

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

(
(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 11,497,634
Edwards Ex. 1073

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Page 273

1 I-N-D-E-X

2 WITNESS:

PAGE:

3 STEPHEN BRECKER, MD

4 Examination by Mr. Stowell

288

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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

1 on a graphics program.

2 BY MR. STOWELL:

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

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

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

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

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

22 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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2 1016 Pico Boulevard

Santa Monica, California 90405

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4 Case: Edward Lifesciences Corp., et al., v. Aortic Innovations, LLC

Date of deposition: August 31, 2022

5 Deponent: Stephen J.D. Brecker Vol II

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15

16

17

18

19

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21

22

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A	291:22 298:19 362:15	apply 333:21	340:1	360:6,11
a.m 270:17	allows 331:17,18	appreciate	aspects 280:10	backup 276:8
274:8	amount 302:17	303:22 306:16	280:11 333:13	balloon 321:5
able 329:5,7	analysis 324:19	appropriate	345:8	322:3
absent 362:21	346:19,20	288:7 290:18	assembly 321:6	balloon-expan...
absolutely 279:7	352:7,12,15	291:8 292:14	322:4	280:3,13
accurate 275:6	353:4,12 354:6	300:7 305:12	assess 328:5	281:11,13
276:9 313:3	354:13,17	363:10	assessment	308:15 309:2,4
338:7 339:12	analyzed 319:15	area 289:12	349:20 358:1	309:8
accurately	354:18	314:8 315:2	assume 283:15	Barnes 271:5
324:20	anatomy 323:1	325:16	284:4	294:16
acknowledge	325:11,14	areas 299:18,20	assumed 349:12	base 347:15
363:7	and/or 362:11	320:8 357:9,11	assuming 354:7	348:2
act 323:2	answer 280:12	arguments	assumption	Based 330:2
action 361:8	281:8 283:1	302:9	313:22 315:15	basis 295:3
actions 361:10	290:1 314:13	arrangement	325:10 327:4	BEAR 271:3
add 355:21	314:15 315:8	312:11 331:11	335:7 357:17	behalf 271:2
added 354:4	324:19 329:3	331:17 345:14	358:11	272:2 294:14
355:18	329:11 333:11	art 331:10	assumptions	behave 320:7
additional	334:12,12	332:20 333:12	315:18	behavior 320:17
357:19	337:3 339:12	334:6 338:11	attached 309:16	321:13
address 331:3	353:13 354:1	338:20 345:13	312:21 313:6,7	believe 282:17
addressed	354:22 356:4	artifact 352:10	313:15,20,21	301:11,12
329:22 331:2	answers 363:11	353:5,9	314:19 315:7	311:2,5 313:13
adjourned	363:13	artificial 329:9	315:11 363:12	313:18 315:5
306:16	anybody 275:7	aside 302:17	attachment	323:6 325:2
advantage	aortic 270:8	asked 284:6	315:15 319:15	334:5 335:6,17
298:16	274:6 277:21	287:13 298:4	attorney 361:9	335:22 346:15
advise 362:12	315:21 322:5	299:1,9 301:13	attributed	357:3,18
advised 362:7	325:11 362:4	302:3,11,13	318:18	best 305:14
afraid 300:6	363:4 364:8	303:6,11	audio 276:7,10	beyond 310:20
agency 276:4	apart 318:13,21	306:13 307:10	276:11	312:6 313:10
agree 281:12	apologize 306:9	319:13,14	August 270:16	357:8 358:12
286:10,14,22	APPEAL 270:2	328:17 329:14	274:7 361:21	big 276:4
341:16 351:12	appear 319:18	354:5	362:4 363:5	bigger 344:14
358:18	338:3 351:11	asking 280:20	364:10	357:8
agreed 337:2	appearance	281:2 284:1,8	available 352:21	billing 292:19
agreeing 349:3	316:9 318:8	291:11 298:13	353:1	Billy 272:22
al 274:6 362:4	352:2,3	300:9 301:14	Avi 271:17	275:9
363:4 364:8	APPEARANC...	301:22 302:1,5	aware 279:21	biomedical
Ali 272:15	271:1 272:1	304:17,22	280:21 281:3,5	314:1
alignment	appears 301:12	306:8 327:19	B	bit 279:11
320:21 322:3	301:17 344:14	328:20 335:16	back 276:18	324:19 344:13
alleged 348:4	361:4	336:3,4 337:1	289:20 299:22	board 270:2
allegedly 352:8	applicable	343:10 352:14	306:12 307:1	284:21 287:9
353:4	362:15	353:10	328:14 359:17	287:17 288:8
allowed 274:19		aspect 333:18		288:10,11,14

289:9 290:7	busy 300:4	296:4	cogent 302:12	309:3
291:4,14 292:5		Change 364:11	collagen 310:3	compress 342:11
292:11 294:3	C	changed 328:21	312:17	compressed
294:10 296:16	C 271:5 274:1	changes 363:12	colleagues	322:18 323:7
297:10 299:15	c/o 362:1	characteristics	303:17	323:13 324:1,3
299:20 300:1	calcium 323:20	328:22 348:12	colorable 291:15	324:7 342:17
302:7 303:14	calculation	characterizati...	columns 337:20	compressibility
bottles 348:18	318:7	310:9	combination	350:18
Boulevard 272:6	California 271:9	characterizati...	303:4	compressible
362:2	272:7 362:2	292:15	combined 297:5	357:12,15,20
box 363:10	call 284:21	characterized	come 289:20	358:6,20
break 307:5	288:8,9,13	300:21 315:20	308:2 311:11	compression
355:2,6 359:10	289:8 290:7	check 311:15	311:14 335:16	321:5 323:3,4
359:16,22	292:5,19 294:3	363:10	335:21 342:8	324:5,6
360:6,10	294:12 297:9	Cheung 327:15	343:20 362:9	comprised
Brecker 270:15	300:6 306:12	342:6 344:20	comfortable	334:19
273:3 274:4	306:13,21	circumferenti...	314:18	CON'T 272:1
276:18 277:18	362:17	321:9	coming 335:7	concerned
278:16 283:7,8	called 295:3	claim 320:18	comment 283:9	283:19
283:22 284:3,8	303:14	321:15,22	commentary	conclude 360:14
285:15 287:13	calling 301:10	322:7	347:11	concluded
298:11 302:10	camera 329:5	claims 281:1	comments	306:21 360:17
306:12 307:4	capital 276:4	320:16 321:12	354:19	360:20
330:18 355:9	caption 361:6	322:9 323:3	commission	conclusion
358:14 359:9	capture 276:8	335:3 337:8	361:20	297:16 311:12
359:20 362:1,5	cardiologist	clarification	common 275:4	conclusions
363:5 364:9	341:14 345:5	300:16	303:7 317:14	335:8
Brecker's	care 304:1	clean 285:10	Commonwealth	conduct 292:13
300:10,22	carefully 299:6	286:18 290:4	361:3,19	304:21
301:13,18	carry 331:15	clear 275:1,16	compacted	conference
302:14,21	case 289:13,15	317:20 321:6	316:14 317:6	295:2
Brian 271:5	298:2,18	345:12	compare 324:12	conferred 305:6
294:16	299:21 300:14	clearly 348:19	344:11	configuration
brian.barnes...	336:11,13	353:8	complete 289:16	321:10
271:12	362:4 363:4	clinical 333:4,6	289:21 293:2,3	configurations
briefing 299:6	364:8	clock 287:4,6,11	293:8,12 324:6	358:5
broadest 354:18	catch 306:6	close 355:4	362:8 363:11	confirm 274:21
broke 277:3	cell 321:10	closely 316:22	363:13	295:19 352:8
building 301:6	certain 344:5	cloth 347:5,12	completed	353:4
Buller 271:16	349:15 358:5	347:22 350:11	314:14	confused 300:19
331:12 341:2	certainly 324:18	358:6	completely	consent 362:22
341:16 349:4	333:16	cloths 346:1	300:15 324:2	consequently
349:21	CERTIFICATE	CLR 270:19	325:14 327:13	284:4
Buller's 347:11	361:1	361:17	338:7 345:10	consider 316:7
bundle 311:13	certify 361:3	clumped 310:8	complex 337:1	341:8
bundles 310:9	cetera 328:2	clumps 311:3	337:20	considered
310:16 311:3,5	challenged	coaching 287:15	component	307:22 308:21

