UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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( )
(EDWARDS LIFESCIENCES CORPORATION AND)
(EDWARDS LIFESCIENCES LLC,)
(Petitioners,)
(v.)
(AORTIC INNOVATIONS, LLC,)
(Patent Owner.)
(IPR2021-01527)
(Patent 10,792,172)
(_____)

*** VOLUME 2 ***

CONTINUED VIRTUAL DEPOSITION OF

STEPHEN J.D. BRECKER Vol II, MD, FRCP, FECS, FACC

Wednesday, August 31, 2022

8:28 a.m. PDT

REPORTER: Dawn A. Jaques, CSR, CLR

_____

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Edwards v. Aortic Innovations
U.S. Patent 11,491,033
Edwards Ex. 1073

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1 I-N-D-E-X

2 WITNESS: PAGE:

3 STEPHEN BRECKER, MD

4 Examination by Mr. Stowell 288

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6

7 E-X-H-I-B-I-T-S

8 PREVIOUSLY MARKED EXHIBITS REFERRED TO

9 EXHIBIT NUMBER: PAGE:

10

11 Exhibit 1101 U.S. patent number 277

12 10,881,538

13 Exhibit 1007 Walther reference 344

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1 P R O C E E D I N G S
2 THE VIDEOGRAPHER: We are on the
3 record. This is Volume 2 in the continuing
4 deposition of Dr. Stephen Brecker in the
5 matter of Edwards Lifesciences Corporation,
6 et al., v. Aortic Innovations, LLC.
7 Today's date is August 31st, 2022.
8 The time is 8:28 a.m. Pacific Daylight Time.
9 The witness is still under oath, and
10 counsel may proceed.
11 MR. LOWENSTEIN: I have a question
12 before we start.
13 I just heard a tone that said
14 "recording in progress." This is -- the video
15 is not being recorded, correct?
16 THE VIDEOGRAPHER: Yes, the video is
17 being recorded.
18 MR. LOWENSTEIN: Nope, that is
19 unacceptable. You're not allowed to videotape
20 the deposition in an IPR. That was not in
21 your deposition notice. Please confirm it
22 will be deleted.

1 MR. STOWELL: Yeah, to be clear,
2 Edwards has not requested a video transcript
3 of the deposition. My understanding is that
4 this is common. The court reporter records
5 the video so they can review and have an
6 accurate transcript, and the video is never
7 provided to anybody.
8 MR. LOWENSTEIN: Well, does Mr. -- I
9 can't see his name. His first name is Billy.
10 I can't see his surname.
11 THE VIDEOGRAPHER: Yeah, I'm just
12 following the job that I was given. So if
13 it's not to be recorded, I needed to be told
14 that, and I'm just doing what my job --
15 MR. LOWENSTEIN: Okay, so just to be
16 clear, this is not to be videotaped.
17 THE VIDEOGRAPHER: Okay. Well,
18 then, yesterday shouldn't have been videotaped
19 either then, so --
20 MR. LOWENSTEIN: Yes, delete the
21 video, please.
22 THE REPORTER: May I interject? If

1 I could please interject.
2 Mr. Lowenstein, just so that you
3 know, I did get an instruction from the court
4 reporting agency, and it is in big capital
5 letters "NO VIDEO."
6 And what Mr. Stowell said is
7 correct, it's more so that I have an audio
8 backup so that I can make sure that I capture
9 everything and there's an accurate transcript.
10 MR. LOWENSTEIN: Audio is fine. No
11 objection to the audio.
12 THE REPORTER: So there is an
13 instruction for no video, just so you have
14 peace of mind. Thank you.
15 MR. LOWENSTEIN: Very good. Thank
16 you.
17 BY MR. STOWELL:
18 Q Okay, welcome back, Dr. Brecker.
19 As you heard, you are still under
20 oath, and you are required to tell the truth
21 just as if you were testifying in a court of
22 law. Do you understand that?

1 A Yes, I do.
2 Q Did you discuss your deposition
3 testimony with anyone since we broke
4 yesterday?
5 A Not at all. Nobody.
6 Q Yesterday you described some
7 materials that you had in front of you for the
8 deposition.
9 Do you still have those materials in
10 front of you for today's continuation of the
11 deposition?
12 A Yes, exactly the same. Nothing
13 else.
14 Q I'll ask our hot seat operator to
15 pull up U.S. patent number 10,881,538. And
16 this document has been previously marked as
17 Exhibit 1001 in IPR 2022-00193.
18 Dr. Brecker, do you recognize the
19 '538 patent?
20 A Yes.
21 Q Is this one of the Aortic
22 Innovations patents that you have opined about

1 in this matter?
2 MR. LOWENSTEIN: Objection, form.
3 THE WITNESS: Yes.
4 BY MR. STOWELL:
5 Q Does your declaration, Exhibit 2051,
6 contain your opinions about this patent?
7 A Yes.
8 Q If you could turn to FIG. 20 in the
9 '538 patent, which is on sheet 17 of 19.
10 Please let me know when you are there.
11 THE VIDEOGRAPHER: I'm sorry, which
12 figure?
13 MR. STOWELL: FIG. 20.
14 THE VIDEOGRAPHER: FIG. 20.
15 BY MR. STOWELL:
16 Q Do you have it visible, Dr. Brecker?
17 A I do.
18 Q And do you recognize FIG. 20 as one
19 of the heart valve embodiments described in
20 the patent?
21 MR. LOWENSTEIN: Objection, form,
22 scope.

1 THE WITNESS: I do. I would just
2 like a minute to read some of the
3 specifications describing this figure.
4 BY MR. STOWELL:
5 Q Sure, sure.
6 A I'm nearly done. I'm just reading
7 through. I just want to be absolutely sure.
8 Okay, I'm happy with the -- I've
9 just read a short portion of the description
10 to refresh myself. Depending on the question,
11 I may need to read a little bit more, but I'm
12 happy to proceed.
13 Q Understood. Do you recognize that
14 the heart valve in FIG. 20 is described as
15 having a dual frame?
16 MR. LOWENSTEIN: Objection, form,
17 scope.
18 THE WITNESS: Yeah, so for the
19 purposes of this deposition, I've not
20 expressed opinions or descriptions in terms of
21 this figure. However, I am aware that this is
22 one of the dual frame embodiments.

1 BY MR. STOWELL:
2 Q And in FIG. 20, it's described as
3 having a balloon-expandable inner frame number
4 218, correct?
5 MR. LOWENSTEIN: Objection, form,
6 scope.
7 THE WITNESS: So I've not given an
8 opinion on this in my declaration. So in
9 terms of preparation for this deposition,
10 these aspects, which may have wider
11 implications, are not aspects that I've given
12 opinions on, but I can answer your question
13 that there is a balloon-expandable inner
14 frame.
15 BY MR. STOWELL:
16 Q And when you say you haven't given
17 opinions on this, are you referring to FIG. 20
18 specifically?
19 A Yes, the questions that you're
20 asking me. So I've not -- obviously, I have
21 read through this patent, and I am aware of
22 this structure particularly and in detail as

1 the claims relate to this.
2 But the questions that you're asking
3 me I am aware may have much wider implications
4 than the IPR, because this figure does not --
5 I'm not aware that I've given an opinion of it
6 in my declaration.
7 If I have, please direct me to it,
8 but I can answer your questions of a factual
9 nature because it is in the description and in
10 the specification. So, yes, there is an
11 balloon-expandable inner frame.
12 Q Okay. And would you agree that the
13 balloon-expandable inner frame 218 is
14 described as being secured to a self-expanding
15 outer frame 416?
16 MR. LOWENSTEIN: Objection, form,
17 scope.
18 THE WITNESS: So you'll have to just
19 let me read through the description.
20 Yes, that is correct.
21 BY MR. STOWELL:
22 Q There is a portion on this figure at

1 the upper right, number 64, that's described
2 as being an elongated distal section.
3 Do you know the purpose of the
4 elongated distal section, item 64?
5 MR. LOWENSTEIN: Objection, form,
6 scope.
7 THE WITNESS: I have not given an
8 opinion on that.
9 BY MR. STOWELL:
10 Q Do you recall from your review of
11 the '538 patent the function of the elongated
12 distal section, item 64?
13 MR. LOWENSTEIN: Objection, form,
14 scope.
15 THE WITNESS: So I've not given an
16 opinion on that for the purposes of this
17 deposition, or I believe in my declaration.
18 If there is reference to it in my declaration,
19 I'm happy to review that.
20 As I say, I am happy to read --
21 I think what I'm going to need to do is just
22 read the rest of the description of this

1 figure in detail now, and then I can answer
2 the factual questions.
3 BY MR. STOWELL:
4 Q Okay, if you want to -- if you need
5 to read more of the patent, please do so.
6 MR. LOWENSTEIN: Mr. Stowell, while
7 Dr. Brecker is reviewing -- actually, I'm
8 going to ask Dr. Brecker to leave the room for
9 my comment. You can continue with your --
10 THE WITNESS: So I'll take this and
11 step outside.
12 MR. LOWENSTEIN: Sure.
13 (The witness exited the room.)
14 MR. LOWENSTEIN: We're still on the
15 record, I assume, Madam Court Reporter?
16 THE REPORTER: Yes, we're on the
17 record.
18 MR. LOWENSTEIN: As we spoke after
19 the deposition yesterday, I was very concerned
20 that your questions were going outside the
21 scope of the declaration in the IPRs for which
22 Dr. Brecker is being deposed.

