meaning in the cardiovascular field
19 in 2012?
20 A. I haven't given that specific
21 question any thought. It's an interesting
22 question.

1 I haven't given it any thought.
2 Q. In your practice, did you ever use
3 the term "graft" in 2012 or before that date?
4 A. The word "graft" would have been
5 used frequently in my practice in 2012 in a
6 number of potentially different contexts, but
7 you're asking me about the meaning of a word
8 which could have quite a lot of consequences as
9 I understand it, and I'm not going to make that
10 definition today.
11 Cardiologists use the word "graft"
12 very frequently. Plastic surgeons use the word
13 "graft." Vascular surgeons use the word
14 "graft." It has -- it -- it can be used, but
15 that is not your -- you're asking about a
16 situation rather divorced from the specific way
17 in which it may or may not be used within a
18 claim and so I'm not going to go any further. I
19 haven't defined the term "graft."
20 Q. And when you used "graft" in your
21 practice in 2012, what were you referring to?
22 A. Well, I may have used the word --

1 well, I would have used the word talking about
2 certain forms of surgery, certain types of
3 device, in that context, but I wouldn't -- as I
4 say, I'm not going to limit myself or try to be
5 very definitive in this at this point.
6 Q. Would you agree that the meaning of
7 graft would depend on the context?
8 MR. LOWENSTEIN: Objection; form.
9 THE WITNESS: Well, you're asking
10 me a question in a complete vacuum. You
11 know, if someone came up to me in the
12 street and said, what's the meaning of --
13 what -- does the meaning of "graft" depend
14 on the context, I mean, it's a -- it's
15 such a general question. It might or it
16 might not.
17 I mean, the word "graft" as it
18 appears in the '236 Patent claim is a
19 subject of, I understand, claim
20 construction, which is a complex area. It
21 requires a lot of thought and research,
22 potentially, and it's not something I

1 considered for the purposes of this IPR.
2 The word itself in English, outside
3 of the context of the '236 Patent and
4 outside of the context of the IPR, can
5 have many different meanings.
6 BY MR. STOWELL:
7 Q. So for today let's focus on the
8 '236 Patent and Claim 1. And do you have an
9 opinion on the meaning of the term "graft" in
10 Claim 1 of the '236 Patent?
11 A. So I think I've answered that. And
12 if I haven't been clear, let me say I have not
13 defined the term "graft." I have not attributed
14 it any specific or limiting meaning.
15 Q. When you were analyzing the prior
16 art to determine whether or not it had a graft
17 covering, what definition of graft covering were
18 you applying?
19 A. Well, I think what we should do is,
20 you should take me to the specific pieces of
21 prior art and the specific use of the term, but
22 you're asking in a very, very general question.

1 So I'm happy to go to my
2 declaration. And I -- I mean, I'm -- if I've --
3 looking right from the very beginning of my
4 declaration, I've stated that the claims require
5 a transcatheter aortic valve assembly that is
6 free of an outer graft covering between the
7 first portion of fibers and the outer frame.
8 And that is what is demonstrated and taught in
9 Figure 8.
10 The prior art that I think you're
11 referring to, let's just talk about Walther for
12 example, has around it a cover of graft
13 material. It is a graft cover. And I haven't
14 gone any further than that.
15 I say, again, Dr. Buller has
16 stated, and I agree with him, that PET can be a
17 graft cover. And there's agreement that woven
18 PET is an inner graft cover. And so that's --
19 that's how I framed it. That's how I've used
20 it.
21 And my -- my opinion, as you've
22 asked me about the prior art, is the Walther's

1 cloth is, in my opinion, a graft cover.
2 Q. And so I'm asking a much more
3 simple question. What does the term "graft
4 covering" in Claim 1 of the '236 Patent mean?
5 MR. LOWENSTEIN: Objection; form.
6 THE WITNESS: So I haven't given a
7 definition of graft cover. I haven't
8 given a construction of graft cover.
9 I understand it to be a covering of
10 graft material. I've -- I've given you
11 that answer a number of times.
12 BY MR. STOWELL:
13 Q. Yeah. And as we sit here today,
14 you are unable to further elaborate on the
15 meaning of graft material; is that correct?
16 MR. LOWENSTEIN: Objection; form.
17 THE WITNESS: So for the purposes
18 of this IPR, I have not given a definition
19 of graft or graft material, but I have
20 given you an example.
21 So the answer to your question
22 is -- is, no, I -- I don't -- I have given

1 you an example of graft material. We're
2 agreed that woven PET can be a graft
3 cover, a cover of graft material of woven
4 PET.
5 BY MR. STOWELL:
6 Q. Is the graft covering required by
7 Claim 1 of the '236 Patent, is it required to
8 have any specific properties?
9 MR. LOWENSTEIN: Objection; form,
10 scope.
11 THE WITNESS: So the graft cover in
12 Claim 1 has to be [as read]: "A
13 cylindrically extending polymeric inner
14 graft cover extending at least partially
15 radially outwardly of the prosthetic heart
16 valve and radially inwardly of the outer
17 frame for providing sealing to the
18 prosthetic heart valve."
19 Those are the requirements of that
20 claim limitation. The inner graft
21 covering is stitched to the outer frame,
22 and that is what -- that is what the claim

1 says.
2 BY MR. STOWELL:
3 Q. Other than what's written in the
4 claim, does the inner graft covering in Claim 1
5 of the '236 Patent need to have any other
6 properties?
7 MR. LOWENSTEIN: Objection; form,
8 scope.
9 THE WITNESS: Yeah, as -- as I've
10 said, I haven't -- I haven't given any
11 opinion on that. If -- if you think I
12 have, 'cause you are asking me the same
13 question so many times, I'd like to go to
14 it in my declaration and clarify it. I
15 don't believe I've given an opinion on
16 that for the purposes of this IPR.
17 BY MR. STOWELL:
18 Q. Does the graft covering claimed in
19 Figure 1 of the '236 Patent need to have any
20 specific thickness or range of thicknesses?
21 MR. LOWENSTEIN: Objection; form,
22 Scope.

1 THE WITNESS: So I've not given any
2 opinion on that for this IPR.
3 BY MR. STOWELL:
4 Q. Is the graft covering claimed in
5 Figure 21 -- or let me start over.
6 How -- are there any limits on the
7 thickness of the inner graft covering claimed in
8 figure -- or in the '236 Patent Claim 1?
9 MR. LOWENSTEIN: Objection; form,
10 scope.
11 THE WITNESS: Sorry. Could you ask
12 that question again?
13 BY MR. STOWELL:
14 Q. Does the '236 Patent place any
15 limits on the thickness of the graft covering
16 claimed in Claim 1?
17 MR. LOWENSTEIN: Objection; form,
18 scope.
19 THE WITNESS: I have not -- I have
20 not addressed that. I don't think I have
21 given any opinion of -- to that for this
22 IPR.

1 BY MR. STOWELL:
2 Q. Does the inner graft covering
3 claimed in Claim 1 need to have any specific
4 density?
5 MR. LOWENSTEIN: Objection; form,
6 scope.
7 THE WITNESS: So I have not given
8 any opinion on how dense a graft cover has
9 to be in -- you said "specific density."
10 I have not given an opinion on that. I
11 know Dr. Buller described, I think, a
12 graft cover as something of low porosity,
13 and I would agree. I have not given, and
14 I don't think Dr. Buller has, limits on
15 measurement and I don't think I've given
16 an opinion on that.
17 BY MR. STOWELL:
18 Q. So is it your opinion that the
19 graft covering claimed in Claim 1 of the
20 '236 Patent must have a low porosity?
21 A. So I think graft covers, as a
22 general -- as -- as a term, we've -- we've --

1 I've said, I've expressed agreement with
2 Dr. Buller's view that, for example, woven PET
3 is low porosity and can be a graft cover. I
4 have not gone any further than that.
5 Q. Does the graft covering claimed in
6 Claim 1 of the '236 Patent need to be or need to
7 have a low porosity?
8 MR. LOWENSTEIN: Objection; form.
9 THE WITNESS: So with respect to
10 the specific use of the term, I've not --
11 it -- within a claim, I've not applied a
12 definition, but a graft cover would have a
13 property of low porosity.
14 BY MR. STOWELL:
15 Q. So a graft covering would have a
16 low porosity; is that correct?
17 A. Yes, that's correct.
18 Q. And how dense --
19 MR. LOWENSTEIN: Sorry. I'm sorry.
20 He wasn't done.
21 THE WITNESS: I hadn't -- I hadn't
22 finished.

1 Something of low porosity, with
2 holes, would not be considered a graft
3 cover.
4 BY MR. STOWELL:
5 Q. So how would a material with holes
6 have a low porosity?
7 A. You are asking a extremely general
8 question in a complete vacuum. How would a
9 material with holes have low porosity? That's
10 such a general question. I think I'd need you
11 to be more specific.
12 Q. You testified, "something of low
13 porosity with holes would not be considered a
14 graft cover."
15 A. So a graft --
16 Q. What did you mean by "something of
17 low porosity with holes"?
18 A. I'm sorry. If I said "low
19 porosity," I misspoke.
20 I'm sorry. Could -- could I --
21 could you read -- could I see back or could you
22 read back the testimony that I just gave because

1 I may have misspoken?
2 What I'm -- what I'm talking about
3 is something that is porous with holes cannot be
4 a graft cover. Something of low porosity, high
5 density would not be a -- wouldn't have holes
6 and wouldn't be a graft cover. I'm -- I'm
7 sorry. I'm getting -- I'm -- I'm just getting
8 mixed up.
9 Can you just read back to me the
10 testimony I gave and I will clarify it?
11 Q. Yeah, it's quite lengthy, so why
12 don't I ask the first question again and you can
13 provide a response.
14 A graft covering would have a low
15 porosity; is that correct?
16 A. Yes, low porosity is a feature of a
17 graft cover.
18 Q. And when you use the term "low
19 porosity," what do you mean?
20 A. Something that is not very porous.
21 Q. Can you provide any sort of
22 measurements for something that is low -- that

1 has a low porosity?
2 A. No, I have not done that analysis
3 or experiment.
4 So I -- let -- let me clarify. A
5 graft material that is of low porosity can be a
6 graft cover. A graft material of high porosity
7 with holes cannot be a graft cover. And that
8 corrects whatever else I may have said.
9 Q. Does a material of low porosity
10 need to prevent the flow of fluid through the
11 material?
12 MR. LOWENSTEIN: Objection; form.
13 THE WITNESS: A mater -- a -- I've
14 not gone further than saying whether the
15 material would be of low or of high
16 porosity, but clearly something that was
17 of high porosity would allow fluid through
18 and something of low porosity would let
19 very -- would let less, if any, fluid
20 through. I've not made a definition of
21 it. I've not quantified it. I'm using
22 the terms qualitatively in a descriptive

1 way, but I think a cardiologist would
2 understand, without applying numbers in
3 the context of a graft cover, what high
4 and low porosity means.
5 A low porosity graft cover would be
6 something that is relatively dense, would
7 not let fluid through. And something that
8 is of high porosity, not dense, would,
9 potentially with holes, would let fluid
10 through. And I wouldn't go further than
11 that.
12 BY MR. STOWELL:
13 Q. Are there any materials that you're
14 aware of that a cardiologist would consult to
15 determine whether a material is low porosity or
16 high porosity?
17 MR. LOWENSTEIN: Objection; form.
18 THE WITNESS: I -- to the best of
19 my knowledge, I haven't given an opinion
20 on that.
21 BY MR. STOWELL:
22 Q. Can a graft covering have openings

1 through its thickness?
2 MR. LOWENSTEIN: Objection; form.
3 THE WITNESS: Well, I think for
4 something -- something to be a graft
5 cover, it has to be dense, low porosity,
6 without openings. The converse, if a
7 material is porous with openings, it is
8 not a graft cover.
9 BY MR. STOWELL:
10 Q. So is it fair to say that a graft
11 covering cannot have openings through its
12 thickness?
13 MR. LOWENSTEIN: Objection; form.
14 THE WITNESS: If there was an
15 opening through -- well, you're -- you're
16 saying it's a graft cover with openings.
17 If some -- if a material has openings that
18 go all the way through, it can't be a
19 graft cover.
20 BY MR. STOWELL:
21 Q. Can a graft covering be woven?
22 A. So we've -- we've said right at the

1 start that woven PET is an example of a graft
2 cover. It can be a graft cover.
3 Q. Can a graft covering be loosely
4 woven?
5 A. So I don't think I've given an
6 opinion on that question. I -- what I can say
7 is that tightly woven PET, for example, can be a
8 graft cover. I don't think I have given an
9 opinion on anything other than that.
10 Q. Can there be woven PETs that are
11 not the graft covering?
12 A. So my answer is that woven PET can
13 be a graft cover. I have not -- I don't think
14 I've stated that woven PET defines a graft cover
15 or mandates it, but it certainly can be.
16 Q. In what circumstances would woven
17 PET not be a graft covering?
18 A. So I'd just like to go to my
19 declaration 'cause I think I do put this as a
20 footnote.
21 (Reviewing document.)
22 Because I -- when I put that

1 footnote, I think I summarized exactly my views
2 on it. And it might just take me a minute to
3 find it.
4 (Reviewing document.)
5 Q. Dr. Brecker, are you looking in
6 Exhibit 2103 right now?
7 A. I am.
8 (Exhibit 2103, Second Declaration
9 of Dr. Stephen J.D. Brecker, was
10 previously marked for identification.)
11 THE WITNESS: (Reviewing document.)
12 So it is at the foot of Page 92.
13 And I state -- and it's a footnote to --
14 oh, okay. So let me just read it because
15 it will clarify.
16 "This is not to say either that all
17 'woven' bases would necessarily constitute
18 a graft nor would a knit base necessarily
19 preclude a graft. Among other things, a
20 tightly-woven, tightly-knitted, or
21 non-porous, dense felt layer may well
22 constitute a graft."

1 So that's -- that's the position.
2 BY MR. STOWELL:
3 Q. And my question was: In what
4 circumstances would woven PET not be a graft
5 covering?
6 A. So I have not addressed that
7 specific point. I haven't given an opinion on
8 that.
9 Q. Can a graft covering be made of
10 knitted material?
11 A. Well, we can go back to that
12 footnote where I state that a knit base isn't --
13 doesn't -- this is not to state that a knit
14 base necessary -- necessarily precludes a graft.
15 Q. Under what circumstances would a
16 knit base form a graft covering?
17 A. Well, I think I've said it. A
18 tightly knitted, non-porous, dense felt layer,
19 for example, might well constitute a graft.
20 Q. Is felt knitted?
21 A. So I've simply stated that, I've --
22 I mean, something that is tightly knitted,

1 that's dense and non-porous could be a graft. I
2 haven't gone into the structure of felt other
3 than what is stated in my declaration.
4 Q. Would a knitted material need to be
5 tightly knitted to be a graft covering?
6 A. A tightly knitted, non-porous,
7 dense material could be a graft cover. I
8 haven't given an opinion on the alternative
9 other than to say that a loose material with
10 holes all the way through would not be a graft
11 cover.
12 Q. You testified that a tightly
13 knitted, non-porous, dense material could be a
14 graft covering. Are there situations where a
15 tightly knitted, non-porous, dense material
16 would not be a graft covering?
17 MR. LOWENSTEIN: Objection; form.
18 THE WITNESS: So I haven't
19 considered every possible eventuality.
20 I've simply stated that a material -- if a
21 material was tightly woven, dense,
22 non-porous, it's a graft covering. I have

1 not considered beyond that.
2 BY MR. STOWELL:
3 Q. If a material was loosely knitted,
4 would it be a graft covering?
5 A. I think you asked that question and
6 I answered it, didn't I? I can say the same
7 answer.
8 Something that's loosely knitted
9 potentially with holes all the way through, so
10 that you -- you -- that would not be a graft --
11 that wouldn't constitute a graft cover.
12 Q. Is it fair to say that whether a
13 material qualifies as a graft covering depends
14 on the tightness of the weaving or knitting?
15 A. Well, that's one -- that's one
16 feature.
17 Q. So the tightness of the weaving or
18 knitting is one feature that determines whether
19 a material is a graft covering; is that fair?
20 A. I think that's what I've said. I
21 mean, I'm going back to that -- that quote from
22 my declaration where I say: This is not to say

1 that all woven bases would necessarily
2 constitute a graft nor would a knit base
3 necessarily preclude it. A tightly woven,
4 tightly knitted, or non-porous, dense felt layer
5 may well constitute a graft.
6 I'm not -- I'm not trying to be
7 limiting or giving the limits of -- of this. I
8 know that a dense material that's non-porous
9 would be a graft cover.
10 Q. And so going off of Footnote 2, are
11 the other features that determine whether a
12 material is a graft covering are the porosity
13 and the density of the material?
14 A. Those are additional features.
15 It's not to limit it to only those features.
16 Q. What features besides the tightness
17 of the weaving or knitting, the porosity, and
18 the density would determine whether a material
19 was a graft covering?
20 MR. LOWENSTEIN: Objection, scope.
21 THE WITNESS: So I've not tried to
22 be exhaustive in my declaration or the

1 opinions I've given in this IPR. I know
2 that woven PET that's low porosity, high
3 density would be a graft cover. I also
4 know that a very loose material that has
5 holes through it would not. I have not
6 tried to be exhaustive in defining every
7 aspect and I haven't done that.
8 MR. STOWELL: Okay. We've been
9 going about an hour. Why don't we take a
10 quick ten-minute break and reconvene after
11 that. Does that work?
12 MR. LOWENSTEIN: Yeah. So 10:30?
13 MR. STOWELL: 10:30 sounds great.
14 (A recess is held from 10:20 a.m.
15 to 10:37 a.m.)
16 BY MR. STOWELL:
17 Q. All right. Dr. Brecker, welcome
18 back.
19 Does the '236 Patent specification
20 describe any graft coverings?
21 A. I don't think the specification
22 describes any graft covering.