315:12 334:3 349:15 350:4 consistently 331:5 332:10 consult 303:17 314:8 consulted 315:16 contact 287:17 288:10 294:10 contacting 299:15 contain 278:6 context 286:7 351:16 continuation 277:10 continue 283:9 284:17 288:20 292:21 296:7 continued 270:14 299:12 continuing 274:3 321:21 copy 362:10 Copying 362:21 Copyright 362:21 Corp 362:4 363:4 364:8 Corporation 270:4 274:5 correct 274:15 276:7 280:4 281:20 301:16 310:4 315:22 326:21 338:6 344:7 347:4 353:19,20 355:15,16 357:4 363:10 363:13 counsel 274:10 291:21 295:6 295:11 298:13 361:7,9 362:11 362:14	count 318:9,11 countable 318:8 counterintuitive 331:8 334:3 couple 351:15 355:5 course 328:20 court 275:4 276:3,21 283:15 284:10 291:12 292:16 294:17,18,21 294:22 295:1 296:21 300:19 302:15 303:15 303:19,21 305:4 306:14 covering 321:4 331:17 348:6,8 348:9,11,13,20 348:22 349:16 350:5 354:12 354:16 coverings 327:14 covers 342:5 Craig 271:6 294:16 craig.summer... 271:13 create 331:10 334:4 356:16 356:22 creating 317:1 336:14 337:5 crimp 331:18 cross-examina... 295:5 296:12 305:10 306:22 CSR 270:19 361:17 curved 358:10 customary 316:20 339:2 cut 356:7 D	D 274:1 D.C 270:21 363:2 364:3 date 274:7 362:4 363:5,17,22 364:10,22 Dawn 270:19 361:2,17 day 297:3 Daylight 274:8 dealing 346:4 dealt 330:21 debate 357:7 declaration 278:5 280:8 281:6 282:17 282:18 283:21 285:16 296:1 296:13 298:12 301:13,18 302:22 304:15 308:2 310:19 311:16,18,22 312:1 315:2,19 318:22 319:11 330:16 331:22 332:8 334:2 343:6 344:12 344:13,19 353:18 354:10 356:22 declined 300:2 deem 290:17 define 309:12 defined 330:9 definition 317:13 318:7 318:18,19,20 319:11 324:4 330:8 335:16 335:22 336:4 349:20 definitions 337:2 definitive 333:10 delay 299:16	305:15 delete 275:20 deleted 274:22 deliverable 331:19 demanded 296:14 demonstrate 352:19 demonstrated 347:16 dense 327:13 340:17,20 341:5 348:22 352:8 353:5 354:12,14 densely 317:5 density 316:13 317:9,18 318:4 318:19 327:12 338:12,21 349:2,15,20 depend 323:17 Depending 279:10 depends 357:5 deployed 342:15 deponent 362:5 362:9,11 deposed 283:22 deposition 270:14 274:4 274:20,21 275:3 277:2,8 277:11 279:19 280:9 282:17 283:19 287:2 287:18 289:3,7 289:8,18,21 290:8 291:11 292:13,21 293:8,13,16 294:1,9 295:12 295:16 296:7 296:14,17,19 297:3,6,8,11 297:16 299:12	300:8 302:18 304:21 305:3,8 305:16,22 306:11 359:21 360:15,17,20 361:3,6,8 362:4,14 363:5 363:8 364:10 depositions 303:12,13 describe 312:6 327:2 described 277:6 278:19 279:14 280:2 281:14 282:1 310:20 310:21 311:1 312:4,20 327:14 341:3 describes 313:14 340:1 describing 279:3 310:20 description 279:9 281:9,19 282:22 310:5 311:3,6 313:5 313:19 319:17 320:6 321:6,18 322:10,12 356:12 358:3 descriptions 279:20 descriptive 319:1 designed 295:19 308:20 309:1,7 detail 280:22 283:1 338:8 details 341:8 350:9 determination 300:1 determine 334:7 344:4 developing 315:12
---	---	---	---	--

device 325:13,15 327:10 343:14 343:15 344:2 345:4 351:12 351:13 353:11 353:14	distributed 315:22 316:8 316:12,17,21 317:2,5,9 318:11,14 319:3,7,19 327:9 328:9 329:17 331:4 332:9,21 358:21	E E 274:1,1 E-X-H-I-B-I-... 273:7 Edward 272:5 362:4 363:4 364:8 Edwards 270:4 270:5 274:5 275:2 294:15 360:4 eight 301:20 either 275:19 284:18 293:22 319:12 349:21 349:22 electronically 362:21 element 321:1,7 elongate 304:12 304:13 307:11 307:18 elongated 282:2 282:4,11 email 271:11 272:9 284:15 288:11 298:22 299:11,20 embodiments 278:19 279:22 348:17 358:9 emergency 295:3 employed 361:7 361:9 employee 361:9 enablement 297:21 300:12 302:6,9 endovascularly 331:19 engage 323:1 engaged 313:8 321:20 engineer 314:8 315:17 engineering	314:1 England 300:3 English 317:14 339:3 enlarged 317:21 343:8 344:1 entertain 305:13 entitled 285:20 290:13 291:2 292:13 errata 362:13 363:12 364:6 Esq 271:4,5,6,17 272:4,5,17 essentially 321:13 estimate 352:4 et 274:6 328:2 362:4 363:4 364:8 evaluating 341:20 342:19 evaluation 341:22 everybody 305:21 everybody's 293:22 everyone's 292:4 293:14,20 evidence 270:20 272:22 305:9 354:13 362:20 362:21 363:1 364:1 exact 357:6 exactly 277:12 291:21 305:2 310:19 334:1 344:5 examination 273:4 288:18 examined 352:16 363:7 example 285:15 316:14 317:22 343:5	examples 308:18 excerpted 295:21 excuse 286:12 286:12,16 Exhibit 272:21 273:9,11,13 277:17 278:5 315:13 316:4 326:16 334:16 338:14 344:7 344:18 347:2 351:21 353:18 358:17 EXHIBITS 273:8 exited 283:13 expand 322:4 expanded 320:1 320:12 322:18 323:2,8,13 324:10 325:4 342:10,16 343:12 expansion 322:13 expended 325:19 experience 312:16 333:4,6 333:14 experienced 345:5 experiments 350:21 expert 271:16 295:21,22 304:14 346:9 346:12,14 expert's 295:19 296:3,5 expires 361:20 explain 295:7 319:22 345:12 explains 320:11 explanation 302:12
---	---	---	---	---