1 It seems that you are again asking
2 questions that do not relate to the issues
3 that Dr. Brecker has set forth opinions on,
4 and consequently, I can only assume,
5 particularly because you haven't told me when
6 I asked you what relevance your questioning
7 yesterday had to his opinions, that you are
8 again asking Dr. Brecker questions about the
9 patent for purposes of the underlying
10 district court litigation that have no
11 relevance to this proceeding.
12 This is improper. I've objected
13 several times, both on and off the record. We
14 talked about this yesterday. We sent you an
15 email about this yesterday; we did not receive
16 a response.
17 And so if you're going to continue
18 in this vein, you're going to need to either
19 tell me why your line of questioning is
20 relevant to the IPR, or we will have to have a
21 call with the Board.
22 MR. STOWELL: Mr. Lowenstein, as we

1 discussed yesterday, I responded to your
2 questions in real time regarding why my
3 questions were relevant to the IPR.
4 MR. LOWENSTEIN: That is not true.
5 MR. STOWELL: We didn't think
6 your --
7 MR. LOWENSTEIN: That is not true.
8 MR. STOWELL: -- yesterday required
9 a response -- please don't talk over me,
10 Mr. Lowenstein, so we can have a clean record.
11 MR. LOWENSTEIN: Please speak
12 truthfully.
13 MR. STOWELL: The questions this
14 morning are also related to the IPR.
15 For example, Dr. Brecker has a picture of
16 FIG. 20 on page 19 of his declaration. So,
17 obviously --
18 MR. LOWENSTEIN: Well, let's look at
19 that.
20 MR. STOWELL: -- we're entitled to
21 ask --
22 MR. LOWENSTEIN: Let's look at that.

1 MR. STOWELL: -- questions
2 regarding --
3 MR. LOWENSTEIN: Let's look at that.
4 Let's look at that. So --
5 MR. STOWELL: Why don't we --
6 MR. LOWENSTEIN: This is in the
7 context --
8 MR. STOWELL: Let's go off the --
9 MR. LOWENSTEIN: No, no, we're not
10 going off the record. We both need to agree
11 to go off the record.
12 THE REPORTER: Excuse me, excuse
13 me --
14 MR. LOWENSTEIN: I do not agree to
15 go off the record.
16 THE REPORTER: Excuse me.
17 Mr. Lowenstein, you are talking over each
18 other and I'm not getting a clean record.
19 MR. LOWENSTEIN: Sure, that's fine.
20 THE REPORTER: If you will please --
21 MR. LOWENSTEIN: Let's stay on the
22 record. I do not agree to go off the record.

1 MR. STOWELL: Mr. Lowenstein, you
2 are simply wasting deposition time.
3 MR. LOWENSTEIN: We can stop the
4 clock for that.
5 MR. STOWELL: Okay, so we'll stop
6 the clock.
7 MR. LOWENSTEIN: Because right now
8 we're going to have to have the question of
9 whether we need to go to the Board, which I
10 prefer not to do.
11 MR. STOWELL: Let's stop the clock.
12 MR. LOWENSTEIN: And let the record
13 reflect that I asked Dr. Brecker to leave the
14 room for this so there would be no question of
15 any coaching or anything like that.
16 I would like to resolve this without
17 having to contact the Board, which I've never
18 had to do in any deposition before.
19 MR. STOWELL: And neither have I.
20 MR. LOWENSTEIN: You just said his
21 opinion on page 19. So that, as you can see,
22 is a figure -- is a set of figures showing

1 fibers, that's it.
2 That does not mean he offered all
3 sorts of manners of opinions on FIG. 20. He
4 just showed FIG. 20 as yet another
5 instantiation of fibers.
6 MR. STOWELL: Mr. Lowenstein, my
7 questions this morning have been appropriate.
8 If you want to call the Board, we can do that.
9 MR. LOWENSTEIN: We're going to call
10 the Board. So we're going to contact the
11 Board. We're going to email.
12 What I would suggest is you table
13 this line of questioning so we can have a call
14 with the Board, and then you can return to it
15 after the issue has been resolved, but perhaps
16 for the time being you can turn to some
17 questioning that is actually pertinent to the
18 examination. Is that reasonable?
19 MR. STOWELL: No, that's not. We'll
20 continue with our line of questioning. If you
21 would like to --
22 MR. LOWENSTEIN: No, we can't do

1 that.
2 MR. STOWELL: -- suspend the
3 deposition --
4 MR. LOWENSTEIN: We need to --
5 look --
6 MR. STOWELL: If you would like to
7 suspend the deposition, we can pause the
8 deposition, you can set up your call with the
9 Board, and then we would like to resume --
10 MR. LOWENSTEIN: We don't have time
11 for that. Why don't you just move to a
12 different area that actually is pertinent to
13 this case.
14 MR. STOWELL: Because this line of
15 questioning is pertinent to the case, and we
16 are going to complete this line of
17 questioning.
18 If you want to table the deposition,
19 we can do so for now, we can go off the
20 record, and then we want to come right back on
21 the record and complete the deposition --
22 MR. LOWENSTEIN: No, I'm going to

1 instruct the witness not to answer because we
2 haven't gotten this issue resolved.
3 MR. STOWELL: Mr. Lowenstein, just
4 so we have a clean record, please stop
5 interrupting.
6 My suggestion is if you want to have
7 a call with the Board, we'll pull the
8 deposition on pause --
9 MR. LOWENSTEIN: And what if that
10 takes 6 hours? So we're all just going to
11 wait here for 6 hours?
12 MR. STOWELL: That's what's going to
13 happen, yes. In the meantime, you're entitled
14 to make your scope objection --
15 MR. LOWENSTEIN: Why don't we go off
16 the record for a moment.
17 MR. STOWELL: -- as you deem
18 appropriate.
19 MR. LOWENSTEIN: Is that okay if we
20 go off the record for a moment?
21 MR. STOWELL: Just a second. Stop
22 talking over me.

1 MR. LOWENSTEIN: Oh, my Lord.
2 MR. STOWELL: You're entitled to
3 make your scope objection, and if you want to
4 raise that objection with the Board and try to
5 strike subject matter later on, you'll have
6 that opportunity.
7 MR. LOWENSTEIN: No, no, that's not
8 appropriate. You've spent almost -- let's
9 stay on the record.
10 By my measure, you spent two-thirds
11 of the deposition yesterday asking questions
12 about the district court litigation.
13 I notified you twice that, if you
14 did this, we would have to go to the Board.
15 You've not made any colorable showing that
16 your questioning has anything to do with these
17 IPRs. So, no, this is inappropriate.
18 MR. STOWELL: Mr. Lowenstein --
19 MR. LOWENSTEIN: I'm sorry,
20 I'm sorry. My practice is IPRs. I've been
21 counsel in hundreds of IPRs. I know exactly
22 what you are allowed to ask questions about

1 and what you are not, and you are well past
2 that line.
3 And so I don't think it's reasonable
4 to waste everyone's time for 6 hours so we can
5 set up a call with the Board, so why don't you
6 just move on to a line of questioning that is
7 relevant to the IPR?
8 You can hold this line of
9 questioning, and then we can return to it
10 after we have had an opportunity to talk to
11 the Board.
12 MR. STOWELL: Mr. Lowenstein, we're
13 entitled to conduct the deposition as we see
14 fit. These questions are appropriate. Your
15 characterizations of the questions as relating
16 to the district court litigation are
17 incorrect.
18 MR. LOWENSTEIN: We have 10 people,
19 give or take, on this call. We're all billing
20 at very high rates. Can we please just
21 continue with the deposition on other matters,
22 tabling this so we can resolve it later?