1 Q. Does the specification describe any
2 material or components that are the equivalent
3 of a graft covering?
4 MR. LOWENSTEIN: Objection, scope.
5 THE WITNESS: So I think the
6 specification mentions several. I'd have
7 to go through it to look at exactly where
8 it brings up the script or where it
9 mentions materials. I mean, there's one
10 bit, for example, at Column 9, Line 26
11 where it says, [as read]: "The proximal
12 frame has an outer surface that is covered
13 with low profile polyester, or ePTFE, or
14 other nonporous covering material."
15 So, I mean, there are other
16 examples of where the materials are
17 mentioned. Column 8, Line 43, "The outer
18 surface of the self-expanding frame is
19 covered with low profile polyester,
20 ePTFE." And there's several other
21 mentions of a similar nature.
22 I think the question you asked me

1 before about graft cover, it doesn't
2 mention the term "graft cover" if that --
3 that was the question, but it mentions
4 covers or materials that are recognized to
5 be graft covers.
6 BY MR. STOWELL:
7 Q. Well, let's start, you've
8 identified a section in Column 9 around Line 26
9 which describes a covering material 122. All
10 right. This is the section you were talking
11 about?
12 A. Yes, yeah, I think I mentioned that
13 one. I mean, it's -- they're throughout the
14 specification, it mentions materials.
15 Q. And is it your understanding that
16 the covering material that's described in Column
17 9 at Line 28 is an example of a graft covering?
18 MR. LOWENSTEIN: Objection; form,
19 scope.
20 THE WITNESS: So we -- if we're
21 now -- I mean, I -- I picked out some
22 areas where my -- I was drawn to graft

1 materials. If we're now going to discuss
2 a very specific paragraph of this patent
3 specification, I need to read through the
4 paragraph, see what figure it is referring
5 to. So if you give me a minute, I will do
6 that.
7 BY MR. STOWELL:
8 Q. Okay.
9 A. So Paragraph 9, Line 26 is
10 referring to Figure 4, I think.
11 So Figure 4 is a distal component.
12 That's not the component that engages the
13 transcatheter valve, so that's the first thing
14 to say, and, therefore, this is now separate to
15 the use of the term "graft cover" in Claim 1.
16 Q. Why don't we look at Figure 10.
17 How about that?
18 MR. LOWENSTEIN: Done with your
19 answer?
20 THE WITNESS: No, I haven't -- I
21 haven't finished. Just --
22 BY MR. STOWELL:

1 Q. Oh, okay.
2 A. So what this is saying is that the
3 proximal component of this distal section of the
4 frame may be covered with a low-profile
5 polyester ePTFE or non-porous covering material.
6 And that's -- that's what the specification says
7 and that's really as far as I would go.
8 So if you now want to take me to
9 Figure 10.
10 Okay. I'm looking at Figure 10.
11 Q. Yeah. And does Figure 10 have a
12 graft covering?
13 A. Now, I want to be accurate on this.
14 I'd like to just read through the description of
15 Figure 10.
16 Q. The description is in Column 13.
17 A. So Figure 10 is the so-called stent
18 of the inner frame and there is a
19 balloon-expandable frame. So obviously there --
20 there are different embodiments. I'm just
21 reading through and then I want to go to my
22 declaration.

1 (Reviewing document.)
2 So Figure 10 is showing the stent
3 of the inner frame. And in Claim 1 we know that
4 the inner frame includes a cylindrically
5 extending polymeric inner graft covering.
6 So in Figure 8 -- I need to look at
7 Figure 8 in conjunction with Figure 10 -- what
8 we see, as I state in my declaration, is -- I'm
9 looking at the bottom bit of it -- there is an
10 absence of a graft covering. And Figure 10 is,
11 I believe, a component of Figure 8.
12 Sorry. I just want to read what
13 Figure 8 -- sorry. Figure...
14 (Reviewing document.)
15 So Figure 8 is the proximal
16 component, so there is an inner polymeric graft.
17 And your question was: Is there a graft cover,
18 was it, or an outer graft cover?
19 Q. My question is: Does Figure 10
20 have a graft covering?
21 MR. LOWENSTEIN: Objection, scope.
22 THE WITNESS: Well, Figure 10 has

1 the inner polymeric graft. So it's an
2 inner graft. It doesn't have an outer
3 graft covering.
4 BY MR. STOWELL:
5 Q. Now, my question is -- isn't using
6 "inner" or "outer."
7 Does it have a graft covering as
8 that phrase is -- as --
9 A. An inner graft --
10 Q. -- you understand that phrase?
11 A. An inner graft cover. You could --
12 well, the claim says the inner frame includes a
13 polymeric inner graft covering.
14 Q. And so you believe Figure 10
15 includes an inner graft covering; is that your
16 testimony?
17 MR. LOWENSTEIN: Objection, scope.
18 THE WITNESS: Well, I haven't
19 recorded Figure 10 in my -- in my
20 declaration. I have Figure 8. Figure 8
21 shows an inner graft cover, but not an
22 outer graft cover.

1 So Figure 10 has an inner graft
2 cover.
3 BY MR. STOWELL:
4 Q. And what in Figure 10 is the inner
5 graft cover?
6 A. Well, I'm reading the specification
7 which says, "The stent 244 of the inner frame
8 218 has a diameter."
9 "The balloon-expandable frame 218
10 is expandable during implantation from an
11 expanded [sic] diameter."
12 Q. Where are you reading from just so
13 we can follow along?
14 A. Column 13 and going to Column 14.
15 Q. Did that section help you resolve
16 what in Figure 10 is the inner graft covering?
17 A. So I'm just trying to get the
18 correct -- so it's -- it's the -- it's --
19 I mean, I think we're seeing the inner graft
20 cover 24 [sic] on 248.
21 Q. So, Dr. Brecker, if we look at
22 Column 13 and we begin at Line 51 --

1 A. Yes.
2 Q. -- the patent describes that in the
3 illustrative embodiment, quote, "The outer
4 surface 248 of the stent 244 is covered with
5 low-profile polyester comma" --
6 A. Yes.
7 Q. -- "ePTFE comma" --
8 A. Yes.
9 Q. -- "or other nonporous covering
10 material 250 that prevents fluid from passing
11 through the outer surface 248."
12 Do you see that?
13 A. I do.
14 Q. Does that section help you identify
15 what in Figure 10 is the graft covering?
16 MR. LOWENSTEIN: Objection; form.
17 THE WITNESS: Well, it's -- it is
18 what is on top of 248. It's as described
19 there, as I said.
20 BY MR. STOWELL:
21 Q. So you believe that the --
22 A. So in figure --

1 MR. LOWENSTEIN: I'm sorry. He's
2 not done answering.
3 THE WITNESS: In Figure 10, the
4 outer surface 248 is covered by
5 low-profile ePTFE or other non-porous
6 covering material, and that would fulfill
7 the inner graft cover.
8 BY MR. STOWELL:
9 Q. So it's your position that the
10 covering material 250 is the graft -- is a graft
11 covering?
12 A. I'm just trying to see the...
13 Yes. Yes.
14 Q. Does the '236 Patent use "covering
15 material" interchangeably with "graft covering"?
16 MR. LOWENSTEIN: Objection; form,
17 scope.
18 THE WITNESS: So I -- I haven't
19 tried to define those terms.
20 BY MR. STOWELL:
21 Q. Is covering material in the
22 '236 Patent synonymous with graft covering?

1 MR. LOWENSTEIN: Objection; form,
2 scope.
3 THE WITNESS: I have not given an
4 opinion on that. Certainly some of the
5 covering materials would be inner graft
6 covers.
7 BY MR. STOWELL:
8 Q. In the portion in Column 13 in the
9 section we just read that starts at Line 51, are
10 any of the materials that are identified there,
11 would they not be a graft covering?
12 MR. LOWENSTEIN: Objection; form.
13 THE WITNESS: Sorry. In which
14 paragraph?
15 BY MR. STOWELL:
16 Q. So we were reading from Column 13,
17 beginning at Line 51.
18 A. Yes.
19 Q. And there are materials listed in
20 that sentence; correct?
21 A. Low-profile polyester, ePTFE, or
22 other non-porous covering material.

1 Q. And are each of those described
2 materials a graft covering in your opinion?
3 MR. LOWENSTEIN: Objection; form,
4 scope.
5 THE WITNESS: So I haven't given an
6 opinion on what materials can or can't be,
7 specific materials, because it's not only
8 the material, as we've mentioned, so those
9 materials could be graft covers.
10 BY MR. STOWELL:
11 Q. Well, here the sentence goes on to
12 say that the materials prevent fluid from
13 passing through the outer surface 248.
14 Does that clause help you determine
15 whether or not the materials are a graft
16 covering?
17 MR. LOWENSTEIN: Objection; form,
18 scope.
19 THE WITNESS: So that's one of the
20 characteristics of a graft cover.
21 BY MR. STOWELL:
22 Q. And so reading that sentence as a

1 whole, are you able to tell me whether the
2 materials listed there are graft coverings?
3 A. Well --
4 MR. LOWENSTEIN: Objection; form,
5 scope.
6 THE WITNESS: So you're taking
7 examples of materials that they say could
8 be used and you're -- you're asking me a
9 very general question in, are all
10 embodiments of all of those materials
11 always graft covers. And I've said I
12 haven't given an opinion on all of the
13 possible versions of all of the possible
14 materials.
15 I've stated that a graft cover is
16 of low porosity and I've given an example
17 of woven PET. I'm aware that other
18 materials can be graft covers, but you
19 could choose a material and say, "Is that
20 always a graft cover?" And PET isn't
21 always a graft cover. There are versions
22 of PET that plainly would not be a graft

1 cover.
2 BY MR. STOWELL:
3 Q. I think you misunderstood my
4 question. We're talking about a very specific
5 passage on Paragraph [sic] 13 that's describing
6 Figure 10. And there it describes, for example,
7 a low-profile polyester that prevents fluid from
8 passing through the outer surface 248.
9 Would that low-profile polyester be
10 a graft covering?
11 MR. LOWENSTEIN: Objection; form,
12 scope.
13 THE WITNESS: So I've not given an
14 opinion on polyester, I don't think,
15 anywhere in my declaration. If I have,
16 please take me to it.
17 As I've said, certain materials can
18 be graft covers. The mere fact that it's
19 a material doesn't make it a graft cover
20 and -- and you're asking me a very general
21 question.
22 BY MR. STOWELL:

1 Q. Is PET a form of polyester?
2 A. I would need to do further research
3 on exactly the classification of all of these,
4 so I can't answer that.
5 Q. So without knowing whether the
6 materials that are described in Column 13 around
7 Line 51 are graft coverings, how are you able to
8 definitively say that Figure 10 includes an
9 inner graft covering?
10 MR. LOWENSTEIN: Objection; form.
11 THE WITNESS: Well, if it's covered
12 by a tightly woven non-porous material, it
13 will be an inner graft cover in this -- in
14 this scenario.
15 The implication from that area of
16 the specification is that a low-profile
17 polyester non-porous material would
18 qualify as an inner graft cover. I
19 haven't given an opinion on that. And
20 I've given examples of what graft covers
21 are.
22 As I say, you're asking me very

1 general questions.
2 BY MR. STOWELL:
3 Q. Is the covering material in Figure
4 10 described as being tightly woven?
5 A. I don't see that in the
6 specification, but I just need to read through.
7 So the specification goes on to say
8 it can be "covered with standard polyester,
9 ePTFE or other non porous materials." I mean, I
10 can't see the term "tightly woven" immediately.
11 That's not to say it's not there. I just can't
12 find it.
13 (Reviewing document.)
14 I mean, it says it can be covered
15 here higher up.
16 I mean, all -- all I can do is read
17 what it says. And it says, "It should be
18 appreciated that in other embodiments the stent
19 may be formed from a polymeric material."
20 "In the illustrative embodiment,
21 the outer surface of the stent is covered with
22 low-profile polyester, ePTFE, or other nonporous

1 covering material that prevents fluid from
2 passing through the outer surface."
3 "It should be appreciated that the
4 stent may be covered with standard polyester,
5 ePTFE, or other nonporous materials."
6 I've not made any specific analysis
7 beyond what's put there.
8 Q. Do you have any opinion on whether
9 the covering material in Figure 10 is tightly
10 woven?
11 MR. LOWENSTEIN: Objection to
12 scope.
13 THE WITNESS: So all I can say is
14 that it's non-porous. That's all I can
15 say from the -- from the material that's
16 in the specification. It says it can be
17 covered with standard polyester, ePTFE, or
18 other non-porous materials. And it's
19 something that will prevent fluid from
20 going through it. I mean, the implication
21 is that some of those materials, if not
22 all of them, would have to be tightly

1 woven. They have to be dense and
2 non-porous to qualify as a graft cover.
3 They've got to prevent fluid from going
4 through.
5 BY MR. STOWELL:
6 Q. What is low-profile polyester?
7 MR. LOWENSTEIN: Objection, scope.
8 THE WITNESS: So I haven't given an
9 opinion on that.
10 BY MR. STOWELL:
11 Q. But do you know from your
12 experience in the field what low-profile
13 polyester is?
14 A. I've not considered the range of
15 materials to polyester for the purposes of my
16 declaration.
17 Q. Do you know what the differences
18 are between low-profile polyester and standard
19 polyester?
20 MR. LOWENSTEIN: Objection; form,
21 scope.
22 THE WITNESS: Well, other -- other

1 than stating the obvious, which is that
2 low-profile polyester has a -- presumably
3 a lower profile than standard polyester,
4 but I have not given any opinion on that
5 in terms of defining it or...
6 BY MR. STOWELL:
7 Q. When we look at Figure 10, the
8 covering material 250 is on the outside of the
9 stent 244; correct?
10 A. That is -- that is correct.
11 Q. And what are we seeing -- you see
12 the kind of crosshatching lines, Line 248 is
13 pointing to one of them. What are those
14 crosshatch lines?
15 MR. LOWENSTEIN: Objection, scope.
16 THE WITNESS: I haven't given any
17 specific interpretation of those lines.
18 BY MR. STOWELL:
19 Q. Well, Item 244 is a stent. Do you
20 believe that the lines that we are seeing are
21 the struts of the stent 244?
22 A. Not necessarily, no.

1 Q. What else could they be?
2 MR. LOWENSTEIN: Objection, scope.
3 THE WITNESS: They could simply be
4 just illustrations of a material because
5 the -- the term "strut" is giving a very
6 specific implication to the structure of
7 this.
8 BY MR. STOWELL:
9 Q. So what does lead line 248 point
10 to?
11 MR. LOWENSTEIN: Objection, scope.
12 THE WITNESS: So 248 is pointing to
13 the outer surface of 244.
14 BY MR. STOWELL:
15 Q. And does that help clarify what
16 those crosshatch lines are in Figure 10?
17 MR. LOWENSTEIN: Objection, scope.
18 THE WITNESS: No, it simply says
19 this is representing the outer surface.
20 BY MR. STOWELL:
21 Q. Of the stent, though; correct?
22 A. Of stent 244, correct.

1 Q. Okay. So the lines that we see,
2 the crosshatch lines, those are the outer
3 surface of stent 244?
4 MR. LOWENSTEIN: Objection, scope.
5 THE WITNESS: So I'll read from the
6 specification. "In the illustrative
7 embodiment, the outer surface 248 of the
8 stent 244."
9 That's how I've read it. I haven't
10 attributed any further analysis of it and
11 I haven't put any reliance on it in my
12 declaration.
13 BY MR. STOWELL:
14 Q. So you don't have an opinion about
15 what the crosshatch lines in Figure 10
16 illustrate?
17 MR. LOWENSTEIN: Okay.
18 Dr. Brecker, please answer this question,
19 but afterwards I'm going to ask you to
20 leave the room so I can make a record.
21 THE WITNESS: So I've not --
22 MR. LOWENSTEIN: Okay. First of

1 all, objection, scope.
2 THE WITNESS: I have not used those
3 crosshatchings in forming any of my
4 opinions. I have not made any assumption
5 one way or the other as to what the
6 crosshatchings themselves represent, so I
7 haven't given an opinion on it.
8 Furthermore, I have not used them in my --
9 in coming to my opinions.
10 MR. LOWENSTEIN: Dr. Brecker, can
11 you please leave the room for a moment and
12 stay on the record.
13 (The witness is not present.)
14 MR. LOWENSTEIN: Let me note --
15 MR. STOWELL: Well, if Dr. Brecker
16 is going to leave, we should go off the
17 record.
18 MR. LOWENSTEIN: No, we are staying
19 on the record. I do not agree to go off
20 the record unless both attorneys agree.
21 MR. STOWELL: Mr. Lowenstein,
22 obviously --

1 MR. LOWENSTEIN: I'm sorry. I'm
2 speaking. Your questions are obviously
3 not relevant to any issue in this IPR.
4 You are obviously answering [sic]
5 questions relating solely to the district
6 court litigation. He is not opining on
7 this issue, so I'm putting you on notice
8 that I object to your questions and should
9 it continue in this vein, I'm afraid we'll
10 have to postpone the deposition yet again
11 to call the Board.
12 So I've made my record. I will
13 invite Dr. Brecker in again.
14 MR. STOWELL: Mr. Lowenstein,
15 please stop interrupting the deposition.
16 The questions are relevant to the IPR.
17 You obstructed the deposition last
18 time and we were ordered to continue. The
19 same result would continue this time. So
20 please reframe from interrupting the
21 deposition so we can complete the
22 deposition without obstruction.

1 MR. LOWENSTEIN: If you refine --
2 if you confine your questioning to the
3 appropriate scope of this IPR deposition
4 rather than fishing for the litigation,
5 there will no -- be no need for
6 interruptions or delay. I'm going to
7 invite Mr. -- Dr. Brecker in.
8 (Pause.)
9 MR. LOWENSTEIN: For the record,
10 Dr. Brecker is now back in the room.
11 (The witness is present.)
12 BY MR. STOWELL:
13 Q. Before we -- before you left the
14 room Dr. Brecker, or were ordered to leave the
15 room, we were talking about Column 13, Line 51.
16 Are there any differences between the described
17 covering material in Column 13 and the claimed
18 graft covering that you can identify?
19 MR. LOWENSTEIN: Objection; form,
20 scope.
21 THE WITNESS: So I'd like to go
22 back to the claims. The claims recite a

1 cylindrically extending polymeric inner
2 graft covering. So that's as -- that is
3 as far as I have gone in my interpretation
4 of what the inner graft covering is with
5 respect to the claims. I've not applied
6 any further definition or limits to it.
7 BY MR. STOWELL:
8 Q. Can you identify any portions of
9 the '236 Patent specification that describe a
10 cylindrically extending polymeric inner graft
11 covering?
12 MR. LOWENSTEIN: Objection, scope.
13 THE WITNESS: Well, I'd have to
14 have a look through the specification in
15 full.
16 BY MR. STOWELL:
17 Q. Are you aware of any portion --
18 MR. LOWENSTEIN: I'm sorry. Were
19 you -- were you done ask -- looking or
20 were you done with your answer?
21 THE WITNESS: No. I'd like a
22 little bit of time to take a look.

