UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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( )
(EDWARDS LIFESCIENCES CORPORATION AND)
(EDWARDS LIFESCIENCES LLC,)
(Petitioners,)
(v.)
(AORTIC INNOVATIONS, LLC,)
(Patent Owner.)
(_____)

IPR2021-01527
Patent 10,792,172

VIRTUAL VIDEOTAPED DEPOSITION OF
STEPHEN J.D. BRECKER Vol I, MD, FRCP, FECS, FACC
Tuesday, August 30, 2022
8:34 a.m. PDT

REPORTER: Dawn A. Jaques, CSR, CLR

_____

DIGITAL EVIDENCE GROUP
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Edwards v. Aortic Innovations
U.S. Patent 11,491,033
Edwards Ex. 1072

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20 Billy Fahnert, Digital Evidence Group
21
22

1 I-N-D-E-X

2 WITNESS: PAGE:

3 STEPHEN BRECKER, MD

4 Examination by Mr. Stowell 7

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6

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

8 BRECKER DEPOSITION EXHIBIT: PAGE:

9

10 Exhibit 1100 Declaration of Dr. Stephen
11 Brecker IPR2017-00060
12 Patent 8,992,608.....86
13 Exhibit 1101 2014 European Heart Journal
14 article, "Treatment of aortic
15 stenosis with a self-expanding
16 transcatheter valve: the
17 International Multi-centre
18 ADVANCE Study (13 pages).....146

19

20

21

22

1 Exhibits CON'T

2 PREVIOUSLY MARKED EXHIBITS REFERRED TO

3

4

EXHIBIT NUMBER:	PAGE:
1043	167
2009	185
2051	57

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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 the remote video deposition
4 of Dr. Stephen Brecker, in the matter of
5 Edwards Lifesciences Corporation and Edwards
6 Lifesciences LLC v. Aortic Innovations, LLC,
7 in the United States Patent and Trademark
8 Office, before the Patent and Appeal Board.
9 My name is Billy Fahnert. I am the
10 video technician today. The court reporter is
11 Dawn Jaques. We are here on behalf of Digital
12 Evidence Group.
13 Today's date is August 30th, 2022.
14 The time is 8:34 a.m. Pacific Daylight Time.
15 All parties have stipulated to the
16 witness being sworn in remotely. The
17 appearances of counsel are noted on the
18 stenographic record, and the witness can now
19 be sworn in.
20 THE REPORTER: If you'll raise your
21 right hand, sir, to be sworn.
22 (The witness was administered the oath.)

1 Whereupon,
2 STEPHEN J.D. BRECKER, M.D.,
3 was called as a witness, after having
4 been first duly sworn by the Notary
5 Public, was examined and testified as
6 follows:
7 EXAMINATION BY COUNSEL FOR THE PETITIONERS
8 BY MR. STOWELL:
9 Q Good morning, Dr. Brecker. I
10 introduced myself off the transcript. My name
11 is Josh Stowell. I will be deposing you on
12 behalf of Edwards today.
13 Do you understand that you are under
14 oath just as if you were testifying in a court
15 of law and that you are required to tell the
16 truth today?
17 A Yes, I do.
18 Q The court reporter is writing down
19 everything that we say, so all of your answers
20 will need to be verbal today.
21 Do you understand?
22 A I do.

1 Q We'll try to avoid talking over each
2 other today so that we get a clean transcript.
3 Please wait until I finish my question before
4 answering, and I will try to wait for you to
5 answer before I ask my next question.
6 Is that understood?
7 A Yes, it is, yes.
8 Q If you don't understand one of my
9 questions at any point today, please let me
10 know. If you don't speak up, the assumption
11 will be that you have understood the question.
12 Is that fair?
13 A Yes, I understand.
14 Q Your counsel, Mr. Lowenstein, may
15 make short objections during today's
16 deposition. However, you will still need to
17 answer all of my questions unless you are
18 specifically instructed not to answer.
19 Do you understand?
20 MR. LOWENSTEIN: Objection, form.
21 THE WITNESS: I do understand.
22

1 BY MR. STOWELL:
2 Q I'll try to go about an hour between
3 breaks today. If you need a break in the
4 interim, just let me know. The only thing
5 I'll ask is that we finish the question we're
6 on before we take a break. Is that fair?
7 A Yes, that sounds good.
8 Q And this deposition is being done
9 remotely, so please let me know if you
10 encounter any technical difficulties. If you
11 don't say anything, we will assume that the
12 technology is working okay. Is that fair?
13 A Yes, that's fair.
14 Q Is there any reason you can't
15 provide truthful and accurate testimony today?
16 A There is not.
17 Q Have you had any food, drink, or
18 medication that would inhibit your ability to
19 testify truthfully today?
20 A No, no.
21 Q And where are you sitting for
22 today's deposition?

1 A I am in the offices of Lowenstein &
2 Weatherwax in Santa Monica.
3 Q And did you come to the
4 United States exclusively for this deposition?
5 A I did, yes.
6 Q And when did you arrive in the
7 United States?
8 A I arrived late on Thursday evening,
9 the 25th.
10 Q And did you travel to the
11 United States directly from the UK?
12 A I did.
13 Q Are you required to take any special
14 precautions while you are traveling due to
15 your position as an interventional
16 cardiologist?
17 A The hospital I work at has not had
18 any specific restrictions.
19 The precautions are that I'm fully
20 vaccinated. I've had COVID quite recently,
21 and I wear a mask when I can.
22 So those are the restrictions.

1 There's no specific restrictions in
2 my role as an interventional cardiologist.
3 Q Other than the standard travel
4 difficulties that are all too common today,
5 did you encounter any hurdles in traveling to
6 the United States for this trip?
7 A Yes, I did.
8 Q And what were the hurdles?
9 A So the flight was delayed quite a
10 lot because the flight that was due to depart
11 prior to my flight to Los Angeles was
12 canceled, and so they had to off-load all of
13 those passengers and their luggage and put
14 them onto our flight.
15 Q Okay. So I consider that within the
16 umbrella of typical standard difficult --
17 standard travel difficulties today.
18 Did you encounter any other hurdles
19 in traveling to the United States?
20 A I can't think of anything, no. It
21 was quite a long and delayed journey, but
22 there were no hurdles as such.

1 I mean, there was a very, very long
2 line at Los Angeles Airport through
3 immigration checks, but apart from that, no.
4 Q So in the future, if you need to
5 come to the U.S. for another deposition in
6 these matters, I take it that should not be a
7 problem. Is that fair?
8 MR. LOWENSTEIN: Objection, form.
9 THE WITNESS: I don't think anyone
10 can predict what's going to happen with the
11 next wave. Certainly at our hospital, we are
12 gearing up for a major wave in the autumn,
13 that's despite a booster program.
14 So I don't think anyone can predict
15 what's going to happen even in two or three
16 months' time, but if this autumn and winter
17 are smooth and there are no restrictions on
18 travel and no new variants, it's anyone's
19 guess, frankly.
20 BY MR. STOWELL:
21 Q Okay. But if conditions remain as
22 they are today, is it fair to say that you

1 would have no problems traveling to the
2 U.S. in the future for another deposition?
3 MR. LOWENSTEIN: Objection, form.
4 THE WITNESS: If the conditions are
5 as we are today, then no.
6 BY MR. STOWELL:
7 Q What is your setup, technology
8 setup, for today's deposition?
9 A Well, I have two computer screens in
10 front of me. I can see your image as a small
11 image on the right of the screen. There's
12 then a lot -- this is on the screen that's
13 directly in front of me. Then there is an
14 exhibit window screen.
15 And then there is a separate monitor
16 to the left, which I believe is on a -- an
17 uploaded image, uploaded pieces of evidence.
18 Q Okay. So you have two desktop
19 monitors set up today; is that fair?
20 A Yes.
21 Q Okay. And there's an exhibit window
22 on one of the monitors; is that right?

1 A Yes. The one that's directly in
2 front of me, it says "Exhibit Window," and
3 then there is a -- as I say, there's a monitor
4 off to the left which has the word "Box" in
5 blue on the top, which I think is like a
6 dropbox type interface.
7 Q Okay. So as we go through the
8 deposition today, if we use exhibits, the
9 exhibits should be placed in that second
10 screen that you have, the drop screen, where
11 you can download them and review them in full
12 if you want to, okay?
13 The hot seat operator will also pull
14 up the exhibits in the exhibit window so you
15 can view them.
16 Does that make sense?
17 A Yes.
18 Q Okay. I understand that
19 Mr. Lowenstein is in the room with you today;
20 is that correct?
21 A He is. He's on my left.
22 Q Is anyone else in the room with you

1 today?
2 A Yes. Mr. Hsieh.
3 Q And where is Mr. Hsieh sitting in
4 relation to you?
5 A He is on Mr. Lowenstein's left.
6 Q And is there anyone else in the room
7 with you today?
8 A There's no one else in the room.
9 Q Did you bring any materials with you
10 to the deposition today?
11 A Yes.
12 Q What did you bring with you?
13 A So I have clean printed copies of my
14 declaration of the AI patents, and of some of
15 the other patents. I can go through the ones
16 that I've got in front of me.
17 The Spencer 2, Levi, Walther, and
18 Spencer 1 I have as hard copy, and I have the
19 AI patents.
20 Q And when you refer to the
21 AI patents, are you referring -- do you have
22 the U.S. patent number 10,792,172 in front of

1 you?
2 A Yes, '172, I have that one.
3 Q And do you have U.S. patent number
4 10,857,011?
5 A I do.
6 Q And do you have U.S. patent number
7 10,881,538?
8 A I do.
9 Q Do you have U.S. patent
10 number 10,966,846?
11 A I do.
12 Q And you probably know this from your
13 prior patent work, but we typically refer to
14 the patents by the last three digits of the
15 patent number. So, for example, we would
16 refer to U.S. patent number 10,792,172 as
17 the '172 patent.
18 Are you familiar with that naming
19 nomenclature?
20 A Yes, I am.
21 Q Okay. And so if I refer to the
22 '172 patent today, will you know what patent

1 I'm referring to?
2 A Yes, I will.
3 Q You mentioned your declarations.
4 What exhibit number is on the declaration or
5 declarations you have in front of you today?
6 A 2051.
7 Q Do you have any other declarations
8 in materials with you today?
9 A I have hard copies of Exhibit 2002.
10 Q And what IPR is Exhibit 2002
11 from that you have in your --
12 A I'm sorry, I overspoke you. I don't
13 think you finished.
14 Q Yeah. What IPR is Exhibit 2002 from
15 that you have in your materials?
16 A So I have two. One is
17 IPR2022-00549, and IPR2022-00556.
18 Q Now, you have submitted two
19 additional declarations that are not in your
20 materials in these IPRs that are the subject
21 of the deposition today, correct?
22 MR. LOWENSTEIN: Objection, form.

1 THE WITNESS: So there were some
2 declarations before the one Exhibit 2051,
3 which is a consolidated declaration, and
4 I think there were more than two.
5 BY MR. STOWELL:
6 Q Right. So for today's deposition,
7 in total, you have submitted five
8 declarations; is that fair?
9 MR. LOWENSTEIN: Objection, form.
10 THE WITNESS: Yes. There were four
11 initial, and then --
12 MR. LOWENSTEIN: Objection, form.
13 Go ahead.
14 THE WITNESS: There were four
15 initial declarations, and then one second
16 declaration that was a consolidated
17 declaration.
18 BY MR. STOWELL:
19 Q And of the four initial
20 declarations, you have two of those
21 declarations with you today; is that correct?
22 MR. LOWENSTEIN: Objection, form.

1 THE WITNESS: No. I think the two
2 that I have with me relate to other matters,
3 not -- they're not two of the four that the
4 consolidated declaration encompasses.
5 BY MR. STOWELL:
6 Q Okay. So you have two declarations
7 that you had submitted in other IPRs with you
8 today; is that fair?
9 A Yes, that's correct.
10 I gave you those IPR numbers.
11 Q And with the declarations, do you
12 have all of the exhibits that you attached to
13 those declarations?
14 MR. LOWENSTEIN: Objection, form.
15 THE WITNESS: I do not. I do not
16 have hard copies of those exhibits.
17 The only hard copies that I have in
18 front of me are the ones that I've specified,
19 the AI patents and the patents that -- or,
20 rather, the documents, the exhibits which I
21 itemized, starting with Spencer 2.
22

1 BY MR. STOWELL:
2 Q With your declaration, Exhibit 2051,
3 there were two exhibits: an Exhibit A, which
4 looked to be your CV, and an Exhibit B that
5 was a listing of your patent cases.
6 Do you have those exhibits with you
7 today?
8 A I do not. Those have not been
9 printed out.
10 Q Have you made any notes on the
11 materials that you have brought with you
12 today?
13 A I have not.
14 Q Have any of the materials you
15 brought with you today been highlighted?
16 A They have not. Actually, there are
17 some highlights that I think I recalled
18 seeing, yes, but they're not highlights that I
19 made.
20 So these were printed out copies,
21 but I think they may have just been copies
22 that had like one highlight. So there are

1 some highlights on one/two of them, but
2 they're not highlights that I've made or have
3 attached significance to.
4 Q Do you know who made the highlights?
5 A I do not.
6 Q Have any sticky tabs or other
7 indicators been added to the materials that
8 you have in front of you today?
9 A So I had some sticky tabs on one of
10 them, which they're basically just tabs for
11 markers for where I had got up to reading, but
12 I'm happy to remove those. They were
13 literally just like bookmarks for me. They
14 don't highlight anything in particular.
15 Those have been removed.
16 Q Other than those sticky tabs, are
17 there any other tabs on the materials today?
18 A No, there is not.
19 Q And so other than the highlighting
20 that was mentioned, is it fair to say that you
21 have clean copies of documents in front of you
22 today?

1 A Yes, I do. Yes, that is correct.
2 Q Do you have any devices set up to
3 communicate with people during today's
4 deposition?
5 A I do not.
6 MR. LOWENSTEIN: Objection, form.
7 BY MR. STOWELL:
8 Q Are you aware that now that the
9 deposition has started, that you may not speak
10 to anyone about your deposition testimony
11 until we conclude the deposition, which will
12 likely be tomorrow?
13 MR. LOWENSTEIN: Objection, form.
14 THE WITNESS: I am aware that I'm
15 not able to speak to anyone.
16 Can I just make a request that I get
17 completely clean copies? So it's only two of
18 the patents that have any highlights on. All
19 of the others are completely clean.
20 There are two patents, which I will
21 give, with your permission, to Mr. Hsieh to
22 give me completely clean copies of.