1 MR. STOWELL: No. We're going to
2 complete the line of questioning in the order
3 that we plan to complete it.
4 It doesn't make any sense to try to
5 table a set of questions if, as you say, it's
6 going to take 6 hours or something to get a
7 resolution here.
8 So let's complete the deposition,
9 you can make your objection on the record to
10 scope --
11 MR. LOWENSTEIN: No, no, no, we're
12 not. We're not going to complete the
13 deposition. We're going to just waste
14 everyone's time, I guess.
15 MR. STOWELL: Okay. So it sounds
16 like we need to suspend the deposition --
17 MR. LOWENSTEIN: I would prefer not
18 to, but that seems to be the only option you
19 are giving us because you seem hell-bent on
20 wasting everyone's time.
21 MR. STOWELL: Look, my -- I don't
22 want to waste everybody's time either, but you

1 need to suspend the deposition. I'm not going
2 to suspend it. If you want to suspend it for
3 a call to the Board, you may do so.
4 MR. LOWENSTEIN: So be it.
5 Suspended.
6 MR. STOWELL: Okay.
7 THE VIDEOGRAPHER: Okay, going off
8 the record. The time is 8:47.
9 (The deposition was suspended to
10 wait for contact with the Board.)
11 (The following is a transcript of
12 the call with Judge John New:)
13 MR. STOWELL: Yes, Your Honor,
14 Josh Stowell with Knobbe Martens on behalf of
15 Petitioner, Edwards Lifesciences, and joining
16 me today are Craig Summers and Brian Barnes.
17 THE COURT: Thank you very much.
18 Shall we wait a few more minutes for the court
19 reporter?
20 (Pause in the proceedings for the
21 court reporter to reconnect.)
22 THE COURT: Since both parties are

1 present and the court reporter is present, I
2 understand that this conference has been
3 called on an emergency basis due to an impasse
4 between the parties regarding the scope of
5 cross-examination.
6 Counsel for Petitioner, can you
7 please explain this?
8 MR. STOWELL: Yes, Your Honor. This
9 is Josh Stowell of Knobbe Martens.
10 This morning, Mr. Lowenstein, who's
11 counsel for the Patent Owner, suspended the
12 deposition after about 10 minutes.
13 The questioning at that time related
14 to the figures in one of the patents that is
15 at issue in one of the IPRs that is the
16 subject of the deposition today.
17 Specifically, FIG. 20.
18 The questions were foundational,
19 designed to confirm the expert's understanding
20 of the drawings and the features in the
21 drawing. The expert had included an excerpted
22 version of the figure in his expert

1 declaration.
2 The questions were regarding the
3 expert's understanding of the figures in the
4 patents being challenged and are directly
5 relevant to the IPR and the expert's opinions.
6 We told Mr. Lowenstein that the
7 deposition should continue, and that if
8 Mr. Lowenstein wanted to preserve objections
9 regarding scope or relevance, he could make
10 those objections on the record and could later
11 strike if he thought that the scope of the
12 cross-examination was outside of his
13 declaration. Mr. Lowenstein refused and
14 demanded to suspend the deposition.
15 We are requesting -- or we would
16 request that the Board order the resumption of
17 the deposition, with an instruction to
18 Mr. Lowenstein not to further impede the
19 deposition, and to limit his objections to a
20 single word.
21 THE COURT: Very good.
22 Mr. Lowenstein, your response,

1 please.
2 MR. LOWENSTEIN: Yes. So this is
3 the second day of deposition. We had 5 hours
4 on the record yesterday, we have up to 5 hours
5 on the record today. It's a combined
6 deposition for four IPRs.
7 This is the first time I've ever
8 suspended a deposition in 17 years of
9 practice, the first time I've ever had to call
10 the Board, or any other judge, during a
11 deposition, and here's why.
12 We had 5 hours on the record
13 yesterday, and I would say about 60% had
14 nothing to do with the issues in the IPR. I
15 made several scope objections.
16 At the conclusion of the deposition,
17 I had notified Mr. Stowell that I thought his
18 questioning was improper because so much
19 seemed to do with the issues in the underlying
20 litigation, seemed to be issues relating to
21 enablement or indefiniteness, or whatever it
22 was. It had nothing to do with the issues at

1 hand.
2 The references in this case are
3 references like Levi, Spenser, Spenser II,
4 Walther. No questions were asked about those
5 references. I think Walther came up once,
6 mostly in relation to questioning about
7 Russell, which actually was one of the
8 instances where questioning was relevant to
9 the issue at hand.
10 Here's the thing. Not only did
11 Dr. Brecker not offer testimony in his
12 declaration on the vast scope of issues that
13 they're asking about, I am not counsel in the
14 underlying litigation, so it seems to me,
15 quite transparent, that what Petitioner is
16 trying to do is take advantage of an IPR
17 litigator and the witness, an IPR witness, in
18 order to make their case in the litigation,
19 and that's not allowed.
20 You have to stay within the scope,
21 and I'm a little surprised that Mr. Stowell
22 neglected to mention that we told him by email

1 and on the phone, but I asked him, "Can you
2 tell me what relationship your questioning has
3 to the issues in the IPR?" He refused to tell
4 me.
5 And I think I would know -- because
6 I worked very, very carefully on the briefing,
7 I think I would know if there was some
8 relevance. I couldn't discern any possible
9 relevance, and when I asked, he refused to
10 tell me.
11 We sent him an email after the
12 deposition informing him that if he continued
13 to ask questions about the litigation that had
14 no relevance to the IPR, we would be
15 contacting the Board this morning.
16 We've been on a two-hour plus delay
17 because Mr. Stowell refused to move on to
18 other areas of the questions.
19 What I suggested to him is let's
20 email the board, you can ask about other areas
21 that are relevant to the case, and we'll
22 return back to this line of questioning once

1 we get a determination from the Board.
2 Mr. Stowell declined, even though we have a
3 witness here from England, and my firm is
4 very, very busy with other matters.
5 It's a significant waste of our
6 time, I'm afraid, but we have to have the call
7 because it's not appropriate to use the IPR
8 deposition to spend 60 plus percent of the
9 time asking about issues that have nothing to
10 do with Dr. Brecker's opinions or the issues
11 before the panel that are just to make out
12 some sort of enablement or indefiniteness, or
13 who knows what, I don't know. I'm not in the
14 case.
15 It's completely inappropriate, and I
16 would respectfully request clarification as to
17 how we should proceed in view of this impasse.
18 Thank you.
19 THE COURT: I'm a little confused,
20 Mr. Lowenstein, in that the object of the
21 impasse, at least as characterized by
22 Mr. Stowell, has to do with Dr. Brecker's

1 opinion of FIG. 22A [sic], which does seem to
2 be relevant to this. Why is that an issue at
3 this moment?
4 MR. LOWENSTEIN: Because -- let me
5 respond to that.
6 This is building off of 5 hours from
7 yesterday. It's not as if this is the first
8 question. If it were the first question that
9 were outside the scope, I would hardly be
10 calling Your Honor.
11 And I believe it was about FIG. 20.
12 I believe FIG. 20 appears in
13 Dr. Brecker's declaration. I asked how is
14 this relevant? And they're asking questions
15 about the frame, the dual frame structure.
16 Correct me if I'm wrong, but the only thing
17 they pointed me to is FIG. 20 appears on
18 page 17 of Dr. Brecker's declaration, which
19 has one, two, three, four, five, six, seven,
20 eight, nine other figures from the patent
21 directed towards the fibers.
22 They weren't asking about the fiber.

1 They were asking about the dual frame
2 structure and something else about the valve.
3 It had nothing to do -- I asked him what it
4 had to do with the litigation, and they told
5 me they're asking questions relating to some
6 operability or enablement inquiry, and it's
7 obviously not before the Board, and I was told
8 that a lot of the questions were about some
9 operability or enablement arguments, not about
10 issues Dr. Brecker testified about.
11 And when I asked, there was no
12 cogent explanation given to me as to how the
13 specific questions being asked about FIG. 20
14 had any relation to Dr. Brecker's testimony.
15 THE COURT: I understand your
16 frustration, Mr. Lowenstein. Nevertheless,
17 there is a limited amount of time set aside
18 for this deposition.
19 MR. LOWENSTEIN: There are 10 hours,
20 but they've spent, like I said, no questions
21 of any substance about Dr. Brecker's
22 declaration, no questions about Walther in

1 relation to the Russell reference, no
2 questions about Spenser or Spenser II, and
3 those are the references. Those are the
4 references that make up the combination.
5 I'm not saying every single question
6 they asked is irrelevant. They did ask some
7 questions about common iliac, which I thought
8 were relevant to some issues at hand. I'm
9 sure there were some other relevant questions.
10 I'm not suggesting that every single
11 question asked was irrelevant, but I've been
12 in a lot of depositions, I've been in a lot of
13 IPR depositions, and like I said, this is the
14 first time I've called the Board.
15 THE COURT: Very good. I would ask
16 you gentlemen to wait for one moment while I
17 consult with my colleagues.
18 MR. LOWENSTEIN: Thank you.
19 THE COURT: Thank you.
20 (Pause in the proceedings.)
21 THE COURT: Thank you for your
22 patience. I appreciate this.