1 MR. STOWELL: Mr. Lowenstein, your
2 speaking -- I'm not going to call them
3 objections, but those are inappropriate
4 and you are obstructing the deposition.
5 MR. LOWENSTEIN: No one's
6 interrupting the witness when he's
7 answering your question.
8 THE WITNESS: So your -- could you
9 just repeat the question you said?
10 BY MR. STOWELL:
11 Q. Can you identify any portions of
12 the '236 Patent specification that describe a
13 cylindrically extending polymeric inner graft
14 covering?
15 MR. LOWENSTEIN: Objection; scope,
16 form.
17 THE WITNESS: So sitting here now,
18 I have not identified the term within the
19 specification.
20 BY MR. STOWELL:
21 Q. Are you aware of any figures in the
22 patent specification that illustrate a

1 cylindrically extending polymeric inner graft
2 covering?
3 MR. LOWENSTEIN: Objection; form,
4 scope.
5 THE WITNESS: Well, you're --
6 you're using the words as a whole. There
7 is clearly figures demonstrating the inner
8 graft covering.
9 BY MR. STOWELL:
10 Q. And what figures do you believe
11 illustrate the inner graft covering?
12 MR. LOWENSTEIN: Objection; form,
13 scope.
14 THE WITNESS: Well, for one, we
15 were discussing Figure 10.
16 BY MR. STOWELL:
17 Q. And you believe Figure 10
18 illustrates an inner graft covering; is that
19 correct?
20 THE REPORTER: Mr. Lowenstein, if
21 you said something, I didn't hear you.
22 MR. LOWENSTEIN: I said objection,

1 scope.
2 THE REPORTER: Thank you.
3 MR. LOWENSTEIN: Thank you.
4 THE WITNESS: So we've -- we've --
5 we've agreed that Figure 10 shows an inner
6 graft cover. Or when I say "shows," the
7 figure has a description in the
8 specification that says in the
9 illustrative embodiment, the outer surface
10 is covered.
11 BY MR. STOWELL:
12 Q. And you believe that covering is an
13 inner graft covering --
14 MR. LOWENSTEIN: Objection --
15 BY MR. STOWELL:
16 Q. -- is that correct?
17 MR. LOWENSTEIN: -- scope.
18 THE WITNESS: I've said that's what
19 I believe.
20 BY MR. STOWELL:
21 Q. Are there other figures in the
22 patent that you believe illustrate an inner

1 graft covering?
2 MR. LOWENSTEIN: Objection, scope.
3 THE WITNESS: So I have not been
4 through each and every figure labeling it
5 as if, "Does this one show an inner graft
6 cover? Does that one?" I'm happy to do
7 that, but I would need time.
8 BY MR. STOWELL:
9 Q. As we sit here, are you able to
10 identify any other figures that you believe have
11 an inner graft covering?
12 MR. LOWENSTEIN: He's looking at
13 the patent.
14 Objection, scope.
15 THE WITNESS: So I said right at
16 the start that Figure 8 shows the inner
17 frame and graft -- graft. And I've put
18 that in Paragraph 33 of my declaration
19 where I label it. Now, that's the one
20 I've chosen. I mean, as I say, we could
21 go through the whole patent, all of the
22 figures and analyze them. I haven't done

1 that.
2 BY MR. STOWELL:
3 Q. In Figure 33 of your expert report
4 -- or of your expert declaration, Exhibit 2103,
5 you have a -- you've cropped a portion of Figure
6 8; correct?
7 MR. LOWENSTEIN: I think you said
8 Figure 30 -- you meant to say Paragraph
9 33?
10 MR. STOWELL: Yeah, sorry. Let me
11 start over.
12 BY MR. STOWELL:
13 Q. In Paragraph 33 of your expert
14 declaration, which is Exhibit 2103, you have a
15 cropped portion of Figure 8; correct?
16 A. Yes, that is correct.
17 Q. And in that figure you have added a
18 label in yellow that says "Inner Polymeric
19 Frame/Graft"; correct?
20 A. Yes.
21 Q. Is it your position that a frame
22 and a graft are the same thing?

1 MR. LOWENSTEIN: Objection; form,
2 scope.
3 THE WITNESS: I don't believe I've
4 ever said they are the same thing. I
5 think there is agreement that an inner
6 frame can be a graft cover.
7 BY MR. STOWELL:
8 Q. And in Figure 8, is there an item
9 number associated with what you have identified
10 as the inner polymeric frame/graft?
11 A. Okay. I'll just need to go back to
12 the patent and look at the specification.
13 (Reviewing document.)
14 So, sorry. Could you repeat your
15 question?
16 Q. In Figure 8 is there an item number
17 associated with what you have identified as the
18 inner polymeric frame/graft?
19 A. So in the specification, the -- I'm
20 looking at Column 12, Line 9, "The dual-frame
21 214 of the proximal component 212 includes a
22 self-expanding outer frame 216 and a

1 balloon-expandable inner frame 218 that is
2 secured to the self-expanding outer frame 216
3 and houses the valve 32."
4 Based on that, in my figure at
5 Paragraph 33, it's not very clear where the lead
6 line of 218 ends, but that is -- the lead line
7 of 218 is referring to the balloon-expandable
8 inner frame and I've labeled that as the inner
9 polymeric frame/graft.
10 Q. And do you agree that the item 218
11 in Figure 8 is also reflected in Figure 10 of
12 the '236 Patent?
13 MR. LOWENSTEIN: Objection, scope.
14 THE WITNESS: The -- the paper copy
15 that I have, the staples have come out and
16 the figures are all out of order. Well,
17 it's just going -- well, it's just going
18 to be a --
19 THE REPORTER: Mr. Lowenstein, I
20 can't hear what you're saying.
21 MR. LOWENSTEIN: I was off -- I was
22 going to offer my copy, but I --

1 THE WITNESS: Do you have a
2 stapler? That will just be the easiest
3 thing because I can then just staple this
4 and it'll --
5 MR. LOWENSTEIN: Do you have a
6 stapler?
7 Are you sure you have it in order?
8 THE WITNESS: It's in order now.
9 MR. LOWENSTEIN: Okay.
10 THE WITNESS: And then we can look
11 at Figure 10.
12 MR. LOWENSTEIN: You also have an
13 electronic version.
14 THE WITNESS: I do, but I just find
15 it easier to go between the paper version
16 of the -- okay.
17 So looking at Figure 10 the
18 quest -- your question was is 218 shown in
19 Figure 10. And I don't see the number or
20 lead line on Figure 10, but I'd like to
21 just read the specification again.
22 (Reviewing document.)

1 Yeah, so Figure 10, although the
2 lead line and the number 218 doesn't
3 appear on Figure -- I'm sorry. 218,
4 it's -- it's at the top, and that is the
5 balloon-expandable inner frame 218.
6 BY MR. STOWELL:
7 Q. So your testimony about Figure 10
8 then would also apply to Figure 8; correct?
9 MR. LOWENSTEIN: Objection; form,
10 scope.
11 THE WITNESS: Yes, we're talking
12 about the inner graft cover. I've used my
13 Paragraph 33 to demonstrate the absence of
14 an outer graft cover. And on occasions I
15 think your questions have just referred to
16 the term "graft cover," so I want to be
17 very clear about this. These embodiments
18 clearly lack an outer graft cover, but
19 have an inner.
20 BY MR. STOWELL:
21 Q. Let's go to Exhibit 2103 Page 31.
22 This is the second Brecker declaration.

1 MR. LOWENSTEIN: You said Page 31;
2 right?
3 MR. STOWELL: Correct. Page 31.
4 THE WITNESS: Yeah.
5 BY MR. STOWELL:
6 Q. And on Page 31, you have cropped a
7 portion of Figure 9 from the '236 Patent;
8 correct?
9 A. Yes.
10 Q. And in this figure we see Item 234
11 on the left-hand side; correct?
12 A. Yes.
13 Q. And item 234 is referred to in the
14 patent as collagen fibers; correct?
15 A. So I'd need to just go to the
16 specification.
17 MR. LOWENSTEIN: Objection; form,
18 scope.
19 THE WITNESS: I'd need to go to the
20 specification.
21 So as shown in Figure 9 -- I'm just
22 going to read this through.

1 (Reviewing document.)
2 Sorry. I just need to read this.
3 These descriptions are quite long.
4 (Reviewing document.)
5 I'm just trying to find 234 in the
6 specification. I might just have a look
7 on the electronic version.
8 BY MR. STOWELL:
9 Q. Just to help, it you look at Column
10 12, Line 43, that may provide some assistance.
11 A. Thank you very much.
12 So Column 12 is referring to Figure
13 8 and says, "In the illustrative embodiment,
14 collagen fibers 234 are attached." So in that
15 illustrative embodiment there, 234 is referring
16 to collagen fibers.
17 Q. Is there a graft covering in the
18 segment of Figure 9 that you have cropped on
19 Page 31 of your declaration?
20 MR. LOWENSTEIN: Objection; form.
21 THE WITNESS: So it's quite clear
22 there is no outer graft covering. I'd

1 have to go -- I'd have to have another
2 read through these. As I say, they're
3 very detailed descriptions of figures and
4 I -- to -- to answer your question, what I
5 can certainly say straight away is there
6 is no outer graft covering.
7 BY MR. STOWELL:
8 Q. Is there any other graft covering
9 in the portion of Figure 9 on Page 31 of your
10 declaration?
11 MR. LOWENSTEIN: Objection, scope.
12 THE WITNESS: So I want to be
13 absolutely sure. My initial feeling is
14 not, but I would just like to be
15 absolutely sure and just read through.
16 (Reviewing document.)
17 I don't believe Figure 9 shows any
18 graft covering. I just need a little bit
19 more time.
20 (Reviewing document.)
21 Just give me a little bit longer.
22 I'm just reading through.

1 (Reviewing document.)
2 So we're talking [as read]: As
3 shown in Figure 9, the proximal section
4 220 and the inwardly tapered section 222
5 of the self-expanding frame 216 formed in
6 an open-cell configuration, and the
7 sections 62, 64 are formed in a Z-stent
8 configuration. It should be appreciated
9 that in other embodiments the sections may
10 be formed in a single configuration,
11 including an open-cell stent configuration
12 or Z-stent configuration. The sections
13 may be formed as a single monolithic
14 component. The outer surface 240 of the
15 sections 62, 64, 220 -- sorry, 62, 64, and
16 222 are covered with a low-profile
17 polyester, ePTFE, or other non-porous
18 covering material 242 such that fluid is
19 prevented.
20 Now, the outer surface that it's
21 referring to is at -- in my figure, which
22 as you say is cropped, I'm now looking at

1 the original patent figure, the sections
2 that are covered are 62, 64, and 222 which
3 are all higher than the section 220 and;
4 therefore, 2 -- what I've shown lacks a
5 graft, any form of graft cover.
6 It doesn't say anything on this
7 figure otherwise.
8 So the graft cover as would apply
9 potentially is not in the bit that I've
10 shown. So it's -- on this section, which
11 is the section housing the valve and
12 engaging the annulus, there is no outer
13 graft cover. There's no graft cover.
14 BY MR. STOWELL:
15 Q. Why don't you consider the collagen
16 fibers to be a graft covering?
17 MR. LOWENSTEIN: Objection; form.
18 THE WITNESS: Oh, these are --
19 these are sparsely distributed fibers, a
20 very high porosity, a very low density,
21 and they've got holes in and you can see
22 the frame.

1 BY MR. STOWELL:
2 Q. And when you say the fibers are
3 sparsely distributed, are you basing that on the
4 figure alone or a portion of the specification?
5 A. Well, I think I'm taking all of the
6 evidence I've got. Certainly the figure on its
7 own is quite compelling. I'd have to look
8 through the specification in more detail to be
9 sure as to exactly where it describes it.
10 Q. Does the '236 Patent describe the
11 collagen fibers as having very high porosity?
12 MR. LOWENSTEIN: Objection; form.
13 THE WITNESS: I don't think the
14 specification describes that.
15 BY MR. STOWELL:
16 Q. Does the specification require the
17 collagen fibers to have a very low density?
18 MR. LOWENSTEIN: Objection; form.
19 THE WITNESS: Does the
20 specification require? No, but the claim
21 -- the specification is the description.
22 The claims, the way I read the

1 claims where there are openings through
2 the thickness, is pretty clear to me that
3 this is low density, high porosity. I'm
4 fairly sure I've dealt with this in my
5 declaration.
6 I -- I was just looking through my
7 declaration. I don't have anything else
8 to say.
9 BY MR. STOWELL:
10 Q. Okay. If the collagen fibers in
11 Figure 9 were denser, could they form a graft
12 covering?
13 MR. LOWENSTEIN: Objection; form,
14 scope.
15 THE WITNESS: So I -- I've not --
16 I've not expressed an opinion other than
17 to say that the fibers in the figures are
18 sparsely distributed. There are gaps.
19 There are spaces. They go through to the
20 frame. And no one would have considered
21 that, I don't believe, that that is a
22 graft covering. And I'm basing that on

1 the way in which the claims are written,
2 figures, and the design intent as well
3 of what these were.
4 BY MR. STOWELL:
5 Q. So that didn't answer my question.
6 If the collagen fibers in Figure 9
7 were denser, could they form a graft covering?
8 MR. LOWENSTEIN: Objection; form.
9 THE WITNESS: So I haven't -- I
10 haven't addressed other -- I have not
11 formed an opinion, I don't have an opinion
12 on other designs of fibers that you're
13 referring to.
14 I've used what is in the patent to
15 come to a conclusion that these are
16 sparsely distributed and could not be
17 considered a graft covering.
18 BY MR. STOWELL:
19 Q. You stated, I believe, that you
20 think that the collagen fibers have a very high
21 porosity. Am I getting that right?
22 MR. LOWENSTEIN: Objection; form.

1 THE WITNESS: The -- the fiber --
2 the fibers as illustrated as a material
3 would have -- would be very porous.
4 BY MR. STOWELL:
5 Q. And by "very porous," do you mean
6 fluid would freely flow -- flow through the
7 stent frame?
8 MR. LOWENSTEIN: Objection; form.
9 THE WITNESS: I don't think I've
10 stated that. That would be one way of
11 demonstrating it.
12 BY MR. STOWELL:
13 Q. What would be the other ways of
14 demonstrating that the collagen fibers are very
15 porous?
16 MR. LOWENSTEIN: Objection; form,
17 scope.
18 THE WITNESS: Yeah, I've not
19 addressed that in my declaration. I think
20 these fibers couldn't be seen to be
21 anything other than very porous in the way
22 that they're presented. And they're in

1 stark contrast to the graft covers that
2 have been cited in prior art.
3 BY MR. STOWELL:
4 Q. Are the collagen fibers very porous
5 when the device is implanted in a patient?
6 MR. LOWENSTEIN: Objection; form.
7 THE WITNESS: Yeah, I don't think I
8 have given a analysis of that in my
9 declaration. It's possible that I've made
10 a -- an assessment.
11 I mean, I say, looking just at my
12 Paragraph 22, "that a sparse distribution
13 of fibers with significant gaps and spaces
14 would be porous."
15 Your question was what would the
16 porosity be when in the body. And I --
17 clearly when they're compressed down and
18 there's no -- the spaces between them are
19 less, then they would form a sealing
20 interface. And that they would do that is
21 perhaps counterintuitive.
22 So what I've put in my declaration

1 is that a sparse distribution of fibers
2 with significant gaps and spaces would be
3 porous until compressed in the body. That
4 they would form a seal is an unexpected
5 result. So I haven't done an experiment.
6 BY MR. STOWELL:
7 Q. And so if we look, for example, at
8 Figure 21 of the '236 Patent, are the collagen
9 fibers in Figure 21 very porous?
10 A. So let's -- if we can look at the
11 specification and also in my -- I address this
12 in -- in my declaration at Paragraph 162.
13 Figure 21 is showing the valve deployed, but let
14 me just get to where it's described in the
15 specification.
16 As shown in Figure 21, the inner
17 frame is initially unexpanded within the outer
18 frame. The inner frame 218 may be deployed by
19 expanding the balloon assembly. Expansion of
20 the balloon-expandable inner frame engages the
21 inner frame with the outer frame and compresses
22 the collagen fibers and hydrogel-coated proximal

1 segment of the outer frame against the aortic
2 annulus 210.
3 And then in my declaration what I
4 state is, as -- Figure 21 shows how to align in
5 the patient and Figure 22 shows how they are
6 then configured to form the sealing interface.
7 Q. And so in Figure 21 of the
8 '236 Patent, are the collagen fibers very
9 porous?
10 A. So the appearance of the figure --
11 of the collagen fibers in Figure 21 is not the
12 same as in the previous drawing. The patent
13 teaches these fibers will address PVL when
14 compressed within the body. So the reading of
15 that is that they become less porous when they
16 are compressed within the body.
17 Q. And so does the compressibility of
18 a material contribute to its porosity?
19 A. That's such a general question in a
20 vacuum I can't answer that.
21 Q. In the case of woven PET fabrics,
22 does the compressibility of the material

1 contribute to the porosity?
2 MR. LOWENSTEIN: Objection; form,
3 scope.
4 THE WITNESS: I don't think I've
5 done any analysis or given an opinion on
6 that.
7 BY MR. STOWELL:
8 Q. Let's look at Paragraph 36 of your
9 declaration, Exhibit 2103. It's on Page 22.
10 A. Yes.
11 Q. You state at the end of that
12 paragraph, "I also agree that PET cloth or
13 fabric can be a graft covering."
14 Do you see that?
15 A. (Reviewing document.)
16 Yes.
17 Q. And is it your opinion that any
18 object made of PET is a graft covering?
19 MR. LOWENSTEIN: Objection; form,
20 scope. I'll remove the scope objection.
21 Objection; form.
22 THE WITNESS: I haven't said that.

1 BY MR. STOWELL:
2 Q. You would agree that not every
3 object made of PET is a graft covering; right?
4 A. I would agree with that.
5 Q. And would you agree that not every
6 component on a heart valve made of PET is a
7 graft covering?
8 A. Well, I'm trying -- you're asking
9 an extremely general question, and there are
10 more than probably 800 different designs of
11 heart valves. I couldn't tell you how they've
12 all used PET in different sections.
13 Q. To be clear, I'm not asking you to
14 tell me how they would all use PET.
15 I'm just asking if you would agree
16 with the statement that not every component on a
17 heart valve that is made of PET is a graft
18 covering.
19 A. I'd have to really think about that
20 and know what the components were that you're
21 talking about. I mean, there may be some
22 components that are formed of PET that are not

1 graft covers, but -- I mean, I'm -- I'm not sure
2 what you're referring to.
3 Q. Would you agree that not every PET
4 cloth or fabric is a graft covering?
5 A. Sorry. Say that again.
6 Q. Would you agree that not every PET
7 cloth or fabric is a graft covering?
8 A. Well, I'm going to go back to what
9 I've -- the way I've put this, which is that not
10 all woven bases would be considered a graft. I
11 mean, there are certainly forms of PET that
12 would not be a graft cover. I think we've
13 agreed that.
14 Q. But do you agree that not every PET
15 cloth or fabric is a graft covering?
16 A. Not every PET cloth is necessarily
17 a graft covering. I've said that PET can be a
18 graft covering. I mean, I can think of
19 examples. If it was low density, high porosity
20 PET with holes in it, it wouldn't be a graft
21 covering.
22 Q. So just knowing that a material is

1 made of PET fabric doesn't tell you whether that
2 material is a graft covering; correct?
3 A. That's correct. I've always had
4 the view that PET can be a graft cover. It
5 doesn't define it.
6 Q. In Paragraph 36, in the very first
7 sentence -- or after the first sentence, you
8 cite to a portion of Dr. Buller's declaration at
9 Paragraph 109; correct?
10 A. Yes.
11 Q. And the portion you cite there is
12 referring to the Cribier reference; is that
13 right?
14 A. Yes. I'd -- I'll get that.
15 MR. LOWENSTEIN: I'm sorry. Are
16 you asking him to get Cribier or the
17 Buller declaration?
18 MR. STOWELL: I was asking about
19 the -- the statement in the declaration.
20 I believe Dr. Brecker volunteered to get
21 Cribier.
22 MR. LOWENSTEIN: Oh.