1 MR. HSIEH: I believe those
2 highlightings were in the original exhibits as
3 submitted.
4 THE WITNESS: Oh, okay. So I've
5 just been told that these highlights were in
6 the original submitted exhibits. I can show
7 you them if you would like.
8 BY MR. STOWELL:
9 Q Why don't you just tell me what
10 exhibits are you looking at there that have
11 the highlights?
12 A Okay. So there is the '011 patent
13 and the '172 patent, and for each of those
14 IPRs, they are Edwards Exhibits 1001. So
15 these highlights would appear to be were on
16 the original exhibit.
17 Q Okay, thank you.
18 And other than patent '011 and
19 patent '172, you haven't seen any highlights
20 on any of the other documents you have in
21 front of you today; is that correct?
22 A That's correct. I haven't been

1 through every page, but I have done a skim
2 through, and I can't see any other highlights.
3 Q Thank you. You were hired by
4 Patent Owner, Aortic Innovations, in this
5 matter, correct?
6 A My engagement was through
7 Lowenstein & Weatherwax, and I'm aware that
8 their client is Aortic Innovations.
9 I had no direct contact with Aortic
10 Innovations initially.
11 Q And who contacted you to work on
12 this matter?
13 A That's a good question. I think it
14 must have been Mr. Lowenstein, but it could
15 have been somebody else who sent the
16 original email, it was via email, and I don't
17 recall exactly who the first contact was made
18 from.
19 Q Okay. But you recall that the first
20 contact was made through email?
21 A Yes, I think so. I think so. It
22 wouldn't have been via -- well, I think it was

1 via email. I can't be 100% sure.
2 It's potentially possible that there
3 was a phone message, but I don't recall that.
4 There's so many -- I get so many emails and
5 messages every day, I can't remember where the
6 initial contact came from. My recollection is
7 that it was an email.
8 Q And do you remember when you were
9 first contacted for this matter?
10 A I can't remember the date. I could
11 look it up, but I can't -- I would have to go
12 to look at my emails.
13 Q Can you provide an estimate of
14 roughly when you were contacted?
15 A Well, it would have been last year,
16 obviously, and I just can't. Last year was
17 such a -- well, for everyone, such a crazy
18 year. Honestly, if I tried to give you the
19 month, I would be wrong I think.
20 I could find out. I would be able
21 to find out quite easily, but it would mean me
22 looking at emails.

1 Q Before being contacted to work on
2 this matter, were you familiar with Aortic
3 Innovations?
4 A I was not.
5 Q So it's fair to say that before
6 being contacted on this matter, you had not
7 done any work for or with Aortic Innovations?
8 A Certainly I have not.
9 Q Outside of working on this matter,
10 do you currently have any other relationship
11 with Aortic Innovations?
12 A I do not.
13 MR. LOWENSTEIN: Objection, form,
14 but go ahead.
15 BY MR. STOWELL:
16 Q The inventor on all of the patents
17 today is Dr. Ali Shahriari; is that correct?
18 A Yes, that is correct.
19 Q Were you familiar with Dr. Shahriari
20 before you were contacted to work on this
21 matter?
22 A I was not.

1 Q Since you have been retained to work
2 on this matter, have you spoken to
3 Dr. Shahriari?
4 A Yes.
5 Q And how many times have you spoken
6 to Dr. Shahriari?
7 A Well, it would be a small number,
8 and typically only in meetings with other
9 people. It's possible only once or twice.
10 So I've never had an individual
11 meeting with him. I have only been in an
12 online meeting where we have had a
13 conversation with others present, and my
14 recollection is that might only be a very
15 small number of times.
16 Q So your recollection is you may have
17 had one or two online meetings in which
18 Dr. Shahriari was present?
19 A Yes, more than one.
20 Q And what were the purposes of the
21 meetings that you participated in with
22 Dr. Shahriari?

1 A So I think one of them would have
2 been after Dr. Buller's deposition, possibly
3 during the deposition.
4 I don't recall other meetings, but
5 it's possible. I just don't have any
6 recollection of any other specific meeting.
7 I have had a very brief conversation
8 in which he was involved in the last day or
9 two as well.
10 So my recollection is that it would
11 have been around the time of Dr. Buller's
12 deposition, and then just literally a
13 three-minute, four-minute conversation in the
14 last day or two.
15 Q And why were you speaking to
16 Dr. Shahriari around the time of Dr. Buller's
17 deposition?
18 A So Dr. Shahriari was also present at
19 Dr. Buller's deposition online, and there
20 would have been a group discussion about the
21 testimony.
22 Q And you mentioned other people were

1 present for that conversation.
2 Who else was present?
3 A I mean, I think -- I can't give you
4 the exact list. My sense is that Mr. Nifong
5 would have been there, possibly
6 Mr. Lowenstein.
7 It's online, and it's sometimes
8 difficult to remember. So it's -- yeah, I
9 don't recall the chapter and verse of who was
10 there.
11 Q So what about Dr. Buller's testimony
12 was being discussed with Dr. Shahriari?
13 A Well, my recollection is there was
14 quite a lot of issues raised, but you're
15 asking me about a conversation that was
16 several months ago.
17 It would have been about aspects of
18 the testimony that was being given, so I can
19 recall issues of vascular access were being
20 discussed.
21 I can recall there were issues about
22 the number of patients with aortic stenosis

1 who would die untreated; that was discussed.
2 There may have been other issues as
3 well.
4 Q And why was Mr. Nifong participating
5 in your conversation with Dr. Shahriari?
6 A Well, it wasn't my conversation with
7 Dr. Shahriari as such. That would
8 mischaracterize the meeting.
9 The meeting was the sort of meeting
10 that I'm sure you have, which is a debrief
11 type meeting after an expert's testimony is
12 completed.
13 Q Did anything from the discussion
14 with Dr. Shahriari around the time of
15 Dr. Buller's deposition influence the opinions
16 you've given in this case?
17 A Not at all.
18 Q You mentioned that --
19 A Sorry, if I could just -- sorry, I
20 had paused, but it didn't influence my
21 opinions. I'll leave it at that. It didn't
22 influence my opinion.

1 Q You also mentioned you had a brief
2 conversation with Dr. Shahriari in the last
3 day or two. What was the purpose of that
4 conversation?
5 A We were discussing the patents, we
6 were discussing Dr. Shahriari's background,
7 but it was a very, very brief conversation.
8 Q What did you discuss about the
9 patents?
10 A So, obviously, there's been a lot of
11 discussion. I can't recall the exact content
12 of what point we had discussed.
13 Q Do you remember the general content
14 of what you discussed?
15 A Well, I know we discussed the fact
16 that Dr. Shahriari was a cardiovascular
17 surgeon. I've had a lot of discussions about
18 the patents in the last three days, so I
19 cannot recall what it was that we -- honestly,
20 I just can't recall what we discussed
21 specifically with respect to the patent.
22 I believe we may have -- we may have

1 discussed some aspect, but it may have been
2 that we were discussing that, and then
3 Dr. Shahriari came on the call, and we
4 certainly clarified his experience as a
5 cardiovascular surgeon.
6 Q You also mentioned that you talked
7 about Dr. Shahriari's background. What did
8 you discuss with respect to his background?
9 A Exactly what I've just said, his
10 experience as a cardiovascular surgeon.
11 Q So based on your experience in the
12 industry, are you aware of anything that
13 Dr. Shahriari had done to advance the field of
14 transcatheter heart valves?
15 MR. LOWENSTEIN: Objection, form.
16 Objection, scope.
17 THE WITNESS: Yes, quite a lot.
18 BY MR. STOWELL:
19 Q And what are you aware of?
20 MR. LOWENSTEIN: Same objections.
21 THE WITNESS: So I'm aware that
22 Dr. Shahriari has been an innovator in

1 previous technologies. I'm not familiar with
2 those technologies, but I am aware that they
3 relate to the field of endovascular stent
4 graft type technology and repair technology
5 for aortic disease.
6 I am aware of the patents that are
7 being discussed currently, and the innovative
8 and inventive ideas that those patents contain
9 in the field of transcatheter heart valve
10 technology.
11 BY MR. STOWELL:
12 Q And are you aware of any other
13 contributions by Dr. Shahriari to the field of
14 transcatheter heart valves?
15 MR. LOWENSTEIN: Objection, form.
16 Objection, scope.
17 THE WITNESS: Sorry, could you
18 repeat that question? Because I think I had
19 just answered it, but I might have missed an
20 extra bit that you wanted.
21 BY MR. STOWELL:
22 Q Yeah. So you spoke about, I believe

1 you said Dr. Shahriari's contributions to
2 stent graph technology, and that you are aware
3 of the patents that are at issue in this
4 deposition.
5 Are you aware of any other
6 contributions that Dr. Shahriari has made to
7 the field of transcatheter heart valves?
8 MR. LOWENSTEIN: Objection, form.
9 Objection, scope.
10 THE WITNESS: So I think those areas
11 that I've talked about contain a huge amount.
12 There's a lot of crossover
13 technology in delivery systems between
14 endovascular stent graph technology, aortic
15 repair, and transcatheter heart valves.
16 So all of that technology is of
17 value in advancing the field of transcatheter
18 heart valve technology.
19 I'm aware of the patents that we are
20 discussing. I'm also aware that there are
21 other developments and innovations, but I'm
22 not aware of the details of those.

1 BY MR. STOWELL:
2 Q You had mentioned you were aware
3 that he was an innovator on previous
4 technologies relating to stent graph
5 technology.
6 Did the technology you're referring
7 to in that instance include a transcatheter
8 heart valve?
9 MR. LOWENSTEIN: Objection, form.
10 Objection, scope.
11 THE WITNESS: I'm not aware of that.
12 BY MR. STOWELL:
13 Q Have you ever read any papers by
14 Dr. Shahriari relating to transcatheter heart
15 valves?
16 MR. LOWENSTEIN: Objection, scope.
17 THE WITNESS: I have read all of the
18 patents.
19 BY MR. STOWELL:
20 Q Aside from the patents, have you
21 read any other --
22 MR. LOWENSTEIN: Hold on.

1 Josh, you've been asking a lot of
2 questions that are obviously for your
3 litigation case. I've let it go on a little
4 bit, but it's going on a little long.
5 If you intend to keep trying to ask
6 questions about your trial testimony, why
7 don't we get on a call with the Board so we
8 can clarify the scope of this deposition,
9 which is the declaration that Dr. Brecker has
10 offered in these cases.
11 MR. STOWELL: Would you like me to
12 repeat the question?
13 MR. LOWENSTEIN: Excuse me. Should
14 we have a call with the Board? Because you're
15 obviously asking questions that have no
16 relevance to these IPRs.
17 MR. STOWELL: Nathan, you know
18 that's not correct. You know Dr. --
19 MR. LOWENSTEIN: It is correct. If
20 you like to get on a call with the Board,
21 let's call the Board.
22 MR. STOWELL: Okay. If you would

1 like to put the deposition on hold and go off
2 the record and you would like to initiate a
3 call with the Board, we can do that.
4 As you're aware, in his declaration,
5 Dr. Brecker has made statements about
6 Dr. Shahriari's alleged contribution to the
7 art. We are entitled to ask about the scope
8 of the contribution.
9 MR. LOWENSTEIN: You're obviously
10 asking questions for your litigation, not this
11 IPR. We have a standing objection.
12 If you continue in this vein,
13 I think we may have to have a call with the
14 Board. Please continue.
15 BY MR. STOWELL:
16 Q Okay. Dr. Brecker, sorry for the
17 interruption.
18 Have you ever read any other
19 publications besides the patents that are at
20 issue in this deposition by Dr. Shahriari
21 relating to transcatheter heart valves?
22 MR. LOWENSTEIN: Objection, scope.

1 THE WITNESS: I may have done.
2 BY MR. STOWELL:
3 Q Do you recall any as you sit here
4 today?
5 MR. LOWENSTEIN: Objection, scope.
6 THE WITNESS: So I have not prepared
7 any type of analysis at this point on that.
8 I may well have read material. I
9 read five or six scientific papers per week.
10 It is quite possible that I have read
11 something by Dr. Shahriari.
12 Sitting here now, I cannot give you
13 chapter and verse. I don't -- I could find
14 out, but I can't tell you now.
15 BY MR. STOWELL:
16 Q Have you ever seen Dr. Shahriari
17 speak at any conferences on the topic of
18 transcatheter heart valves?
19 MR. LOWENSTEIN: Objection, scope.
20 THE WITNESS: It's possible.
21 BY MR. STOWELL:
22 Q Do you recall any instances of that

1 as you sit here today?
2 MR. LOWENSTEIN: Objection, scope.
3 THE WITNESS: I would have to give
4 the same answer, that I go to a very large
5 number of scientific meetings, sessions,
6 speakers. I could not tell you, sitting here
7 now, whether I have seen Dr. Shahriari speak.
8 BY MR. STOWELL:
9 Q And you're aware that this
10 deposition covers four different IPRs
11 involving four Aortic Innovations patents,
12 correct?
13 A I am aware of that, yes.
14 Q Do you understand that all four
15 patents share the same specification?
16 A I had understood that, but I would
17 have to have a look through the patents to
18 confirm it.
19 Q When you say you had understood
20 that, what do you mean?
21 A That is my understanding.
22 Q Were you familiar with any of the

1 four patents at issue in this deposition
2 before you were contacted to work on this
3 matter?
4 A I was not.
5 Q Are you aware that there is also a
6 district court litigation pending between
7 Aortic Innovations and Edwards?
8 A I am aware of that.
9 Q And what do you know about the
10 district court litigation?
11 A I don't know anything about it at
12 this point.
13 Q Do you know which party is the
14 Plaintiff and which party is the Defendant in
15 the litigation?
16 A Sitting here now, I do not.
17 Q Do you know which patents are
18 involved in the litigation?
19 A I do not.
20 Q Do you know if any of the patents
21 that are the subject of today's deposition are
22 at issue in the litigation?

1 A I do not.
2 Q Do you have any intention right now
3 to provide testimony in the district court
4 litigation?
5 A So my understanding is today was
6 about the IPRs and the declaration that I've
7 submitted. I'm not aware if I'm able to go
8 into the details of the question you've
9 answered -- you've asked me.
10 Q And why is that?
11 MR. LOWENSTEIN: Objection, form.
12 Objection, scope.
13 THE WITNESS: Well, my understanding
14 is that today is a deposition about the IPRs,
15 the four IPRs on which I've submitted the
16 declaration.
17 I have not come today prepared to
18 discuss the issues of litigation.
19 BY MR. STOWELL:
20 Q Right. And to clarify, I'm not
21 asking you to discuss the issues in the
22 litigation.

1 I'm just asking have you agreed to
2 provide testimony in the district court
3 litigation on behalf of Aortic Innovations?
4 MR. LOWENSTEIN: Objection, form.
5 Objection, scope.
6 THE WITNESS: So I may have done,
7 but I cannot tell you, sitting here now, if I
8 will be the expert in the district court
9 litigation.
10 BY MR. STOWELL:
11 Q And why is that?
12 MR. LOWENSTEIN: Objection, form.
13 Objection, scope.
14 THE WITNESS: Well, there are
15 several reasons. The first is I don't know if
16 I'm permitted to answer.
17 The second is I have not had any
18 communication about the district court
19 litigation for quite a long time, so I have no
20 sense of the status of it, nor my involvement
21 in it.
22

1 BY MR. STOWELL:
2 Q You mentioned you hadn't had any
3 conversations about the district court
4 litigation for quite a long time.
5 When was the last time you had some
6 exposure to the district court litigation?
7 MR. LOWENSTEIN: Objection, scope.
8 THE WITNESS: I have not had any
9 exposure to the district court litigation.
10 BY MR. STOWELL:
11 Q When was the last time you discussed
12 the district court litigation with someone?
13 MR. LOWENSTEIN: Objection, form.
14 Objection, scope.
15 THE WITNESS: I have not discussed
16 the district court litigation. I haven't had
17 any discussion about the detail of it.
18 BY MR. STOWELL:
19 Q When you said I have not had any
20 communication about the district court
21 litigation for quite a long time, what did you
22 mean?