explicit 313:19	323:6,12,19,22	353:19 355:14	281:16 282:5	324:2 329:7
express 362:22	324:2,7,11,12	356:13	282:13 307:19	334:17
expressed	324:13 325:3	figure 278:12	308:8,17	FRCP 270:15
279:20 315:13	325:18 326:5	279:3,21 281:4	309:10,18	front 277:7,10
331:21	327:8 328:4,7	281:22 283:1	310:10,17	307:6 311:19
extending 312:5	328:17,21	287:22 295:22	311:8 312:13	frustration
312:6,17 321:9	329:1,2,15	307:6 332:7	312:22 313:17	302:16
321:16 331:3	330:12 331:3,4	355:22 356:16	314:5,21	function 282:11
334:20 358:7	331:9,11,13,16	356:18,19,21	316:18 318:5	304:11,18
extends 321:8	332:3,9,20	357:3	318:15 319:8	307:17,22
exterior 350:13	334:4,7,7,20	figures 287:22	320:3,13	333:18
eye 349:8	340:17 345:14	295:14 296:3	322:20 323:15	further 296:18
	345:19,22	301:20 304:22	324:14 325:5	305:15 306:15
F	346:4 347:14	305:1 315:20	325:20 326:6	350:13 360:2
fabric 316:15	348:2 350:12	317:19 319:2	328:11 329:19	360:14 361:8
358:7	355:18,21	319:18 322:12	330:5 332:5	
fabrics 350:18	357:6,7,10,14	331:6,14	333:1 334:9	G
FACC 270:15	357:19 358:1,7	332:11,17	335:4,13 336:7	G 274:1
fact 339:13	358:9,18	342:6,7,7,15	336:20 337:15	gaps 324:11,12
factual 281:8	fibrous 304:16	351:20	338:4 339:9,20	324:13,22
283:2	311:1 320:20	financially	340:9 341:10	325:3
Fahnert 272:22	321:2,8,16,19	361:9	342:1,22 349:9	generally 337:9
fair 310:9	321:22 322:5	fine 276:10	349:17 350:6	gentlemen
314:10,17	323:3 331:2	286:19 355:8,9	350:19 358:22	303:16
357:4	334:18 335:1	355:10	formed 321:10	getting 286:18
far 318:13,21	335:10,17,20	finish 347:6,8,14	326:4	give 292:19
features 295:20	336:5,12,14,18	347:16 348:1,5	forming 308:1	317:4,17 318:3
304:17 336:6	337:6,13 338:2	350:11 354:15	forms 352:17	326:11 333:10
337:22 346:7	347:6,8,14,16	finished 343:18	formula 333:21	339:12 341:4,4
346:13,21	348:1,5 350:11	353:22	forth 284:3	341:7,12 352:6
FECS 270:15	350:12 354:15	firm 300:3	forward 305:7	given 275:12
Federal 305:9	FIG 278:8,13,14	first 275:9 297:7	362:13	280:7,11,16
fiber 301:22	278:18 279:14	297:9 301:7,8	foundational	281:5 282:7,15
fibers 288:1,5	280:2,17	303:14 320:17	295:18	302:12 315:3,5
301:21 310:3,7	285:16 288:3,4	320:22	four 297:6	317:12 318:17
310:16 311:6	295:17 301:1	fit 292:14	301:19 345:6	318:20 319:10
312:4,11,17,20	301:11,12,17	five 301:19	frame 279:15,22	319:17 324:17
313:7,14	302:13 307:5,8	Floor 271:8	280:3,14	324:21 330:11
314:19 315:6	307:14 308:6	follow 312:2	281:11,13,15	332:2,6,14
315:10,20	310:2,5,8	following 275:12	301:15,15	346:19 349:19
316:7,14	311:7 312:12	294:11	302:1 304:14	359:1,2,7
317:10,19	312:21 314:20	forbidden	304:16 307:12	361:7 363:11
318:4,8,9,13	317:22,22	362:21	308:6,15,16	363:13
319:1,6,18	319:2 322:13	foregoing 361:3	310:4 313:15	giving 293:19
320:1,7,12,17	324:13 328:8	361:4 363:7	314:19 315:7	glancing 330:19
321:13,16,19	329:16 330:12	form 278:2,21	315:11 321:4	glass 343:16
322:17,22	332:3,15 353:7	279:16 280:5	321:20 322:2	go 286:8,11,15