1 Mr. Stowell, do you care to respond
2 to that?
3 MR. STOWELL: Yes, Your Honor.
4 Obviously, it's difficult to respond
5 precisely because Mr. Lowenstein hasn't
6 specifically identified the objectionable
7 questions from yesterday that he's talking
8 about today, but the last question on the
9 record today was, "Do you recall from your
10 review of the '538 patent," which is one of
11 the patents at issue in the IPR, "the function
12 of the elongate distal section?"
13 The elongate is part of the outer
14 frame. Their expert has said in his
15 declaration that the specification discloses
16 an outer frame that has a fibrous network, and
17 so we were asking about the features of the
18 network and what their function is.
19 So I'm not sure what relief
20 Mr. Lowenstein is seeking, but it would be
21 very difficult to conduct a deposition about a
22 patent without asking about the figures and

1 the witness's understanding of the figures,
2 which is exactly what was happening in the
3 deposition.
4 THE COURT: All right, thank you,
5 Mr. Stowell.
6 Members of the panel conferred, and
7 I'm going to instruct you to go forward with
8 the deposition. I'm going to remind you of
9 Federal Rule of Evidence 611(b) about the
10 scope of permissible cross-examination.
11 I'm going to ask that objections be
12 preserved, and if necessary, when appropriate
13 in this proceeding, we can entertain a motion
14 to strike, but I think it's best to go on with
15 this rather than have further delay in the
16 procedure of the deposition.
17 Are there any questions?
18 MR. LOWENSTEIN: No, Your Honor.
19 Thank you.
20 MR. STOWELL: Just while we have
21 everybody on the line, Mr. Lowenstein, can you
22 be prepared to restart the deposition in

1 30 minutes?
2 MR. LOWENSTEIN: We would like to
3 start now. I mean, does the panel need to be
4 held up?
5 MR. STOWELL: Sorry, what? I didn't
6 catch that.
7 MR. LOWENSTEIN: Oh, I'm sorry, I
8 thought that was Mr. Stowell asking me. Was
9 that Your Honor? I apologize.
10 We can be ready to start the
11 deposition presumably as soon as we get off
12 this call, provided Dr. Brecker is back. We
13 asked him to leave during this call for us.
14 THE COURT: Very good. If there's
15 no further questions, we are going to stand
16 adjourned. Thank you all, and appreciate your
17 time. Goodbye.
18 MR. LOWENSTEIN: Thank you,
19 Your Honor.
20 MR. STOWELL: Thank you, Your Honor.
21 (The call concluded with Judge New.)
22 (Resuming cross-examination.)

1 THE VIDEOGRAPHER: We are back on
2 the record. The time is 11:47.
3 BY MR. STOWELL:
4 Q Okay, Dr. Brecker, before we took a
5 break there, we were talking about FIG. 20.
6 Do you still have that figure in front of you?
7 A I don't, no. I do now.
8 Q This is FIG. 20 in the '538 patent.
9 A Yes.
10 Q And I had asked you a question
11 regarding item 64, which is the elongate
12 distal section of the outer frame.
13 Do you see item 64 on the top right
14 of FIG. 20?
15 A Yes.
16 Q And do you recall from your review
17 of the patents what the function of item 64,
18 the elongate distal section, is?
19 MR. LOWENSTEIN: Objection, form,
20 scope.
21 THE WITNESS: So I haven't used -- I
22 haven't considered the function of the upper

1 part in forming the opinions that I've put in
2 my declaration. It hasn't come up in my
3 discussions, nor in my preparation.
4 BY MR. STOWELL:
5 Q Okay. Have you ever seen a dual
6 frame valve like the valve pictured in FIG. 20
7 of the '538 patent?
8 MR. LOWENSTEIN: Objection, form,
9 scope.
10 THE WITNESS: I have not seen a
11 valve like this before, no.
12 BY MR. STOWELL:
13 Q Have you ever seen in your practice
14 a transcatheter heart valve that has a
15 balloon-expandable frame positioned inside of
16 a self-expanding frame?
17 MR. LOWENSTEIN: Objection, form.
18 THE WITNESS: So there are examples
19 where that has been done, but not to my
20 knowledge, as a valve that is designed in that
21 way, although I have not really considered
22 whether -- in your question, do you mean a

1 valve that is designed to have both a
2 balloon-expandable and a self-expanding
3 component, or do you mean have I ever seen a
4 balloon-expandable valve placed within a
5 self-expanding valve?
6 BY MR. STOWELL:
7 Q I mean a valve that is designed to
8 have a balloon-expandable valve placed inside
9 of a self-expanding valve.
10 MR. LOWENSTEIN: Objection, form,
11 scope.
12 THE WITNESS: And how do you define
13 "placed inside"?
14 BY MR. STOWELL:
15 Q How about is positioned within the
16 self-expanding valve and is attached to the
17 self-expanding valve.
18 MR. LOWENSTEIN: Objection, form,
19 scope.
20 THE WITNESS: So to my knowledge, I
21 have not.
22

1 BY MR. STOWELL:
2 Q The valve pictured in FIG. 20 also
3 has collagen fibers, item 234, sticking out
4 from the self-expanding frame, correct?
5 A That is the description for FIG. 20,
6 item 234, yes.
7 Q And the fibers that are shown in
8 FIG. 20 are clumped together in little
9 bundles. Is that a fair characterization?
10 MR. LOWENSTEIN: Objection, form.
11 THE WITNESS: I wouldn't use that
12 terminology. I've not -- I don't think I've
13 used that terminology.
14 BY MR. STOWELL:
15 Q What terminology would you use for
16 the individual bundles of fibers?
17 MR. LOWENSTEIN: Objection, form.
18 THE WITNESS: Well, I'd like to go
19 to my declaration to see exactly how they're
20 described, but I wouldn't go beyond describing
21 them as they're described within the patent.
22 So within this patent, they're

1 described as a fibrous network, so I haven't
2 made any -- I don't believe I've made any
3 description of them as clumps or bundles.
4 BY MR. STOWELL:
5 Q Okay. And do you believe bundles of
6 fibers would be an incorrect description of
7 what's shown in FIG. 20?
8 MR. LOWENSTEIN: Objection, form,
9 scope.
10 THE WITNESS: I'm not sure. It may
11 be, it may not be. I haven't come to a
12 conclusion about that. I've not -- I don't
13 think the word "bundle," to my knowledge, has
14 come up in my discussions or preparations, but
15 I would just like to check, to go to my
16 declaration, if I may.
17 BY MR. STOWELL:
18 Q Do you have your declaration in
19 front of you?
20 A Yes, I do.
21 Q Why don't you take a look at your
22 declaration and then tell me where you're

1 reviewing in the declaration so that I can
2 follow along.
3 A I'm looking at page 79. So they're
4 described as a plurality of fibers, outwardly
5 extending, and I wouldn't -- I wouldn't
6 describe them beyond that, radially extending.
7 I don't see anywhere where the words
8 that you suggested I used by myself or the
9 patent.
10 Q Have you ever seen a valve with an
11 arrangement of fibers like those shown in
12 FIG. 20?
13 MR. LOWENSTEIN: Objection, form.
14 THE WITNESS: I have not.
15 BY MR. STOWELL:
16 Q Have you ever had any experience
17 with a valve with collagen fibers extending
18 from the outer surface of the valve?
19 A I don't think I have.
20 Q How are the fibers described in
21 FIG. 20 attached to the valve?
22 MR. LOWENSTEIN: Objection, form,

1 scope.
2 THE WITNESS: So again, I want to be
3 accurate here, and I'm going to have to again
4 look to the patent.
5 So there's a description that they
6 are attached. So it indicates that they're
7 attached, it indicates that the fibers are
8 directly engaged with. The precise
9 manufacturing method I am uncertain of from
10 this. I wouldn't go beyond using the
11 terminology in the patent.
12 BY MR. STOWELL:
13 Q And do you believe that the
14 '538 patent describes how the fibers are
15 attached to the frame?
16 MR. LOWENSTEIN: Objection, scope.
17 I'll object to the form as well.
18 THE WITNESS: So I don't believe
19 that there is an explicit description of how
20 they are attached or secured other than
21 stating that they are attached and secured,
22 and the assumption is that that would be by

1 known biomedical engineering methods.
2 BY MR. STOWELL:
3 Q And what would those known methods
4 have been?
5 MR. LOWENSTEIN: Objection, form,
6 scope.
7 THE WITNESS: So that would be an
8 area that I would consult with an engineer on.
9 BY MR. STOWELL:
10 Q Is it fair to say that you're not
11 offering any opinions --
12 MR. LOWENSTEIN: Hold on.
13 Are you done with your answer?
14 THE WITNESS: Yes, I've completed my
15 answer.
16 BY MR. STOWELL:
17 Q Is it fair to say that you're not
18 comfortable today offering opinions regarding
19 how the fibers are attached to the frame in
20 FIG. 20?
21 MR. LOWENSTEIN: Objection, form,
22 scope.

1 THE WITNESS: So I'm very happy for
2 you to take me to any area of my declaration
3 if I have omitted to say something I've given
4 an opinion on.
5 I don't believe I've given an
6 opinion on the method by which the fibers are
7 attached to the frame, and that would be my
8 answer.
9 BY MR. STOWELL:
10 Q Is the method by which the fibers
11 are attached to the frame something that you
12 considered in developing your opinions that
13 are expressed in Exhibit 2051?
14 A Well, other than making an
15 assumption that the attachment would be by
16 known methods, which I would have consulted an
17 engineer about, I've not used any other
18 specific assumptions.
19 Q In your declaration, you have
20 characterized the fibers in the figures of the
21 Aortic Innovations patents as "sparsely
22 distributed," correct?