1 A I meant exactly what --
2 MR. LOWENSTEIN: Objection, form.
3 Objection, scope.
4 THE WITNESS: I meant exactly what I
5 said. I had had some communication about a
6 potential district court litigation between
7 Aortic Innovations and Edwards a long time
8 ago. I can't tell you the date.
9 Again, it's something I could look
10 up and I could give you an accurate answer,
11 but I can't do that sitting here now. It's
12 not something I had prepared for for today.
13 That communication was from a law
14 firm, not this law firm that I am in at the
15 moment --
16 MR. LOWENSTEIN: Hold on. I'm going
17 to caution you not to reveal anything that may
18 be subject to some sort of privilege or
19 confidentiality in that litigation.
20 THE WITNESS: Yeah, so I don't think
21 I can answer your question. I don't think I'm
22 permitted to.

1 BY MR. STOWELL:
2 Q Okay. But it's fair to say you were
3 contacted by another law firm not present
4 today regarding the district court litigation,
5 is that fair?
6 MR. LOWENSTEIN: Okay, I've let this
7 go on far enough. All you're asking are
8 questions about the district court litigation.
9 That's not what this deposition is about.
10 I've already raised this. You've
11 asked 15, 20 minutes in a row exclusively
12 about the district court litigation. This is
13 extremely improper.
14 Can we please get back to the
15 subject of this deposition and not your
16 hunting and fishing for testimony in the
17 district court litigation, please?
18 MR. STOWELL: Nathan, we are
19 entitled to explore the information that
20 Dr. Brecker has been exposed to that is
21 relevant to these IPRs. This is part of that
22 exploration. Obviously, we can ask

1 him questions.
2 MR. LOWENSTEIN: No, no. I have
3 been involved in hundreds of IPR depositions.
4 I've never had anyone go this deep into an
5 irrelevant litigation that is not the topic of
6 this IPR.
7 BY MR. STOWELL:
8 Q Dr. Brecker, can you answer my last
9 question?
10 MR. LOWENSTEIN: Objection, form.
11 Objection, scope. I'm sure he has no idea
12 what your last question was.
13 MR. STOWELL: Nathan, you can limit
14 your objections to a single word, as required
15 by the rules.
16 MR. LOWENSTEIN: Well, you can limit
17 your questioning to the subject of this
18 deposition as opposed to your trying to hunt
19 for information in the district court, which
20 is completely improper.
21 MR. STOWELL: Nathan, your objection
22 is improper. You can limit it to a single

1 word.
2 BY MR. STOWELL:
3 Q Dr. Brecker, is it fair to say you
4 were contacted by another law firm not present
5 today regarding the district court litigation?
6 MR. LOWENSTEIN: Objection, form.
7 Objection, scope.
8 I will caution the witness not to
9 reveal any information that he may be
10 prohibited from doing so under some
11 confidentiality or privilege.
12 THE WITNESS: I was contacted. Let
13 me be clear and let me clarify it, and then
14 hopefully we can move on.
15 Sitting here today, I know nothing
16 about the details of the district court
17 litigation.
18 I could not tell you which party is
19 Plaintiff and which is Defendant. I could not
20 tell you which patents are involved. I could
21 not tell you anything because I don't know.
22

1 BY MR. STOWELL:
2 Q Okay, thank you.
3 Did you prepare for today's
4 deposition?
5 A Yes, I did.
6 Q And what did you do to prepare?
7 A I read through my declaration, so
8 the consolidated declaration; and I read
9 through, in part, a lot of the AI patents; and
10 I've read through a number of pieces of the
11 prior art, including the exhibits, Spenser,
12 Spenser II, Walther, Levi, et cetera. I've
13 had discussions with Mr. Hsieh mostly over the
14 past few days.
15 Q How much time --
16 A Sorry. I'm sorry. I've also had
17 some briefer discussions with Mr. Lowenstein.
18 Q How much time do you estimate you've
19 spent preparing for the deposition today?
20 A So I've done my own reading. I did
21 that -- I did quite a bit of reading before I
22 came.

1 I didn't do very much on the day
2 after I arrived because it was a very late
3 arrival and jetlag.
4 And then over the Saturday, Sunday
5 and Monday, I've been in the office for a few
6 hours each of those days, not full days.
7 So I couldn't give you a number, but
8 that is the -- that's the preparation: that I
9 did some reading on days before coming, and
10 then the meetings that we've had here.
11 Q So you met with counsel in the
12 office on Saturday, Sunday, and Monday; is
13 that correct?
14 A Yes, I think those were the -- yes.
15 They were not full days because, obviously,
16 with the 8-hour time difference, it's
17 difficult to keep going.
18 Q Understood.
19 And those meetings in the office,
20 you said those were primarily with Mr. Hsieh;
21 is that correct?
22 A Primarily, yes.

1 Q And you mentioned that you also had
2 some meetings with Mr. Lowenstein; is that
3 correct?
4 A That is correct.
5 Q And did you meet with anybody else
6 to prepare for your deposition today?
7 A No, I've had no interactions on the
8 content of this with anyone else. I'm trying
9 to think. No.
10 Q Other than the materials that you
11 have in front of you today, did you review any
12 other documents to prepare for your deposition
13 today?
14 A Well, there are a large number of
15 exhibits. There's a large number of
16 declarations, there's a lot of patents.
17 I've looked at a number of
18 documents. I've looked at Dr. Buller's
19 declarations, I've looked at some of the
20 exhibits that he submitted.
21 I've tried to review as much as
22 possible, but I have not looked through in

1 detail every single document pertaining to
2 this case. There are probably tens of
3 thousands of pages.
4 Q But you did look at other documents
5 that are not in front of you today as part of
6 your preparation for today's deposition; is
7 that fair?
8 A Yes, I've certainly been looking at
9 other documents.
10 Q And did any of the documents that
11 you reviewed in preparation for your
12 deposition refresh your recollection regarding
13 any of the facts or issues in this IPR?
14 A I mean, that's a very general
15 question, and if I said yes, you would ask me
16 which documents and which facts, and I can't
17 answer that.
18 I mean, when I review documents,
19 some of it is familiar. Some of the things --
20 some things you read through a document you've
21 read before and you see something different.
22 I can't give you a list of each fact

1 from each document that may have refreshed my
2 memory on something, but --
3 Q But you -- sorry, go ahead.
4 A Sorry, yes. I have no doubt that in
5 reading one or more of the documents, I
6 noticed something that had not been emphasized
7 before.
8 Q Earlier we discussed that you had
9 prepared four initial declarations for the
10 IPRs that are the subject of the deposition
11 today; is that correct?
12 A Yes, that's correct.
13 Q How much time did you spend
14 preparing those initial four declarations?
15 A I couldn't really give you an
16 estimate sitting here now. I'd have to go
17 back and look through the diary of the time
18 that I've spent.
19 I mean, it's an iterative process,
20 as you know, and you spend time reading, and
21 then meeting, and then writing. It's tens of
22 hours. I can't tell you how much on each

1 declaration and whether one was more than
2 another, for example.
3 Q What about collectively for those
4 first four declarations? Can you give an
5 estimate of the time you spent preparing those
6 four?
7 A I can't. I hadn't prepared that
8 type of information. It's something I could
9 find out, but I can't tell you sitting here
10 now.
11 Q Do you believe it was more than
12 10 hours?
13 A For the four declarations, yes.
14 Q More than 100 hours?
15 A No.
16 Q More than 50 hours?
17 A For those four declarations, I would
18 be very surprised if it was anything close to
19 50 hours, but it depends what you're asking
20 me, because prior to the declarations, I would
21 have done quite a bit of reading. Prior to
22 even starting a declaration, there would have

1 been meetings.
2 So it really depends what you
3 include in the time taken to write a
4 declaration, whether you include time that
5 you've spent reading the patent in general
6 terms. So I can't give you the detail of the
7 answer that you want.
8 Q And so do you remember that prior to
9 working on the four declarations, the four
10 initial declarations, that you had meetings
11 and you reviewed a lot of documents before
12 working on those declarations?
13 A I would definitely have read.
14 Q Do you recall having meetings before
15 you worked on the declarations?
16 A There would have been. I wouldn't
17 have started a declaration without having a
18 discussion.
19 Q And walk me through the process of
20 how the declarations were created.
21 A So there would have been reading,
22 there would have been discussions, there would

1 have been a draft prepared. I would have
2 written parts of the draft, the lawyers write
3 other parts, and then a draft document is
4 prepared, which I then edit and review.
5 As I say, it's an iterative process,
6 and there would have been more discussion. I
7 would have pushed certain elements that I feel
8 are very important. I would have had
9 discussion about other elements.
10 That's the process. It's no
11 different for this case than other cases I've
12 been involved in. There was no difference.
13 Q And who did you work with on
14 preparing the four initial declarations?
15 A It was a different lawyer in this
16 firm who has now left, and I haven't had any
17 communication, obviously, with him for a
18 number of months, and I'm sure the two people
19 on my left know his name, and I just cannot
20 recall sitting here now. I'm sorry, I just --
21 because, of course, you never meet the
22 individual. You only ever do it online and

1 with Zoom calls. So I'm sorry, I can't give
2 you his name. He was a lawyer in the firm
3 who -- and then, obviously, there were
4 meetings with Mr. Lowenstein as well.
5 Q And when you say it was a lawyer in
6 the firm, you're referring to a lawyer at
7 Lowenstein & Weatherwax?
8 A Yes, that's correct.
9 Q Okay, we've been going about an
10 hour. Why don't we take our first break.
11 MR. LOWENSTEIN: How long?
12 MR. STOWELL: Why don't we go for
13 10 minutes.
14 MR. LOWENSTEIN: All right.
15 THE VIDEOGRAPHER: Okay, going off
16 the record. The time is 9:32.
17 (A break was taken.)
18 THE VIDEOGRAPHER: We are back on
19 the record. The time is 9:42.
20 BY MR. STOWELL:
21 Q Welcome back, Dr. Brecker.
22 Did you speak to anyone regarding

1 your deposition testimony during the break?
2 A I did not.
3 Q If I could ask our hot seat operator
4 to pull up Exhibit 2051.
5 Dr. Brecker, can you see
6 Exhibit 2051 on your screen?
7 A I can.
8 Q And you also have a copy in front of
9 you today, correct?
10 A I do, yes.
11 Q What is Exhibit 2051?
12 A This is entitled Second Declaration,
13 and this is a consolidated declaration
14 relating to four IPRs.
15 Q And if we turn to page 150 of the
16 declaration, is that your signature that we
17 see on page 150?
18 A It is.
19 Q And did you sign this declaration on
20 or about July 11th, 2022?
21 A Yes.
22 Q And when you signed the declaration,

1 you declared that you believe that all the
2 statements in the declaration were true.
3 Was that an accurate statement when
4 you signed the declaration?
5 A Yes, it was.
6 Q Do you still believe all the
7 statements in the declaration are true?
8 A I do.
9 Q Are you aware of any errors or
10 misstatements in Exhibit 2051?
11 A I'm not.
12 Q And how was this declaration
13 created?
14 A Well, this is a consolidated
15 declaration from my four prior declarations.
16 Q And what role did you play in
17 preparing Exhibit 2051?
18 A So, obviously, I had a major role in
19 the original declarations from which this is
20 consolidated.
21 In terms of the cutting, pasting,
22 and reformatting, that was done by

1 Lowenstein & Weatherwax.
2 Q So Exhibit 2051 incorporates some of
3 the portions of your earlier declarations; is
4 that correct?
5 A That is correct.
6 Q And did you play any role in
7 selecting the portions from your earlier
8 declarations that are incorporated into
9 Exhibit 2051?
10 A Well, yes, because there would --
11 again, the whole process is one of back and
12 forth, so discussions and --
13 Q So do you -- sorry, go ahead.
14 A So discussions, and then review.
15 Q And so do you remember selecting
16 portions from your prior declarations for
17 inclusion in Exhibit 2051?
18 A I don't remember a process where I
19 or anyone else said, right, this paragraph
20 must go in. It is a consolidated declaration
21 of the opinions I gave.
22 Q And I'm just trying to figure out

1 who made the decision of which portions to
2 consolidate.
3 Were you involved in the decision of
4 which portions from the prior declarations to
5 include in Exhibit 2051?
6 MR. LOWENSTEIN: Objection, form.
7 THE WITNESS: Yes, I would have been
8 involved because I was involved in the
9 discussions.
10 BY MR. STOWELL:
11 Q Okay. So you recall being involved
12 in deciding which portions of prior
13 declarations should be included in
14 Exhibit 2051?
15 MR. LOWENSTEIN: Objection, form.
16 THE WITNESS: I cannot go through
17 each paragraph and say this paragraph I
18 specifically said should go in, and one other
19 bit should not.
20 It was an iterative process by which
21 the initial declarations were made, and then
22 the relevant sections from those declarations

1 were put into a consolidated declaration.
2 I was involved throughout the
3 process, obviously, but I can't tell you which
4 specific -- if you're going to take me to a
5 specific paragraph and say did I specifically
6 say that this paragraph should or should not
7 go in, I can't give you that detail.
8 I read through all the declarations
9 and documents and made edits, and that's the
10 process.
11 BY MR. STOWELL:
12 Q And my question was more general.
13 Just do you recall identifying any
14 portions from the prior declarations for
15 inclusion in Exhibit 2051?
16 MR. LOWENSTEIN: Objection, form.
17 THE WITNESS: Well, insofar as
18 clearly the opinions I've expressed in the
19 previous declarations had to go into this
20 declaration.
21 BY MR. STOWELL:
22 Q Right, but we've discussed that

1 Exhibit 2051 is a consolidated version of the
2 prior declarations.
3 Did you have any role in selecting
4 which portions of the prior declarations were
5 included in Exhibit 2051?
6 MR. LOWENSTEIN: Objection, form.
7 THE WITNESS: I would have had a
8 role in the discussions that we had.
9 BY MR. STOWELL:
10 Q And did you identify any portions of
11 the prior declarations that should be included
12 in Exhibit 2051?
13 MR. LOWENSTEIN: Same objection.
14 THE WITNESS: Well, it would have
15 been fairly obvious from the discussions as to
16 the opinions I've given, and therefore I had
17 to put those into the declaration.
18 I don't understand. You're asking
19 me in general terms, and in a general answer,
20 my answer is yes.
21 BY MR. STOWELL:
22 Q Okay. So you recall identifying

1 paragraphs in the prior declarations that you
2 wanted included in Exhibit 2051?
3 MR. LOWENSTEIN: Objection, form.
4 THE WITNESS: Well, that's not a
5 general question because you're taking me down
6 to paragraph level, and the answer to that
7 question is I can't give you paragraph detail.
8 All I can state is that it was
9 essential that the opinions I had expressed in
10 the initial declarations were put into this
11 consolidated declaration, and I was involved
12 in discussions and review throughout.
13 So I just -- I'm struggling. If
14 you're going to take me to a particular
15 paragraph and say did I specifically say that
16 this paragraph must go in? The answer to that
17 question is I can't tell you.
18 BY MR. STOWELL:
19 Q And that's not a question I have
20 asked. I'm just asking whether you remember
21 specifically identifying any paragraphs in the
22 original declarations that should be included

1 in Exhibit 2051?
2 MR. LOWENSTEIN: Objection, form.
3 THE WITNESS: Well, again, you're
4 asking me specifics. You've said do I
5 remember a discussion about specific
6 paragraphs, and the answer to that question is
7 I don't know. I can't tell you about a
8 specific paragraph.
9 I can tell you that I was involved
10 in the discussion regarding the opinions that
11 I needed to express in this consolidated
12 declaration.
13 BY MR. STOWELL:
14 Q Did you speak with anyone besides
15 counsel in preparing Exhibit 2051?
16 A I didn't speak to anyone other than
17 the lawyers. When you say "counsel," are you
18 referring to a specific individual?
19 Q Did you speak to anyone besides
20 lawyers at the Lowenstein firm in preparing
21 Exhibit 2051?
22 A No.