286:22 287:9	H	273:1	indicates 313:6	inwardly 321:17
289:19 290:15	hand 298:1,9	identical 325:15	313:7	IPR 274:20
290:20 291:14	303:8	identified 304:6	individual	277:17 281:4
305:7,14	happen 290:13	identify 347:19	310:16	284:20 285:3
310:18,20	320:11	II 270:15 298:3	inflating 322:3	285:14 292:7
311:15 313:10	happening 305:2	303:2 328:2	inflation 321:5	296:5 297:14
316:1 320:7	happens 319:22	342:5 344:20	informing	298:16,17
328:13 329:12	322:11 346:2	353:19 355:2	299:12	299:3,14 300:7
337:21 338:8	happy 279:8,12	355:14 356:6	inner 280:3,13	303:13 304:11
going 282:21	282:19,20	356:13 358:2,4	281:11,13	IPR2021-01527
283:8,20	315:1	358:15,16	354:12	270:10
284:17,18	heard 274:13	362:1,5 363:5	Innovations	IPRs 283:21
286:10 287:8	276:19 338:17	364:9	270:8 274:6	291:17,20,21
288:9,10,11	heart 278:19	II's 358:19	277:22 315:21	295:15 297:6
289:16,22	279:14 308:14	iliac 303:7	362:4 363:4	irrelevant 303:6
290:10,12	320:19	image 316:10,11	364:8	303:11
293:1,6,12,13	held 306:4	343:9,9,11	inquiry 302:6	Irvine 271:9
294:1,7 305:7	hell-bent 293:19	344:11,12,12	inside 308:15	isolation 332:15
305:8,11	help 316:3	344:14 354:3,5	309:8,13 327:5	issue 288:15
306:15 313:3	hereof 361:6	images 317:21	inspect 334:6	290:2 295:15
319:12 329:1	hesitate 362:17	343:19,22	instance 337:5	298:9 301:2
350:13 359:9	high 292:20	352:16,20,22	343:7	304:11 329:22
359:14 360:8	349:2	353:2,16 354:9	instances 298:8	issues 284:2
360:16	highlight 354:4	354:19	instantiation	297:14,19,20
good 276:15	hold 292:8	impasse 295:3	288:5	297:22 298:12
296:21 303:15	314:12	300:17,21	instruct 290:1	299:3 300:9,10
306:14 359:13	Honor 294:13	impede 296:18	305:7	302:10 303:8
Goodbye 306:17	295:8 301:10	implanted 326:3	instruction	item 282:4,12
gotten 290:2	304:3 305:18	implanting	276:3,13	307:11,13,17
governing	306:9,19,20	333:8	296:17	310:3,6
362:15	hook-shaped	implications	interaction	itemize 337:21
graft 321:4	358:10	280:11 281:3	325:13	
331:16 348:5,7	hot 277:14	improper	interchangeable	J
348:8,8,11,13	hours 290:10,11	284:12 297:18	335:3	J.D 270:15 362:1
348:19,21,22	292:4 293:6	inappropriate	interested	362:5 363:5
349:15 350:4	297:3,4,12	291:17 300:15	361:10	364:9
354:12,16	301:6 302:19	included 295:21	interesting	Jaques 270:19
graphics 356:1	Hsieh 272:5	353:18	324:18 325:8	361:2,17
356:20 357:1	hsieh@lowens...	includes 321:16	interject 275:22	job 275:12,14
grids 321:9	272:11	321:19	276:1	John 294:12
322:8	hundreds	including 331:15	interpretation	joining 294:15
Group 270:20	291:21	362:21	319:19 356:18	Josh 294:14
272:22 362:20	hypothetical	incorrect 292:17	interrupting	295:9
362:21 363:1	329:10	311:6	290:5	Joshua 271:4
364:1		increase 329:2	invention 331:18	joshua.stowell...
guess 293:14	I	indefiniteness	339:19 340:8	271:11
	I-N-D-E-X	297:21 300:12	Inventor 272:15	judge 294:12

297:10 306:21 Justin 272:17	level 351:19,22 352:4 Levi 298:3 344:20 Lifesciences 270:4,5 274:5 294:15 362:4 363:4 364:8 limit 296:19 limited 302:17 limits 331:19 line 284:19 288:13,20 289:14,16 292:2,6,8 293:2 299:22 305:21 316:5 357:6,8 364:11 lines 355:18,22 356:2 357:8,13 357:19 litigation 284:10 291:12 292:16 297:20 298:14 298:18 299:13 302:4 litigator 298:17 little 279:11 298:21 300:19 310:8 357:8,13 LLC 270:5,8 274:6 362:4 363:4 364:1,8 LLP 271:3 272:3 362:1 long 337:19 look 285:18,22 286:3,4 289:5 293:21 311:21 313:4 316:3 330:15 334:15 335:19 342:5 343:5 344:20 345:2,7,7,9,14 345:17 346:3,5 346:15 355:7 356:12	looked 327:9 332:16 333:16 343:13,15 352:20 looking 312:3 316:11 317:22 319:2 326:22 327:1 343:17 343:19,20 344:8 345:4 349:12 354:3 358:4 Lord 291:1 lot 302:8 303:12 303:12 320:6 low 316:13 327:12 340:20 340:22 341:3,9 341:15,17 349:2 Lowenstein 272:3,4 274:11 274:18 275:8 275:15,20 276:2,10,15 278:2,21 279:16 280:5 281:16 282:5 282:13 283:6 283:12,14,18 284:22 285:4,7 285:10,11,18 285:22 286:3,6 286:9,14,17,19 286:21 287:1,3 287:7,12,20 288:6,9,22 289:4,10,22 290:3,9,15,19 291:1,7,18,19 292:12,18 293:11,17 294:4 295:10 296:6,8,13,18 296:22 297:2 300:20 301:4 302:16,19	303:18 304:5 304:20 305:18 305:21 306:2,7 306:18 307:19 308:8,17 309:10,18 310:10,17 311:8 312:13 312:22 313:16 314:5,12,21 316:18 317:11 318:5,15 319:8 320:3,13 322:20 323:9 323:15 324:14 325:5,20 326:6 328:11 329:19 330:5,14 332:5 333:1 334:9 335:4,13 336:7 336:20 337:15 338:4,15 339:9 339:20 340:9 341:10 342:1 342:22 346:10 346:17 347:19 348:14 349:9 349:17 350:6 350:19 353:22 355:1,8 356:3 356:7,9 358:22 359:12 360:5 360:13 362:1 lowenstein@lo... 272:10 lump 323:20	353:6 magnified 343:8 351:18 magnifying 343:16 Main 271:7 making 315:14 325:10 manner 326:17 manners 288:3 manufacturing 313:9 marked 273:8 277:16 Martens 271:3 294:14 295:9 material 334:19 335:2 336:19 337:5,14 341:3 341:9 342:12 348:21 349:1 357:12,15,21 358:6,8,20 materials 277:7 277:9 342:20 348:16 353:12 matter 274:5 278:1 291:5 339:13 350:17 362:8 matters 292:21 300:4 MD 270:15 273:3 mean 288:2 306:3 308:22 309:3,7 316:11 316:16 317:3 332:12 336:11 336:11 337:19 339:1 340:22 341:15 342:4 342:14 343:3 343:12 344:22 347:7 349:7 353:7 356:5 357:5
K Knobbe 271:3 294:14 295:9 know 276:3 278:10 282:3 291:21 299:5,7 300:13 320:10 325:11 332:20 334:12 351:19 351:22 355:3 knowledge 308:20 309:20 311:13 known 314:1,3 315:16 knows 300:13	L L.L.C 363:1 labeled 352:9 labels 355:17 law 272:18 276:22 layer 352:8 353:5 354:12 354:15 lead 355:18,22 356:2 leaflet 320:21 323:21 leaflets 321:3 322:6 leak 334:8 leakage 328:10 329:18 leave 283:8 287:13 306:13 left 330:19 333:9 length 319:5 let's 285:18,22 286:3,4,8,21 287:11 291:8 293:8 299:19 334:15 letters 276:5	lowenstein@lo... 272:10 M M 270:21 363:1 364:2 Madam 283:15 magic 333:20 magnification 342:21 343:13 343:14 344:16 351:20 352:1,5 352:11,17		