1 THE WITNESS: No, I'd actually got
2 Buller, and it says -- or the bit that I'm
3 quoting, first of all, PET is a polymeric
4 graft covering.
5 (Exhibit 1003, Declaration of Nigel
6 Buller, M.D., was previously marked for
7 identification.)
8 BY MR. STOWELL:
9 Q. Are you at Paragraph 109 of
10 Dr. Brecker's --
11 A. Yes.
12 Q. -- declaration?
13 A. Dr. Buller's declaration, yes.
14 THE REPORTER: I'm sorry. I didn't
15 hear that. I'm sorry. I just didn't hear
16 your answer.
17 THE WITNESS: Paragraph 109 of
18 Dr. Buller's declaration states, "PET is a
19 type of polyester and also a polymer and
20 is a polymeric graft covering."
21 BY MR. STOWELL:
22 Q. So you agree that the Cribier

1 reference that Dr. Buller is referring to in
2 Paragraph 109 of his declaration describes the
3 STAPIEN heart valve; correct?
4 A. SAPIEN. SAPIEN, yes.
5 Q. Correct, SAPIEN.
6 A. It's the -- yeah, the Edwards
7 SAPIEN is that -- is the drawing that's shown,
8 and what is shown is a PET in a graft cover.
9 Q. And so you agree with Dr. Buller
10 that SAPIEN included a PET fabric cuff?
11 A. It included a PET inner graft
12 cover.
13 Q. And the Cribier reference describes
14 that as a polyethylene terephthalate PET fabric
15 cuff; correct?
16 A. Yes, I would get -- have to get
17 Cribier to be absolutely sure, but I have no
18 reason to believe that it was any different.
19 Which reference is Cribier, is it
20 1012?
21 Q. Correct.
22 A. So I'm just looking at the drawing,

1 and, yes, it's described. I'm looking at
2 Figure 1 of Cribier, the lower portion covered
3 with a PET cuff.
4 Q. And in the figure that's in
5 Paragraph 109 of Dr. Buller's declaration, you
6 agreed that the whiter material that he has
7 labeled "graft covering" is a graft covering;
8 correct?
9 A. Yes, that's an inner graft
10 covering.
11 Q. And why do you believe it's an
12 inner graft covering?
13 A. Because it's on the inside.
14 Q. On the inside of what?
15 A. Of the frame.
16 Q. Do you agree with Dr. Buller that
17 PET is a type of polyester?
18 A. I don't have any reason to
19 disagree.
20 Q. Do you know that to be true?
21 A. I think so. But as I say, I'm not
22 giving an opinion on the different

1 classification of polymers.
2 Q. Do you agree that PET is a polymer?
3 A. Yes.
4 Q. And I believe from our last
5 deposition, you have personal experience with
6 the Edwards SAPIEN valve; is that accurate?
7 A. Yes.
8 Q. Have you implanted the valve in
9 patients?
10 A. The Edwards SAPIEN, yes, s3, and
11 Ultra, and possibly XT.
12 Q. And do you know the purpose of
13 SAPIEN's PET fabric cuff?
14 A. So all of the inner cuffs, the
15 inner skirts or covers were designed to prevent
16 through-the-frame-flow.
17 Q. Did you say
18 "through-the-frame-flow"?
19 A. Correct, through-the-frame-flow.
20 Q. It's a tongue twister.
21 A. A tongue twister.
22 Q. And when you say

1 "through-the-frame-flow," are you referring to
2 blood flow?
3 MR. LOWENSTEIN: Objection; scope.
4 THE WITNESS: Yes. So when
5 implanted, the purpose of that in a skirt
6 -- I mean, there are other -- there can be
7 other purposes to it as well, but the
8 principal feeling on all of the very early
9 designs was you would have to have an
10 inner skirt because if you just had the
11 valve sewn to the bottom of the frame with
12 no skirt, then given the difficulty in
13 precisely positioning the valve, you could
14 be off by a millimeter and you would then
15 be presenting the blood with a clear flow
16 from aortic route to the left ventricular
17 outflow tract. So it was clear that there
18 was a need for an inner skirt to prevent
19 the flow through the frame.
20 BY MR. STOWELL:
21 Q. Does SAPIEN's fabric cuff prevent
22 leaks between the outside of the frame and the

1 patient's native tissue?
2 A. No, you're -- what you're referring
3 to is the conventional understanding of
4 paravalvular leak. We could get into a whole
5 discussion about how you define that and what
6 the different types are, but if I just classify
7 through the frame and around the frame, this
8 inner skirt does not address around the frame
9 flow.
10 Q. The Edwards SAPIEN valve did not
11 have an outer skirt or seal; correct?
12 A. That's correct.
13 MR. STOWELL: Let's see. We're at
14 about noon and I think we're at a good
15 place to stop. Why don't we break for
16 lunch.
17 MR. LOWENSTEIN: How long would you
18 like?
19 THE REPORTER: Would you like to go
20 off the record?
21 MR. LOWENSTEIN: Yes, let's go off
22 the record.

1 MR. STOWELL: Yes, let's go off.
2 (A recess is held from 11:57 a.m.
3 to 12:49 p.m.)
4 BY MR. STOWELL:
5 Q. Dr. Brecker, why don't we turn to
6 Page 23 of Exhibit 2103. That is your second
7 expert declaration.
8 A. Yes.
9 Q. And on this page we see a picture
10 of the Walther valve; correct?
11 A. Yes.
12 Q. And the Walther valve is a Edwards
13 SAPIEN valve with an outer PET cloth around its
14 exterior; correct?
15 A. Yes.
16 Q. And do you have an opinion
17 regarding how Walther's outer cloth is made?
18 A. Well, there's quite a lot to say on
19 that. So "yes" is the answer.
20 Q. And what's your opinion regarding
21 how Walther's outer cloth is made?
22 A. Well, if we start just with

1 Walther, itself, and I'm looking at the -- the
2 Walther reference.
3 Q. You're looking at Exhibit 1007?
4 A. Yes.
5 (Exhibit 1007, Walther article, was
6 previously marked for identification.)
7 THE WITNESS: So what it says is,
8 an added PET cloth was stitched onto the
9 perimeter of each SAPIEN valve, and it was
10 tested in hypertensive conditions. So
11 this needed to be quite a firm material
12 for the purposes of this paper. I mean,
13 when I say "firm," it needs to be a
14 material with structure and robustness.
15 And we know that woven PET can be this
16 type of cover and we know that fibers
17 emanate from it.
18 Now, part of the description in
19 Walther is the purpose for which this
20 cloth was designed, and that was to
21 enhance sealing, to prevent migration.
22 And, indeed, they tested that and they

1 showed the results in that study.
2 So it's pretty clear that this
3 material would be a woven backing with a
4 fibrous finish. And I've -- I've
5 described that and I've talked about that
6 at in my report.
7 Further information, though, has
8 come to light -- or not come to light, but
9 the -- the authorship of the Walther paper
10 includes a materials expert, someone who
11 has designed exactly these types of
12 materials, cloths for exactly the stated
13 purposes in Dehdashtian. And that --
14 sorry, in Walther. And that person is
15 Mark Dehdashtian. And we have a
16 publication of Mark Dehdashian --
17 Dehdashtian talking about a towel-like
18 graft, a woven structure with fibers
19 emanating from it for exactly the reasons
20 that Walther states this cloth was put on.
21 And that to me is very, very compelling
22 information about the material that is

1 used in the Walther description and very
2 likely contributed to specifically by Mark
3 Dehdashtian.
4 And Mark Dehdashtian says that
5 these fibers that emanate from the outer
6 surface are there to induce tissue
7 ingrowth, encourage tissue ingrowth, and
8 prevent migration of the device that
9 they're put on. And that's exactly what
10 Walther is using it for.
11 So my opinion is that it is very
12 compelling that the material used in
13 Walther is a woven PET base with fibers
14 emanating from the top designed to induce
15 -- from the top surface, the outer
16 surface, designed to encourage tissue
17 ingrowth.
18 BY MR. STOWELL:
19 Q. So looking at the Walther reference
20 specifically, what portion of the reference
21 leads you to believe that the outer cloth has a
22 woven PET base?

1 A. Well, we know that the structures
2 -- this is being put on a valve and it's got to
3 have some structure to prevent emobolization of
4 material from it. So there's -- there is a lot
5 that one can glean from the purpose for which
6 it's used.
7 The cloth is described as PET and
8 it's stitched, so the stitches have to go
9 through. And I believe that that, together with
10 the other reasons I've mentioned, is -- suggests
11 very, very strongly that this is a woven base
12 with fibers emanating from it.
13 Q. Could stitches be used on a knitted
14 material?
15 A. So I've not given an opinion one
16 way or another about that. It is possible.
17 Q. Did you consider whether a knitted
18 outer cloth would satisfy the structural
19 limitations you believe are required by the
20 Walther valve?
21 A. No, I've already stated that a knit
22 base would not preclude a graft. We know that

1 Dr. Buller described Walther's cloth as a velour
2 type of woven PET.
3 Q. So have you ruled out that
4 Walther's outer cloth is knitted?
5 A. I haven't needed to -- I haven't
6 needed to disagree in any way with Dr. Buller.
7 He's testified that the outer cloth is
8 velour-like woven PET, and I agree.
9 Q. What's your understanding of the
10 term "velour-like"?
11 A. So velour is where there are fibers
12 emanating from a base. I mean, the common usage
13 I recall it is in a pile carpet, a velour-type
14 pile carpet.
15 Q. And --
16 A. That was just an illustration. I
17 mean, it's fibers emanating from a base. And I,
18 as I say, I agree with Dr. Buller. That's what
19 I believe Walther to be. I have no reason to
20 disagree with him at all. He said it's woven
21 fibers.
22 Q. And do you --

1 A. And I think it's significant that
2 if he says that, he is instructed by Edwards.
3 And Walther is in -- is in Edwards' possession.
4 Walther's -- this was an Edwards device and
5 these are Edwards offers as it were. So I would
6 have no reason to disagree with that.
7 Q. You believe a pile carpet is
8 velour. Is -- am I understanding your testimony
9 correctly?
10 A. I've not said that. I was using it
11 as an example. I'm not making a definition of
12 velour. I'm explaining my understanding of the
13 term "velour."
14 And I can -- I'd like to go to how
15 I've used it in my declaration. So, I mean --
16 well, I talk about it at 26, 20 -- Pages 26 and
17 27.
18 Dr. Buller's called it a
19 velour-like cloth. In fact, he testified, I
20 think, that Walther and Spenser II were
21 velour-like. As I said, I've agreed with that.
22 There are other references in literature to it.

1 Q. And so is your understanding of the
2 term "velour-like" to simply be the same as
3 Velour?
4 A. No. Velour is velour and
5 velour-like is like velour. I haven't done any
6 form of definition of those terms. I'm using it
7 as one would use English. This is like velour.
8 Q. So in the Walther reference you had
9 identified the stitching as one piece of the
10 reference that made you think that there was a
11 woven PET base.
12 Are there any other -- is there any
13 other disclosure in the Walther reference that
14 leads you to believe that the outer cloth has a
15 woven PET base?
16 MR. LOWENSTEIN: Objection; form.
17 THE WITNESS: So the fact that Mark
18 Dehdashtian is an author is another piece
19 of very compelling circumstantial
20 evidence.
21 BY MR. STOWELL:
22 Q. When you were talking about Mark

1 Dehdashtian earlier, you said it was likely that
2 he had contributed material relating to the
3 cloth.
4 Will you acknowledge that you are
5 speculating regarding whether Mark Dehdashtian
6 contributed the outer cloth material to Walther?
7 MR. LOWENSTEIN: Objection; form.
8 THE WITNESS: I -- I think
9 speculation is way, way, way too weak to
10 describe how I feel.
11 We can go to the Dehdashtian
12 reference. This is someone who at exactly
13 this time period was describing the
14 invention of exactly these type of fabrics
15 for exactly these type of reasons. To
16 think otherwise would be speculating, I
17 think. To me it's very compelling.
18 BY MR. STOWELL:
19 Q. But you'll concede that you don't
20 know that Mark Dehdashtian contributed the
21 structure of the cloth to the Walther reference;
22 right?

1 A. I have not spoken to him. I
2 haven't spoken to Thomas Walther. They're both,
3 as far as I know, alive and well.
4 And this is an Edwards device.
5 I've not seen any evidence at all provided by
6 Edwards to suggest that the material in Walther
7 is not like Mark Dehdashtian describes. He's
8 the second author on the paper, which is a very
9 senior position on the author -- on the
10 authorship. He's not buried in the middle of 20
11 authors. He's the second author. He's -- he's
12 made a significant contribution to this paper.
13 And his field of expertise is not
14 in valve -- the actual valve material or the
15 procedure itself. His expertise is in designing
16 cloths and he's designed a cloth for exactly
17 this reason at the time.
18 Can I be 100 percent sure? Of
19 course not. But where you have two pieces of
20 scientific evidence like this, if you look at
21 Walther and Dehdashtian next to each other, it's
22 so strongly compelling to me that I'm as sure

1 as I -- as I could be just reading the two
2 documents.
3 If someone has made that type of
4 contribution to the literature and they're named
5 on another paper, it is an assumption. It's the
6 natural assumption to -- to think that they've
7 contributed that.
8 Why would they have contributed
9 anything else? Particularly, when the whole
10 thrust of Walther is not about the Edwards
11 SAPIEN valve. It's not about a surgical valve.
12 It's about putting a material on the outside.
13 That's what it's about. To me, it's -- I can't
14 see why anyone wouldn't be compelled in that
15 direction to come to that conclusion.
16 Q. You said that Mark Dehdashtian
17 was -- his expertise was in fabrics and
18 materials.
19 Do you have anything to support
20 that other than the single Dehdashtian patent
21 you've identified in this case?
22 A. Well, we could do a literature

1 search.
2 Q. That wasn't the question.
3 Do you have --
4 A. Not --
5 Q. -- any other support for that
6 statement?
7 A. So I don't have it at my
8 fingertips. I can't give you chapter and verse,
9 but I'd like to have a look at Dehdashtian.
10 Oh, there -- there are several
11 other pieces of prior -- well, I can immediately
12 see two other pieces of prior art with his name
13 on it.
14 And, I mean, if we go -- if you go
15 to the Field of Invention, and it's -- he's one
16 of two inventors and, [as read]: "The present
17 invention, it relates to prosthetic vascular
18 grafts and, more particularly, a vascular graft
19 having an external texture to promote tissue
20 ingrowth into the graft to enhance fixation and,
21 inter alia, preclude perigraft leakage."
22 If you then go to Walther, you see

1 Dehdashtian's name and you read the introduction
2 and you read that there's a concern that
3 expanding a SAPIEN valve in a surgical valve
4 might leave gaps. So you want something to
5 prevent paravalvular leak.
6 And, furthermore, it goes on -- it
7 couldn't be clearer really. The addition of an
8 outer cloth to the SAPIEN cloth valve is
9 designed to reduce paravalvular leak by creating
10 a seal between the two valves and improve
11 resistance to migration. And that is precisely
12 what Dehdashtian -- the purpose of Dehdashtian's
13 patent is, to enhance fixation.
14 Q. Dr. Brecker, you didn't answer my
15 question.
16 Do you have any other authority, as
17 we sit here today, to support your statement
18 that Mark Dehdashtian was -- had his expertise
19 in fabrics and materials?
20 MR. LOWENSTEIN: Objection; form.
21 THE WITNESS: So there are two
22 other citations of Dehdashtian's work

1 which we would have to get to confirm.
2 BY MR. STOWELL:
3 Q. And did you -- did you review those
4 other citations prior to today's deposition?
5 A. I cannot recall. It's obviously a
6 name that I have come across. And he's a author
7 on Spenser II. And the only addition to Spenser
8 II when his name was added was an external
9 material to prevent paravalvular leak and
10 enhance fixation. So there's a -- that's
11 another piece of information.
12 So here with Spenser II, Spenser II
13 is originally written without the outer seal,
14 without the outer material, and without Mark
15 Dehdashtian. And when Spenser II is -- when the
16 patent is issued, Dehdashtian's been added and
17 the outer seal has been added. Again, that's --
18 that's additional compelling evidence.
19 You asked me, sitting here now, was
20 I aware of any other evidence. And, yes, there
21 is another piece of evidence.
22 Q. Other than the stitching mentioned

1 in Walther and Mark Dehdashtian on Walther, is
2 there any other disclosure in Walther that leads
3 you to believe that the outer cloth has a woven
4 PET base?
5 MR. LOWENSTEIN: Objection; form.
6 THE WITNESS: Well, I've already
7 mentioned Edwards' position on it, or
8 Dr. Buller's position for Edwards, that
9 it's a woven structure. And that's --
10 Edwards owns Walther as it were.
11 You could ask me if I was aware of
12 any evidence to the contrary, which if
13 there was evidence to the contrary, one
14 would have expected that to have surfaced.
15 But I just -- I don't have that infor -- I
16 don't have any information to hand that
17 it's not woven.
18 BY MR. STOWELL:
19 Q. Dr. Brecker, you're not answering
20 my question.
21 Other than the stitching --
22 THE REPORTER: I didn't hear that.

1 BY MR. STOWELL:
2 Q. Other than the --
3 MR. STOWELL: Yeah. Okay. Let's
4 start this again.
5 BY MR. STOWELL:
6 Q. Other than the stitching mentioned
7 in Walther and Mark Dehdashtian's name on
8 Walther, is there any other disclosure in
9 Walther that leads you to believe that the outer
10 cloth has a woven PET base?
11 MR. LOWENSTEIN: Objection; form.
12 THE WITNESS: Okay. So we can
13 expand this because there are -- there are
14 very strong implications.
15 We don't get a great view of,
16 or potentially any view of the inner
17 surface of Walther in its disclosures, but
18 we know what was going on at this time and
19 we know that this was with a prototype
20 9000 MIS valve. And we know that there
21 were two other valves with the same
22 prototype around which material was

1 placed. And, in my view, you can see a
2 woven backing layer on them. And so my
3 opinion is that this is a woven backing
4 layer.
5 If you are asking me does Walther
6 actually state the word "woven" in its
7 text? The answer is no. But I have set
8 out the reasons on which I've based my
9 opinion.
10 BY MR. STOWELL:
11 Q. And once again you drifted away
12 from the Walther reference there. So listen
13 carefully to my question.
14 Other than the stitching mentioned
15 in Walther and Mark Dehdashtian's name on
16 Walther, is there any other disclosure in
17 Walther that leads you to believe that the outer
18 cloth has a woven PET base?
19 MR. LOWENSTEIN: Objection; form.
20 THE WITNESS: Probably. I'd have
21 to read it again now to find the other
22 references.