1 Q I understand you are charging
2 £625 per hour for your work on this case; is
3 that accurate?
4 A Yes, that's correct.
5 Q And how many total hours have you
6 billed for your work on these matters so far?
7 A I haven't added it up.
8 I should state that I'm not on an
9 hourly rate for the time I'm in the U.S. I
10 have a daily rate that relates to a certain
11 number of hours, but it's not like 24 hours.
12 I mean, it's a daily charge.
13 I can't tell you the number of
14 hours, the exact number of hours. I haven't
15 added it up.
16 Q Can you provide an estimate?
17 A Well, again, it's tens of hours.
18 I'd be surprised if it was more than 100 hours
19 prior to coming to the United States. I don't
20 think it's anything like that, but I don't
21 know, I haven't added it up. I could be
22 surprised if I looked it through, but I don't

1 know.
2 Q And you mentioned a daily rate for
3 time in the U.S. What is your daily rate for
4 the time you're in the United States?
5 A It's 8 hours a day.
6 Q And what is the compensation for
7 8 hours per day?
8 A It's £625 per hour.
9 Q So for each day --
10 A I'm sorry, multiplied by 8.
11 Q So for each day you're in the
12 United States, you charge for 8 hours
13 regardless of how many hours you put into the
14 case; is that accurate?
15 A Yes.
16 Q How much income have you received
17 from your work on these matters thus far?
18 A I have not added that up.
19 Q Can you give an estimate?
20 A Well, the estimate is based on the
21 number of hours, and prior to coming to the
22 states, I've said that think it's less than

1 100 hours. But I have to be completely
2 honest, I have not added it up in preparation
3 for this.
4 Q I noticed in your declaration that
5 you use the abbreviation T-A-V-R, or TAVR.
6 What does TAVR stand for?
7 A So TAVR stands for transcatheter
8 aortic valve replacement.
9 Q And is that a -- sorry, go ahead.
10 A The terminology, and the evolution
11 of the terminology, and the way in which it
12 differs in different parts of the world is an
13 interesting bit of the history to this.
14 Q Is TAVR a term you regularly use in
15 your practice?
16 A So in the United Kingdom, it is
17 generally referred to as TAVI, T-A-V-I, and
18 that is relating to transcatheter aortic valve
19 implantation.
20 There is a reason why in the
21 United States it changed from TAVI to TAVR.
22 Prior to that, it had been known as PAVR or

1 PAVI.
2 Q And so if we use the term "TAVR"
3 today, will you understand that that term
4 means transcatheter aortic valve replacement?
5 A Yes.
6 Q I also noticed in your declaration
7 you used the abbreviation "PVL."
8 What does PVL stand for?
9 A Paravalvular leak.
10 Q And is PVL a term that you use
11 regularly in your practice?
12 A It is.
13 Q And so is it okay if we use the term
14 "PVL" during today's deposition to refer to
15 paravalvular leak?
16 A Yes, it is.
17 Q I also noticed in your declaration
18 that you used the abbreviation "POSITA,"
19 P-O-S-I-T-A. What does POSITA stand for?
20 A So there are a couple of spellings,
21 but it's a person of ordinary skill in the
22 art.

1 Q And is POSITA a term you are
2 familiar with from your work on patent cases?
3 MR. LOWENSTEIN: Object to the form.
4 THE WITNESS: I'm familiar with the
5 term in any event, but yes, from patent cases.
6 BY MR. STOWELL:
7 Q Okay. So is it okay if we use the
8 term "POSITA" today during the deposition to
9 refer to a person of ordinary skill in the
10 art?
11 A Yes, it is.
12 Q I may also use the term "THV" today
13 to refer to transcatheter heart valves. Are
14 you familiar with the term "THV"?
15 A I am. That is not a term that is in
16 sort of current colloquial use.
17 Q Is it a term that's commonly used in
18 the art to refer to transcatheter heart
19 valves?
20 A THV? It's not an abbreviation that
21 many people use, the abbreviation.
22 Transcatheter heart valves is understood.

1 Q Okay. So for the purpose of today's
2 deposition, we'll do our best to refer to
3 transcatheter heart valves rather than THV.
4 Is that okay?
5 A Yes.
6 Q If our hot seat operator could go to
7 page 210 of 210 in Exhibit 2051. It's
8 actually the last page of Exhibit 2051.
9 Dr. Brecker, can you see what you've
10 called Exhibit B here in your declaration,
11 Exhibit 2051?
12 A Yes.
13 Q And is this a list of the patent
14 cases in which you have served as an expert?
15 A Yes. It obviously doesn't include
16 the current ones.
17 Q Now, have you been involved in other
18 types of legal cases besides patent cases?
19 A Yes.
20 Q And what types of cases, aside from
21 patent cases, have you been involved in?
22 MR. LOWENSTEIN: Objection, scope.

1 THE WITNESS: So I have been
2 involved in clinical negligence cases in the
3 United Kingdom, and as part of my role at
4 St. George's, I undertake serious instant
5 review at St. George's, at the hospital.
6 BY MR. STOWELL:
7 Q What is a serious instant review?
8 A So that's where some activity has
9 had an adverse outcome, and it's necessary to
10 assess whether there were avoidable factors,
11 and to address learning from those potentially
12 avoidable factors that may have led to an
13 adverse outcome. And I've also undertaken
14 that for other hospitals.
15 Q Is the serious instant review part
16 of a legal proceeding?
17 A Often it would involve a coroner and
18 an inquest, so yes. They're not synonymous
19 with that.
20 Q You mentioned that you have
21 participated in clinical negligence cases in
22 the UK.

1 Have you ever participated in any
2 negligence cases in the United States?
3 A I have not.
4 Q How many clinical negligence cases
5 would you estimate you've participated in over
6 the years?
7 A I couldn't give you a number.
8 Q Can you provide an estimate?
9 A So it depends what you mean by an
10 involvement. Quite often I would get asked to
11 review a case, either for an external hospital
12 or a patient's family, and I do quite a lot of
13 those reviews. In fact, they don't lead to
14 anything beyond the review. So it's a one-off
15 review of a case, and then there is no further
16 involvement.
17 Q In any of the clinical negligence
18 cases, do you submit sworn testimony, either
19 in court or through a declaration or
20 affidavit?
21 A Yes. Typically, there would be a
22 report on the case.

1 Q And is that a report that you would
2 prepare?
3 A Yes.
4 Q And roughly how many reports do you
5 think you've prepared over the years?
6 A I can't give you an answer to that.
7 Q Are you ever deposed as part of the
8 clinical negligence cases?
9 A There is no deposition type process
10 for them. Clinical negligence is a civil
11 matter. Once an expert report has been
12 submitted, there will then be negotiation
13 between the parties. Each party will have an
14 expert report, although increasingly there
15 would be what is known as a joint expert
16 report, where an individual is appointed by
17 both parties.
18 Once the report has been put in,
19 then there's no deposition type process. The
20 only proceeding would be if the case then
21 proceeded to court. That is increasingly
22 rare. So nearly always there is either no

1 case to answer, or the case would settle, and
2 so there would be no further involvement from
3 myself other than the report.
4 Q How many times have you testified in
5 court for a clinical negligence case?
6 A So as I said, it's a very rare
7 scenario. Not for several years, let me put
8 it like that. Possibly a total of 30 years,
9 25 years of doing it, maybe half a
10 dozen times, maybe a few more, maybe a few
11 less.
12 It's exceptionally rare for a case
13 to go to court. It does happen, but as I say,
14 I have not been called as an expert witness in
15 a clinical negligence trial for several years.
16 Q Turning back to Exhibit B to
17 Exhibit 2051, the first case listed there is
18 AGA v. Occlutech UK.
19 Which party did you serve as an
20 expert for in that case?
21 A I served for AGA.
22 Q And what was the technology at issue

1 in that case?
2 A This was a medical device to close
3 what is known as a septal defect, so holes in
4 the heart. And the devices are made with like
5 a Nitinol mesh with a fabric.
6 Q And when you served as an expert on
7 that case, had you had experience with septal
8 defect devices prior to the case?
9 A Oh, yes, huge amount.
10 Q It says "Trial" next to the case
11 name there. What does "Trial" indicate on
12 your list?
13 A So this was a court case of patent
14 infringement, and it was a case held in the
15 high court in London.
16 Q And AGA was the Patent Owner in that
17 case; is that correct?
18 A Well, you're asking details of
19 something from a long time ago, and I believe
20 so, but I don't -- I can't remember the
21 details of it. I don't remember the specific
22 details.

1 I think it would have been an AGA
2 patent, and Occlutech had infringed. So that
3 is my recollection, but beyond that, I really
4 haven't looked at that since 2009.
5 Q And did you testify at trial in that
6 case?
7 A Yes. Yes, I would have done.
8 Q And did you prepare any sort of
9 written declaration or report for that case?
10 A I would have done.
11 Q And do you recall the outcome of the
12 case?
13 A So there were two trials, and I just
14 can't remember the nuances, whether there was
15 a license, whether the patent wasn't
16 infringed. I just don't remember all of the
17 outcomes. I don't remember the two outcomes.
18 My recollection is that one did
19 not -- was not successful for AGA and one was,
20 but I honestly, sitting here now, I cannot
21 recall the details, and I certainly haven't
22 had any involvement since 20- -- well, since

1 the latter trial. I don't remember the
2 details.
3 Q And so the second one on your list
4 here is labeled as 2014, AGA v. Occlutech.
5 Did that case also involve septal
6 defect devices?
7 MR. LOWENSTEIN: Objection, form.
8 THE WITNESS: Yeah, so they were
9 both septal -- they were the same device.
10 My recollection was one was to do
11 with the design; and the other, my
12 recollection -- and you'll have to forgive me
13 because, as I say, this is not anything I
14 reviewed in preparation for today.
15 My recollection is that the
16 discussion centered on whether or not the
17 procedure that had been done as part of a live
18 case demonstration of the technology many
19 years earlier, whether that had disclosed the
20 technology, something like that.
21 So that was the type of issues. As
22 I say, it was a septal defect closure device.

1 It is a device that is put in through the
2 groin into the heart to close a hole. I did,
3 still do, a very large number of those
4 procedures.
5 It's a device of self-expanding
6 Nitinol with fabric in it, and as I say, I've
7 done a lot of those procedures, written a book
8 on it, and done research on it, so yes.
9 BY MR. STOWELL:
10 Q The second case on your list is
11 Edwards v. CoreValve. I take it you were an
12 expert for CoreValve in that matter; is that
13 correct?
14 A So I wouldn't say I was an expert.
15 I was asked as a user of CoreValve
16 to give an impact statement -- this is my
17 recollection, and again, I haven't looked at
18 this for 10 years.
19 My recollection is that Edwards
20 were -- and I may be wrong, so I want to
21 preface my remarks by that -- but my
22 recollection on this specific issue was what

1 would be the impact if CoreValve were to be
2 removed from the market? What would the
3 impact of that be on patients in terms of the
4 harm that would come to those patients with
5 aortic stenosis who would die as a result of
6 not having CoreValve available.
7 That is my recollection, but as I
8 say, I haven't looked at it for 10 years.
9 Q Is it fair to say you submitted that
10 impact statement on behalf of CoreValve in
11 that case?
12 A So I can't recall if it was at that
13 point still CoreValve or Medtronic, but yes,
14 it was not on behalf of Edwards because it was
15 the impact of removing CoreValve, which I
16 believe Edwards were attempting to do, but I
17 don't recall. I don't -- honestly, I just
18 don't recall the details.
19 I was not an expert witness in the
20 case, so I was not an expert witness in the
21 trial that had led to that, and I was not
22 involved in anything other -- I was one of

1 many people who had given impact statements.
2 So perhaps it's incorrect to list it
3 there as a patent expert. I was giving a
4 statement as a user of one of the valves, but
5 in full transparency, I feel I should declare
6 that.
7 Q I appreciate that. Thank you.
8 If we go down to the fourth entry,
9 that entry says 2018 Boston v. Edwards.
10 A Yes.
11 Q You were an expert on behalf of
12 Boston in that matter; is that correct?
13 A That's correct.
14 Q And Boston refers to Boston
15 Scientific; is that right?
16 A That's correct.
17 Q And you served as an expert in both
18 an IPR and at a trial in that case; is that
19 correct?
20 A Yes. Dr. Buller and I were both --
21 I think we were both experts for both parts of
22 that.

1 Q And Dr. Buller was one of the
2 experts for Edwards in that matter, correct?
3 A That's correct.
4 Q The fifth entry there is Abbott v.
5 Edwards. Did you provide testimony on behalf
6 of Abbott in that matter?
7 A I did not. I was asked -- I think I
8 was asked, again, to give advice, and I was
9 not involved in that case, so I did not
10 give -- I may have written a statement, but I
11 did not participate as an expert witness.
12 I was approached, do you know
13 initially by Edwards. So I was initially
14 approached by Edwards, but I had already
15 declined. So, again, I can't remember the
16 precise timeline of this.
17 I know I was approached by Edwards'
18 lawyers in one of the cases, either that one
19 or the Meril case. I think it was the Abbott
20 case, but again, I don't recall.
21 Either way, the most that I would
22 have done is written a statement for Abbott,

1 and that was the sum total of my involvement.
2 I was then not involved at all.
3 Q And so did you prepare a statement
4 for Abbott?
5 A It would have been a very, very
6 short statement, I think. It would have been
7 a very short piece of advice about the
8 technology.
9 Q And do you know if that statement
10 was ever filed with a court?
11 A I do not, and I don't think it was.
12 I wasn't involved in the case after that
13 statement. So it may have been, but I
14 don't -- I certainly had no further
15 involvement. It was a very short involvement.
16 Q You also have listed here a 2020
17 case between Edwards and Meril. You served as
18 an expert for Meril in that case; is that
19 correct?
20 A That is correct. My recollection is
21 that that was the case that Edwards had
22 approached -- or that Edwards approached me

1 on, but I had already reviewed information
2 from Meril, so I immediately declared the
3 conflict and was engaged by Meril.
4 Q And did you testify at trial in that
5 case?
6 A I did.
7 Q And then next you have two IPRs,
8 2020 and 2021, between Medtronic and Teleflex.
9 Which party were you serving for as
10 an expert in those IPRs?
11 A So I was engaged by Medtronic.
12 Q And what is the technology at issue
13 in those IPRs?
14 A This is an interventional cardiology
15 device known as an extension catheter.
16 Q And is that a device that you used
17 in your practice prior to becoming involved in
18 the IPRs?
19 A I had.
20 Q And did you submit declarations in
21 both of the IPRs that are listed in Exhibit B?
22 A Yes.

1 Q And because Medtronic is listed
2 first there, I take it you were challenging
3 the patentability of some Teleflex patents in
4 those IPRs; is that correct?
5 A Yes.
6 Q I'm going to ask our hot seat
7 operator to pull up an exhibit that should be
8 listed as Edwards v. Boston, IPR2017-00060.
9 THE VIDEOGRAPHER: I'm sorry -- oh,
10 yeah, I see it. Sorry, my bad.
11 BY MR. STOWELL:
12 Q Dr. Brecker, do you recognize this
13 document?
14 A Yes. It's one of a declaration that
15 I had submitted in this case.
16 Q Okay. And to be clear, this is a
17 declaration you submitted in one of the
18 Edwards v. Boston IPRs; is that correct?
19 A Yes.
20 Q And if we turn to page 45 of the
21 document (PDF page 47), is that your signature
22 on page 45?