means 326:12	necessarily 325:14 327:3 333:10	noticing 362:14	335:4,13 336:7	327:4,5,13,16
meant 354:7		notified 291:13	336:20 337:15	328:2,5,18
measure 291:10		297:17	338:4 339:9,20	329:4,9 338:11
measurements 317:18 318:3 341:8	necessary 305:12	noting 362:14	340:9 341:10	338:20 339:1,8
Members 305:6	need 279:11	number 273:9	342:1,22	339:18 340:2,7
memory 356:15	282:21 283:4	273:11 277:15	346:17 348:14	340:13,18
mention 298:22	284:18 286:10	280:3 282:1	349:9,17 350:6	342:10,12
mentioned 361:5	287:9 289:4	329:2 333:21	350:19 358:22	344:15
method 313:9	293:16 294:1	340:19,21	objectionable 304:6	open 321:10
315:6,10	306:3 318:13	341:13 345:8	objections 296:8	operability 302:6,9
methods 314:1,3	340:17 349:14	352:6	296:10,19	operator 277:14
315:16	350:3	numerical 318:7	297:15 305:11	opined 277:22
mind 276:14	needed 275:13	318:19,20	obvious 342:9	opinion 280:8
317:10 338:15	neglected 298:22	319:14 341:18	obviously 280:20 285:17	281:5 282:8,16
minute 279:2	neither 287:19	349:20	302:7 304:4	287:21 301:1
356:12	361:7	NW 270:21	321:11 322:10	315:4,6 324:17
minutes 294:18	network 304:16	363:1 364:2	323:19 337:4	324:21 330:11
295:12 306:1	304:18 311:1	O	354:8 356:16	331:21 332:2,7
355:6 359:11	317:1 320:20	O 274:1	offer 298:11	332:13 340:16
missed 323:10	321:2,8,16,19	oath 274:9	offered 288:2	342:8 343:20
340:12	321:22 322:5	276:20	offering 314:11	346:19 348:9
moment 290:16	323:4 331:2	object 300:20	314:18	359:2,7
290:20 301:3	334:4,18 335:2	313:17	office 270:1	opinions 278:6
303:16	335:11,17,20	objected 284:12	362:9,17	279:20 280:12
Monica 272:7	336:5,12,14,18	objection 276:11	Oh 291:1 306:7	280:17 284:3,7
362:2	337:6,13 338:2	278:2,21	okay 275:15,17	288:3 296:5
morning 285:14	never 275:6	279:16 280:5	276:18 279:8	300:10 308:1
288:7 295:10	287:17	281:16 282:5	281:12 283:4	314:11,18
299:15	Nevertheless 302:16	282:13 290:14	287:5 290:19	315:12 350:16
motion 305:13	New 294:12	291:3,4 293:9	293:15 294:6,7	opportunity 291:6 292:10
move 289:11	306:21	307:19 308:8	307:4 308:5	option 293:18
292:6 299:17	Nifong 272:17	308:17 309:10	311:5 326:19	362:11,12
moving 355:1	Nigel 271:16	309:18 310:10	328:16 330:21	order 293:2
	nine 301:20	310:17 311:8	336:3 347:9	296:16 298:18
	NK 272:18	312:13,22	351:17 355:13	ordinary 332:19
N	non-uniform 325:12	313:16 314:5	359:6,9,12	334:5
N 274:1	Nope 274:18	314:21 316:18	360:8,11,16	original 343:21
naked 349:8	normal 344:9	317:11 318:5	OLSON 271:3	344:2 356:6
name 275:9,9	Notary 361:1,2	318:15 319:8	omitted 315:3	362:13
363:5 364:9	361:18 363:22	320:3,13,14	once 298:5	outcome 361:10
narrow 331:17	note 354:11	322:20 323:15	299:22	outer 281:15
Nathan 272:4	noted 363:12	324:14 325:5	opacity 341:20	304:13,16
native 320:21	notice 274:21	325:20 326:6	342:20	307:12 312:18
321:2 323:1,18	330:18	328:11 329:19	opaque 325:18	321:3,20 322:2
nature 281:9		330:5,14 332:5	326:5,10,11,15	326:4 331:16
nearly 279:6		333:1 334:9		

334:17,18	326:18,20	337:18 339:7	Petitioner	porosity 340:20
335:2,12 336:6	330:22 334:15	339:17 340:6	294:15 295:6	340:22 341:3,5
336:12,14	334:16 338:10	344:21 345:15	298:15 336:1	341:9,13,15,17
337:14 339:18	338:14,19	345:18 346:3	353:15 354:11	349:2
340:7 342:20	344:18 345:16	346:16	Petitioner's	porous 341:6
350:10 354:16	345:22 346:4,8	patent's 331:5	354:18	portion 279:9
outline 355:7	347:2,10,18,20	331:13 332:10	Petitioners	281:22
outside 283:11	351:2 353:17	patented 339:18	270:6 271:2,15	portions 345:20
283:20 296:12	355:13 358:4	340:7	phone 271:10	POSITA 345:5
301:9 322:17	358:15 359:4	patents 277:22	272:8 299:1	position 348:4
323:7,12 327:4	paragraphs	295:14 296:4	phrase 317:8	positioned
327:10 328:8	347:10 351:16	304:11 307:17	physically	308:15 309:15
329:6,16	paravalvular	315:21 337:20	356:22	320:19 322:1
357:11,15,20	328:9 329:17	patience 303:22	Pico 272:6 362:2	possible 299:8
358:19	334:8	patient 320:2	picture 285:15	325:9 335:15
outwardly 312:4	part 304:13	321:3 322:19	353:19	practice 291:20
322:1,6 331:3	308:1 325:15	323:8,14	pictured 308:6	297:9 308:13
334:20	partially 322:1	324:11 325:4	310:2 330:12	precise 313:8
overlapping	particular	325:19 326:4	332:3 346:14	precisely 304:5
320:20 322:2	333:18 336:11	327:3,5,6,10	357:21 358:19	prefer 287:10
oversized 323:21	336:13 337:4	327:20,22	pictures 346:8	293:17
Owner 270:9	particularly	328:5,18,19,22	351:4,9,11,13	preparation
272:2,13	280:22 284:5	329:2,7	pixilation	280:9 308:3
295:11	parties 294:22	pause 289:7	352:10 353:6	350:16
	295:4 361:8,9	290:8 294:20	place 329:5	preparations
P	parts 324:1	303:20	361:5	311:14
P 274:1	337:12	PDT 270:17	placed 309:4,8	prepared 305:22
p.m 360:19	pass 360:4	360:19	309:13	present 271:15
Pacific 274:8	patent 270:1,2,9	peace 276:14	plainer 345:2	272:13 295:1,1
page 273:2,9	270:11 272:2	people 292:18	plan 293:3	331:13
285:16 287:21	272:13,18	percent 300:8	plastic 348:18	presented
301:18 312:3	273:11 277:15	period 362:15	play 319:6	344:21 345:15
316:2,4,5	277:19 278:6,9	permissible	please 274:21	345:18 346:16
343:6 344:9	278:20 280:21	305:10	275:21 276:1	352:19
346:11,14	282:11 283:5	person 332:19	278:10 281:7	preserve 296:8
362:14 363:4	284:9 295:11	333:12 334:5	283:5 285:9,11	preserved
364:11	301:20 304:10	pertinent 288:17	286:20 290:4	305:12
pages 331:1	304:22 307:8	289:12,15	292:20 295:7	presumably
351:3,5,20	308:7 310:21	PET 347:4,5,7	297:1 362:7,12	306:11
352:9 361:4	310:22 312:9	347:12,14,22	362:13,16	pretty 345:12
363:7	313:4,11,14	347:22 348:5,7	plenty 322:15	prevent 328:9
panel 300:11	317:17,21	348:13,17,19	plurality 312:4	329:17 330:4
305:6 306:3	318:3 319:20	348:21 349:14	plus 299:16	330:13 332:4
paper 343:21	319:22 320:6	350:3,9,10,11	300:8	332:21 334:8
344:1,10	320:11 330:3,3	350:18 352:8	point 328:7	previous 328:14
paragraph	330:20 332:16	353:5 354:12	329:15 359:8	329:13
316:4 326:16	335:19 337:8	354:14	pointed 301:17	previously 273:8