1 It doesn't have the word "woven" in
2 it, but I could -- I could give you other
3 bits of Walther on which I -- which I've
4 used.
5 BY MR. STOWELL:
6 Q. Well, when you rendered the
7 opinions that are in your declaration, were
8 there any other portions of Walther that you are
9 relying on for your statement that Walther has a
10 dense PET base layer?
11 MR. LOWENSTEIN: Objection; form.
12 THE WITNESS: I don't think in my
13 declaration I've set out other evidence
14 from Walther that this was a woven PET,
15 but I just -- just reading through it now,
16 which you've asked me, is there anything
17 else in it...
18 (Reviewing document.)
19 I mean, there -- there is, as I
20 say, strong -- there's strong
21 circumstantial evidence I've outlined.
22 There is the fact that this is described

1 as a cloth. We know what the structure of
2 outer cloths used for this purpose was.
3 This mentions outer cloth designed to
4 prevent paravalvular leak.
5 We know that these were 9000 MIS
6 models. It said it was stitched.
7 As I've said, I could -- I could go
8 on reading it through.
9 BY MR. STOWELL:
10 Q. I'm interested in the portions of
11 Walther that you relied upon in reaching your
12 conclusion that Walther has a PET -- a dense PET
13 base.
14 A. Well, I've -- I've already set out
15 the ones and I'm looking for others. But where
16 the expert witness or the company who owns this,
17 and Walth -- and Walther's PET cloth is in
18 Edwards' ownership, as it were, they say it's
19 woven PET. So I haven't just made that
20 assumption necessarily. I've looked at these
21 other pieces of evidence and I agree with it.
22 Q. You're aware that Dr. Buller

1 disagrees with your statement that Walther's
2 outer cloth has a woven PET base; correct?
3 MR. LOWENSTEIN: Objection; form.
4 THE WITNESS: I have -- I would
5 need to be taken to where he disagrees
6 with that because I think he said that. I
7 thought -- I thought that was said several
8 times in testimony and it's -- it's in my
9 declaration is...
10 BY MR. STOWELL:
11 Q. So part of -- part of the basis for
12 your --
13 A. Well, I'm still reading through.
14 You've asked me to find any -- whatever -- you
15 know, I've read Walther and come to conclusions.
16 You've asked me -- I've set out the evidence on
17 which I've come to my conclusion.
18 You keep asking me to go back to
19 Walther, so I'm doing that now.
20 (Reviewing document.)
21 Q. Yeah. And to be clear, I didn't
22 ask you to go back to Walther. I asked you to

1 identify the portions of Walther that you relied
2 upon in reaching your conclusion that Walther
3 has a dense PET base.
4 MR. LOWENSTEIN: Objection; form.
5 THE WITNESS: Well, other than what
6 I've set out in my declaration, I haven't
7 identified anything else.
8 BY MR. STOWELL:
9 Q. Do you agree that Walther's outer
10 cloth differs from SAPIEN's inner fabric cuff?
11 MR. LOWENSTEIN: Objection; form.
12 THE WITNESS: Well, I haven't
13 actually given an opinion on that specific
14 comparison. SAPIEN's inner material is
15 PET. Walther's material is woven PET with
16 a fibrous finish. So they're not
17 identical in any -- in any -- by any
18 means.
19 BY MR. STOWELL:
20 Q. Do you agree that the thicknesses
21 are different between Walther's outer cloth and
22 SAPIEN's inner fabric cuff?

1 A. Yes, I would agree with that.
2 Q. Would you agree that the densities
3 of the materials are different between Walther's
4 outer cloth and SAPIEN's inner fabric cuff?
5 MR. LOWENSTEIN: Objection; form.
6 THE WITNESS: I don't think I've
7 given an opinion on the comparison of
8 densities.
9 BY MR. STOWELL:
10 Q. Can you give an opinion as you sit
11 here today?
12 MR. LOWENSTEIN: Objection; form.
13 THE WITNESS: I cannot.
14 BY MR. STOWELL:
15 Q. Would you agree that the porosity
16 differs between Walther's outer cloth and
17 SAPIEN's inner fabric cuff?
18 MR. LOWENSTEIN: Objection; form.
19 THE WITNESS: I have not given an
20 opinion on the comparison of the porosity
21 of those two things.
22 BY MR. STOWELL:

1 Q. Can you give that opinion as you
2 sit here today?
3 MR. LOWENSTEIN: Objection; form.
4 THE WITNESS: I have not given an
5 opinion on it and I am not going to do it
6 on the fly.
7 BY MR. STOWELL:
8 Q. Would you agree that the
9 compressibility differs between Walther's outer
10 cloth and SAPIEN's inner fabric cuff?
11 A. So I haven't given an opinion on a
12 direct comparison of those two things.
13 Q. Can you make that comparison today?
14 A. I don't think that would be
15 appropriate for me to do. I haven't given it --
16 I haven't given a comparison of compressibility
17 of those two structures any thought. I wouldn't
18 want to do it on the fly.
19 Q. Did you consider the porosity of
20 Walther's outer cloth when you were giving your
21 opinions in declaration Exhibit 2103?
22 A. So if we go to my declaration, what

1 I'm aware of is the type of material that it is
2 my opinion that Walther is, which is a woven PET
3 with fibrous finish, would have a low porosity.
4 In terms of assuming or rather in terms of
5 coming to the opinion that that is a graft
6 cover, that is one of the features of it.
7 Q. And what are you basing your
8 opinion that Walther's outer cloth would have a
9 low porosity on?
10 MR. LOWENSTEIN: Objection; form.
11 THE WITNESS: So Walther's
12 outer cloth has the stated aim to reduce
13 paravalvular leak and to enhance fixation.
14 And so with those aims in mind, if
15 Walther's outer cloth was very porous or
16 even just porous, it would not prevent
17 paravalvular leak.
18 BY MR. STOWELL:
19 Q. When you're referring to
20 paravalvular leak --
21 A. I haven't --
22 Q. Sorry.

1 MR. LOWENSTEIN: He's not done.
2 He's not done.
3 THE WITNESS: I -- I'm pretty sure
4 Dr. Buller has given similar testimony,
5 that a solution for paravalvular leak at
6 around, or particularly at the time of
7 Walther, would have -- people would have
8 felt it had to have -- that it could not
9 be porous.
10 I'm finished.
11 BY MR. STOWELL:
12 Q. When you're referring to
13 paravalvular leak in this context, are you
14 referring to the conventional definition of
15 paravalvular leak that you talked about earlier?
16 A. I'm referring to it as around the
17 frame. That's putting Walther on -- sorry,
18 putting the cloth around the SAPIEN valve on
19 Walther, it will prevent through-the-frame
20 leakage, but you've obviously got the inner
21 skirt of the SAPIEN valve doing that. So that's
22 not what it's there for. It's there to prevent

1 around-the-frame leakage.
2 Q. How do you know that Walther's
3 outer cloth would prevent through-the-frame
4 leakage?
5 A. I'm sorry?
6 Q. How do you know that Walther's
7 outer cloth would prevent through-the-frame
8 leakage?
9 A. Well, theoretically -- I mean, I'm
10 not quite sure that that question makes sense
11 because you've got an inner -- inner cloth --
12 you have the inner skirt, the inner frame --
13 sorry, the inner skirt of the SAPIEN valve, so
14 the blood that is on the inside and would come
15 through the frame would have to go through the
16 inner skirt, and that's -- there's no blood
17 getting there.
18 There would be, potentially, blood
19 coming over the top of the skirt of SAPIEN. It
20 would then hit the outer skirt or the outer
21 material, and this is a dense, non-porous woven
22 PET, so it wouldn't let -- it wouldn't let the

1 blood through.
2 I'm -- that's my answer to that
3 question.
4 Q. Well, you had testified that
5 "putting the cloth around the SAPIEN valve on
6 Walther, it will prevent through-the-frame
7 leakage." And I'm trying to figure out what you
8 meant -- what you based that statement on.
9 A. Did I not say it would prevent
10 around-the-frame leakage?
11 Q. No. I'm reading it here, "prevent
12 through-the-frame leakage."
13 A. Well, it would prevent
14 through-the-frame leakage above the skirt of
15 SAPIEN 'cause the skirt of SAPIEN would prevent
16 through-the-frame leakage. So the --
17 Q. And --
18 A. -- blood wouldn't get, as it were,
19 through the -- the skirt, the inner skirt of
20 SAPIEN in order to be stopped as it were by the
21 outer skirt.
22 I guess I'm talking about the bit

1 above the inner skirt of SAPIEN.
2 Q. And what leads you to believe that
3 Walther's outer cloth at the point above
4 SAPIEN's outer skirt would prevent
5 through-the-frame leakage at that point?
6 A. So you're asking me why would
7 Walther -- Walther's skirt prevent blood flowing
8 through it?
9 Q. I'm asking you what the basis is
10 for that opinion.
11 A. Because that's the purpose it's
12 there for.
13 Q. Does Walther say that it prevents
14 through-the-frame leakage?
15 A. No, I don't think it does, but, in
16 fact -- I mean, I -- I'm not quite sure what
17 you're getting at.
18 Walther's material is clearly
19 consistent with a velour-like woven PET cloth.
20 And that is -- a dense, non-porous material will
21 prevent blood flowing through it. That's what
22 it was there for and that's the purpose of it.

1 It won't let blood flow through.
2 Now, it prevent -- the intent is it
3 will prevent paravalvular leak around the
4 outside of the frame. It has no need to prevent
5 through-the-frame leakage where the inner skirt
6 of SAPIEN is. But above the inner skirt of
7 SAPIEN, in the areas where the outer skirt is
8 and there's no inner skirt, the -- that outer
9 seal would prevent blood flow through it. And
10 the reason is it's a dense, non-porous, woven
11 PET material.
12 Q. Is every velour-like woven PET
13 cloth non-porous?
14 A. I don't think I've considered that.
15 I mean, I think there are types of PET,
16 certainly, that would be porous if they've got
17 holes in.
18 Q. What is the alleged dense PET layer
19 in Walther's cloth made of?
20 MR. LOWENSTEIN: Objection; form.
21 THE WITNESS: It's woven PET.
22 BY MR. STOWELL:

1 Q. And is it made of PET fibers?
2 A. I've said it's made of woven PET.
3 And if -- if a -- that would be a fibrous
4 material.
5 Q. And so would it be made of fibers?
6 A. Well, woven PET is made of woven
7 PET fibers, yes.
8 Q. Is the fibrous finish on Walther's
9 cloth a dense PET layer?
10 A. So I don't think I've given an
11 opinion on the -- dissecting the different
12 components out. I haven't done any specific
13 exercise on that line when I've considered
14 Walther's cloth. Although, I can see it is made
15 of a woven backing with a fibrous finish and in
16 its entirety, the -- the structure is
17 non-porous.
18 So it depends what you mean by the
19 fibrous finish. You know, if you take -- pull
20 out a couple of the fibers and just have the
21 sparsely distributed fibers from the base, is
22 that component porous? Well, it would be, but

1 I'm not considering it in part.
2 Q. Is the -- the fibrous finish
3 portion of Walther's outer cloth porous?
4 MR. LOWENSTEIN: Objection; form.
5 THE WITNESS: Well, it's -- I think
6 that's the same question.
7 What I've said is you could -- you
8 could separate out the -- the cloth and
9 pull out some of the fibers, the fibers.
10 It depends what you mean by the
11 fibrous finish portion. If you mean if
12 you took those fibers away from the base,
13 or do you mean those fibers on the base?
14 I mean, all I can say is that the
15 structure as a whole when used as a whole
16 with both components is not porous.
17 You could dissect it apart and come
18 up with different properties for different
19 portions, but I haven't done that and I
20 haven't used that as part of any opinion
21 I've given.
22 BY MR. STOWELL:

1 Q. Can fluid flow through the fibrous
2 finish portion of Walther's outer cloth?
3 A. You are just asking the same
4 question in the same way or with different
5 words, and I give the same answer.
6 Q. Do you know whether fluid can flow
7 through the fibrous finish portion of Walther's
8 outer cloth?
9 A. That's the third or fourth time
10 you're asking me and I've said that I don't
11 know. I have not dissected out the different
12 portions. I've considered this as a whole.
13 You could pull a few fibers off of
14 Walther and ask me is that porous, and the
15 answer is, yes.
16 If this fibrous finish portion is
17 compressed down in the model that Walther
18 describes, it's not porous. But how much of
19 that is the fibrous finish and how much is the
20 woven PET base, I've not done that type of
21 analysis.
22 Q. How is the fibrous finish attached

1 to the alleged dense PET layer on Walther's
2 outer cloth?
3 MR. LOWENSTEIN: Objection; form.
4 THE WITNESS: I've not done any
5 analysis of the structure other than
6 to describe what I think it is. I haven't
7 -- I don't think I've addressed in my
8 declaration, if you think I have, please
9 let me know, but I don't think I have
10 actually discussed the structure of it.
11 BY MR. STOWELL:
12 Q. So is it fair to say you don't have
13 an opinion regarding how the fibrous finish
14 portion of Walther's outer cloth is made?
15 MR. LOWENSTEIN: Objection; form.
16 THE WITNESS: Well, other than the
17 description of the velour-like woven PET.
18 So it's velour-like, but the specifics of
19 the manufacture process, I -- I can't give
20 you.
21 BY MR. STOWELL:
22 Q. Do you have an opinion on how

1 velour-like materials are manufactured?
2 A. I haven't addressed that in my
3 report, although there are some references. So
4 I'm looking at Paragraph 48 where Walther's
5 cloth is described as woven-like -- sorry,
6 "velour-like woven PET," and it resembles
7 the material that's used in Hartley.
8 Now, that was a piece of prior art
9 that was distinguished from the claims that
10 we're discussing in application. And the
11 applicant, as I've put here, explained a "velour
12 band would not be free of an outer graft
13 covering." It's a "continuous band of velour
14 material fastened to the graft by stitching.
15 The velour provides loops of fibrous material
16 which can be incorporated into the wall of the
17 lumen into which the graft is placed by fibrous
18 ingrowth."
19 And then from Chu, [as read]:
20 "Velour fabrics adds floating portions of yarn
21 on the surface." And I think in a previous
22 declaration I have a picture from Chu which

1 shows the way the fibers are arranged. And then
2 they can be cut if the fibers extend from the
3 surface.
4 So, I mean, I can't go beyond that.
5 Q. Do you believe that the -- what
6 you've called the fibrous finish on Walther's
7 outer cloth is loops of fibers?
8 A. I don't think I've suggested that.
9 Q. As we -- sorry. Go ahead.
10 A. It -- it's possible some of it is
11 looped, some of it is fibers that end, oh, just
12 are straight. When I say "straight," I mean not
13 looped. I don't mean straight. I mean, some of
14 it may be looped. Some of it may be unlooped.
15 We can't really tell.
16 Q. How is the alleged dense PET layer
17 on Walther's outer cloth attached to the frame?
18 A. Well, we're told in Walther that
19 it's sutured to the frame. I can go back to
20 Walther. I mean, I know it said it's sutured.
21 I just have to find it.
22 Yes, so it's under "Methods."

1 "Bench-top testing specific to the
2 valve-in-valve application was carried out on
3 SAPIEN cloth valves" --
4 THE REPORTER: I'm sorry. Doctor.
5 Doctor. I'm sorry. It's not coming
6 through clear enough with your paper up.
7 THE WITNESS: Sorry. I'm sorry.
8 [As read]: "Bench-top testing
9 specific to the valve-in-valve application
10 was carried out on SAPIEN cloth valves.
11 An added PET cloth was stitched onto the
12 perimeter of each SAPIEN valve."
13 BY MR. STOWELL:
14 Q. Is the dense PET layer carried by
15 the frame in Walther?
16 A. I don't know what you mean by
17 "carried by the frame." I'm sorry. It's --
18 Q. You're not familiar with the term
19 "carried by the frame"?
20 A. The outer -- the cloth material is
21 sutured, stitched to the frame. How is that
22 different to carried by the frame?

1 I don't understand the question.
2 Q. Do you believe stitched by the
3 frame means that the outer cloth is carried by
4 the frame?
5 MR. LOWENSTEIN: Objection; form.
6 THE WITNESS: So I've asked you to
7 clarify it.
8 BY MR. STOWELL:
9 Q. So carried by the frame is used in
10 the '236 Patent claims. And I'm asking you is
11 the dense PET layer carried by the frame in
12 Walther?
13 MR. LOWENSTEIN: Objection; form,
14 scope.
15 THE WITNESS: Okay. So I'd like to
16 look at that in the '236 claims. So
17 you're using a term from a claim and
18 asking me whether Walther practices that
19 or -- I'm not sure what you're asking or
20 where -- can you take me to where it says
21 "carried by the frame"?
22 BY MR. STOWELL:

1 Q. Yeah. If you look down at the
2 bottom of Claim 1 there on the Column 21, it
3 says -- here it refers to "a second portion of
4 fibers carried by the outer frame."
5 You see that?
6 A. Yes.
7 Q. Did you understand what "carried by
8 the outer frame" meant when you read Claim 1?
9 MR. LOWENSTEIN: Objection; form,
10 scope.
11 THE WITNESS: I've not made any
12 definition of the term "carry." I've read
13 it and I've understood it to mean that the
14 second portion of fibers are attached to
15 the outer frame; and I haven't made any
16 limitation or put any further construction
17 on that term.
18 BY MR. STOWELL:
19 Q. And so we can agree that Walther's
20 outer -- or Walther's alleged dense PET layer is
21 attached to Walther's frame; correct?
22 MR. LOWENSTEIN: Objection; scope.

1 THE WITNESS: Well, again, it's --
2 it's as if you're making the different
3 terms highly significant. I'm not. I'm
4 saying Walther's outer skirt is exactly as
5 Walther says, it's stitched to the frame.
6 Now, you can use any number of
7 synonyms, attached or carried in general
8 terms. And I'm not talking about the way
9 it's used in the claims. I'm just using
10 how one would speak about something that
11 is sutured to something else.
12 I haven't read Walther with a
13 particular judgment on the way it's
14 attached, other than it's stitched.
15 BY MR. STOWELL:
16 Q. You don't dispute that Walther's
17 alleged dense PET layer is attached to Walther's
18 outer frame, do you?
19 MR. LOWENSTEIN: Objection, scope.
20 THE WITNESS: In the general usage
21 of the word "attach," no, I don't object
22 to that.

1 BY MR. STOWELL:
2 Q. Does Walther's alleged dense PET
3 layer press against the outer frame when the
4 valve is implanted?
5 MR. LOWENSTEIN: Objection; scope.
6 THE WITNESS: Well, the frame will
7 -- when the frame is expanded, it will
8 press onto that PET layer.
9 BY MR. STOWELL:
10 Q. Does Walther's alleged dense PET
11 layer create a seal against the outer frame?
12 MR. LOWENSTEIN: Objection; scope,
13 form.
14 THE WITNESS: I'd like to see the
15 way that Walther actually describes it.
16 The seal that Walther teaches or this
17 paper describes is between the two valves.
18 So it's between the SAPIEN valve and the
19 surgical valve; and, therefore, the outer
20 cloth of Walther is creating that seal
21 that they describe between the two valves.
22 BY MR. STOWELL:

1 Q. Earlier you testified that
2 Walther's outer cloth would prevent fluid from
3 flowing through the frame higher than the inner
4 skirt.
5 Doesn't that suggest that Walther's
6 outer cloth creates a seal against the frame?
7 A. Well, it's not so much that that
8 does it. It's not so much the point you've just
9 made. It's -- Walther describes the addition of
10 the outer cloth creating a seal between the two
11 valves. That is what it does. It's not because
12 it prevents flow through the frame. That's not
13 the reason that it creates a seal between the
14 two valves. They're separate.
15 Q. So going back to my original
16 question, does Walther's alleged dense PET layer
17 create a seal against the outer frame?
18 A. Well, it doesn't state that
19 explicitly, but the outer frame is part by which
20 you mean the SAPIEN valve, and the --
21 Q. Correct, the outer frame of the
22 SAPIEN valve.