1 A Yes, it is.
2 Q And did you sign this declaration on
3 or about June 23rd, 2017?
4 A So I would have done.
5 Q And did you believe that the
6 statements in the declaration were true and
7 correct when you signed the declaration?
8 A I would have done.
9 Q Are you aware of any mistakes in
10 this declaration?
11 A So you're asking me about something
12 from five years ago. I have no doubt there
13 are some errors, but I can't sit here -- I
14 haven't looked at this for some time, so I
15 can't answer your question. I don't -- I'm
16 not aware. I don't know.
17 Q Do you remember ever making any
18 corrections to this declaration?
19 A I don't know.
20 Q And we're going to mark this with a
21 new exhibit number so that it's clear for the
22 record. My colleague is just pulling that up,

1 so give me a second here.
2 MR. LOWENSTEIN: Can you email me
3 any new exhibits that you enter in this
4 deposition?
5 MR. STOWELL: Sure, we can send you
6 a copy. So let's mark this declaration of
7 Stephen Brecker as Exhibit 1100 in this IPR --
8 or in the four IPRs, okay?
9 (Exhibit 1100 was marked
10 for identification.)
11 BY MR. STOWELL:
12 Q This declaration was submitted --
13 MR. LOWENSTEIN: I'll object just to
14 preserve my objection. Go ahead.
15 MR. STOWELL: Sorry, Counsel, what
16 was the objection?
17 MR. LOWENSTEIN: Hearsay. At least
18 hearsay, possibly others, but we'll see.
19 BY MR. STOWELL:
20 Q So as we sit here today,
21 Dr. Brecker, you don't recall making any
22 corrections to this declaration at any point

1 in time; is that fair?
2 A I haven't said that. I just don't
3 recall. I have not -- I may well have not
4 looked at this document since the -- since the
5 date or during that IPR.
6 So there were a lot of documents in
7 that case. You're showing me the front page
8 of one of them. I can't answer your question.
9 I don't know.
10 Q Do you remember the patent that was
11 issued in this IPR? It's listed there on the
12 front page, 8,992,608.
13 MR. LOWENSTEIN: Objection, scope.
14 Go ahead.
15 THE WITNESS: Yes, I recall the
16 patent.
17 BY MR. STOWELL:
18 Q And was the patent referred to as
19 the Haug, H-A-U-G, patent during this IPR?
20 A I referred -- we referred to it as
21 the '608 patent.
22 Q Do you recognize the '608 patent as

1 having an inventor by the name of Haug,
2 H-A-U-G?
3 MR. LOWENSTEIN: Objection, scope.
4 THE WITNESS: So I haven't looked at
5 that patent for a long time. I believe that
6 is the name of the inventor.
7 BY MR. STOWELL:
8 Q Do you recall the technology that
9 the '608 patent dealt with?
10 A So the '608 patent is a complex and
11 long patent. This case related to the
12 paravalvular leak solution that was innovative
13 in the '608 patent.
14 Q And when you say the paravalvular
15 leak, was that paravalvular leak around a
16 transcatheter heart valve?
17 A Yes, it was.
18 Q And was one of the solutions for
19 paravalvular leak that was described in the
20 '608 patent a fabric seal on the outside of
21 the valve?
22 MR. LOWENSTEIN: Objection. I'm

1 going to also add that this exhibit is
2 untimely. Objection, form. Objection, scope.
3 THE WITNESS: So I have not looked
4 at this patent and all the language for some
5 time. I'm aware that this included a
6 paravalvular leak solution with a bunched up
7 seal.
8 BY MR. STOWELL:
9 Q What do you mean by "bunched up"?
10 A So you may well be asking me about
11 claim construction in this case, and I just
12 don't -- I'm not prepared to do that. By
13 "this case," I mean the Boston IPR case.
14 I'm aware of the invention and how
15 this device worked, and the device worked by
16 bunching up and creating flaps and pockets.
17 Q And when you say "bunching up," what
18 was bunched up?
19 MR. LOWENSTEIN: Objection, form,
20 scope.
21 THE WITNESS: Yeah, I've not
22 reviewed this patent or my declaration in

1 sufficient detail to go through this.
2 I'm happy to do that now, but I
3 would need time to read through the patent and
4 read through my declaration.
5 BY MR. STOWELL:
6 Q So when you referred to something
7 that was bunched up, what structure were you
8 referring to?
9 A Well, that's what I say. I'm very
10 happy to read through the patent and read
11 through my declaration and answer your
12 questions accurately.
13 MR. LOWENSTEIN: I'd just like to
14 state for the record that the only thing that
15 Dr. Brecker can see is the cover page of this
16 exhibit, and nothing more, and it has not been
17 sent to counsel for Aortic, so we preserve all
18 of our objections.
19 BY MR. STOWELL:
20 Q Why don't we turn to page 24 of what
21 we have marked as Exhibit 1100.
22 MR. LOWENSTEIN: Same objections.

1 THE WITNESS: So I would like to
2 make a request, and that is that I have time
3 to read that document.
4 MR. STOWELL: Let's go to page 24,
5 please. This is page 22.
6 MR. LOWENSTEIN: Excuse me, can you
7 please send us the document? I've asked three
8 times.
9 THE VIDEOGRAPHER: The document --
10 MR. LOWENSTEIN: There's a Box
11 document. Please allow us to see the entire
12 document. We're not going to answer any more
13 questions until you give us the document in a
14 form that Dr. Brecker can look at.
15 THE VIDEOGRAPHER: There's a folder.
16 The documents are in the Box folder that can
17 be downloaded.
18 (Discussion held off the record.)
19 THE WITNESS: So this is a document
20 of 113 pages that I haven't looked at for
21 several years.
22 If you're going to ask me questions

1 about it, I'm going to need to have time to
2 read it.
3 BY MR. STOWELL:
4 Q Well, let's start with paragraph 48
5 that's on page 24.
6 MR. LOWENSTEIN: Objection, form.
7 Objection, scope. Objection --
8 MR. STOWELL: Mr. Lowenstein, please
9 allow me to finish my question before you
10 object.
11 Let's start with paragraph 48 on
12 page 24. Can you review this paragraph, and
13 you're welcome to review the paragraphs before
14 and after, and let me know if this is an
15 accurate description of your understanding of
16 what the '608 patent --
17 MR. LOWENSTEIN: Excuse me. You can
18 review whatever you want.
19 MR. STOWELL: Hold on. Dr. Brecker,
20 just a second.
21 Mr. Lowenstein, please allow me to
22 ask my question. You spoke over me again

1 there.
2 MR. LOWENSTEIN: I did not, but
3 you're not here to tell the witness what he
4 can and cannot look at in the document.
5 He already explained to you that
6 this is a five-year-old document, so don't
7 tell him he can only look at such and such
8 paragraphs.
9 MR. STOWELL: Mr. Lowenstein, this
10 is not an objection that you are making. You
11 are instructed to simply make a one-word
12 objection. You are coaching the witness.
13 MR. LOWENSTEIN: I am happy to move
14 forward. Can we please get along with the
15 deposition? Let's move on with the --
16 THE WITNESS: So you're asking me
17 about the '608 patent that I have not looked
18 at for a very long time, and in order to
19 answer your questions, I am going to need to
20 have time to review the '608 patent.
21 BY MR. STOWELL:
22 Q Okay. So you would be unable to

1 answer the question regarding paragraph 48
2 without reviewing the entire declaration and
3 the '608 patent; is that fair?
4 MR. LOWENSTEIN: There is no
5 question pending about paragraph 48.
6 Objection.
7 THE WITNESS: That is not -- that is
8 not fair. What you have just said is not
9 fair.
10 You're saying -- I don't know what
11 question you're going to ask me, and what I'm
12 saying is I need time to review a
13 five-year-old declaration that runs to
14 113 pages, and the '608 patent, that my
15 recollection is it runs to a very large number
16 of pages.
17 (Beeping sound.) Sorry, I don't
18 know what -- there was some kind of alert.
19 What you're asking me to do,
20 I think, I need to have time to review the
21 '608 patent and my declaration, and then I
22 would be very happy to answer your question on

1 paragraph 48.
2 BY MR. STOWELL:
3 Q Okay. But as we sit here right now,
4 can you tell me whether paragraph fairly
5 summarizes what the '608 patent was about?
6 MR. LOWENSTEIN: Objection, form.
7 Objection, scope.
8 THE WITNESS: Sitting here now,
9 you're asking me does paragraph 48 summarize
10 the '608 patent? And without reviewing the
11 patent that runs to something like -- and this
12 is off the top of my head -- 80 pages, I can't
13 answer your question. I need to review the
14 patent and review my declaration.
15 BY MR. STOWELL:
16 Q Do you have any reason to believe
17 that the material in paragraph 48 of
18 Exhibit 1100 is inaccurate?
19 MR. LOWENSTEIN: Objection, form.
20 Objection, scope. Objection to the exhibit.
21 THE WITNESS: So you're asking me
22 about a document that runs to 113 pages and is

1 five years old that I have not looked at.
2 You're asking me about a patent that
3 I have not reviewed for the purposes of this
4 deposition.
5 In order to answer your question, I
6 need to review the patent and review my
7 declaration, and then I would be very happy to
8 answer your question.
9 BY MR. STOWELL:
10 Q In this IPR2017-0060 that we've
11 marked as Exhibit 1100, you were arguing that
12 the challenged claims of the Haug patent were
13 valid, correct?
14 MR. LOWENSTEIN: Objection, form.
15 Objection, scope. Objection to the exhibit.
16 THE WITNESS: You're asking about
17 detail of the case that I simply am not
18 prepared to answer on the hoof without having
19 reviewed the documents that I need to answer
20 your questions accurately.
21 BY MR. STOWELL:
22 Q So you don't recall what your

1 position was with regard to the validity of
2 the '608 patent in this IPR?
3 MR. LOWENSTEIN: Objection, form.
4 Objection, scope. Objection to the exhibit.
5 THE WITNESS: This was a very
6 complex case that involved both IPR and trial.
7 I gave a number of declarations, a number of
8 depositions, and testified at trial.
9 You're asking me about something
10 from five years ago. I need to review the
11 patent and my declaration, and I need to have
12 the time to do that, and then I would be happy
13 to answer your questions.
14 BY MR. STOWELL:
15 Q Okay. But as we sit here, is it
16 fair to say you don't recall what your
17 position was with respect to the validity of
18 the '608 patent in this IPR?
19 MR. LOWENSTEIN: Objection, form.
20 Objection, scope.
21 THE WITNESS: No, that's not fair to
22 say for the reasons I gave earlier. It is not

1 fair to characterize what I have said by
2 saying I can't give you an answer.
3 I am saying I can give you an
4 answer, but I would need to review my
5 declaration and the patent and know what
6 question you're asking.
7 BY MR. STOWELL:
8 Q Okay. So in order to provide a
9 response, you would need to review the patent
10 and the declaration?
11 MR. LOWENSTEIN: Objection, form.
12 MR. STOWELL: Is that your
13 testimony?
14 MR. LOWENSTEIN: Objection, scope.
15 MR. STOWELL: Just a second.
16 Mr. Lowenstein, you spoke over me once again.
17 Please wait on your objections until the
18 question is complete.
19 MR. LOWENSTEIN: Sorry. When the
20 question is so objectionable, I can't restrain
21 myself.
22 THE WITNESS: Could you ask your

1 question again because I've forgotten it.
2 BY MR. STOWELL:
3 Q So your testimony is that in order
4 to provide a response to my question regarding
5 your position in this IPR, you would need to
6 review the patent and the declaration first?
7 MR. LOWENSTEIN: This IPR? What
8 IPR? Can you please be more precise?
9 MR. STOWELL: Mr. Lowenstein, that
10 is an inappropriate objection.
11 MR. LOWENSTEIN: No, it's not.
12 MR. STOWELL: It's happened numerous
13 times.
14 MR. LOWENSTEIN: You're saying "this
15 IPR." Are you talking about the Boston
16 Scientific five-year-old IPR, or are you
17 talking about the present IPR?
18 MR. STOWELL: Mr. Lowenstein, you
19 are coaching this witness. This is
20 inappropriate.
21 MR. LOWENSTEIN: Okay. Objection,
22 form, scope.

1 THE WITNESS: I'm sorry, I've lost
2 my train of thought here. Could you repeat
3 the question?
4 BY MR. STOWELL:
5 Q I will. So your testimony today is
6 that in order to provide a response to my
7 question regarding your position on validity
8 in the Boston IPR, you would need to review
9 the patent and the declaration first?
10 MR. LOWENSTEIN: Objection, form.
11 Objection, scope.
12 THE WITNESS: You are asking me
13 about something from five years ago. I think
14 it is only reasonable that I am given time to
15 review the material on which you wish me to
16 provide an accurate answer.
17 I could give you an answer on the
18 hoof. I don't think that's very sensible for
19 me to do.
20 BY MR. STOWELL:
21 Q In this IPR, do you recall that
22 Dr. Buller argued that the challenged claims

1 of the '608 patent were invalid?
2 MR. LOWENSTEIN: Objection, scope.
3 THE WITNESS: You're asking me about
4 a case from five years ago in which there was
5 an IPR and a trial. There were complex
6 issues. My recollection is there were
7 four-way arguments. There were arguments both
8 in each direction, both on this and on other
9 patents.
10 I would need to review material to
11 answer questions that you are asking me about
12 a case from five years ago. I've not prepared
13 to review this material. I was not asked to
14 review this material in preparation for this
15 deposition.
16 BY MR. STOWELL:
17 Q Do you recall what the outcome of
18 this particular IPR in the Boston case was?
19 MR. LOWENSTEIN: Objection, form.
20 Objection, scope.
21 THE WITNESS: I cannot recall -- I
22 can recall the outcome of the trial, but

1 simply to try to give you a one-word answer, I
2 can't do that.
3 As I said, this was a very complex
4 case, it involved a lot of issues, and I don't
5 recall all of the details from five years ago.
6 A lot has happened in the last five years, and
7 I have not reviewed any material relating to
8 this case in preparation for my deposition
9 today.
10 BY MR. STOWELL:
11 Q Do you recall whether the Board in
12 this Boston IPR involving the '608 patent
13 found the challenged claims of the '608 patent
14 invalid?
15 MR. LOWENSTEIN: Objection, form.
16 Objection, scope.
17 THE WITNESS: So you're asking me
18 about a case from five years ago, and in the
19 interim period, a lot has happened.
20 I'm very happy to prepare answers to
21 all of your questions on this case, and I
22 could give you an answer on the fly, but I

1 want to be accurate, and therefore I'm going
2 to need to review material, and it's only fair
3 that you give me time to review the material
4 in order to determine my answers.
5 BY MR. STOWELL:
6 Q And to be clear, I'm just asking for
7 your best recollection today. If you don't
8 have a recollection, that's fine.
9 MR. LOWENSTEIN: Objection, form.
10 Objection, scope.
11 THE WITNESS: So I simply think it's
12 inappropriate for me to give a vague
13 recollection on something from five years ago
14 that could potentially have importance.
15 You're asking me very important
16 questions, very interesting questions
17 actually, and I'd like to answer those
18 accurately.
19 BY MR. STOWELL:
20 Q I understand from your declaration
21 that you have performed over 1300 TAVR
22 procedures; is that correct?