277:16	304:8 307:10	radially 312:6	361:7	299:2
print 344:9	308:22 318:2	321:17 322:1	recorded 274:15	relative 361:9
printed 344:9	323:10 324:18	331:3 334:19	274:17 275:13	relatively 349:2
prior 331:10	325:8 326:1,9	raise 291:4	363:11,14	relevance 284:6
338:11,20	328:14 329:3	rates 292:20	recording	284:11 296:9
345:13 356:16	329:13,14	read 279:2,9,11	274:14	299:8,9,14
probably 341:1	332:1 333:11	280:21 281:19	records 275:4	relevant 284:20
procedure	334:12,13	282:20,22	reduced 361:6	285:3 292:7
305:16 362:16	336:10 337:1	283:5 332:11	refer 335:11	296:5 298:8
proceed 274:10	338:16 340:4	334:21 347:9	336:5,10	299:21 301:2
279:12 300:17	356:15	351:15,15	338:10,19	301:14 303:8,9
proceeding	questioning	359:3 363:7	345:19 347:4	relief 304:19
284:11 305:13	284:6,19	reading 279:6	reference 273:13	relies 354:11
proceedings	288:13,17,20	353:21 358:13	282:18 303:1	remind 305:8
294:20 303:20	289:15,17	360:21	referenced	repeat 323:9
profile 331:18	291:16 292:6,9	ready 306:10	362:8	329:14 332:1
program 357:1	293:2 295:13	362:8	references 298:2	340:3
progress 274:14	297:18 298:6,8	real 285:2	298:3,5 303:3	repeated 322:7
property 327:2	299:2,22	really 308:21	303:4 321:12	repeatedly
prosthetic 322:6	questions 280:19	326:9 345:2	REFERRED	354:11
provide 347:10	281:2,8 283:2	353:9	273:8	repeating
provided 275:7	283:20 284:2,8	reasonable	referring 280:17	338:16
306:12 356:19	285:2,3,13	288:18 292:3	333:7 335:21	report 329:22
Public 361:1,2	286:1 288:7	recall 282:10	352:13 353:1	346:9,12,14
361:18	291:11,22	304:9 307:16	refers 337:22	reporter 270:19
pull 277:15	292:14,15	343:22	reflect 287:13	275:4,22
290:7 320:8	293:5 295:18	receive 284:15	refresh 279:10	276:12 283:15
purchased	296:2 298:4	recognize	356:14	283:16 286:12
362:10	299:13,18	277:18 278:18	refused 296:13	286:16,20
purely 353:16	301:14 302:5,8	279:13	299:3,9,17	294:19,21
purpose 282:3	302:13,20,22	reconnect	regarding 285:2	295:1
purposes 279:19	303:2,7,9	294:21	286:2 295:4	reporting 276:4
282:16 284:9	304:7 305:17	record 274:3	296:2,9 307:11	represent 357:9
put 308:1 332:8	306:15 319:13	283:15,17	314:18 317:18	representation
343:12 345:3	355:4 360:3,14	284:13 285:10	318:3 340:16	317:20 318:1
345:11 354:10	362:16 363:11	286:10,11,15	Registration	318:10 322:11
PVL 330:4,13	363:13	286:18,22,22	361:22	representative
331:4,20 332:4	quite 298:15	287:12 289:20	relate 281:1	357:10
332:22 333:9	320:5 337:1	289:21 290:4	284:2	reproduced
	343:10,18	290:16,20	related 285:14	355:14
Q	353:8	291:9 293:9	295:13 361:7	request 296:16
quantitative	quote 347:5,6	294:8 296:10	relating 292:15	300:16
357:22		297:4,5,12	297:20 302:5	requested 275:2
question 274:11	R	304:9 307:2	relation 298:6	requesting
279:10 280:12	R 274:1	356:10 358:16	302:14 303:1	296:15
287:8,14 301:8	radial 320:21	359:15,18	323:18	required 276:20
301:8 303:5,11	322:2	360:9,12,17	relationship	285:8