1 A. So it's between the out -- it's
2 between the outer frame of the SAPIEN valve and
3 the inner frame of the surgical valve. That's
4 where the seal is created.
5 Q. And does Walther's alleged dense
6 PET layer on the outer cloth create a seal
7 against the outer frame?
8 MR. LOWENSTEIN: Objection; form.
9 THE WITNESS: That's not what
10 Walther says it does. Walther says it
11 creates it between. It's not to say that
12 it couldn't or that it doesn't, but I'm
13 not reading anything more into it than
14 what Walther says. What Walther says, the
15 seal is between the two valves, and that's
16 how I've read it.
17 BY MR. STOWELL:
18 Q. So is it fair to say that you have
19 no opinion regarding whether Walther's alleged
20 dense PET layer on its outer cloth creates a
21 seal against the SAPIEN's outer frame?
22 A. I don't think I've actually stated

1 that specific point in any opinion I've given so
2 far. I've said that the seal is between the two
3 valves; therefore, it's between the outer frame
4 of the SAPIEN and the inner frame of the
5 surgical valve. That's how I would describe the
6 seal.
7 If you're saying is there a seal,
8 for example, created at any one point in that,
9 the whole thing is sealed between the two
10 valves. That's the aim of the cloth is to seal
11 the space between the two valves.
12 Q. So what additional information
13 would you need to be able to tell whether
14 Walther's alleged dense PET layer on the outer
15 cloth creates a seal against SAPIEN's outer
16 frame?
17 MR. LOWENSTEIN: Objection; form.
18 THE WITNESS: Well, I think
19 you're -- you're asking me to make too
20 much of an interpretation of how this
21 cloth is functioning, to try and dissect
22 out the different bits. It may well make

1 a seal at that point. I mean, there can't
2 be any blood flow down through there.
3 But whether it's exactly as you've
4 described or whether it's just the cloth
5 within the space as a whole, whether --
6 how much of it is the fibrous finish, I
7 haven't given that -- I haven't really
8 thought about where in that space between
9 the two valves the seal is occurring other
10 than to say that for there to be no
11 paravalvular leak there, the whole thing
12 must be sealed as a whole, I'm looking at
13 it.
14 So I don't -- I don't quite know --
15 if you -- if you were to ask me -- another
16 question is: Does the fibrous finish make
17 a seal in the very middle of the frame --
18 of the space itself? Again, I'd give the
19 same answer. I haven't dissected it out.
20 The whole thing is -- is sealed.
21 BY MR. STOWELL:
22 Q. On Page 24 of Exhibit 2103 of your

1 declaration, you have a couple figures. Why
2 don't we pull that up or let me know when you
3 get there.
4 A. Yes, I've got those.
5 Q. Okay. On the bottom picture there
6 are some yellow lines that have been drawn on
7 the figure.
8 Do you see that?
9 A. Yes. They're not coming up on your
10 screen, actually, but they are on my paper
11 image.
12 Q. Oh, I can see them on the screen
13 here, yeah.
14 A. It may just be the --
15 MR. LOWENSTEIN: Yeah, I can't see
16 it either.
17 THE WITNESS: -- the laptop here,
18 but -- yeah, and the bottom figure of Page
19 24 has some illustrative yellow lines
20 drawn on.
21 BY MR. STOWELL:
22 Q. And did you create the yellow

1 lines?
2 A. I didn't do the artwork myself, no.
3 Q. But did you review and approve the
4 yellow lines?
5 A. Yes, the yellow lines are just
6 there to show where I'm looking. I, personally,
7 don't think you necessarily need those yellow
8 lines. I think they're very clearly seen as
9 white lines in the image above and in the image
10 on the opposite page.
11 Q. And what are the -- what's the
12 yellow coloring supposed to signify?
13 A. Just the line is supposed to
14 signify where those -- that dense PET layer is
15 -- is located.
16 Q. And what are the -- what are the
17 breaks --
18 A. Sorry. I haven't -- I haven't --
19 Q. Sorry.
20 A. -- finished.
21 The fact that there were breaks in
22 the lines, there's no significance to that.

1 That's not meant to say, for example, that
2 there's no PET layer there.
3 Q. So why isn't there a yellow line
4 where the breaks are?
5 A. Well, this is just to show the
6 track of this PET layer.
7 Q. What do you mean by "the track"?
8 A. The line that the PET layer makes,
9 the circular -- it's around the outside. It's
10 on the back of the Walther material, and that's
11 where the backing layer is.
12 Q. And did you consider the fact that
13 the yellow line is broken in rendering your
14 opinions in your declaration about Walther's
15 outer cloth?
16 A. I've not attributed any
17 significance to the breaks in the line. If we
18 look over the page, all I say is, "yellow
19 highlighting added."
20 I mean, if you -- it'll be the
21 artist, as it were, has put that there to show
22 where it is. I don't attribute significance to

1 where that line is and where the breaks are.
2 Q. But you reviewed the yellow lines
3 to make sure they're accurate; correct?
4 A. Well, they're accurate in that that
5 is the position of the dense PET layer, correct.
6 Q. Now, if you are incorrect and
7 Walther does not have a dense PET layer, would
8 you agree that Walther is free of an outer graft
9 covering?
10 MR. LOWENSTEIN: Objection; form,
11 scope.
12 THE WITNESS: So I haven't
13 considered that as a -- that Walther's
14 outer layer does not have a backing. I
15 haven't given that -- I don't think I've
16 expressed an opinion on that.
17 BY MR. STOWELL:
18 Q. Looking at these highly magnified
19 photos on Figure 24, does this help --
20 MR. LOWENSTEIN: I think he's on
21 Page 24.
22 BY MR. STOWELL:

1 Q. -- help provide any clarity on how
2 the fibrous finish is attached to the alleged
3 dense PET layer?
4 MR. LOWENSTEIN: Objection; form.
5 THE WITNESS: Sorry. Could you --
6 could you repeat? Did you say how -- does
7 the image help me determine how it's
8 attached?
9 BY MR. STOWELL:
10 Q. Correct. Yeah. Looking at these
11 highly magnified photos on Page 24, does it help
12 provide any clarity for you on how the fibrous
13 finish is attached to the allegedly dense PET
14 layer?
15 A. No, I don't think the figures help.
16 MR. STOWELL: Okay. We've been
17 going another hour. Why don't we take a
18 quick ten-minute break?
19 THE REPORTER: Okay with everyone?
20 MR. STOWELL: Yep.
21 MR. LOWENSTEIN: Yeah, of course.
22 (A recess is held from 1:53 p.m. to

1 2:09 p.m.)
2 BY MR. STOWELL:
3 Q. Dr. Brecker, if Walther's outer
4 cloth is porous, would it be free -- would
5 Walther's outer cloth be free of a graft
6 covering?
7 MR. LOWENSTEIN: Objection; form.
8 THE WITNESS: So that's not --
9 that's not a -- the only definition.
10 That's not -- I haven't defined graft
11 cover. I've said that if something is
12 non-porous, woven PET dense, then it's a
13 graft cover, no holes.
14 I've not -- I've not defined all
15 the other possibilities. When I look at
16 structures like the fibers in the
17 '236 Patent or, for example, the Ultra
18 skirt, I see sparse distribution and
19 holes. And that's free. That's not a
20 graft cover.
21 So beyond that, I've not given
22 specific opinions about if this material

1 had this property, would it be a graft
2 cover; or if that material had that
3 property, would it be. I haven't done
4 that analysis.
5 BY MR. STOWELL:
6 Q. So you don't have an opinion
7 whether if Walther's outer cloth was porous,
8 would it be free of an outer graft covering?
9 MR. LOWENSTEIN: Objection; form,
10 scope.
11 THE WITNESS: I have not given an
12 opinion on it. I haven't considered that.
13 BY MR. STOWELL:
14 Q. In your declaration, Exhibit 2103,
15 at Page 25, in the first paragraph you refer to
16 a "conventional densely woven PET cloth."
17 You see where I am? It's about the
18 fifth line down.
19 A. Yes.
20 Q. What did you mean by
21 "conventional"?
22 A. Just the standard use of the word.

1 I haven't applied any particular meaning to it.
2 Q. So you're using the plain and
3 ordinary meaning of conventional in that phrase?
4 Is that what you're saying?
5 A. I wouldn't even go so far as to try
6 and give it a significance other than to say
7 this is -- this is consistent with my
8 understanding that typical densely woven PET
9 cloth.
10 I mean, I -- I don't want to give a
11 dictionary definition. I'm just -- or give it
12 any significance. It may seem to be too
13 significant a word. I'm just saying my
14 understanding of typical, communal garden,
15 conventional densely woven PET cloth.
16 Q. And when you're talking about these
17 typical cloths, were you referring to the 2012
18 time period?
19 A. Yes. All of the opinions are based
20 on a 2012 time period.
21 Q. And so in 2012, there were
22 conventional, densely woven PET cloths; is that

1 accurate?
2 A. Well, you're -- you're attributing
3 more significance to the word "conventional"
4 than I've intended. Let's say standard.
5 Q. Okay.
6 A. Or I want to just use -- maybe
7 even this is consistent with my understanding
8 that densely woven PET cloths constitute graft
9 covering. It's just the typical cloth.
10 Q. And so in 2012, there were typical
11 densely woven PET cloths?
12 A. There were densely woven PET
13 cloths, but -- around this time. I mean, you're
14 -- again, you're -- you're pinning it to a
15 particular date and asking what -- was this a --
16 what is a conventional densely woven PET cloth
17 in 2012. I think this is probably more
18 significance than I'm intending.
19 What I'm -- what I'm trying to get
20 across is the description of a densely woven PET
21 cloth as being something I recognize as the
22 standard sort of densely woven PET cloth that

1 was in use in medical practice.
2 Q. Is SAPIEN's inner fabric cuff an
3 example of a conventional or standard densely
4 woven PET cloth?
5 A. So, again, I would want to go to
6 Cribier and just see how it is described. It's
7 described as PET. There's not -- I don't think
8 they describe it as anything in particular.
9 They just say it's a PET cuff.
10 (Reviewing document.)
11 Yeah, I don't -- I don't think
12 there's anything unusual about the PET cuff of
13 the Edwards SAPIEN valve.
14 Q. And so is SAPIEN's inner fabric
15 cuff an example of a conventional or standard
16 densely woven PET cloth as you use that term in
17 your declaration?
18 A. I would think this is a -- this is
19 a typical PET cloth, densely woven, low
20 porosity, yes.
21 Q. Is Walther's outer cloth an example
22 of a conventional densely woven PET cloth?

1 MR. LOWENSTEIN: Objection; form.
2 THE WITNESS: Hold on. Let me just
3 put this one back, otherwise, I've got so
4 many out at the moment that I'm going to
5 drown in them.
6 Right. So I'm now looking at my
7 declaration, the top of Page 25 where I
8 say it. Let me just read this.
9 [As read]: I note that Dr. Buller
10 acknowledges that graft material can be
11 made of polyester, includes PET, relies on
12 a dense PET cloth as the claimed inner
13 graft covering. This is consistent with
14 my understanding that a conventionally --
15 a conventional densely woven PET cloth
16 constitutes a graft covering. I
17 understand Dr." -- let me just read
18 through this.
19 (Reviewing document.)
20 Okay. And, sorry, your question
21 was?
22 BY MR. STOWELL:

1 Q. Is Walther's outer cloth an example
2 of a conventional densely woven PET cloth?
3 A. Well, not in its entirety because
4 Walther is velour-like woven PET and, therefore,
5 has this fibrous finish on it, which the type of
6 cloth that's used for the Cribier in a skirt
7 does not have.
8 Q. Would Spenser II's outer
9 compressible material be a conventional densely
10 woven PET cloth?
11 A. Well, then we have to -- no,
12 because that also, on my opinion, is likely to
13 be the type of cloth described by Dehdashtian.
14 It's got fibers emanating from the surface. And
15 Dehdashtian describes a towel-like graft with
16 fibers from the outer surface.
17 Q. Would Levi's outer skirt be a
18 conventional densely woven PET cloth?
19 MR. LOWENSTEIN: Objection; form.
20 THE WITNESS: So Levi's outer skirt
21 is more akin to a densely woven PET cloth.
22 It doesn't have the fibrous finish.

1 BY MR. STOWELL:
2 Q. You say "more akin."
3 A. Yes.
4 Q. How does it differ from a
5 conventional densely woven PET cloth?
6 A. Well, I haven't -- as I say, I
7 haven't defined "conventional." I'm not
8 attributing significance to the word
9 "conventional."
10 Walther's -- sorry. Levi's PET
11 cloth -- I mean -- or the -- the cover -- I
12 would like to just get Levi and have a look at
13 it while I'm -- I have -- I don't think I've got
14 that one. I'm not sure.
15 What number is it?
16 Q. 1008.
17 MR. LOWENSTEIN: 1008.
18 THE WITNESS: Sorry?
19 BY MR. STOWELL:
20 Q. 1008.
21 A. I have it. Okay.
22 (Exhibit 1008, United States Patent

1 No. 9, 393,110 B2, was previously marked
2 for identification.)
3 Easier on here.
4 So it's described as the outer
5 skirt.
6 All right. So I don't -- I mean,
7 there may be features about Levi's design.
8 It's certainly a dense PET.
9 Q. You're not able to say today,
10 though, whether it's a conventional densely
11 woven PET cloth?
12 MR. LOWENSTEIN: Objection; form.
13 THE WITNESS: Well, you're --
14 you're asking me to attribute some
15 significance to the term "conventional."
16 And other than saying that the outer skirt
17 of Levi is in my opinion a graft cover, I
18 haven't gone further than that.
19 BY MR. STOWELL:
20 Q. And I'm not asking you to attribute
21 any significance. I'm just using the words that
22 you used in your own declaration and trying to

1 figure out what you meant by them.
2 Are you able to say today whether
3 Levi's outer skirt is a conventional densely
4 woven PET cloth?
5 A. I haven't -- I haven't considered
6 whether there are additional features of Levi
7 that might make it a slightly unusual form of
8 PET. I -- I have not -- what I would say is
9 simply that it is a -- a graft cover. It's a
10 densely woven PET, low porosity cover, outer
11 skirt. I'm just looking at the screen.
12 No, I -- I haven't given specific
13 analysis of the type of PET of the Levi skirt
14 over and above it being dense and a graft cover,
15 and fulfilling the requirements of a graft cover
16 as I believe the Board did.
17 Q. Are there other products that were
18 available in 2012 that you consider as having a
19 conventional densely woven PET cloth?
20 MR. LOWENSTEIN: Objection; form,
21 scope.
22 THE WITNESS: Yeah, I have -- I

1 haven't gone into that in my -- in coming
2 to the opinions for this -- for this IPR.
3 BY MR. STOWELL:
4 Q. But based on your experience in the
5 industry around that time frame, 2012, can you
6 think of any products that you worked with that
7 would have a conventional densely woven PET
8 cloth?
9 MR. LOWENSTEIN: Objection; form,
10 scope.
11 THE WITNESS: Well, other than the
12 ones we've been discussing? I mean,
13 there --
14 BY MR. STOWELL:
15 Q. Correct.
16 A. Well, there were stent grafts made
17 of woven PET, densely woven pet. I -- I can't
18 -- I haven't given that thought or I haven't
19 used that in coming to any opinions.
20 Q. You mentioned stent grafts. Are
21 you thinking of any particular models of stent
22 graft?

1 A. No, not a particular one.
2 Q. Let's go to Page 44 of Exhibit
3 2103.
4 MR. LOWENSTEIN: I'm sorry. You
5 said page or paragraph?
6 THE WITNESS: Page 44.
7 BY MR. STOWELL:
8 Q. You begin Paragraph 62 by saying,
9 "I have been informed."
10 What were you informed of?
11 A. That Mark Dehdashtian had produced
12 a piece of -- had produced a patent that we --
13 well, I had not been aware of before. I was
14 aware that he was second author of Walther's
15 paper and I was also aware that he was an
16 inventor of Spenser II. Those, I was aware of.
17 What I was informed about were two
18 things. Number one, that he produced the
19 Dehdashtian patent; and, secondly, although I
20 would have been aware of it, but not necessarily
21 in the forefront of my mind, there had been a
22 addition to Spenser II between the application

1 and the publication, and that addition was the
2 addition of Mark Dehdashtian and Figure 22 with
3 the outer cloth.
4 Q. And who informed you of this
5 information?
6 A. This was the lawyers for AI in
7 Lowenstein & Weatherwax.
8 Q. When were you informed of the
9 information?
10 A. I can't -- I can't remember
11 actually. It was -- it's after my previous
12 deposition.
13 Q. How were you informed of the
14 information?
15 A. Probably by e-mail, I would think.
16 I can't be a hundred percent sure that we hadn't
17 had a discussion, but probably by e-mail.
18 Q. And prior to this probable e-mail
19 exchange, you were not familiar with the
20 Dehdashtian patent, Exhibit 2101; correct?
21 A. Correct. I was familiar with the
22 name and the authorships, but not that specific

1 patent.
2 Q. And the e-mail you received with
3 this information, who -- who initiated that
4 e-mail exchange?
5 MR. LOWENSTEIN: Objection; form.
6 THE WITNESS: Again, I can't tell
7 you with a hundred percent certainty. My
8 suspicion is it was either Mr. Lowenstein
9 or Mr. Katz, but I -- I honestly can't be
10 a hundred percent sure who it was. I
11 think it was one of them.
12 BY MR. STOWELL:
13 Q. Let's turn to Page 92 of Exhibit
14 2103.
15 A. Yes.
16 Q. In Paragraph 148, you make a
17 statement that, "Ultra includes a translucent
18 outer skirt."
19 In this paragraph you're referring
20 to the SAPIEN 3 Ultra device; correct?
21 A. Yes, that's correct.
22 Q. And what do you mean by

1 "translucent"?
2 A. That you can see through it.
3 Q. Is that the definition that you've
4 applied to translucent when you used it here?
5 A. I've just used translucent in the
6 way that it would be used in standard common
7 usage. I haven't applied a scientific
8 application to it. Some -- if something is
9 translucent, you can see what's on the other
10 side of it.
11 Q. Well, translucent actually means
12 that it allows -- the translucent material
13 allows the passage of light, but it's not clear
14 what lies beyond the material.
15 Is that consistent with your
16 understanding and the meaning of translucent?
17 MR. LOWENSTEIN: Objection; form.
18 THE WITNESS: Again, it may be that
19 there's too much significance being placed
20 on my use of the term "translucent."
21 What I've been -- what I wanted to
22 convey in that paragraph is that the outer

1 skirt of SAPIEN 3 Ultra is such that you
2 can see the frame beneath it.
3 BY MR. STOWELL:
4 Q. And when you -- when you say "see
5 the frame," do you mean see the frame clearly?
6 A. I've not given a construction on
7 "see."
8 If I -- so when I look at some of
9 these structures, like Walther and Spenser II,
10 you cannot see what is underneath. When I pick
11 up an Ultra, I can see what's underneath the
12 skirt. I can see the frame.
13 Q. Why did you call out translucence
14 in Paragraph 148?
15 A. What do you mean by "call out"?
16 Use? Why did I use that word?
17 Q. Sure.
18 A. I was merely trying to express that
19 you could see the frame underneath the skirt.
20 Q. Is there any connection between
21 translucent and the properties of a graft
22 covering as claimed in the '236 Patent?