1 MR. LOWENSTEIN: Are you talking
2 about the declaration in the current case, or
3 are you still asking about the Boston
4 Scientific case?
5 MR. STOWELL: Mr. Lowenstein, it is
6 up for the witness to ask for clarification if
7 he needs that.
8 MR. LOWENSTEIN: No.
9 MR. STOWELL: It is an improper
10 objection.
11 MR. LOWENSTEIN: Look, can we please
12 be adults? You just asked 10, 20 minutes of
13 questions about one IPR, then you're switching
14 to the other, and you said "this IPR."
15 Can you just clarify your question?
16 That's it.
17 MR. STOWELL: Mr. Lowenstein, you
18 are continuing to make inappropriate
19 objections.
20 MR. LOWENSTEIN: Let's move on with
21 our lives. Please ask a question.
22

1 BY MR. STOWELL:
2 Q Dr. Brecker, I understand from
3 Exhibit 2051 that you have performed over 1300
4 TAVR procedures; is that correct?
5 A Yes, that's correct.
6 Q And I understand that you have also
7 proctored over 600 TAVR procedures; is that
8 correct?
9 A Yes.
10 Q And are the proctored cases separate
11 from the 1300 cases that you have performed?
12 A There's some overlap, and I can
13 explain that. 1300 cases -- and it's more
14 than that now. We're doing lots of cases
15 every week. My hospital is doing up to
16 10 cases a week, so the numbers are a moving
17 target.
18 In proctoring, there are three
19 different kind of models. One is that you
20 would stand behind the patient -- sorry, stand
21 behind the doctors who are doing it. You
22 would not even touch the catheter or the

1 device or the patient.
2 There's another model where you
3 stand in the copilot seat. So the two
4 operators would stand by the bed, the first
5 operator closest to the access site, the
6 second operator on their right, and a lot of
7 the proctoring I would have done I would have
8 done like that. You know, holding the wire,
9 moving the wire, assisting, and that's a
10 procedure that I would have done.
11 And then a much smaller number would
12 be where, as a proctor, you actually do the
13 procedure. You're the first operator.
14 So in assessing the numbers, I mean,
15 I've been involved in -- "been involved in" --
16 a very large number, and it just depends how
17 you define the first operator, second
18 operator, or proctor. So I could say that
19 some of the proctored cases were in addition
20 to the 1300. There's inevitably a bit of
21 overlap, but it's more than 1300 now.
22 Q And I understand that you have

1 performed TAVR procedures with Medtronics,
2 CoreValve, THV, and the follow-on iterations
3 of that; is that correct?
4 A Yes, that is correct.
5 Q How many of the 1300 TAVR procedures
6 were with Medtronic THV?
7 A Well, more than 50%, probably more
8 than 60%, but I couldn't give you the exact
9 number. Could be more than that.
10 Q Sorry, go ahead.
11 A So my current practice is probably
12 60% Medtronic, 40% Edwards Sapien.
13 Q And how many of the proctored cases
14 were with a Medtronic product?
15 A Oh, so all of the proctoring I did
16 was -- is with Medtronic.
17 Q I also understand that you have
18 performed TAVR procedures with Boston
19 Scientific's LOTUS valve; is that correct?
20 A Yes.
21 Q And how many of your 1300 TAVR
22 procedures were with the LOTUS valve?

1 A So that would be a small percentage.
2 Obviously, that valve is no longer around. I
3 can't give you the exact number.
4 Q What about an estimate of how many
5 implantations you've done with LOTUS?
6 A Could be less than 100. Could be
7 high tens, like 60, 70, something like that.
8 Q Okay. And then I also understand
9 that you have performed TAVR procedures with
10 Edwards' Sapien line of valves; is that
11 correct?
12 A Yes.
13 Q And how many of your 1300 TAVR
14 procedures were with the Sapien line of
15 valves?
16 A So I haven't done the calculation.
17 The most accurate thing I can tell you now is
18 I'm doing, I would say between 30- and 40%.
19 I think I said 40% Edwards before. So, you
20 know, it could be 36%. I haven't looked
21 recently, but certainly we're using Edwards
22 every week. I can't give you the exact

1 number.
2 Q And is your current usage of Edwards
3 higher than it's been in the past?
4 A Yes.
5 Q Did you ever implant the original
6 Sapien valve?
7 A The first one we would have
8 implanted would have been the -- yes, the
9 Sapien, prior to the XT.
10 Q And can you estimate how many Sapien
11 valves you have implanted?
12 A I can't. I can't give you the exact
13 number.
14 Q Can you give an estimate of the
15 number?
16 MR. LOWENSTEIN: Object to the form.
17 THE WITNESS: So for that particular
18 valve, we were predominantly implanting
19 self-expanding valves then. So for the
20 original Edwards Sapien, some tens of valves.
21 Again, less than 100. I can't give you the
22 exact number.

1 BY MR. STOWELL:
2 Q Have you ever implanted the
3 Sapien XT valve?
4 A Yes, I think I have. Again, we
5 wouldn't necessarily have documented it on
6 spreadsheets as XT.
7 Q Can you provide an estimate of how
8 many XT valves you think you may have
9 implanted?
10 A I can't.
11 Q What about Edwards' Sapien 3 valve?
12 Have you had an opportunity to implant the
13 Edwards' Sapien 3 valve?
14 A Yes, I have.
15 Q And can you provide an estimate of
16 how many Sapien 3 valves you've implanted?
17 A I can't give you the number. I can
18 give you our current numbers at St. George's
19 where I work to give you a sense, but we are
20 doing between 5 and 10 procedures per week, of
21 which between 30- and 40% is Sapien. The
22 majority of those now would be Sapien 3 Ultra,

1 but the largest size would be Sapien 3.
2 Q Has your hospital been implanting
3 Sapien 3 since it became available in the
4 United Kingdom?
5 A I can't give you the exact dates.
6 Q Roughly how many years do you
7 remember implanting the Sapien 3 valve now?
8 A 3 or 4 years, something like that.
9 Q And you mentioned your hospital is
10 using the Sapien 3 Ultra valve. Have you
11 actually implanted the Sapien 3 Ultra valve?
12 A Yes. That's the commonest type of
13 valve that we now use for the
14 balloon-expandable.
15 Q Okay, we've been going about another
16 hour. Why don't we take a break, 10 minutes
17 again.
18 MR. LOWENSTEIN: Sounds good.
19 Thank you.
20 THE VIDEOGRAPHER: Okay, going off
21 the record. The time is 10:48.
22 (A break was taken.)

1 THE VIDEOGRAPHER: We are back on
2 the record. The time is 11:00 a.m.
3 BY MR. STOWELL:
4 Q Dr. Brecker, did you talk to anybody
5 about your deposition testimony during the
6 break?
7 A I did not.
8 Q Would you agree with me that Edwards
9 is a pioneer in the field of transcatheter
10 heart valves?
11 A I would.
12 Q And why would you agree with that
13 statement?
14 A They were able to introduce one of
15 the first two transcatheter valves that have
16 proved to be successful solutions to the
17 problem of the transcatheter valve.
18 Q When you say the problem of a
19 transcatheter valve, what problem are you
20 referring to?
21 A Sorry, I misspoke.
22 To dealing with the problem of

1 aortic stenosis in patients who are not
2 suitable for open heart surgery by the
3 development of the transcatheter valve.
4 Q Have you ever worked with Edwards
5 aside from implanting Edwards' valves?
6 A It's possible, although I can't
7 recall. I have done meetings with them and
8 educational activities, but I've not worked
9 with the company under a contract, if that's
10 your question.
11 If I could just go back to the
12 previous question about pioneering. Of
13 course, the real pioneer was PVT, who
14 developed the valve. Of course, it was then
15 taken over by Edwards. So I kind of think of
16 PVT and Edwards as one entity, although it
17 started with PVT.
18 Q And you mentioned that Edwards
19 launched one of the first two THVs that were
20 on the market. The company that launched that
21 was Edwards at the time, correct, not PVT?
22 A That's correct. The very first

1 implant would have been done I think before
2 the acquisition, but that would have been with
3 the original Cribier valve.
4 Q Before the break we were discussing
5 some of the different THVs that you have
6 implanted, and we were discussing the
7 Medtronic THV.
8 Were all of the Medtronic THVs that
9 you've implanted self-expanding valves?
10 A Yes, they were. Yes, they are.
11 Q And do you understand what I mean by
12 "self-expanding"?
13 A I do.
14 Q And what do you understand that term
15 to mean?
16 A Well, within the field of
17 transcatheter valves, there is an
18 understanding of a binary division between two
19 methods of deployment, and I'm talking about
20 the time period between 2000 and 2010 perhaps,
21 so not including the LOTUS valve.
22 But when transcatheter valve

1 implants started, when I started doing them in
2 2007, it was pretty much a binary distinction
3 between balloon-expandable and
4 self-expandable.
5 Now, there are different methods of
6 self-expansion, and certainly outside of the
7 field of transcatheter valves, self-expansion
8 could mean something different, but
9 effectively those terms were used almost
10 synonymously with the type of valve, where
11 people wanted to refer to the valve without
12 naming the company or brand name.
13 So they would say I think this
14 patient would do well with a self-expanding
15 valve, and the understanding was that that was
16 a Medtronic valve; and someone might say this
17 patient would do better with a
18 balloon-expandable valve, and at the time, it
19 was understood that meant Edwards.
20 So there is an understanding of what
21 "self-expanding" means, but that is -- it's
22 limited to perhaps the experience of what

1 transcatheter valves were available at the
2 time that the term is being used.
3 Q You had mentioned the LOTUS valve
4 may not fit into one of the buckets.
5 What did you mean by that?
6 A Yes, the LOTUS valve was a very
7 interesting design, and it was called
8 "mechanically expanded."
9 So it was not -- it was neither
10 balloon expandable -- you could blow a balloon
11 up in it afterwards, and you could expand it
12 after deployment, but it was referred to,
13 perhaps in order to try to differentiate it,
14 as mechanically expanded.
15 And what that meant was that quite a
16 long frame was shortened, and as it shortened,
17 it expanded, as frames do. So as it
18 shortened, it expanded outwards. And then
19 there was a complex locking mechanism whereby
20 the valve would be locked so that it wouldn't
21 unspring. Now, in fact, that could happen,
22 which was one of the difficulties with the

1 device.
2 But it was called "mechanically
3 expanded" because the deployment was a very
4 deliberate and active process of rotating an
5 activator that would shorten the device and
6 expand it at the same time.
7 Q And when did the LOTUS valve become
8 available for physicians to use?
9 A So I don't have a clear recollection
10 of the date, although 2014 is in my mind as to
11 when I may have done the first implant. It's
12 possible I did some implants before that with
13 very early versions. I don't recall.
14 It was available before that, so it
15 would have been available before then. So I
16 can't remember exactly the date.
17 Q In 2012, what THV devices were
18 commercially available in the UK?
19 A Well, certainly the Medtronic and
20 Edwards. I don't recall if LOTUS was
21 commercially available in 2012. It may have
22 been in clinical trial then.

1 And, of course, the commercial date
2 is less relevant than when valves were
3 starting to be used because all of them were
4 used in clinical research and registries prior
5 to regulatory approval.
6 I'm trying to think when --
7 the Direct Flow was probably available then.
8 The Symetis valve may have been available
9 then.
10 I don't have an absolute
11 recollection of other valves that were
12 commercialized. All of these valves I
13 mentioned were in clinical trial usage, maybe
14 not all in the UK. Maybe some of them were in
15 other countries.
16 Q You mentioned Direct Flow. Which of
17 the two buckets would the Direct Flow valve
18 fit into?
19 A Well, again, I can't -- I
20 never used -- I never deployed it and I never
21 used it, so I can't answer that question.
22 Q Did you ever use the Symetis valve?

1 A I did not.
2 Q Do you know which bucket,
3 self-expanding or balloon-expandable, the
4 Symetis valve would fit into?
5 A That would be self-expanding.
6 Q Do you have any experience with
7 balloon-expandable THVs besides the Sapien
8 line of products?
9 A So I have not used other
10 balloon-expandable valves myself in my own
11 practice other than the Sapien line of
12 products.
13 Q Are you aware of any other
14 balloon-expandable THVs that were in clinical
15 trials or on the market prior to 2012?
16 A Not prior to 2012. No, I don't
17 think so. It's possible that there was, but I
18 can't recall at this point.
19 Q Earlier you mentioned that doctors
20 would talk about patients being better suited
21 for a self-expanding valve or a
22 balloon-expandable valve.

1 What conditions would make a
2 self-expanding valve better for a patient?
3 A So it's difficult to answer your
4 question without giving it more context,
5 because the way this whole field has evolved
6 is fascinating and exciting, and we've learned
7 a lot along the way.
8 So an answer that I might give to
9 you now, we have a very good idea of which
10 types of patients' anatomy are better suited
11 to a self-expanding valve, and that knowledge
12 has really been acquired over a long period of
13 time.
14 To give you some examples, there is
15 a general view that the type of gradients that
16 you are left with when undertaking
17 valve-in-valve TAVI -- so that's where you are
18 putting a transcatheter valve in a previously
19 placed, but now degenerated surgical valve --
20 there is a view that self-expanding technology
21 is better in that setting because the design
22 of the valve is supra-angular -- in other

1 words, the functioning part of the valve lies
2 above the annulus, that's the bit that
3 actually opens, not the base of the leaflet,
4 just the opening is above the annulus -- and
5 you are able to achieve higher valve areas.
6 That was known quite early on.
7 Another example where a
8 self-expanding would be preferable is where
9 there is heavy calcification in the left
10 ventricular outflow tract.
11 So one of the most feared
12 complications of balloon-expandable
13 transcatheter valve is aortic root rupture,
14 and that is highly correlated to heavy
15 calcification in the outflow tract. So many
16 cardiologists feel that heavy calcification in
17 the outflow tract is an indication for
18 self-expanding technology.
19 To turn things around, there are
20 certain anatomies that are much better suited
21 to balloon-expandable technologies. Where you
22 feel that you want to regain coronary access,

1 and your choice is between, for example, a
2 Sapien and a Medtronic valve, many
3 cardiologists feel there are benefits to
4 having the lower frame of the Sapien valve
5 rather than the tall frame of the Medtronic
6 valve in order to regain coronary access.
7 Now, there are exceptions to that rule as
8 well. And I could go on.
9 There are other settings where,
10 for example, in a valve-in-valve, you would
11 want a balloon-expandable valve, and that is,
12 for example, where you have a surgical valve
13 that's failed in a young patient where you may
14 want to have coronary access, but more
15 importantly, where you may need another
16 transcatheter valve in the future.
17 Now there's a big debate as to which
18 type of technology you should put in first,
19 and many people would say, well, if you've got
20 a surgical valve that's failed -- and I had a
21 patient like this just a short while ago, age
22 66, he's going to need another transcatheter

1 valve, so we had to think.
2 You kind of have to think about what
3 are we going to do in 10 years' time or
4 15 years' time or, hopefully, 18 or 20 years'
5 time with this guy, and we elected to put in a
6 Sapien valve first, and there are methods that
7 you can do to expand the surgical valve that's
8 in there to make space.
9 The one final area that I would say
10 you would favor a self-expanding technology is
11 if your coronary height is very low. So if
12 your coronaries are low, it's felt that the
13 balloon-expandable valve may split the native
14 leaflets and cause the other feared
15 complication of TAVI, which is acute coronary
16 occlusion.
17 And I should say, as my final remark
18 on this, that coronary occlusion and aortic
19 rupture are the two most feared complications
20 of TAVI. Those are the ones where you have a
21 high risk of mortality. There are others,
22 like value embolization, but those are the two