research 350:17 350:21	Rules 362:16	334:18 335:2	299:11	344:2,5
resemble 358:6	running 337:20	335:12 336:6	sentence 318:22	skill 332:19
RESERVED 360:22	Russell 298:7 303:1 342:6,16	336:12,14	separate 332:14	333:12 334:6
resolution 293:7	S	337:6,14	serious 333:17	small 325:16
resolve 287:16 292:22	S 271:6 274:1	340:17 346:1,5	set 284:3 287:22	358:7
resolved 288:15	Santa 272:7 362:2	sealing 334:19	289:8 292:5	soon 306:11
respect 319:15 322:7 323:22 337:10	saying 303:5 319:3 327:7	335:2 336:18	293:5 302:17	sorry 278:11
respectfully 300:16	says 358:5	337:14	setup 329:9	291:19,20
respond 301:5 304:1,4	Schwartz 271:17	seals 322:5	seven 301:19	306:5,7 323:9
responded 285:1	scientist 348:16 353:12	323:4 339:18	Shahriari 272:15	325:22 326:20
response 284:16 285:9 296:22 321:4 323:4	scope 278:22 279:17 280:6 281:17 282:6 282:14 283:21 290:14 291:3 293:10 295:4 296:9,11 297:15 298:12 298:20 301:9 305:10 307:20 308:9 309:11 309:19 311:9 313:1,16 314:6 314:22 317:11 318:16 319:9 320:4,14 322:21 324:15 325:6,21 326:7 328:12 329:20 330:6,14 333:2 334:10 335:5 335:14 336:8 336:17,21 337:16 338:5 339:10,21 340:10 341:11 342:2 343:1 346:17 348:14 349:10,18 350:7	340:7	sheet 278:9 362:13 363:12 364:6	329:12 337:18 340:3 343:17 347:21 356:6 356:14
rest 282:22 359:3	see 275:9,10 287:21 292:13 307:13 310:19 312:7 324:13 327:10,11,17 327:21 328:3 328:19 329:7 334:21 338:21 339:6 340:20 343:10 345:6 349:1,6,7 351:7 353:8 355:19	section 282:2,4 282:12 304:12 307:12,18 332:14	shields 321:2	sort 300:12 341:7 342:21
restart 305:22	seeing 333:8	secured 281:14 313:20,21	short 279:9 360:6	sorts 288:3
resume 289:9	seeking 304:20	see 275:9,10 287:21 292:13 307:13 310:19 312:7 324:13 327:10,11,17 327:21 328:3 328:19 329:7 334:21 338:21 339:6 340:20 343:10 345:6 349:1,6,7 351:7 353:8 355:19	show 342:15	sounds 293:15 359:13
Resuming 306:22	seen 308:5,10,13 309:3 312:10 331:10 342:4 345:13	section 282:2,4 282:12 304:12 307:12,18 332:14	showed 288:4	spaces 316:10 317:1 324:22
resumption 296:16	self-expanding 281:14 308:16 309:2,5,9,16 309:17 310:4	see 275:9,10 287:21 292:13 307:13 310:19 312:7 324:13 327:10,11,17 327:21 328:3 328:19 329:7 334:21 338:21 339:6 340:20 343:10 345:6 349:1,6,7 351:7 353:8 355:19	showing 287:22 291:15	sparse 317:1 330:4,4,8 331:8,15 334:3 334:8
return 288:14 292:9 299:22	seal 326:4 331:10 334:4	see 275:9,10 287:21 292:13 307:13 310:19 312:7 324:13 327:10,11,17 327:21 328:3 328:19 329:7 334:21 338:21 339:6 340:20 343:10 345:6 349:1,6,7 351:7 353:8 355:19	shown 310:7 311:7 312:11 346:8 357:20	sparse 317:1 330:4,4,8 331:8,15 334:3 334:8
review 275:5 282:10,19 304:10 307:16 330:2 362:10		selected 362:12	shows 342:16	sparingly 315:21 316:8,12,16,21 317:2,4,8,13 318:11,14,18 319:3,7,11,18 327:9 328:9 329:17 331:4 332:9,21 358:20
reviewing 283:7 312:1		seeing 333:8	sic 301:1	speak 285:11 359:20
right 282:1 287:7 289:20 305:4 307:13 333:15		seeking 304:20	sign 362:9,10	speaking 356:9
role 319:6		seen 308:5,10,13 309:3 312:10 331:10 342:4 345:13	signature 360:21 362:8,14 363:4 363:17 364:22	specific 302:13 315:18 317:9 332:7 345:19 350:4,9
room 283:8,13 287:14		self-expanding 281:14 308:16 309:2,5,9,16 309:17 310:4	signed 362:13	specifically 280:18 295:17 304:6 333:7 337:7,10 340:13 347:5 351:3
rows 321:9 322:8		sense 293:4 329:4 354:18	signing 362:12	
Rule 305:9		sent 284:14	similar 345:7,8 Similarly 331:12	
			simply 287:2 347:18,21 353:14 354:4 357:21	
			Sincerely 362:20	
			single 296:20 303:5,10	
			situation 329:11 347:15	
			six 301:19	
			size 324:22,22	

specification 281:10 304:15 334:17 337:13 338:3 340:1	276:6,17 278:4 278:13,15 279:4 280:1,15 281:21 282:9 283:3,6 284:22 285:5,8,13,20 286:1,5,8 287:1,5,11,19 288:6,19 289:2 289:6,14 290:3 290:12,17,21 291:2,18 292:12 293:1 293:15,21 294:6,13,14 295:8,9 297:17 298:21 299:17 300:2,22 304:1 304:3 305:5,20 306:5,8,20 307:3 308:4,12 309:6,14 310:1 310:14 311:4 311:17 312:15 313:12 314:2,9 314:16 315:9 317:7,16 318:12 319:4 319:21 320:9 322:16 323:5 323:11 324:9 325:1,17 326:2 326:14 328:15 330:1,10,17 332:18 333:5 334:14 335:9 336:2,15 337:11 338:1,9 338:18 339:16 340:5,15 341:19 342:18 343:4 346:11 347:1 348:3 349:5,13 350:2 350:15 351:1 354:20 355:3 355:12 357:2	359:5,13,19 straight 358:9 Street 270:21 271:7 363:1 364:2 strike 291:5 296:11 305:14 structure 280:22 301:15 302:2 327:12,17 336:6 347:12 350:4 subject 291:5 295:16 subjected 353:11 substance 302:21 suggest 288:12 suggested 299:19 312:8 suggesting 303:10 suggestion 290:6 Suite 270:21 363:1 364:2 Summers 271:6 294:16 supervision 361:6 sure 276:8 279:5 279:5,7 283:12 286:19 303:9 304:19 311:10 316:3 343:2,10 surface 312:18 358:8 surname 275:10 surprised 298:21 suspend 289:2,7 293:16 294:1,2 294:2 296:14 suspended 294:5 294:9 295:11 297:8 sworn 361:4	synonym 326:11 339:5 synonymous 317:4 336:13 337:7 T table 288:12 289:18 293:5 tabling 292:22 take 283:10 292:19 293:6 298:16 311:21 315:2 332:12 351:3 355:2,6 359:10 360:6 taken 332:15 359:16 360:10 361:3,5,8 takes 290:10 talk 285:9 292:10 talked 284:14 talking 286:17 290:22 304:7 307:5 327:8 329:10 337:7,9 337:9,17 345:21,22 taught 331:9 TAVR 331:11 331:19 TECHNICIAN 272:21 tell 276:20 284:19 299:2,3 299:10 311:22 316:2 327:22 328:19 339:14 term 319:1 326:15,17 327:2,20 335:10,20 336:17,18 338:2 339:2 341:2 351:18 terminology	310:12,13,15 313:11 terms 279:20 280:9 319:12 327:18 335:1 337:2 341:18 349:22 354:17 testified 302:10 testifying 276:21 testimony 277:3 298:11 302:14 359:21 361:4,5 361:7 thank 276:14,15 294:17 300:18 303:18,19,21 305:4,19 306:16,18,20 326:19 360:3,5 360:13 thereto 361:9 thickness 319:5 342:13 thing 298:10 301:16 320:22 321:14 325:11 things 345:6 think 282:21 285:5 292:3 298:5 299:5,7 305:14 310:12 311:13 312:19 323:16 324:5 324:16,21 325:8 328:3 333:9,20 334:11 336:9 337:3 338:16 339:5,13,15,22 340:11,14 341:1,2,14,16 342:9 344:16 346:18 348:17 349:3,21,22 351:17 353:7,9 355:3 356:15 359:2
---	---	---	--	--