1 A Yes. Could we go to that? Can you
2 just tell me which page that's on?
3 Q Sure. To help you out, look at
4 page 17 of Exhibit 2051, paragraph 37, the
5 last line on the page.
6 A Yes.
7 Q Why do you consider the fibers to be
8 sparsely distributed?
9 A Well, that's the appearance on the
10 image. There's spaces between them.
11 So looking at each image, I mean,
12 they are sparsely distributed. They are
13 rather low density. It's not like they're
14 compacted fibers of, for example, a woven
15 fabric.
16 Q What do you mean by "sparsely
17 distributed"?
18 MR. LOWENSTEIN: Objection, form.
19 THE WITNESS: So nothing other than
20 the customary usage of the word. They are
21 distributed sparsely. They are not touching
22 each other closely in this way, that there are

1 spaces. It's creating a sparse network, if
2 you will. They are sparsely distributed.
3 I can't -- I can't -- I mean, I
4 could give you synonymous for "sparsely," but
5 it is -- they're not densely distributed.
6 They're not compacted together.
7 BY MR. STOWELL:
8 Q When you use the phrase "sparsely
9 distributed," do you have a specific density
10 of fibers in mind?
11 MR. LOWENSTEIN: Objection, scope.
12 THE WITNESS: I have not given a
13 definition of the word "sparsely." I'm using
14 the word as it would be used in common English
15 usage.
16 BY MR. STOWELL:
17 Q Does the '538 patent give any
18 measurements regarding the density of the
19 fibers in the figures?
20 A There's a clear representation in
21 the '538 patent on the enlarged images. So
22 looking at FIG. 8, for example, or FIG. 9,

1 that is a visual representation.
2 Q And so my question was does the
3 patent give any measurements regarding the
4 density of the fibers?
5 MR. LOWENSTEIN: Objection, form.
6 THE WITNESS: So there is no
7 numerical calculation or definition. It is an
8 appearance. Those fibers are countable. You
9 could count those fibers. They are a
10 representation. There are not too many to
11 count. They are sparsely distributed.
12 BY MR. STOWELL:
13 Q How far apart do the fibers need to
14 be to be sparsely distributed?
15 MR. LOWENSTEIN: Objection, form,
16 scope.
17 THE WITNESS: So I have not given a
18 definition of "sparsely." I've not attributed
19 a numerical definition to the density, and I
20 have not given a numerical definition to how
21 far apart they have to be.
22 The sentence in my declaration is a

1 descriptive term in which the fibers in the
2 figures -- and I'm looking at FIG. 8 as I'm
3 saying this -- are sparsely distributed.
4 BY MR. STOWELL:
5 Q Does the length or thickness of the
6 fibers play any role in whether they are
7 sparsely distributed?
8 MR. LOWENSTEIN: Objection, form,
9 scope.
10 THE WITNESS: So I have not given a
11 definition of "sparsely" in my declaration,
12 nor am I going to do so today, either in terms
13 of the questions you've asked or in the one
14 that you've just asked. There is no numerical
15 attachment that I have analyzed with respect
16 to it.
17 The description I've given is the
18 fibers in the figures appear to be sparsely
19 distributed. It is an interpretation of a
20 patent drawing.
21 BY MR. STOWELL:
22 Q Does the patent explain what happens

1 to the fibers when the valve is expanded in
2 the patient?
3 MR. LOWENSTEIN: Objection, form,
4 scope.
5 THE WITNESS: So there is quite a
6 lot of description in the patent about how the
7 fibers behave. I would have to go through it
8 with you to pull those areas up.
9 BY MR. STOWELL:
10 Q Yes, I would like to know where the
11 patent explains what would happen to the
12 fibers when the valve is expanded.
13 MR. LOWENSTEIN: Objection, form.
14 Objection to scope.
15 THE WITNESS: Well, we can start
16 with the claims.
17 So the first behavior of the fibers
18 with the valve is under claim 1, wherein the
19 transcatheter heart valve is positioned so the
20 fibrous network of the valve is in overlapping
21 radial alignment with the native leaflet. So
22 that's the first thing.

1 The second element is where the
2 fibrous network shields against the native
3 valve leaflets of the patient, the outer
4 frame, and the graft covering in response to
5 compression from inflation of the balloon
6 assembly. So that's a very clear description.
7 And then the next element is where
8 this fibrous network extends over to
9 circumferentially extending rows of grids
10 formed in the open cell configuration.
11 Now, there are obviously other
12 references within the claims itself as to the
13 behavior of the fibers, but they essentially
14 say the same thing.
15 There's more. Claim 9, wherein the
16 fibrous network includes fibers extending
17 radially inwardly.
18 The next description is where the
19 fibrous network includes fibers that are
20 directly engaged with the outer frame.
21 I'm just continuing.
22 Then under claim 11, fibrous network

1 positioned partially radially outwardly of the
2 outer frame, again in overlapping radial
3 alignment, and then inflating the balloon
4 assembly to expand the valve, and then the
5 fibrous network seals against the aortic valve
6 outwardly of the prosthetic leaflets, and then
7 there's a repeated claim with respect to the
8 two rows of grids.
9 So that's just within the claims.
10 There is obviously more description and
11 diagrammatic representation of what happens
12 within the figures. So there's a description
13 at FIG. 14 on expansion of the valve.
14 So I'll stop there, but there's
15 plenty.
16 BY MR. STOWELL:
17 Q Are the fibers on the outside of the
18 valve compressed when the valve is expanded in
19 the patient?
20 MR. LOWENSTEIN: Objection, form,
21 scope.
22 THE WITNESS: So those fibers will

1 engage with the native anatomy when the valve
2 is expanded. The act that does that is
3 compression. It's in the claims. The fibrous
4 network seals in response to compression.
5 BY MR. STOWELL:
6 Q So do you believe that the fibers on
7 the outside of the valve are compressed when
8 the valve is expanded in a patient?
9 MR. LOWENSTEIN: Sorry, repeat the
10 question. I missed it.
11 BY MR. STOWELL:
12 Q Are the fibers on the outside of the
13 valve compressed when the valve is expanded in
14 the patient?
15 MR. LOWENSTEIN: Objection, form.
16 THE WITNESS: I think that some of
17 them will be, but it will depend on where the
18 valve is in relation to native tissue.
19 So, obviously, if those fibers are
20 up against a lump of calcium on the valve
21 leaflet, and the valve is oversized with
22 respect to it, then those fibers will be

1 compressed. There may be other parts on the
2 frame where the fibers are not completely
3 compressed.
4 So I've not made any definition of
5 "compression," and I don't think you have, nor
6 of complete compression, but when you say are
7 the fibers compressed? Well, some of them
8 will be, maybe most of them.
9 BY MR. STOWELL:
10 Q When the valve is expanded in the
11 patient, how will the gaps in the fibers -- or
12 the gaps between the fibers compare to the
13 gaps between the fibers we see in FIG. 20?
14 MR. LOWENSTEIN: Objection, form,
15 scope.
16 THE WITNESS: I don't think that
17 I've given an opinion on that. That's an
18 interesting question, actually. I'd certainly
19 have to have a bit more analysis to answer
20 that accurately.
21 I don't think I've given an opinion
22 as to size of gaps versus size of spaces.

1 BY MR. STOWELL:
2 Q Do you believe that there will still
3 be gaps between the fibers when the valve is
4 expanded in the patient?
5 MR. LOWENSTEIN: Objection, form,
6 scope.
7 THE WITNESS: It's another
8 interesting question, and I'd have to think
9 about that. It's possible, but again, you're
10 making an assumption of uniformity, and the
11 one thing we know about aortic valve anatomy
12 is it's non-uniform.
13 So the interaction of a device with
14 anatomy is not necessarily completely
15 identical in every part of that device, even
16 over a small area.
17 BY MR. STOWELL:
18 Q Would the fibers be opaque when the
19 valve is expended in the patient?
20 MR. LOWENSTEIN: Objection, form,
21 scope.
22 THE WITNESS: Yeah, I'm sorry, I

1 don't understand the question.
2 BY MR. STOWELL:
3 Q When the valve is implanted in the
4 patient, would the outer seal formed by the
5 fibers be opaque?
6 MR. LOWENSTEIN: Objection, form,
7 scope.
8 THE WITNESS: I still don't
9 understand the question really.
10 When you say "opaque," could you
11 just give me a synonym? Opaque to me is
12 something that means unclear or not
13 transparent.
14 BY MR. STOWELL:
15 Q You used the term "opaque" in
16 paragraph 38 of Exhibit 2051. I'm using the
17 term in the same manner that you have used it
18 in that paragraph.
19 A Okay, thank you. Could you direct
20 me? Sorry, paragraph 38?
21 Q Correct.
22 A Well, this is looking at -- this is

1 looking at something. I was not using the
2 term to describe the property of something
3 necessarily within a patient, but the
4 assumption is if something is opaque outside
5 of the patient, it will be opaque inside the
6 patient.
7 And what I'm saying is that the
8 fibers on -- that we've been talking about are
9 sparsely distributed. If you looked at the
10 device outside of a patient, you would see
11 through them. You would see the underlying
12 structure, they're low density, and that is
13 completely different to the opaque dense
14 coverings that are described by Walther and
15 Cheung.
16 And so that's how I viewed "opaque,"
17 you can't see the underlying structure in
18 terms of what's underneath.
19 Now, you're asking me to transfer
20 that term when the valve is in the patient,
21 which you can't even see the valve when it's
22 in the patient, so how could you tell?