1 more common ones.
2 Q Thank you for that explanation.
3 In this IPR, we're interested in
4 roughly the 2012 time frame. Those, you know,
5 benefits of self-expanding and
6 balloon-expandable valves that you just
7 described, would those have been known in
8 2012?
9 A Yes. The one that may not is the
10 sequence of transcatheter valves that you
11 would want to do in a patient who is young,
12 because that's something where the indication
13 has increased.
14 So now a patient in their 60s who's
15 had a previous surgical valve, we have no
16 worries about doing a transcatheter
17 valve-in-valve implant. In 2012, I think the
18 surgeons would probably have said we'll do a
19 reoperation, we'll do another surgical valve,
20 and then you can do a TAVI in 15 years' time.
21 But the other ones I mentioned — the
22 valve-in-valve in general, coronary occlusion,

1 outflow tract calcification and rupture — that
2 was all known in 2012.
3 Q And who at the hospital will make
4 the decision about which type of valve to
5 implant?
6 A So from the very beginning of this
7 technology, unlike almost any other procedure,
8 something called a heart team approach
9 evolved, and it was very refreshing and it was
10 very exciting, because prior to that, pretty
11 much an individual physician would make an
12 individual choice about a patient.
13 Now, things did change with coronary
14 disease and the development of what was known
15 as a multidisciplinary team meeting, but
16 that's taken a long time to evolve, and it
17 really was only evolving in 2012, I would say.
18 For transcatheter valves from the
19 outset, there was a recognition that you had
20 to have a multidisciplinary heart team
21 approach, not just with interventional
22 cardiologists and surgeons, but also imaging

1 cardiologists, intensive care unit doctors.
2 And so from the outset, the choice
3 of valve has been made at a collaborative
4 multidisciplinary team meeting where you
5 review the echo and the CT scan and things
6 like that.
7 Q So in 2012, who are the people at
8 the hospital that would have been involved on
9 the heart team?
10 A So that would include the people I
11 just mentioned: interventional cardiologists,
12 cardiovascular surgeon, imaging cardiologists,
13 and often there was someone from the intensive
14 care unit, not always.
15 And then for specific cases, you may
16 call in other particular specialties to join
17 the meeting, very commonly vascular surgeons
18 if the cardiovascular surgeon was not a
19 vascular surgeon. In the U.S., typically my
20 experience was that the cardiac surgeons were
21 also vascular surgeons. That's a very
22 distinct separation, for example, in the UK;

1 and respiratory medicine for patients with
2 lung disease, things like that.
3 Q Would you agree that TAVR procedures
4 encompass many different delivery routes to
5 the heart?
6 A Yes, there are many potential
7 delivery routes. The overwhelming majority
8 now are transfemoral. The vast, vast, vast
9 majority are transfemoral, but many other
10 potential routes have been tried over the
11 years.
12 Q What are the potential routes that
13 you're aware of as having been tried for a
14 TAVR procedure?
15 A Okay, so there's a lot.
16 The ones that I have heard of people
17 doing and/or done myself would include,
18 firstly, transapical.
19 Now, at the start of transplant
20 aortic valve implantation, for the Edwards,
21 depending on which series of patients you look
22 at and studies, but it was often a 50/50 split

1 between transfemoral arterial and transapical.
2 For the Medtronic valve, and now for
3 Edwards as well, there is the so-called
4 subclavian or axillary artery approach.
5 They're anatomically different, there are
6 slightly different entry sites, and those can
7 be done either, as I say, subclavian or
8 axillary. And then there are different
9 methods of doing it either with a small
10 incision and cutdown onto the vessel or a
11 percutaneous needle being advanced into the
12 vessel directly.
13 The original method, which was
14 discarded quite quickly, was a transvenous
15 approach, which went through the vein, but
16 this was the original method that Cribier had
17 tried because the devices were, frankly, too
18 large for the femoral artery, and it was also
19 felt that a venous rupture was less serious
20 than an arterial rupture. That's not always
21 the case.
22 But the method was extremely

1 complicated and very challenging technically
2 of going up through the femoral vein into the
3 right atrium, doing a transseptal puncture
4 across the interatrial septum, and then going
5 into the left ventricle, and then going up out
6 through the aorta in an antegrade fashion.
7 So that was the transvenous
8 transseptal. We've talked about transfemoral,
9 we've talked about transapical, axillary, and
10 subclavian.
11 Now, at later time points -- and
12 those were really the only methods that would
13 have been used at around 2012. There wouldn't
14 have been any others.
15 I don't recall when I first heard
16 about the carotid artery approach, but that
17 was an approach where, for example, the
18 femoral arteries couldn't be used. People
19 felt, well, we could expose the carotid artery
20 and put in a device through that way.
21 Oh, I've forgotten another important
22 route, which was, in fact, very early on used,

1 so probably around 2010, maybe even earlier,
2 would have been the direct aortic route. So
3 that was a very important access route. I
4 could go on about the reasons, but I won't
5 unless you want me to.
6 But direct aortic was a very
7 successful approach, predominantly because the
8 surgeons were very used to do doing
9 mini-thoracotomies and placing large catheters
10 into the aorta, and this is exactly the method
11 that was used to deploy the valve. So direct
12 aortic, transapical, the carotid.
13 More recently, so post-2012, there
14 has been another access route, which is not
15 used very much, which is again, where the
16 femoral arteries may not be usable, people
17 have put a catheter into the -- we have not
18 done this procedure, by the way -- a catheter
19 into the femoral vein and the inferior vena
20 cava, and the inferior vena cava and the aorta
21 are like two big tubes that meet each other
22 over a short distance, and believe it or not,

1 if you puncture from the inferior vena cava
2 into the aorta, you can then dilate that tract
3 and put a sheath cross. That's been used
4 where the femorals, neither right nor left
5 femoral, was available.
6 That has not gained wide usage.
7 It's technically quite difficult, quite a high
8 complication rate, as you can imagine, because
9 you leave a big hole in the aorta; and in
10 addition, it's technically quite challenging.
11 It wasn't around in 2012, in any event.
12 So I'm sure I have left one or two
13 out that I may have been exposed to, but I
14 can't think of any immediately.
15 Q Let's see, we've got about
16 three minutes. Why don't we go back through a
17 couple of these. That was a lot of
18 information.
19 Can you just explain for direct
20 aortic, how that procedure was performed?
21 A Yes. This might take me
22 three minutes, and then maybe we could break

1 after that.
2 So direct aortic is a procedure
3 whereby the patient is put under a general
4 aesthetic, and the surgeon performs a
5 mini-thoracotomy. So a small incision -- and
6 I'm showing an incision of a couple
7 of inches -- either in the right upper thorax,
8 or does an upper mini-sternotomy -- there's
9 two approaches, pros and cons to both -- and a
10 small section of the ascending aorta is
11 exposed.
12 The surgeon then places a needle
13 into the aorta, and a wire is put through the
14 needle, the needle is removed, and then a
15 small sheath is advanced over the wire into
16 the aorta.
17 What happens then is a catheter is
18 placed through that sheath, and the aortic
19 valve is crossed. So the narrow aortic valve
20 is crossed using a catheter through a sheath
21 in the aorta, directly into the aorta, and a
22 wire is placed into the left ventricle.

1 That's quite a tricky maneuver to do
2 because your hands are all up. You're not
3 working on a table. You haven't got -- the
4 ergonomics of it are quite challenging.
5 You then put a stiff wire into the
6 ventricle, and over the stiff wire, you then
7 insert your large sheath into the aorta.
8 As I say, the reason surgeons quite
9 like this is this is how they would -- not the
10 percutaneous method I've described, but rather
11 when they are operating on a patient, they
12 would be very used to putting in a large
13 sheath, a large bypass sheath, or a conduit
14 for bypass into the aorta.
15 Once the sheath is there, I mean the
16 big sheath, 18 or 22 French or bigger, you can
17 then advance over the stiff preshape wire
18 that's in the ventricle, you can advance your
19 transcatheter valve.
20 You deploy your valve, and of course
21 you're very close to the valve itself. The
22 rest of the catheter is -- you need someone to

1 hold it because -- it would normally all be in
2 the patient, but because you're so close to
3 the valve, it's not.
4 But you deploy the valve, and you
5 can do either self-expanding or
6 balloon-expandable, and I've done both with
7 this technique, and you then take the valve
8 out -- sorry, the delivery system out, the
9 valve is in place, and then it's down to the
10 surgeon just to put a few stitches, which are
11 already placed there, around the hole in the
12 aorta and to close the sternotomy.
13 There were benefits to this in that
14 you could use a much larger sheath. It was
15 not -- obviously, you would do it in patients
16 who an endovascular method wasn't feasible,
17 there's no access from the femorals or
18 subclavian. Some people used it in preference
19 to the subclavian.
20 I would say now it's fallen out of
21 practice. I haven't heard of anyone doing a
22 direct aortic transcatheter valve procedure

1 for a rather long time.
2 Q Just a couple quick follow-up
3 questions, and then we'll take our break.
4 So this direct aortic transcatheter
5 valve implantation method was known and used
6 prior to 2012; is that correct?
7 A Yes, it's correct. It was used with
8 transapical.
9 Q And with --
10 A When I say "with," typically the
11 surgeon would either say I think this is
12 better for transapical or this is better for
13 direct aortic, but the method was a surgical
14 method, direct aortic.
15 Q Would you consider the direct aortic
16 method to be an endovascular procedure?
17 A No, no.
18 Q And why not?
19 A It's not what anyone would
20 understand to be endovascular.
21 Q And why wouldn't anyone understand
22 it to be endovascular?

1 A Because endovascular is going via a
2 peripheral vessel, advancing a method, so
3 advancing a sheath and the device in that way.
4 So transfemoral, subclavian, those
5 would be endovascular, but these are surgical.
6 The direct aortic and transapical I would not
7 consider to be endovascular.
8 Q And so in your opinion, are
9 endovascular procedures limited to delivery
10 through peripheral vessels?
11 MR. LOWENSTEIN: Objection, form.
12 THE WITNESS: So I've not given a
13 definition in my declaration of endovascular,
14 I don't think. I'm happy to have a look. If
15 you think I have, then I'd appreciate you
16 directing me to it.
17 I know that direct aortic
18 transcatheter valve implantation has never
19 been considered. No one ever considered it
20 endovascular.
21 MR. LOWENSTEIN: Okay, so should we
22 take our break?

1 MR. STOWELL: Yes, we can take a
2 break now.
3 MR. LOWENSTEIN: When are we
4 reconvening? Why don't we go off the record.
5 MR. STOWELL: Yeah, let's go off the
6 record.
7 THE VIDEOGRAPHER: Going off the
8 record. The time is 11:34.
9 (Lunch break taken.)
10 THE VIDEOGRAPHER: We are back on
11 the record. The time is 12:51.
12 BY MR. STOWELL:
13 Q Dr. Brecker, did you speak to anyone
14 about your deposition testimony during the
15 break?
16 A I did not.
17 Q Before the break, we were talking
18 about access routes for TAVR procedures, and
19 you mentioned the subclavian delivery route.
20 Can you explain how a TAVR would be
21 delivered through the subclavian route?
22 A So that is quite a complicated

1 procedure. There's a lot of procedural steps.
2 I mean, I'm happy to go through them.
3 It typically would involve a
4 surgical cutdown onto the vessel. It can be
5 done under local or general anesthetic, more
6 typically general. The vessel is entered with
7 a needle, a wire is placed in the vessel, a
8 sheath is placed in the vessel, a catheter is
9 placed in the sheath, and the catheter is then
10 used to advance a wire across the valve, a
11 stiff preshaped wire is put in the ventricle.
12 And then you can either put a sheath
13 into -- typically it won't take much more than
14 an 18 sheath -- into the subclavian vessel,
15 and then you advance your transcatheter valve
16 through that. It then requires a surgical
17 repair after the procedure.
18 There are quite a lot of
19 complications to the procedure, or can be.
20 The technique has been modified more recently
21 to have a more distal approach than the
22 subclavian artery, typically the axillary

1 artery, which is further distal.
2 Q And is delivery of a TAVR through
3 the subclavian artery an endovascular
4 procedure?
5 A So I haven't given an opinion on
6 that. It is endovascular in as far as it's --
7 well, I have not really considered whether
8 that would be endovascular, because the term
9 "endovascular" -- for all purposes in terms of
10 endovascular surgery, for example, everyone
11 understands that's a femoral or -- femoral
12 access, typically.
13 I would have to give some thought as
14 to whether you would consider a subclavian
15 approach endovascular. Certainly
16 cardiologists have never referred to the
17 alternative access as endovascular, any of the
18 alternative access, but I can see how some
19 people would consider subclavian endovascular.
20 Q You also mentioned the axillary
21 route. Is that spelled A-X-I-L-L-A-R-Y?
22 A Yes, that's -- I have to spell it

1 out. Axillary, I think it's two Ls. I'll
2 just write. Yes, A-X-I-L-L-A-R-Y.
3 Q And can you explain how a TAVR would
4 be delivered through the axillary route?
5 A Well, that can be very similar. It
6 can be done identically. It's just a
7 different site of entry into the vessel.
8 Q Would delivery through the axillary
9 route be considered endovascular delivery?
10 A So I would give the same answer as
11 I've given before. I've not given an opinion
12 on that in my declaration, and I'd have to
13 give it some thought.
14 I've never heard of it as delivered
15 endovascularly, but I can see why some people
16 would consider the axillary approach
17 endovascular.
18 Q Would you agree that, in 2012, TAVR
19 procedures were considered an alternative to
20 open heart surgery?
21 A So that's not completely correct.
22 TAVR was the only option for many

1 patients in 2012. There wasn't an
2 alternative. They were patients who were not
3 suitable for surgery.
4 It wasn't until the
5 intermediate-risk trials and the low-risk
6 trials where patients could have had either
7 surgery that you would have considered it an
8 alternative.
9 In 2012, there were certainly
10 patients having TAVR who could have had
11 surgery, and that contrasted to our earlier
12 experience where we were undertaking TAVR only
13 on those patients who would not have been
14 surgical candidates, and therefore I wouldn't
15 have characterized them as having an
16 alternative.
17 Q So in 2012, would you agree that
18 there was a group of patients that could only
19 have their aortic valve replaced via a TAVR
20 procedure?
21 A In 2012, there were patients who
22 could not have surgery, and therefore could

1 only have had their procedure by TAVR, that is
2 correct.
3 Q Why would a person of skill in the
4 art in 2012 have used one of the delivery
5 routes we've discussed other than the
6 transfemoral route?
7 A If it was felt that the transfemoral
8 route was completely unavailable, the
9 alternative would be, if it was felt that
10 going via the transfemoral route would carry
11 highers risks than one of the other routes.
12 Q And what were some reasons why the
13 transfemoral route might be completely
14 unavailable?
15 A Well, typically, calcific
16 atheromatous disease in either of the femoral
17 vessels.
18 Q And what does that mean?
19 A Calcified plaques of atheroma
20 overlie the vessel, and when you put in the
21 sutures to the vessel prior to putting the
22 sheath in, they can simply pull through it and