thought 296:11 297:17 303:7 306:8 345:12	339:6 TRIAL 270:2 true 285:4,7 361:6 363:10 363:12	275:3 295:19 296:3 305:1 347:11,13 350:10 357:14	valves 333:8 341:21 342:15 345:6,17 346:2	298:4,5 302:22 327:14 328:1 342:6 343:6 344:3,5,6,7,8 344:15,20 347:17 348:9 351:12 353:2,8 353:11
three 301:19 345:7	truth 276:20 truthfully 285:12	Understood 279:13 uniformity 325:10	various 352:17 358:8 vast 298:12 vein 284:18 version 295:22 versus 324:22	Walther's 347:4 347:12,22 350:10 354:15
time 274:8,8 285:2 287:2 288:16 289:10 292:4 293:14 293:20,22 294:8 295:13 297:7,9 300:6 300:9 302:17 303:14 306:17 307:2 332:12 359:15,18 360:2,3,9,12 361:5 362:15	try 291:4 293:4 355:5 trying 298:16 turn 278:8 288:16 351:2 turning 331:1,7 twice 291:13 two 301:19 322:8 351:4 two-hour 299:16 two-thirds 291:10 type 352:12 typewriting 361:6	upper 282:1 307:22 usage 316:20 317:15 339:3 use 300:7 310:11 310:15 317:8 333:3,13 337:8 339:7 uses 335:19	video 274:14,16 275:2,5,6,21 276:5,13 VIDEOGRAP... 272:21 274:2 274:16 275:11 275:17 278:11 278:14 294:7 307:1 359:14 359:17 360:8 360:11,16 videotape 274:19 videotaped 275:16,18 view 300:17 viewed 327:16 viewing 335:1 Virginia 361:3 361:19 VIRTUAL 270:14 visible 278:16 visual 318:1 328:21 352:1,3 visually 334:6 Vol 270:15 362:1,5 363:5 364:9 Volume 270:13 274:3	want 279:7 283:4 288:8 289:18,20 290:6 291:3 293:22 294:2 313:2 351:15 356:6 wanted 296:8 Washington 270:21 363:2 364:3 waste 292:4 293:13,22 300:5 wasting 287:2 293:20 way 308:21 316:22 341:2 343:8 we'll 287:5 288:19 290:7 299:21 355:6 360:6,6 we're 283:14,16 285:20 286:9 287:8 288:9,10 288:11 290:10 292:12,19 293:1,11,12,13 329:10 337:17 345:21,22 355:4 we've 299:16 327:8 359:9 WEATHERW... 272:3 362:1
times 284:13 tissue 323:18 today 294:16 295:16 297:5 304:8,9 314:18 319:12 today's 274:7 277:10 told 275:13 284:5 296:6 298:22 302:4,7 348:18 tone 274:13 top 307:13 351:4 touching 316:21 TRADEMARK 270:1 transcatheter 308:14 320:19 345:6 transcript 275:2 275:6 276:9 294:11 362:7,9 363:8 transcription 363:11,13 transfer 327:19 transparent 298:15 326:13	U U.S 273:11 277:15 unacceptable 274:19 unaware 331:12 uncertain 313:9 unclear 326:12 underlying 284:9 297:19 298:14 327:11 327:17 underneath 327:18 329:8 347:6,8 348:5 354:5,15 understand 276:22 295:2 302:15 326:1,9 335:10,20 336:4,16 341:15 354:14 understanding	V v 270:7 274:6 362:4 363:4 364:8 vacuum 332:15 337:9 valve 278:19 279:14 302:2 308:6,6,11,14 308:20 309:1,4 309:5,7,8,9,16 309:17 310:2 312:10,17,18 312:21 320:1 320:12,18,19 320:20 321:3 322:4,5,13,18 322:18 323:1,7 323:8,13,13,18 323:20,21 324:10 325:3 325:11,19 326:3 327:20 327:21 329:6 332:21 341:21 343:7,7,11 345:20 354:7,8	W wait 290:11 294:10,18 303:16 waive 362:11 Walther 273:13	

Wednesday 270:16 welcome 276:18 weren't 301:22 wider 280:10 281:3 witness 271:16 273:2 274:9 278:3 279:1,18 280:7 281:18 282:7,15 283:10,13 290:1 298:17 298:17 300:3 307:21 308:10 308:18 309:12 309:20 310:11 310:18 311:10 312:14 313:2 313:18 314:7 314:14 315:1 316:19 317:12 318:6,17 319:10 320:5 320:15 322:22 323:16 324:16 325:7,22 326:8 328:13 329:21 330:7,15 332:6 333:3 334:11 335:6,15 336:9 336:22 337:17 338:6 339:11 339:22 340:11 341:12 342:3 343:2 346:18 347:21 348:15 349:11,19 350:8,20 354:2 355:10 356:5,9 356:11 359:1 360:4 361:4,5 361:7 362:10 363:5,17 364:9 witness's 305:1 word 296:20 311:13 316:20	317:13,14 330:8 339:7 340:13 words 312:7 345:3,11 work 333:19,22 worked 299:6 wouldn't 310:11 310:20 312:5,5 313:10 333:22 348:19 woven 316:14 347:13,15,22 348:7,21 349:14 350:3,9 350:12 wrap 355:5 written 362:22 wrong 301:16 X Y Yeah 275:1,11 279:18 325:22 329:21 356:14 years 297:8 yellow 354:3 yesterday 275:18 277:4,6 283:19 284:7 284:14,15 285:1,8 291:11 297:4,13 301:7 304:7 Z zoomed 351:11 351:13,18 0 1 1 320:18 353:7 1:05 359:15 1:15 359:12,18 360:9 1:19 360:12,18	360:19 10 292:18 295:12 302:19 359:11 10,792,172 270:11 10,881,538 273:12 277:15 1001 277:17 1007 273:13 344:7 1011 358:17 1016 272:6 362:2 11 321:22 11:47 307:2 1101 273:11 132328 361:22 134 347:2,3,21 136 351:2 139 353:17 355:13 14 322:13 145 358:4,15 14th 271:8 17 278:9 297:8 301:18 316:4 172 337:18 1730 270:21 363:1 364:2 19 278:9 285:16 287:21 2 2 270:13 274:3 20 278:8,13,14 278:18 279:14 280:2,17 285:16 288:3,4 295:17 301:11 301:12,17 302:13 307:5,8 307:14 308:6 310:2,5,8 311:7 312:12 312:21 314:20 324:13 328:8	329:16 330:12 332:3,15 20036 270:21 363:2 364:3 202 270:22 363:2 202)-232-0646 362:17 202)232-0646 364:4 2021 362:21 2022 270:16 274:7 362:4 363:5 364:10 2022-00193 277:17 2023 361:21 2040 271:7 2051 278:5 315:13 316:4 326:16 334:16 338:14 344:18 347:2 351:21 353:18 21 343:6 346:8 346:10,11,14 218 280:4 281:13 22 353:19 355:14 356:13 22A 301:1 23 337:20 232-0646 270:22 363:2 234 310:3,6 256 357:12 358:6 277 273:11 288 273:4 3 30 306:1 307-4500 272:8 31 270:16 361:21 362:4 363:5 364:10 310 272:8	31st 274:7 344 273:13 37 316:4 334:15 38 326:16,20 330:22 338:10 338:14,19 39 344:18 345:16 346:10 4 416 281:15 5 5 297:3,4,12 301:6 538 277:19 278:9 282:11 304:10 307:8 308:7 313:14 317:17,21 330:3 337:18 339:7,17 340:6 6 6 290:10,11 292:4 293:6 60 300:8 60% 297:13 611(b) 305:9 64 282:1,4,12 307:11,13,17 7 760-0404 271:10 79 312:3 8 8 317:22 319:2 8:28 270:17 274:8 8:47 294:8 812 270:21 363:1 364:2 89 351:3,20 352:9 9 9 317:22 321:15
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90 351:3,21 352:9 90405 272:7 362:2 92614 271:9 949 271:10				
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