1 What I could say is that Walther,
2 Spenser II, et cetera, would be opaque
3 wherever. I don't think -- I don't see why
4 the fibers in and of themselves should be
5 opaque in the patient, but you can't assess
6 that.
7 Q Is there a point at which the fibers
8 on the outside of FIG. 20 would be too
9 sparsely distributed to prevent paravalvular
10 leakage?
11 MR. LOWENSTEIN: Objection, form,
12 scope.
13 THE WITNESS: So could I just go
14 back to the previous question?
15 BY MR. STOWELL:
16 Q Okay.
17 A You asked me would the fibers be
18 opaque in the patient, and I said you couldn't
19 tell because you can't see through a patient,
20 but of course what you're asking me is -- the
21 fibers haven't changed their visual
22 characteristics within a patient. They

1 haven't -- the fibers -- going into the
2 patient doesn't increase the number of fibers.
3 So my answer to your question is
4 they're not -- it's not opaque in the sense
5 that if you were able to place a camera in
6 between on the outside of this valve in a
7 patient, you would be able to see the frame
8 underneath, and therefore, in a very
9 artificial setup, they would not be opaque.
10 But we're talking in such a hypothetical
11 situation, it's very difficult to answer.
12 So sorry, could we now go to -- that
13 was to your previous question. Could you just
14 repeat the question you just asked?
15 Q Is there a point at which the fibers
16 on the outside of FIG. 20 would be too
17 sparsely distributed to prevent paravalvular
18 leakage?
19 MR. LOWENSTEIN: Objection, form,
20 scope.
21 THE WITNESS: Yeah, I haven't
22 addressed that issue in my report.

1 BY MR. STOWELL:
2 Q Based on your review of the
3 '538 patent, does the patent disclose how
4 sparse would be too sparse to prevent PVL?
5 MR. LOWENSTEIN: Objection, form,
6 scope.
7 THE WITNESS: So there is no
8 definition of the word "sparse." I've not
9 defined it.
10 BY MR. STOWELL:
11 Q Have you given an opinion on whether
12 the fibers that are pictured in FIG. 20 would
13 prevent PVL?
14 MR. LOWENSTEIN: Objection, scope.
15 THE WITNESS: So I'd like to look at
16 my declaration.
17 BY MR. STOWELL:
18 Q Dr. Brecker, I notice you're
19 glancing to your left. Is your --
20 A The other patent is there.
21 Okay, so I've dealt with this
22 paragraph 38, which is where I was at the

1 start of turning pages.
2 The fibrous network addressed -- or
3 outwardly or radially extending fibers address
4 PVL. The sparsely distributed fibers are
5 consistently displayed in the patent's
6 figures.
7 Turning over, I say it's
8 counterintuitive. There's a sparse
9 distribution of fibers that's taught could
10 create a seal. I had not seen any prior art
11 TAVR with this arrangement of fibers.
12 Similarly, Dr. Buller was unaware of any stent
13 with fibers like those present in the patent's
14 figures.
15 I carry on. By including a sparse
16 distribution of fibers without an outer graft
17 covering, this arrangement allows for a narrow
18 crimp profile. Thus, the invention allows for
19 an endovascularly deliverable TAVR that limits
20 PVL.
21 So that is my opinion as expressed
22 in my declaration.

1 Q And so I'll just repeat my question:
2 Have you given an opinion on whether
3 the fibers that are pictured in FIG. 20 would
4 prevent PVL?
5 MR. LOWENSTEIN: Objection, form.
6 THE WITNESS: Well, I have not given
7 an opinion on one specific figure.
8 What I've put in my declaration is
9 that the sparsely distributed fibers are
10 consistently displayed in the patent's
11 figures -- I won't read it again because it
12 will just take time. I mean, that is my
13 opinion.
14 I have not given a separate section
15 on FIG. 20 taken in a vacuum or in isolation.
16 I have looked at the patent as a whole and the
17 figures.
18 BY MR. STOWELL:
19 Q How would a person of ordinary skill
20 in the art know whether the fibers on the
21 valve are too sparsely distributed to prevent
22 PVL?

1 MR. LOWENSTEIN: Objection, form,
2 scope.
3 THE WITNESS: Well, they would use
4 their clinical experience.
5 BY MR. STOWELL:
6 Q What clinical experience
7 specifically are you referring to?
8 A Of implanting valves and seeing how
9 much PVL is left, but I don't think
10 necessarily I can give you one definitive
11 answer to that question.
12 A person of skill in the art would
13 use many different aspects of their
14 experience, and even then, they may only not
15 be right.
16 I have certainly looked at devices
17 where I had serious doubts as to whether one
18 particular aspect of it would function or not,
19 and it did. It did work.
20 So I don't think there is a magic
21 number or formula that you could apply to say
22 this would work and this wouldn't. All I can

1 say is exactly what I've said in my
2 declaration, which is that it could be
3 considered counterintuitive that a sparse
4 network of fibers could create a seal.
5 Q Do you believe a person of ordinary
6 skill in the art could visually inspect the
7 fibers and determine whether the fibers are
8 too sparse to prevent paravalvular leak?
9 MR. LOWENSTEIN: Objection, form,
10 scope.
11 THE WITNESS: I don't think I could
12 answer that question. I don't know the answer
13 to that question.
14 BY MR. STOWELL:
15 Q Let's look at paragraph 37 of
16 Exhibit 2051. In that paragraph you state,
17 "The specification discloses an outer frame
18 that has a fibrous network or an outer seal or
19 sealing material comprised of radially or
20 outwardly extending fibers."
21 Do you see where I just read?
22 A I do.

1 Q Are you viewing the terms "fibrous
2 network," "outer seal," and "sealing material"
3 from the claims as being interchangeable?
4 MR. LOWENSTEIN: Objection, form,
5 scope.
6 THE WITNESS: I don't believe I've
7 made that assumption in coming to my
8 conclusions.
9 BY MR. STOWELL:
10 Q Do you understand the term "fibrous
11 network" to refer to something different than
12 an outer seal?
13 MR. LOWENSTEIN: Objection, form,
14 scope.
15 THE WITNESS: So it's possible that
16 you're asking me to come up with a definition
17 of fibrous network, which I don't believe
18 anyone has done.
19 I look at the patent where it uses
20 the term "fibrous network," and I understand
21 what it's referring to. I haven't come up
22 with a definition. I don't believe the

1 Petitioner has.
2 BY MR. STOWELL:
3 Q Okay, and I'm not asking for a
4 definition. I'm just asking if you understand
5 the fibrous network to refer to the same
6 structure or features as the outer seal?
7 MR. LOWENSTEIN: Objection, form,
8 scope.
9 THE WITNESS: Well, I think your
10 question was more than does it refer to it. I
11 mean, in this particular case -- I mean,
12 fibrous network and outer seal are not
13 synonymous. In this particular case, the
14 fibrous network is creating an outer seal.
15 BY MR. STOWELL:
16 Q Do you understand there to be any
17 difference between the scope of the term
18 "fibrous network" and the term "sealing
19 material"?
20 MR. LOWENSTEIN: Objection, form,
21 scope.
22 THE WITNESS: Well, again, you're

1 asking quite a complex question, and without
2 agreed definitions of those terms, I don't
3 think I can answer.
4 Obviously, in this particular
5 instance, the material that is creating the
6 seal is the fibrous network, but they are not
7 synonymous, and I'm talking specifically about
8 the use in the claims in this patent. I'm not
9 talking generally or in a vacuum. I'm talking
10 specifically with respect to this.
11 BY MR. STOWELL:
12 Q Are there different parts of the
13 specification that disclose a fibrous network,
14 an outer seal, and sealing material?
15 MR. LOWENSTEIN: Objection, form,
16 scope.
17 THE WITNESS: So we're still talking
18 about the '172 -- sorry, the '538 patent, and
19 this is a very -- I mean, they are all long
20 and complex patents, running to 23 columns. I
21 would have to go through it again to itemize
22 where it refers to those features.