1 A. Okay. Let me go to the '236 Patent
2 claims.
3 (Reviewing document.)
4 And your question again, sorry,
5 was?
6 Sorry. Your question was?
7 Q. Yeah. Is there any connection
8 between being translucent and the properties of
9 a graft covering as claimed in the '236 Patent?
10 A. Well, I'm reading the claims of the
11 '236 Patent.
12 (Reviewing document.)
13 The '236 Patent has openings
14 extending through the thickness created by
15 spacing formed between adjacent fibers. The
16 fibers are not a graft cover and the claim is
17 free of an outer graft cover.
18 The material from Ultra that's used
19 in Ultra has holes. You can see through it.
20 You can see what's underneath it. And that to
21 me isn't a graft cover.
22 I've -- I don't think that I'm

1 necessarily thinking that the word "translucent"
2 -- I may not be using it in any construction or
3 any defined way.
4 I certainly agree with Dr. Buller
5 that Ultra -- the skirt is porous. It's a loose
6 fabric. There are holes that go all the way
7 through it. And I would agree with him that
8 it's not a -- not a graft cover. So I think
9 we're agreed on that.
10 When I'm describing it in that
11 paragraph, I'm merely -- what I'm trying to say
12 is there are holes through which you can see
13 what's below, what -- and you can see what's
14 behind it.
15 Q. Is it a requirement for a graft
16 covering to be not translucent?
17 A. Well, I think if -- when I consider
18 a graft cover, I consider all of the properties.
19 I can recite them again. Low porosity, dense,
20 wouldn't see through it.
21 Again, in terms of dissecting out
22 each of these properties and saying, well, if

1 you had a material, a hypothetical material that
2 was dense and non-porous, but you could see
3 through it, would that be a graft cover? I
4 haven't done that type of analysis.
5 I know what is a graft cover and I
6 know what is not a graft cover. And something
7 that is loosely put together, sparse
8 distribution of fibers, holes, and you can see
9 through it, that's not a graft cover.
10 Something that is densely woven,
11 not porous, can't see through it, that's a graft
12 cover.
13 Q. Whether an object is translucent
14 depends on the light surrounding the object;
15 correct?
16 A. I have not got into a definition of
17 the word "translucent."
18 Q. Whether an object --
19 MR. LOWENSTEIN: (Inaudible.)
20 THE WITNESS: I'm not --
21 MR. LOWENSTEIN: Go ahead.
22 THE REPORTER: I'm sorry. I didn't

1 hear that.
2 MR. LOWENSTEIN: I was just asking
3 the Witness to finish his answer.
4 THE WITNESS: I'm not using the
5 word in any way other than to convey that
6 I can see through the material.
7 Yeah, obviously, you have to have
8 some light to be able to see anything.
9 BY MR. STOWELL:
10 Q. And whether an object is
11 translucent also varies based on whether it's
12 wet; correct?
13 A. I've not given an opinion on that.
14 I think some fabrics will behave differently to
15 others in regard to that question. I've not
16 given an opinion on wet or not wet.
17 Q. The translucence of an object can
18 also change based on how much it's compressed;
19 correct?
20 A. Again, as a general question in a
21 vacuum in the ether, I would suspect that -- I
22 can think of examples of materials that you can

1 see through, but if you scrunch them up into a
2 ball, you can't. But beyond that, I'm not
3 making any type of judgment or opinion.
4 Q. The '236 Patent does not discuss
5 the translucence of any covering material or the
6 collagen fibers; correct?
7 A. So the '236 Patent shows clearly
8 the very sparse distribution of fibers that you
9 can see very clearly the structure underneath.
10 And the figures that show that very clearly are
11 Figure 8, Figure 9, and Figure 20. There may be
12 others, but clearly Figure 13 and 14, Figure 11,
13 Figure 12. All of those show that you can see
14 what's underneath. And that's the point I was
15 making.
16 Q. Does the '236 Patent require the
17 outer fibers to be arranged so that you can see
18 the inner frame?
19 MR. LOWENSTEIN: Objection, scope.
20 THE WITNESS: So I've not given an
21 opinion on that.
22 What I can say is that the claims

1 of the '236 Patent, Claim 3 indicates [as
2 read]: "The first portion of fibers
3 defining an opening extending through a
4 thickness thereof that is created by
5 spacing formed between fibers -- adjacent
6 fibers."
7 And Claim 4 goes further to say [as
8 read]: The second portion of fibers
9 opening is defined through a thickness and
10 the spacing -- the -- sorry, the opening
11 extends to the outer frame. So that to me
12 is fairly clear.
13 BY MR. STOWELL:
14 Q. Are you interpreting the term
15 "opening" in Claim 4 to require an opening that
16 is large enough to see the frame?
17 A. Well, I'm -- I deal with this in my
18 declaration, so we should go to that because
19 I show what I mean by "opening." It will be in
20 one of those paragraphs, I think, that I
21 corrected the typo of this morning. Maybe 139.
22 Yeah, so looking at Figure 13, one

1 would be able to see through that. And then all
2 of those other figures that I cited earlier, you
3 would be able to see.
4 The claim doesn't say the words,
5 but when you read the claim, opening extending
6 to the outer frame, and then you look at the
7 figures, I think a POSITA would have that --
8 would have that clear understanding.
9 If you picked up that object, you
10 would be able to see the frame.
11 Q. Let's go to Pages 93 and 94 of your
12 declaration. These are also part of Paragraph
13 148.
14 A. Yes.
15 Q. And why did you select the pictures
16 that we're seeing on Pages 93 and 94?
17 A. Some were selected. Some I
18 selected.
19 Q. And why did you include these
20 pictures on Pages 93 and 94?
21 A. Well, they're representative
22 pictures.

1 Q. And is it your position that in all
2 of these figures you can see the frame through
3 the outer seal?
4 A. Yes, these -- these show that you
5 can see the frame. Some more clearly than
6 others, but you can see the frame in all of
7 them.
8 Q. And --
9 A. Obviously, not -- not the one of
10 the material, itself.
11 Q. And in Figure 1, which is in the
12 upper left-hand corner of Page 93, you believe
13 you can see the frame through the outer skirt in
14 that picture?
15 A. Yes, I'm looking at a paper image.
16 I think it doesn't show so clearly in that image
17 on the screen, but you can -- you can certainly
18 see it on the paper -- the paper photo that I'm
19 looking at.
20 Q. And you believe the level of
21 visibility of the frame in that picture is --
22 suggests that there is no outer graft covering;

1 is that correct?
2 A. I wouldn't just use that picture.
3 I mean, when I pick up Ultra and look at it, I
4 can see the frame.
5 So when I have a valve in my hand
6 before it's put into a patient, I can see the
7 frame.
8 Q. We were talking about openings a
9 minute ago. Where does the '236 Patent describe
10 the required size of the openings?
11 A. So I'm looking at Paragraphs 1 --
12 again, 139, 140, 141, and 142. So I'm reading
13 the claims. I'm reading the specification. I'm
14 looking at the images.
15 And if you look, the other piece of
16 evidence is the prosecution history.
17 The specification and the prosecution history
18 clearly, to me, bring me to the view that these
19 openings are larger. They're purposeful.
20 They're by design.
21 They're not just inherent spaces
22 that would lie between two adjacent fibers in

1 any fabric. These are spaces that are created
2 for a reason, and that's -- that's what I've
3 demonstrated. That's what I've set out.
4 Q. You say "relatively large
5 openings." What do you mean by "relatively
6 large"?
7 A. I haven't put a size on it. I
8 haven't put a number on it.
9 Q. Does the '236 Patent put any sort
10 of limitations on the required size of the
11 openings?
12 A. There's no measurement in the
13 '236 Patent, but you could get a sense, an
14 approximate, a sense. I'm not saying you would
15 measure it with a -- a caliper, but you get a
16 sense of the size of those openings from the
17 Figure 13 that you're showing.
18 Q. And how would you do that?
19 A. Well, you know a very approximate,
20 ballpark range of the size of that structure.
21 Q. And so if you take --
22 A. I've not -- I've not -- I've not

1 put numbers on any of this.
2 Q. You haven't done the analysis where
3 you use the approximate size of the frame to
4 identify the size of the openings?
5 A. I have not done that, no.
6 Q. And do you believe that Figure 13
7 is to scale and the spacing of the openings can
8 be reliably determined from it?
9 MR. LOWENSTEIN: Objection; form,
10 scope.
11 THE WITNESS: No, I don't think you
12 can read anything more than a
13 representation and get a sense. And that
14 representation and sense is that these are
15 purposeful, intentional, relatively large
16 gaps.
17 BY MR. STOWELL:
18 Q. You're saying "intentional." What
19 do you mean by "intentional"?
20 A. They are there by design. They are
21 not just the inherent separation between two
22 adjacent structures.

1 Q. And so if I were to weave an outer
2 cloth with loops extending from the base layer,
3 are the spaces between those loops intentional?
4 A. Well, you've asked such a general
5 question. It's difficult to know what you mean.
6 If you say to me, "If I take up a
7 piece of woven cloth, are spaces engineered in
8 between the two," if the idea is that the fibers
9 abut one another, then, no. If you've got a
10 cloth with a hole in it, then, yes.
11 But what I've said is that these
12 are relatively large. They're by design.
13 They're not just an inherent separation, as
14 you -- as it were between two adjacent fibers in
15 a bit of fabric.
16 That -- that is not what is
17 intended by the claim. It's not how any
18 cardiologist would read that claim, and
19 particularly so when looking at the -- the
20 figures, the specification, et cetera.
21 Q. You're saying the openings need to
22 be by design. Where is that explained in the

1 '236 Patent?
2 A. So this is what's in the -- in the
3 claims. It says -- it's actually claiming, the
4 first portion of fibers defines an opening. So
5 those fibers have been designed in their
6 arrangement to define an opening that extends
7 through a thickness that is created, created,
8 designed by spacing formed between adjacent
9 fibers.
10 And I could do the same with Claim
11 4. These are openings that are created,
12 designed by spacing formed between fiber --
13 adjacent fibers wherein the opening extends to
14 the outer frame.
15 Q. And so to determine whether a cloth
16 meets the limitations in the '236 Patent claim,
17 you would need to know the intent of the
18 designer; correct?
19 MR. LOWENSTEIN: Objection; form,
20 scope.
21 THE WITNESS: Not necessarily.
22 BY MR. STOWELL:

1 Q. Why not?
2 A. I haven't --
3 MR. LOWENSTEIN: Objection; form,
4 scope.
5 THE WITNESS: I haven't considered
6 that in coming to my opinions. Would you
7 have to know the in -- do you mean the --
8 the intentions of the designer? You very
9 rarely know that when you read a patent.
10 Occasionally, you do.
11 Here it's pretty clear, but it's
12 not -- it's not an absolute requirement.
13 It might be very obvious.
14 BY MR. STOWELL:
15 Q. Well, you're saying the openings
16 must be intentionally created. How would you
17 know if the openings are intentionally created
18 without knowing the intent of the designer?
19 MR. LOWENSTEIN: Objection; form,
20 and scope.
21 THE WITNESS: Well, you can tell
22 that the claim -- that the openings are

1 intentionally created by reading Claims 3
2 and 4. You can see that the openings are
3 intentionally created when you look at
4 Figure 13.
5 Now, the whole purpose of this
6 design was to have something that would
7 crimp to a low profile. But you don't
8 need to know that the purpose is to crimp
9 to a low profile to know that those
10 openings are not there just by accident or
11 inherency.
12 BY MR. STOWELL:
13 Q. Does the '236 Patent specification
14 talk at all about how the openings need to be
15 created by design?
16 A. I'd have to have a look at it.
17 '236.
18 I'm just looking through the
19 specification of '236. So I don't believe there
20 is text within the specification that states
21 that the openings are there by design, but there
22 doesn't need to be in my opinion. If you read

1 the claims and look at the figures, you would
2 know that that is not just an accidental
3 opening, that -- that it's claiming that there's
4 an opening there.
5 If this were something that were
6 just present in any design of fibers, how would
7 -- why -- why and how would you make a claim for
8 it?
9 Q. That's a good question.
10 A. So --
11 MR. LOWENSTEIN: Are you finished?
12 Are you done with your answer?
13 THE WITNESS: No.
14 So any object could be reduced to
15 its molecular structure, and you could say
16 there are spaces between the molecules by
17 inherency. That's not what I'm talking
18 about. Any piece of fabric would have
19 spaces between the fibers however it was
20 produced. That's not what I'm talking
21 about and that's not what the patentee is
22 talking about.

1 The patentee is talking about an
2 opening that's created by spacing fibers
3 apart. That is an intentional design.
4 It's -- it's as clear as anything to me
5 and totally different to something that
6 was unintentional or inherent.
7 BY MR. STOWELL:
8 Q. Are you reading in Claim 3, for
9 example, the term "defines" to mean design?
10 A. No, not necessarily.
11 Q. And you'll agree that Claims 3 and
12 4 do not say "intentionally created," do they?
13 A. There is no word "intentional" in
14 Claims 3 and 4, but I can't see how else you
15 would get an opening extending through a
16 thickness that is created -- there's the word, I
17 think -- by spacing formed by adjacent fibers.
18 There's another aspect to it that
19 we haven't discussed, and that's the prosecution
20 history where the applicant had to clarify
21 exactly this point, and what was claimed was the
22 spacing between segments or groupings of fibers

1 as shown in Figure 13.
2 Q. Well, let me ask you about that.
3 What the applicant said was that
4 the applicant is -- is claiming is spacing
5 between segments of some fibers; correct?
6 A. Yes.
7 Q. And so what is a segment of fibers?
8 A. I would say just a grouping of
9 fibers.
10 Q. So on Page 89 of your declaration,
11 it looks like there's a blown-up portion of a
12 figure from the '236 Patent; is that correct?
13 A. That says Figure 10. Whether it's
14 -- it's not from Figure 10 from the '236 Patent.
15 So this is, obviously, a figure
16 from the application, I would image. Oh, it's
17 the '834 Patent. I'm sorry. So it might be
18 figure -- I don't have that document.
19 MR. LOWENSTEIN: Well, we'll get --
20 (inaudible).
21 THE REPORTER: Mr. Lowenstein, I
22 can't hear you.

1 MR. LOWENSTEIN: I just asked my
2 colleague if there's a way to get a copy
3 of Exhibit 2114.
4 THE WITNESS: So 2114 is the '834.
5 MR. LOWENSTEIN: Perhaps, Josh, you
6 could e-mail it. Is that -- is that the
7 best way to do it or...
8 MR. STOWELL: I'm going to ask him
9 about what's in his declaration.
10 BY MR. STOWELL:
11 Q. Do you have an understanding of
12 where the picture in your declaration at Page 89
13 came from?
14 A. I think it's from the -- during the
15 prosecution of '83 -- Patent '834, Figure 10.
16 Q. And do you think this segment that
17 is a segment of this figure that's shown on
18 Page 89 appears anywhere in the '236 Patent?
19 A. I don't think that specific figure
20 'cause I did look, and I don't think -- I mean,
21 it's possible that, actually, it's from Figure 8
22 in '236. I -- I can't be sure.

1 Q. Okay.
2 A. I -- or Figure 9. It's possible.
3 I'd have to -- I'd have to have a closer look at
4 it. I think the -- I've just used the figure as
5 is shown, Figure 10, from that application or
6 patent. I'm just trying to see -- I'm just
7 looking at patents of fibers.
8 It could be from Figure 11. It
9 looks like it might be Figure 11 or -- well, no.
10 No. Maybe Figure 12. I'm -- yeah, it actually
11 looks more like Figure 12 from the '236.
12 Yeah, I think that's from Figure 12
13 of '236.
14 Q. Okay. And in this picture on
15 Page 89 of your declaration, there appear to be
16 little bundles or groupings of fiber along the
17 length of the stent; is that correct?
18 You understand what I'm referring
19 to?
20 A. Yes.
21 Q. And are you referring to those
22 bundles or groups as segments in Paragraph 141?

1 MR. LOWENSTEIN: Objection; form,
2 scope.
3 THE WITNESS: So I've -- I would
4 use -- the word "groupings" maybe is a
5 more easily understood term than
6 "segments."
7 BY MR. STOWELL:
8 Q. Is it your understanding that
9 during the prosecution of the '834 Patent, when
10 the applicant used the term "segments" it was
11 referring to the groupings of fibers?
12 MR. LOWENSTEIN: Objection; form,
13 scope.
14 THE WITNESS: So I think that is
15 how I've interpreted it. I can't -- I
16 can't tell you, sitting here now, without
17 going back to that document as to what was
18 actually stated. But how I've understood
19 it is it's spacings between groupings and
20 fibers.
21 BY MR. STOWELL:
22 Q. You'll agree that within each

1 grouping there are a number of individual
2 fibers; correct?
3 MR. LOWENSTEIN: Objection; form,
4 scope.
5 THE WITNESS: All right. Between
6 -- sorry. Within groupings of fibers
7 there are multiple fibers.
8 BY MR. STOWELL:
9 Q. And there are spaces that we can
10 see between the fibers in the groups; correct?
11 MR. LOWENSTEIN: Objection; form,
12 scope.
13 THE WITNESS: Yes.
14 BY MR. STOWELL:
15 Q. Would those spaces between the
16 fibers within the group meet the limitations in
17 Claims 3 and 4 of the '236 Patent?
18 A. I don't think they would.
19 Q. Why not?
20 A. Well, the claims are that it has to
21 be a portion of fibers that defines an opening
22 extending through a thickness that is created by

1 spacing formed between adjacent fibers. So I
2 don't read that as the spacing between each
3 fiber, one fiber and the next fiber. I would
4 read it as between groupings of fibers.
5 Q. And so what -- what --
6 A. So I've got this document, which
7 I've referred to, it's Exhibit 2114. Could I
8 just take a moment to read this?
9 Q. Sure. You may read it.
10 A. (Reviewing document.)
11 So this document goes into it in
12 some more detail.
13 Q. You are reading Exhibit 2114?
14 A. 2 -- 2114.
15 Q. And are you at Pages 140 to 142?
16 A. I've got Page 8 of 10 at the
17 bottom. This is 211 -- or 141.
18 What the applicant is claiming is
19 the spacing between segments of fibers to mimic
20 the general language of the claims. The second
21 plurality of fibers defines a spacing extending
22 through a thickness thereof.

1 The spacing allows for inward
2 deflection and compression of the fibers when
3 the frame is expanded to fill any voids within
4 the annulus and the seal formed by the fibers.
5 This is well-illustrated in the images shown in
6 the deployed device.
7 So this is the evidence of the
8 design intent of having these spacings, which is
9 to allow inward deflection and compression of
10 the fibers. There's other advantages.
11 And then it's not just that figure
12 that I've duplicated in my report. There's
13 another figure, which clearly shows the spacing
14 is from Figure 11, and it makes it very clear.
15 Actually, just looking at this, I
16 think that that Figure 10 in my report is a typo
17 because the application says Figure 12. And I
18 think we identified it as being from Figure 12.
19 So that is a typo on Page 89, I think, as shown
20 in annotated Figure 10. And that should be
21 Figure 12.
22 And then there is a further

1 annotation in document Exhibit 2114, showing the
2 spacing between the groupings of fibers as the
3 spacing that's intended, not the spacing between
4 the individual fibers in each group.
5 Q. Have you seen Exhibit 2114 before
6 today?
7 A. Yes.
8 Q. Okay. And you testified that --
9 that Claim 3 of the '236 Patent would not cover
10 the spacing between the fibers within a group of
11 fibers.
12 What portion of Claim 3
13 specifically wouldn't be covered?
14 MR. LOWENSTEIN: Objection; form,
15 scope.
16 THE WITNESS: Well, I think pretty
17 much the whole claim.
18 BY MR. STOWELL:
19 Q. Is there -- in the group -- within
20 the grouping of fibers, are there portions of
21 fibers?
22 MR. LOWENSTEIN: Objection; form --

1 THE WITNESS: Well, portion --
2 MR. LOWENSTEIN: -- scope.
3 THE WITNESS: -- portion has a
4 particular meaning in the claim.
5 BY MR. STOWELL:
6 Q. What is the meaning?
7 A. Well, if -- we can go back to the
8 patent, but there is a first portion and a
9 second portion. And if we look at Figure 13 and
10 look at the -- so here the term "portion" is not
11 what I'm referring to with grouping. The first
12 portion of fibers -- I need to look at Figure
13 13.
14 So there are fibers on the inside
15 and fibers on the outside as two separate
16 portions. So for the first portion of fibers,
17 so that -- that is a term, which the claim is
18 using, is not met just by a couple of fibers
19 within a grouping.
20 We can go through each word, but
21 [as read]: "Defining an opening extending
22 through a thickness thereof." I don't think we

1 can see an opening within those fibers. You
2 could see an opening in parts of some of them.
3 "Created by spacing formed between
4 adjacent fibers." Well, there's no intentional
5 space because they're -- they're close together,
6 those fibers. That's not what is meant by the
7 term "opening."
8 Q. So when the groups of fibers were
9 created with individual fibers, you don't think
10 there was an intention to have space between
11 those fibers?
12 A. Well, there is -- there is -- there
13 is some space between them, but that's not
14 what's intended by openings. The openings is
15 between the groupings of fibers, not between one
16 fiber and the fiber next to it.
17 Q. And where -- when you're describing
18 these groupings of fibers, what -- what is the
19 requirement for a grouping?
20 A. I haven't defined the word
21 "grouping."
22 Q. But you believe that they claimed

1 spacings must be between groupings of fibers; is
2 that correct?
3 MR. LOWENSTEIN: Objection; form,
4 scope.
5 THE WITNESS: Well, this is the
6 evidence from the prosecution history
7 which is pretty clear.
8 BY MR. STOWELL:
9 Q. And is there anything in the claims
10 or in the specification that would define how
11 the spacings are supposed to be between
12 groupings of fibers?
13 A. Sorry. Could you ask that question
14 again?
15 Q. Yeah. Is there anything in the
16 '236 Patent specification or claims that
17 specifies that the spacings need to be between
18 groupings of fibers?
19 MR. LOWENSTEIN: Objection; form,
20 scope.
21 THE WITNESS: So that's in the
22 prosecution history, not -- and in the

1 figures, not in the claim, itself.
2 BY MR. STOWELL:
3 Q. What about in the patent
4 specification?
5 A. I'd have to look through it again
6 with that in mind. I can't immediately think of
7 a reference within the specification where the
8 openings defined by the fibers is described, but
9 I think the prosecution history is -- is
10 compelling.
11 Q. So if we're looking at a piece of
12 prior art, how do we determine whether there are
13 groupings of fibers?
14 A. I've not made any definition or
15 construction on the term "grouping." I'm using
16 it to describe a group or grouping of fibers.
17 I've used it to describe what I
18 believe is stated in the prosecution history.
19 I've not tried to apply that to define a
20 grouping of fibers in prior art, Not for the
21 purposes of my opinions in this.
22 Q. As you were analyzing the prior art

1 for preparing your declaration, how did you go
2 about determining whether the spacing between
3 fibers were created by design?
4 A. So can you take me to where I've
5 expressed an opinion on that? I mean, I think
6 it's pretty clear from the prosecution history
7 of this patent.
8 I don't think I've given opinions
9 on that with respect to the prior art, not in
10 this declaration. It's possible, and you'll
11 take me to it, if I have. But I haven't, to my
12 knowledge, I haven't given an opinion on spacing
13 of fibers in Walther, for example.
14 Q. And do you have an opinion
15 regarding whether the fibrous layer in Walther
16 would satisfy Claim 3 for example?
17 MR. LOWENSTEIN: Objection, scope.
18 THE WITNESS: I haven't given an
19 opinion on that.
20 I -- I don't see how you could have
21 an opening extending to the outer frame
22 through Walther though.

1 BY MR. STOWELL:
2 Q. But that's not a requirement of
3 Claim 3, is it?
4 A. No, not of Claim 3. Sorry.
5 Q. Is there any portion of the
6 '236 Patent that you believe excludes inherent
7 spaces between fibers?
8 MR. LOWENSTEIN: Objection; form.
9 THE WITNESS: Well, the prosecution
10 history is included in the patent as a
11 whole. That excludes it. The figures,
12 they exclude it, and the language of the
13 claims, they exclude it.
14 BY MR. STOWELL:
15 Q. Is there any part of the
16 '236 Patent specification that you believe
17 excludes inherent spaces between fibers?
18 A. I don't think it's mentioned in the
19 specification.
20 A POSITA reading the patent,
21 though, and reading the specification would know
22 that inherent spaces between fibers wouldn't

1 fulfill the -- the requirements if this is a PVL
2 solution to get to a low profile.
3 If you just fill the whole thing
4 with fibers, you have something -- you could
5 have something that wouldn't be able to get to
6 low profile.
7 Q. So you just said reading the
8 specification would know that inherent spaces
9 between fibers wouldn't require -- or fulfill
10 the requirements.
11 And what part of the specification
12 are you referring to specifically?
13 A. So it's a transcatheter aortic
14 valve repair with improved paravalvular seal, so
15 just the title. And then just looking right at
16 the very beginning, the present disclosure
17 relates to a device and method of the same for
18 endovascular aortic repair.
19 So you know that you're dealing
20 with -- I mean, a cardiologist reading this as
21 of 2012 would know that the design is for a PVL
22 solution for transfemoral usage. That's what

1 they would understand.
2 And when they see we've got this
3 design with the spaces, looking at Figure 13 and
4 14, it would be fairly clear to a cardiologist
5 that they're done like that on purpose and that
6 any spaces and openings claimed are by design
7 and not just by the fact that any two fibers
8 next to each other could -- could be said to
9 have a space between them.
10 Q. You've been referring to
11 a cardiologist in 2012. Why are you focused on
12 cardiologists?
13 A. Well, I'm reading this as a POSITA,
14 as a cardiologist POSITA.
15 Q. And when you say "cardiologist," do
16 you mean an interventional cardiologist?
17 A. I mean an interventional
18 cardiologist with experience in transcatheter
19 aortic valve implantation.
20 Q. And you focused in your definition
21 of a POSITA on the 2010 to 2012 time period;
22 correct?

1 A. I think I've said 2012.
2 Q. Well, in Paragraph 20, for example,
3 you say, "I believe the level of ordinary skill
4 would be an interventional cardiologist with
5 experience implanting, researching or designing
6 TAVRs in the 2010 to 2012 time frame"; correct?
7 A. Yes, the 2000 time -- 2012 time
8 frame which I understand is the priority date is
9 critical to understanding the operative level of
10 skill. And I'm happy to discuss that again.
11 2010 to 2012 was one of the most explosive
12 periods in TAVR and in interventional cardiology
13 that there has ever been.
14 Q. In 2010, can you estimate how many
15 interventional cardiologists had implanted a
16 TAVI?
17 A. Worldwide? In the U.S.? In the
18 U.K.?
19 Q. Whichever number you know.
20 Worldwide is fine.
21 A. I don't know the actual number, but
22 2010, many hundreds. Could be more than

1 a thousand. I mean, 2000 -- yeah, it probably
2 is more than a thousand worldwide. There are
3 probably a thousand in the U.S. I can't --
4 honestly, I'm guessing. It's -- it's -- I would
5 think it's a lot. I haven't thought about this
6 for a while.
7 Q. What --
8 A. In 2000 -- 2012 is an absolute
9 frenzy of activity.
10 Q. And so in 2010, what products were
11 -- what TAVI products were available for human
12 implantation?
13 A. So 2010, there was the CoreValve.
14 There was the SAPIEN. And when you say
15 "available," there were clinical trials going on
16 on others.
17 I -- sitting here now, I struggle
18 to remember the FDA approval dates of all of the
19 valves and the CE markings of them. I mean, by
20 2012, Lotus was available. There may -- there
21 may well have been some others -- or there were
22 others.

1 I can't recall the dates that they
2 were all introduced. The majority of cases in
3 2010 were being done with SAPIEN and CoreValve,
4 the majority.
5 Q. And CoreValve was a Medtronic
6 product; is that correct?
7 A. It became a Medtronic product. It
8 could have been by -- I'm now trying to remember
9 the acquisition date. It probably was by then
10 Medtronic.
11 Q. And SAPIEN was an Edwards product?
12 A. Yes.
13 Q. And you believe that by 2010
14 hundreds or thousands of interventional
15 cardiologists had implanted TAVI devices in
16 patients?
17 A. I can't say thousands. It was
18 definitely hundreds. It might be more than
19 a thousand. It probably is. I just can't give
20 you an accurate answer.
21 I mean, I can tell you in the U.K.
22 that in 2010 there were probably between 50 and

1 a hundred cardiologists implanting TAVRs. I
2 mean, that's just a very rough estimate. It
3 could be more. It wouldn't be less because each
4 center had to have two or three people involved,
5 and there were between 20 and 25 centers to my
6 knowledge.
7 I mean, I'm -- we're going back 12
8 years and I can't give you the -- I can't give
9 you a 100 percent certainty that these numbers
10 are completely accurate, but they're definitely
11 in the right ballpark.
12 Q. Did you consider Dr. Shahriari's
13 experience when you were defining the person of
14 ordinary skill in the art?
15 A. No, that wasn't a consideration I
16 had.
17 Q. Do you know if Dr. --
18 A. I was --
19 Q. Sorry. Go ahead.
20 A. I was considering what I think an
21 interventional cardiologist at this time who was
22 involved in TAVR would have been doing and what

1 I know they were doing.
2 Q. Do you know if Dr. Shahriari would
3 meet your definition of a POSITA in 2012?
4 MR. LOWENSTEIN: Objection, scope.
5 THE WITNESS: Well, he designed the
6 transcatheter valve. I haven't considered
7 whether he meets the definition of a
8 POSITA, nor would I -- I haven't done that
9 exercise.
10 He's obviously involved in the
11 field and he designed the transcatheter
12 valve; therefore, he fulfills at least two
13 of the domains that I've discussed in
14 Paragraph 21.
15 BY MR. STOWELL:
16 Q. Is Dr. Shahriari an interventional
17 cardiologist?
18 A. I don't believe he is.
19 Q. How many TAVR, T-A-V-R, devices had
20 Dr. Shahriari implanted in 2012?
21 MR. LOWENSTEIN: Objection, scope.
22 THE WITNESS: So these -- these are

1 questions beyond my personal knowledge.
2 BY MR. STOWELL:
3 Q. Was Dr. Shahriari involved in
4 clinical trials relating to TAVR devices in
5 2012?
6 MR. LOWENSTEIN: Objection, scope.
7 THE WITNESS: That is beyond my
8 knowledge about what he was and wasn't
9 involved in.
10 BY MR. STOWELL:
11 Q. Was Dr. Shahriari working in
12 industry on TAVR devices in 2012?
13 MR. LOWENSTEIN: Objection, scope.
14 THE WITNESS: Well, I don't know
15 the date that AI was created, but he was
16 designing medical devices. He had
17 industry links and he designed the
18 transcatheter valve.
19 BY MR. STOWELL:
20 Q. So in Paragraph 21, on -- the
21 portion on Page 18, you mention, "working with
22 industry in TAVR design."

1 Is the act of designing a TAVR
2 device within your definition of "working with
3 industry in TAVR design"?
4 A. Actually designing a valve, yes.
5 Q. Even if the valve was never made or
6 prototyped?
7 MR. LOWENSTEIN: Objection, scope,
8 form.
9 THE WITNESS: I haven't said
10 working in industry with TAVR design where
11 the TAVR became commercially released.
12 I've said being involved in the
13 field of TAVR. And the ways in which you
14 could work with industry would be
15 designing a TAVR. You could be on design
16 panels where you, as a cardiologist, were
17 one of a group of cardiologists that the
18 companies got together, sat in a room, and
19 you brainstormed and you looked at ideas.
20 Then there were also what are known
21 as advisory boards where you are with a
22 group of cardiologists or cardiac surgeons

1 and you're giving advice to the company.
2 And then usability testing where you test
3 the new devices.
4 Now, I'm not saying a POSITA would
5 need to have done all of those. I did all
6 of those. But you have to have done
7 something, I think, in 2012. You have to
8 have had some interaction with the
9 industry to be considered a POSITA.
10 By interaction, even just doing the
11 implants or involved in the implants or --
12 you have to have some connection to it in
13 my opinion to have been a POSITA in 2012.
14 BY MR. STOWELL:
15 Q. What about observing implants?
16 MR. LOWENSTEIN: Objection; form.
17 THE WITNESS: Well, anyone can
18 observe an implant on a YouTube. And you
19 can observe an implant and not gain
20 anything from it. Just being an observer,
21 I don't think that qualifies.
22 We had 20 or 30 people in the room

1 for the first implants in 2007, '8, '9.
2 Thankfully now there's four of us or three
3 of us in the room. No one's interested.
4 But at that time period there would be 20
5 or 30 people in the room. You wouldn't
6 call all of them POSITAs, no.
7 MR. STOWELL: Okay. Let's see.
8 We've been going about another hour. Why
9 don't we take a quick break and go off the
10 record.
11 MR. LOWENSTEIN: Okay.
12 (A recess is held from 3:28 p.m. to
13 3:45 p.m.)
14 BY MR. STOWELL:
15 Q. Dr. Brecker, have you spoken to
16 anyone about the subject matter of your
17 testimony during today's deposition?
18 A. Not at all.
19 MR. STOWELL: I don't have any
20 further questions for you at this time.
21 And Edwards passes the Witness.
22 MR. LOWENSTEIN: Thank you. We'll

1 take a break and we'll determine whether
2 there are any questions, so why don't we
3 get back on at 4:00 roughly.
4 MR. STOWELL: 4:00?
5 MR. LOWENSTEIN: Yeah.
6 MR. STOWELL: Okay.
7 (A recess is held from 3:46 p.m. to
8 4:03 p.m.)
9 MR. LOWENSTEIN: Dr. Brecker, I do
10 have a few questions for you.
11 EXAMINATION
12 BY MR. LOWENSTEIN:
13 Q. Do you recall Mr. Stowell was
14 asking you about certain figures in the
15 '236 Patent that display arrangements of fibers?
16 Does that ring a bell for you?
17 A. Yes.
18 THE REPORTER: I'm sorry. Excuse
19 me. I didn't hear the end of your
20 question. I can't hear you well enough.
21 BY MR. LOWENSTEIN:
22 Q. Does that ring a bell for you?

1 A. The answer is yes.
2 Q. Okay. Do you believe that the term
3 "opening" in the claims of the '236 is limited
4 to the specific arrangement of openings shown in
5 the various figures of the '236 Patent?
6 A. No, I don't think that's the only
7 way it could be interpreted or what it means.
8 Q. Okay. And I would like to show you
9 Exhibit 2026.
10 MR. LOWENSTEIN: And, Josh, are you
11 able to pull that up on your end?
12 MR. STOWELL: Why don't we pull it
13 up in the marked exhibits? Why don't you
14 put it in the marked exhibits and I'll put
15 it up there.
16 MR. LOWENSTEIN: It's on a
17 different computer that's disconnected. I
18 just think it would be easier if you could
19 pull it up on your end. Will can e-mail
20 it to you if you prefer.
21 MR. STOWELL: What's the exhibit
22 number?

1 MR. LOWENSTEIN: 2026.
2 MR. STOWELL: Okay. And for the
3 record, I'll object to questions about
4 2026 as outside the scope of the cross.
5 MR. LOWENSTEIN: Let me know when
6 you're ready.
7 MR. STOWELL: Okay. I have it up.
8 (Exhibit 2026, multipage document
9 titled SAPIEN 3 Ultra Valve,
10 First-In-Human Experience, was previously
11 marked for identification.)
12 BY MR. LOWENSTEIN:
13 Q. Okay. And let's go to page -- I
14 believe it's Page 8, but it doesn't have a page
15 number I'm afraid, but it should show this, just
16 so we're on the same page (indicating).
17 MR. LOWENSTEIN: I know it's a
18 little blurry. Let me know when you're
19 there, Josh.
20 MR. STOWELL: Yes, I can't -- I'm
21 not sure. It's blurry. I'm not sure
22 what --

1 MR. LOWENSTEIN: It's the one with
2 the fabrics for the SAPIEN 3 Flat woven.
3 THE REPORTER: Mr. Lowenstein, you
4 have to understand Zoom. You need to stay
5 in close proximity to the mic. I'm losing
6 syllables.
7 MR. LOWENSTEIN: I understand.
8 THE REPORTER: Okay. Thank you.
9 MR. LOWENSTEIN: I'll just ask the
10 question again. And I'm just making sure
11 opposing counsel has the document so we
12 can ask about it.
13 So, Josh, do you have the image
14 with the SAPIEN 3 Flat woven on the left
15 and Ultra on the right?
16 MR. STOWELL: I have Exhibit 2026.
17 What page are you on?
18 MR. LOWENSTEIN: I believe it's
19 Page 8, but I'm going to ask Dr. Brecker
20 about the image with the SAPIEN 3 Flat
21 woven on the left and the SAPIEN Ultra
22 Textured on the right.

1 MR. STOWELL: Okay. I think I know
2 what page you're on.
3 MR. LOWENSTEIN: Okay. Perfect.
4 BY MR. LOWENSTEIN:
5 Q. Dr. Brecker, are we looking at
6 Exhibit 2026?
7 A. Yes.
8 Q. Okay. And do you see -- I believe
9 we're on Page 8 of the document.
10 Do you see there's a red box with
11 the title "Fabrics Skirt"?
12 A. Yes.
13 Q. And do you see on the left there's
14 the SAPIEN 3 Flat woven?
15 A. Yes.
16 Q. And do you see on the right there's
17 the SAPIEN 3 Ultra Textured?
18 A. Yes.
19 Q. On the image on the left, the
20 SAPIEN 3 Flat woven, do you see any openings as
21 that term is used in the '236 Patent?
22 A. I do not.

1 Q. On the image on the right of the
2 SAPIEN 3 Ultra do you see openings as that term
3 is used in the '236 Patent?
4 A. Yes.
5 Q. Okay.
6 MR. LOWENSTEIN: I finished my
7 redirect. Pass the witness.
8 EXAMINATION
9 BY MR. STOWELL:
10 Q. Dr. Brecker, did you confer with
11 Mr. Lowenstein about your testimony prior to the
12 questions you were just asked on redirect?
13 A. We just had a brief discussion.
14 Q. Okay. And the discussion was about
15 your testimony?
16 A. More about that I was going to be
17 asked some more questions.
18 Q. And were you informed about what
19 the questions would pertain to?
20 A. That it was going to be around this
21 document.
22 Q. And specifically about Page 8?

1 A. Yes.
2 MR. STOWELL: No further questions.
3 MR. LOWENSTEIN: Okay. Thank you,
4 everyone. Let's go off the record.
5 (Time noted: 4:08 p.m. PST)
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1 CERTIFICATE

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6 That Stephen J.D. Brecker, the witness
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11 marriage and that I am in no way interested in
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12 In witness whereof, I have hereunto set my
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2 1016 Pico Boulevard
Santa Monica, California 90405
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5 Deponent: Stephen J.D. Brecker
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