1 BY MR. STOWELL:
2 Q The term "fibrous network" doesn't
3 appear in the specification at all, does it?
4 MR. LOWENSTEIN: Objection, form,
5 scope.
6 THE WITNESS: You may be correct.
7 Again, to be completely accurate, I would have
8 to go through it in detail.
9 BY MR. STOWELL:
10 Q In paragraph 38, you refer to some
11 of the prior art devices as being opaque due
12 to density.
13 A Yes.
14 Q I'm at paragraph 38 of Exhibit 2051.
15 MR. LOWENSTEIN: Would you mind
16 repeating your question? I don't think he
17 heard it.
18 BY MR. STOWELL:
19 Q Yes. In paragraph 38, you refer to
20 some of the prior art devices as being opaque
21 due to density. Do you see where I'm at?
22 A Yes.

1 Q And what do you mean by "opaque"?
2 A I'm using the term in its customary
3 usage in English.
4 Q And what --
5 A Well, I think one synonym would be
6 not transparent. You can't see through it.
7 Q Does the '538 patent use the word
8 "opaque" anywhere?
9 MR. LOWENSTEIN: Objection, form,
10 scope.
11 THE WITNESS: I haven't -- I can't
12 give you an accurate answer to that. I don't
13 think it does, but it's a matter of fact
14 whether it does or not. I can't tell you. I
15 don't think it does.
16 BY MR. STOWELL:
17 Q Does the '538 patent distinguish
18 opaque outer seals from the patented
19 invention?
20 MR. LOWENSTEIN: Objection, form,
21 scope.
22 THE WITNESS: Well, I don't think

1 the specification describes any aspect of this
2 as being opaque.
3 Sorry, could you repeat your
4 question?
5 BY MR. STOWELL:
6 Q Does the '538 patent distinguish
7 opaque outer seals from the patented
8 invention?
9 MR. LOWENSTEIN: Objection to form,
10 scope.
11 THE WITNESS: I don't think it does,
12 but I might have missed -- when you say
13 specifically "opaque," using that word, I
14 don't think it does.
15 BY MR. STOWELL:
16 Q Do you have an opinion regarding how
17 dense the fibers need to be on a seal to be
18 opaque?
19 A I don't have a number. It has to be
20 dense, low porosity, can't see through it, but
21 I don't have a number.
22 Q What do you mean by "low porosity"?

1 A Well, I think I'm probably using the
2 term in the same way as Dr. Buller. I think
3 he described a material as low porosity. I
4 can't give you -- I can't give you units of
5 porosity, but something that's dense and not
6 very porous.
7 Q Can you give me any other sort of
8 measurements or details on what you consider
9 to be a low porosity material?
10 MR. LOWENSTEIN: Objection, form,
11 scope.
12 THE WITNESS: So I cannot give you
13 the units of porosity with a number.
14 I think a cardiologist would
15 understand what they mean by low porosity.
16 I think Dr. Buller and I would agree what
17 something of low porosity was, but not in
18 numerical terms.
19 BY MR. STOWELL:
20 Q When you're evaluating the opacity
21 of the valves, what state is the valve in for
22 that evaluation?

1 MR. LOWENSTEIN: Objection, form,
2 scope.
3 THE WITNESS: All states.
4 I've seen -- I mean, any of these
5 covers, so we could look at Spenser II,
6 Russell, Walther, Cheung, I've used figures,
7 so all of those figures are the figures on
8 which I've come to my opinion.
9 But I think it would be obvious that
10 if something were opaque in an expanded state,
11 if you then compress it down, it would become
12 more opaque. You'd just have more material,
13 more thickness.
14 So, I mean, it's something -- most
15 of the figures show these valves in a deployed
16 state or an expanded state. Russell shows it
17 in the compressed state.
18 BY MR. STOWELL:
19 Q And when you're evaluating the
20 opacity of the outer materials, are you doing
21 that under some sort of magnification?
22 MR. LOWENSTEIN: Objection, form,

1 scope.
2 THE WITNESS: Well, I'm not sure
3 what you mean by that.
4 BY MR. STOWELL:
5 Q Well, for example, if we look at
6 your declaration at page 21, the Walther
7 valve, for instance, has that valve been
8 enlarged or magnified in any way?
9 A Well, the image is the image you
10 see. I'm not quite sure what you're asking.
11 It's an image of the valve that is being
12 expanded. Do you mean has this been put under
13 a magnification? Have I looked at it under
14 magnification? I haven't had the device, so I
15 haven't looked at the device under a
16 magnifying glass.
17 I'm looking -- sorry, I haven't
18 quite finished.
19 I'm looking at the images, and I
20 would have come to my opinion looking at the
21 original paper.
22 Q And do you recall whether the images

1 in that paper had been enlarged from the
2 original size of the device?
3 A Well, we would have to get Walther
4 out, which I do have, and we can determine
5 exactly because Walther has a certain size to
6 it. So I have Walther.
7 Q Walther is Exhibit 1007, correct?
8 A Yes. So I'm looking at Walther on a
9 print, a page that has been printed on normal
10 paper.
11 The image, if I compare it to the
12 image that is in my declaration, the image
13 that is displayed in my declaration is a bit
14 bigger than the image as it appears in
15 Walther. They're both opaque, and I don't
16 think magnification would make a difference to
17 this.
18 Q In paragraph 39 of Exhibit 2051,
19 that's your declaration, you state that
20 Walther, Cheung, Spenser II, and Levi look
21 nothing like what is presented in the patent.
22 What do you mean by that statement?

1 A Well, it's difficult to make it any
2 plainer, really. They look nothing like it.
3 I can't put that into different words.
4 It is looking at the device as a
5 cardiologist, as a POSITA experienced in
6 transcatheter valves, and you see four things
7 that look -- three that look very similar, one
8 that is similar in a number of aspects, and
9 then you look at something else that is
10 completely different.
11 I can't put it in different words to
12 explain it. I thought it was pretty clear. I
13 had not seen any prior art with that
14 arrangement of fibers. They look nothing like
15 what is presented in the patent. They don't.
16 Q So is your statement in paragraph 39
17 that the valves look nothing like what is
18 presented in the patent, is that statement
19 specific to the fibers, or does it refer to
20 other portions of the valve as well?
21 A Well, we're talking about -- in this
22 paragraph, we're talking about the fibers, the

1 seal, and the cloths.
2 Now, as it happens, these valves
3 don't look anything like the patent, but this
4 paragraph is dealing with the fibers and the
5 seal, and they don't look anything like each
6 other.
7 Q Are there any other features that
8 are shown in the pictures on paragraph 21 of
9 your Expert Report that you --
10 MR. LOWENSTEIN: 21 or 39?
11 MR. STOWELL: On page 21 of the
12 expert report. Let me start over.
13 Are there any other features that
14 are pictured on page 21 of your Expert Report
15 that you believe look nothing like what is
16 presented in the patent?
17 MR. LOWENSTEIN: Objection, scope.
18 THE WITNESS: I don't think I've
19 given an opinion or an analysis of that, so I
20 have not done an analysis of the other
21 features.
22

1 BY MR. STOWELL:
2 Q In paragraph 134 of Exhibit 2051 --
3 A 134?
4 Q Correct. You refer to Walther's PET
5 cloth, and specifically the, quote, "PET
6 underneath the fibrous finish," end quote.
7 What do you mean by the PET
8 underneath the fibrous finish?
9 A Okay, so I'd like to just read this
10 paragraph. So these paragraphs provide
11 commentary on Dr. Buller's understanding of
12 the structure of Walther's PET cloth. So his
13 understanding is that it's made of woven
14 fibers with a fibrous finish. So PET in this
15 situation would have a woven base with a
16 fibrous finish, and that's demonstrated by
17 Walther.
18 So the next paragraph is simply --
19 MR. LOWENSTEIN: Can you identify
20 the paragraph?
21 THE WITNESS: Sorry, 134, is simply
22 stating that Walther's PET cloth is woven PET

1 with a fibrous finish, and therefore there
2 will be a base with fibers above it.
3 BY MR. STOWELL:
4 Q Is it your position that the alleged
5 PET underneath the fibrous finish is a graft
6 covering?
7 A Well, woven PET is a graft -- may be
8 a graft covering. That can be a graft
9 covering, and in Walther, it is my opinion
10 that it is.
11 Q You say it may be a graft covering.
12 What characteristics does it have that make
13 the PET a graft covering?
14 MR. LOWENSTEIN: Objection, scope.
15 THE WITNESS: Well, there are
16 many -- I'm not a materials scientist, and
17 there are many embodiments of PET. I think I
18 was told that some plastic bottles are made of
19 PET; they clearly wouldn't be a graft
20 covering.
21 The graft material -- so woven PET
22 can be a graft covering, and it is a dense

1 material that you cannot see through, has a
2 relatively high density and low porosity.
3 So I think I'm agreeing with
4 Dr. Buller on this.
5 BY MR. STOWELL:
6 Q When you say you can't see through
7 it, do you mean can't see through it with the
8 naked eye?
9 MR. LOWENSTEIN: Objection, form,
10 scope.
11 THE WITNESS: That's -- that is, I
12 would say, assumed. You're looking at it.
13 BY MR. STOWELL:
14 Q Does woven PET need to have a
15 certain density to be considered a graft
16 covering?
17 MR. LOWENSTEIN: Objection, form,
18 scope.
19 THE WITNESS: So I've not given
20 definition on numerical assessment to density.
21 I don't think Dr. Buller did either when he
22 used these terms. So I don't think either of

1 us have.
2 BY MR. STOWELL:
3 Q Does woven PET need to have a
4 specific structure to be considered a graft
5 covering?
6 MR. LOWENSTEIN: Objection, form,
7 scope.
8 THE WITNESS: Again, I have not gone
9 into the specific details of woven PET other
10 than understanding that Walther's PET outer
11 cloth is a PET with a fibrous finish. It's
12 made of woven fibers, and it has a fibrous
13 exterior. I'm not going any further than
14 that.
15 BY MR. STOWELL:
16 Q In preparation of your opinions in
17 this matter, did you do any research on the
18 compressibility of PET fabrics?
19 MR. LOWENSTEIN: Objection, form.
20 THE WITNESS: I have not done
21 experiments or research into that.
22

1 BY MR. STOWELL:
2 Q If we can turn to paragraph 136, and
3 I'll specifically take you to pages 89 and 90.
4 There are two pictures at the top of those
5 pages.
6 A Yes.
7 Q Do you see where I'm at?
8 A Yes.
9 Q Did you make these pictures here?
10 A I did not make them.
11 Q The pictures appear to be zoomed in
12 on the Walther device. Would you agree that
13 the pictures are zoomed in on the device?
14 A Yes. Would you just let me -- I
15 just want to read a couple of -- just read the
16 context of these paragraphs.
17 Okay, yes, so I think you used the
18 term "zoomed in" or magnified.
19 Q Do you know what the level of
20 magnification is in the figures on pages 89
21 and 90 of Exhibit 2051?
22 A I do not know the level of

1 magnification over and above the visual
2 appearance.
3 Q And from the visual appearance, do
4 you have an estimate of what the level of
5 magnification is?
6 A I couldn't give you a number.
7 Q Have you done any analysis to
8 confirm that the allegedly dense PET layer on
9 pages 89 and 90 that's been labeled is not
10 just an artifact of the pixilation and
11 magnification?
12 A What type of analysis would you be
13 referring to?
14 Q I'm asking if you've done any
15 analysis.
16 A Well, I've examined the images in
17 various forms of magnification, not just
18 these.
19 These are presented that demonstrate
20 it, but I've looked at all of the images that
21 are available.
22 Q When you say all the images that are

1 available, what are you referring to?
2 A All of the images in Walther.
3 Q Have you done anything else, any
4 other analysis to confirm that the allegedly
5 dense PET layer is not just an artifact of the
6 pixilation and magnification?
7 A Such as? I mean, I think in FIG. 1
8 of Walther you can see it quite clearly,
9 really. I don't think that's an artifact.
10 When you say -- if you're asking me
11 have I had the device of Walther and subjected
12 it to an analysis by a materials scientist,
13 the answer is no because we haven't had the
14 device. It would seem it's being used simply
15 in its -- it's being used by the Petitioner
16 purely as images.
17 Q On paragraph 139 of your
18 declaration, Exhibit 2051, you have included a
19 picture of FIG. 22 of Spenser II, correct?
20 A Yes, that's correct.
21 Can I -- I'm just reading.
22 MR. LOWENSTEIN: Have you finished

1 your last answer?
2 THE WITNESS: No. I was just
3 looking at the image where the yellow has been
4 added simply to highlight it.
5 Underneath the image -- you asked me
6 have I done any analysis, by which I was
7 assuming you meant of the valve, which
8 obviously I haven't had the valve. I've had
9 the images.
10 But as I've put in my declaration, I
11 note the Petitioner repeatedly relies on a
12 dense PET layer as the inner graft covering,
13 and so my analysis is also using that evidence
14 that one would understand there is a dense PET
15 layer underneath Walther's fibrous finish that
16 would be an outer graft covering.
17 So in terms of analysis in the
18 broadest sense, I've analyzed Petitioner's
19 comments as well as the images.
20 BY MR. STOWELL:
21 Q Are you done with your --
22 A I'm done with my answer.

1 MR. LOWENSTEIN: If you are moving
2 to Spenser II, should we take a break?
3 MR. STOWELL: You know, I think
4 we're close on questions here. Why don't I
5 just try to wrap up here in the next couple
6 minutes, and then we'll take a break and I can
7 look over my outline.
8 MR. LOWENSTEIN: If it's fine with
9 Dr. Brecker, it's fine with me.
10 THE WITNESS: Yes, it's fine with
11 me.
12 BY MR. STOWELL:
13 Q Okay. So in paragraph 139, you've
14 reproduced FIG. 22 from Spenser II; is that
15 correct?
16 A Yes, that is correct.
17 Q And there have been some labels
18 added that say "Fibers" with some lead lines,
19 do you see that?
20 A Yes.
21 Q And did you add the "Fibers" and the
22 lead lines to this figure?

1 A Well, I didn't do the graphics.
2 Q What do the lead lines --
3 MR. LOWENSTEIN: Were you done with
4 your answer?
5 THE WITNESS: No, no. I mean --
6 sorry, I want to get the original Spenser II.
7 MR. LOWENSTEIN: Is this cut off,
8 or --
9 (Mr. Lowenstein and witness speaking
10 off record.)
11 THE WITNESS: So could I just have
12 one minute to have a look at the description
13 in Spenser II of FIG. 22?
14 Yeah, sorry, I just had to refresh
15 my memory. I think your question was did I
16 create this figure? So, obviously, prior to
17 this, that we have discussions and
18 interpretation of the figure, and then this
19 figure was provided.
20 I didn't do the graphics myself, but
21 I'm using it, and it's my figure in my
22 declaration, but I didn't physically create it

on a graphics program.

BY MR. STOWELL:

Q But you believe that the figure is correct; is that fair?

A Well, it depends what you mean. The exact end of the line onto the fibers, we could have debate as to whether the fibers are those little lines beyond the bigger line, but it's to represent those areas as being diagrammatically representative of fibers.

Q And so the areas on the outside of the compressible material 256 that have the little lines and dots, is it your understanding that those are the only fibers on the outside of the compressible material?

A No, not at all. I've not made that assumption.

Q Do you believe that there are additional fibers between the lines and dots shown on the outside of the compressible material that simply aren't pictured?

A I've not made a quantitative

1 assessment of how many fibers there are on
2 Spenser II. I haven't made that.
3 All we have is the description in
4 Spenser II, and I'm looking at paragraph 145,
5 where it says, "In certain configurations, the
6 compressible material 256 may resemble a cloth
7 or fabric having small fibers extending from
8 the surface of the material. In various
9 embodiments, the fibers may be straight,
10 curved or hook-shaped."
11 I have not made any assumption
12 beyond that.
13 Q What were you just reading from,
14 Dr. Brecker?
15 A That's Spenser II, paragraph 145.
16 Q And for the record, Spenser II is
17 Exhibit 1011.
18 Would you agree that the fibers that
19 are pictured on the outside of Spenser II's
20 compressible material are sparsely
21 distributed?
22 MR. LOWENSTEIN: Objection, form.

1 THE WITNESS: I have not given -- I
2 don't think I have given an opinion on that.
3 If I could just read through the rest of that
4 paragraph.
5 BY MR. STOWELL:
6 Q Okay.
7 A So I have not given an opinion on
8 that point.
9 Q Okay, Dr. Brecker, we've been going
10 for a while now. Why don't we take a break of
11 10 minutes.
12 MR. LOWENSTEIN: Okay. So 1:15?
13 MR. STOWELL: Sounds good.
14 THE VIDEOGRAPHER: Going off the
15 record. The time is 1:05.
16 (A break was taken.)
17 THE VIDEOGRAPHER: We are back on
18 the record. The time is 1:15.
19 BY MR. STOWELL:
20 Q Dr. Brecker, did you speak with
21 anyone about your deposition testimony during
22 the break?

1 A I did not.
2 Q At this time, I have no further
3 questions for you. I thank you for your time,
4 and Edwards will pass the witness.
5 MR. LOWENSTEIN: Thank you. So
6 we'll take a short break, and we'll be back
7 on.
8 THE VIDEOGRAPHER: Okay. Going off
9 the record. The time is 1:15.
10 (A break was taken.)
11 THE VIDEOGRAPHER: Okay, back on the
12 record. The time is 1:19.
13 MR. LOWENSTEIN: Thank you, we have
14 no further questions. This should conclude
15 the deposition.
16 THE VIDEOGRAPHER: Okay. Going off
17 the record. This deposition is concluded at
18 1:19.
19 (Whereupon, at 1:19 p.m. PDT, the taking
20 of the deposition was concluded.
21 Reading and signature were
22 RESERVED.)

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