1 you can get uncontrolled hemorrhage.
2 You can rupture a vessel if you push
3 too hard.
4 You can pull the artery out on the
5 sheath. So if your sheath is slightly bigger
6 than the artery, you could pull the artery out
7 with the sheath and the patient could die as a
8 result of catastrophic hemorrhage.
9 So a lot of the efforts in the early
10 days of TAVR were all around assessing the
11 vascular risk. This was one of the -- apart
12 from the problems with the valve itself, which
13 I've mentioned, aortic rupture and coronary
14 occlusion, which thankfully were very rare,
15 that contrasts with much, much more common
16 vascular complications.
17 And particularly leading up to 2012,
18 when cardiologists and cardiac surgeons had
19 become more confident doing higher risk
20 patients, we still saw a lot of vascular
21 complications.
22 Q You also mentioned that there may be

1 situations where the transfemoral route
2 carries higher risks than one of the
3 alternative access routes.
4 What would be some situations where
5 the femoral approach would carry higher risks
6 than the other alternative access routes?
7 A Well, the same, calcified
8 atheromatous plaques. You could have plaques
9 that were -- there's a whole spectrum of
10 disease that you can have.
11 If you have it at the entry site
12 only, you might consider trying to put a big
13 sheath in, but you'd have to accept the
14 increased risks.
15 The other point I should make is
16 that we certainly had patients where even
17 though there was no disease, the vessels were
18 simply too small; that would either preclude
19 you or give you a higher risk of a vascular
20 complication.
21 Q And when you say the vessels are too
22 small, you're referring to that the femoral

1 arteries of some patients were too small for a
2 delivery of a transcatheter valve through the
3 femoral artery?
4 A The whole iliofemoral system
5 typically. When the femoral artery is narrow
6 caliber, you tend to have narrow caliber
7 vessels everywhere, including the aorta.
8 So we certainly have had small
9 patients, typically low body surface area
10 women, where the vessels are just too small
11 for any type of access for TAVR. So it's not
12 just the femorals; it would be the iliacs, the
13 subclavian, everything.
14 Q Now, are you familiar with delivery
15 of transcatheter heart valves through the
16 iliac approach?
17 A I'm not familiar with it other than
18 having seen the Kainuma paper. I've never
19 heard of it being done in any center that I
20 have worked in for TAVR, and that must be over
21 a hundred centers.
22 Q I'll ask our hot seat operator to

1 pull up a document titled -- it should be
2 "Brecker treatment of aortic stenosis."
3 Okay, Dr. Brecker, can you see this
4 exhibit?
5 MR. LOWENSTEIN: Can we pull up the
6 entire exhibit? Is that possible on this
7 thing?
8 MR. HSIEH: They haven't updated it
9 yet, but once they update it --
10 THE VIDEOGRAPHER: Is this going to
11 be Exhibit 1101?
12 MR. STOWELL: This will be
13 Exhibit 1101, yes.
14 (Exhibit 1101 was marked
15 for identification.)
16 MR. LOWENSTEIN: Can you email these
17 documents or email the documents in realtime
18 to Mr. Hsieh so we have them as well?
19 MR. STOWELL: They're also on the
20 Box. If you all have computers, you can
21 download there.
22 MR. LOWENSTEIN: Ed, do you have

1 access to this?
2 MR. HSIEH: I have access to the
3 Box, but the Box is not yet updated with 1101.
4 THE VIDEOGRAPHER: Yeah, it should
5 be updated. You've got to hit the refresh.
6 MR. HSIEH: Okay.
7 (Discussion held off the record
8 regarding retrieving documents.)
9 BY MR. STOWELL:
10 Q Okay, Dr. Brecker, do you have
11 access now to Exhibit 1101?
12 A Yes, I do.
13 Q Okay. So on the cover page of this
14 document, there are a number of authors
15 listed. It looks like the last one is you,
16 Stephen Brecker; is that correct?
17 A That's correct.
18 Q And were you involved in the
19 preparation of this paper?
20 A Yes, I was.
21 Q Okay. And what was your involvement
22 in the preparation of the paper?

1 A So I haven't looked at this in a
2 long time, and it's 2014.
3 This was a clinical study, so it was
4 a registry study of patients having CoreValve.
5 I can't remember my precise responsibilities
6 or my precise role.
7 The ADVANCE Study was a large study.
8 I can recall it was more than a thousand
9 patients, and there were a large number of
10 publications that came from it.
11 The senior author on this paper was
12 the first author, Axel Linke, who was the
13 principal investigator.
14 The sum of the papers, the
15 authorship was ordered in terms of recruitment
16 of patients. So I have not -- there was
17 another paper where I know I wrote the paper.
18 This one I did not write. I may have been put
19 as the final author, which after the first
20 author, it's an important position in a
21 multiauthor paper, but it may well have been
22 nothing more than our center recruited a very

1 high number of patients. And I do know that
2 on different papers, different authors took --
3 the authorship was changed.
4 I cannot remember the details of
5 this. You're showing it to me for the first
6 time in many years, and it's not a paper that
7 I've reviewed in preparing my opinions for
8 this case.
9 Q Do you believe you would have
10 reviewed this paper before publication?
11 A Yes. I mean, it would have been --
12 I would have been reviewing it in 2013, nine
13 years ago, because it takes -- for the
14 European Heart Journal, it takes 6, 9 months
15 for it to be published after review. So
16 you're saying do I remember something from
17 nine years ago.
18 Q No, I haven't asked that question.
19 I was just asking if you thought you would
20 have reviewed this paper prior to its
21 publication.
22 A Well, that would have been at least

1 nine years ago. I think, in fact, it -- yeah.
2 I mean, it would have been 2013 that I would
3 have reviewed it.
4 Q Typically when you're listed as an
5 author on a publication, do you review that
6 publication before it is published?
7 A Yes.
8 MR. LOWENSTEIN: Objection, form.
9 THE WITNESS: Yes, I would have
10 reviewed. I've reviewed every paper. I would
11 have reviewed this paper before publication.
12 BY MR. STOWELL:
13 Q And in your ordinary practice, as
14 you're reviewing papers that you're going to
15 be listed as an author on, if you see an
16 error, do you raise that with the authorship
17 group?
18 A Yes. If you see an error, you would
19 report it.
20 Q Let's go to the third page of this
21 document. In the upper left-hand corner, it's
22 2674. And if we look down at the box

1 "Procedural characteristics," do you see where
2 I'm at, Dr. Brecker?
3 A Yes. I'm going to move across to
4 the larger version of it, yes.
5 Q And in this summary here, it's
6 summarizing different information about the
7 approaches that were used, and it specifically
8 says "6 patients (0.6%) were implanted via the
9 iliac approach." Do you see that?
10 A I do.
11 Q And do you know what it means by the
12 iliac approach?
13 A I have not -- as I say, I have not
14 reviewed this paper since 2013, so I would
15 need to review all the procedural details to
16 answer your question.
17 Q Do you believe that the statement
18 "6 patients were implanted via the iliac
19 approach" is factually correct?
20 MR. LOWENSTEIN: Objection, form.
21 THE WITNESS: I would have no reason
22 to suspect that this was incorrect.

1 I want to point out that these
2 patients were recruited between 2010 and 2011,
3 so that's important. And the other important
4 factor is it's almost a thousand patients in
5 this study. So one has to put this into the
6 context of a thousand patients having TAVI --
7 sorry, TAVR -- in 2010-11.
8 So I understand you asked me before
9 was I familiar, I think your question was,
10 with the iliac approach, and I said no, I was
11 not, and sitting here today, since 2011, I've
12 not been aware of any.
13 Clearly, there were some in this
14 study, and having read that, I would have been
15 aware of it, but you're asking me about an
16 opinion from, as I say, nine years ago.
17 BY MR. STOWELL:
18 Q Why would the date of recruitment of
19 the patients have been important, as you
20 mentioned?
21 A Well, because it became pretty clear
22 that that was not an appropriate approach.

1 Q And when you say it became pretty
2 clear, when did it become clear?
3 A Well, my sense certainly was that no
4 one ever did -- first of all, the vast
5 majority of TAVI centers never did an iliac
6 approach. Those that did typically did one
7 and discarded it because of the complications
8 and difficulties.
9 So this speaks to that. A thousand
10 patients, of whom six had iliac, and I think
11 that just actually supports the view that I've
12 expressed.
13 The other -- and I haven't looked at
14 the paper, but I can tell you with certainty
15 that the reasons for doing this would not have
16 been -- the reasons that the iliac would have
17 been used would have been simply as an
18 exploratory method of using an alternative
19 access where the femoral was not available.
20 It wasn't being used because it was
21 a bigger vessel, let me make that clear. It
22 was being used because, like Kainuma, the

1 femoral would not have been usable at all due
2 to calcification.
3 There is another -- I mean, I
4 haven't looked at this paper, and I would like
5 a little bit of time to read it through, if I
6 may, because there is another point that I
7 want to make, but I would like to have a look
8 at the paper first.
9 Q I'm actually done asking you
10 questions about the paper. If you'd like
11 to -- we'll have a break here in a little bit.
12 If you'd like to review it, and then come back
13 and discuss it after the break, I'm happy to
14 do that.
15 MR. LOWENSTEIN: Is it necessary to
16 answer the last question that was pending,
17 Dr. Brecker?
18 THE WITNESS: What I want to find
19 out, because you're obviously asking me this
20 for a reason, and what I want to see is if
21 there is any further information about why the
22 iliac was used.

1 And there is another important
2 inference from the sentence. At this time,
3 there was a real imperative for this to be a
4 femoral procedure. It was very important for
5 CoreValve that they had a very high femoral
6 access rate, and you'll see it's 88.4. And
7 this is in the very early days. This
8 contrasted with Edwards' iliofemoral rate,
9 which would have been significantly lower than
10 that.
11 Now, I don't know if there was an
12 intention to use the iliac. My sense is that
13 it would almost certainly have been because
14 the femoral wasn't used. That is assuming
15 that it was done on purpose.
16 There were a number of cases, and I
17 know this because I reviewed adverse instance,
18 where the external iliac was punctured rather
19 than the common femoral because there is --
20 basically, they just change their name as the
21 vessel goes under the inguinal ligament, and
22 some of those cases would have been classified

1 as an open inverted common iliac where you
2 puncture the external iliac, and the reason is
3 that that is a complication.
4 Now, I don't know, I can't -- that's
5 what I wanted to review, and I was keen to see
6 if there was any further narrative or
7 explanation as to why the iliac had been used,
8 whether this was an inadvertent puncture, or
9 whether it was a purposeful reason because the
10 femoral couldn't be used.
11 As I say, it was not being used as a
12 method to use a larger device than would have
13 gone in to a femoral had the femoral not been
14 diseased.
15 Am I able to look at this document?
16 BY MR. STOWELL:
17 Q Well, why don't we do that at a
18 break. I'm actually done asking questions
19 about the document, and if you see something
20 you would like to raise, we'll handle that how
21 about when we come back from our next break?
22 A Okay.

1 Q Now, I understand from your
2 declaration, Exhibit 2051, you have not
3 implanted a transcatheter heart valve through
4 the common iliac artery; is that correct?
5 A I have not.
6 Q Have you implanted any other medical
7 devices through the common iliac artery?
8 A So I've been involved in vascular
9 surgical endovascular procedures that have
10 involved cutdowns to the iliac, a small
11 number, and it would have been me doing it, or
12 me assisting or observing with our vascular
13 surgeons.
14 Q When you say "a small number," how
15 many are you referring to?
16 A I can't give you the number. It's a
17 small number.
18 Q Less than 10?
19 A Could be around that number, could
20 be a bit less.
21 Q And what devices were being inserted
22 into the patient through the common iliac

1 artery in these procedures?
2 A They would have been aortic
3 stent grafts.
4 I can recall that we did have one
5 case, I think, where we tried an endovascular
6 repair of a dissection, but I haven't reviewed
7 any of that experience in terms of numbers and
8 detail.
9 Q Why was the common iliac artery
10 selected as the site to introduce the aortic
11 stent graphs that you inserted?
12 A I can't recall the details. These
13 are often patients with severe peripheral
14 vascular disease, or they are by definition.
15 Q Is there a reason that the aortic
16 stent grafts weren't implanted in these
17 patients through the femoral artery?
18 A I can't give you the exact details.
19 I haven't got that level of detail.
20 Q Do you remember the French size of
21 the aortic stent graph devices you were
22 inserting through the common iliac artery?

1 A I do not.
2 Q Do you remember what the trade name
3 or the commercial name of the aortic
4 stent grafts you were inserting through the
5 common iliac artery was?
6 A I cannot. It was a long time ago.
7 Q These devices that were inserted
8 through the common iliac artery, why weren't
9 they delivered through an open procedure?
10 A When you say an "open procedure,"
11 what do you mean?
12 Q Like an open chest procedure.
13 A Well, they were for the descending
14 aorta, so you would never open the chest for
15 that.
16 Do you mean why didn't these
17 patients have open surgery?
18 Q Yes.
19 A Well, aneurysm repair became very
20 predominantly endovascular. So there was a
21 big move away from open surgery to
22 endovascular.

1 Q And when did that move occur?
2 A Oh, a while ago. I can't give you
3 the year. More than 10 years ago.
4 Q So the delivery of the aortic stent
5 graphs through the common iliac artery that
6 you did on these patients would have been
7 considered an endovascular procedure; is that
8 correct?
9 A Well, again, endovascular surgery
10 can be done via the femoral or the iliacs,
11 yes.
12 Q And do you recall the outcomes for
13 the patients in these procedures where you
14 inserted the aortic stent grafts through the
15 common iliac artery?
16 A I can only remember that one was
17 unsuccessful. Honestly, I just cannot
18 remember the details.
19 Q Do you believe that the delivery of
20 a transcatheter heart valve through the common
21 iliac artery could be done safely?
22 A So what you have to understand is

1 that of all the patients in the hospital in
2 2012, those undergoing transcatheter aortic
3 valve implantation were amongst the sickest.
4 They typically had multiple comorbidities, and
5 to have done an iliac approach, an iliac
6 cutdown with surgery, was simply considered by
7 the vast, vast majority of people untenable
8 and too high risk.
9 I mean, this subset of patients, an
10 iliac artery cutdown for an elective procedure
11 would have been considered unsafe, in my
12 opinion, and in the opinion of the vast
13 majority of people at the time.
14 You know, it may have been used once
15 as a trial technique by some people exploring
16 alternative access, but in terms of a
17 realistic safe approach, no.
18 Q Did you consider it a safe approach
19 when you implanted the aortic stent grafts
20 through the common iliac artery?
21 A Well, I didn't do that. That was --
22 when I say I didn't do it, I was not the

1 operator. This was being done by vascular
2 surgeons, who had the immediate ability to
3 convert to open surgery.
4 Now, that would apply if you were
5 required -- when I say "convert to open
6 surgery," convert to controlling the vessel
7 with clamps, because if you are cutting down
8 onto the common iliac artery, as I say, this
9 is major invasive surgery in a patient who is
10 vulnerable with multiple comorbidities.
11 So the vascular surgeons would
12 always consider the risk of different
13 alternatives. Now, for them, doing aneurysm
14 repair, the alternative is open surgery.
15 Now, open surgery for aneurysm
16 repair is amongst the highest risk surgery
17 that occurs anywhere in the hospital for any
18 indication, and that is why they sought an
19 alternative of endovascular repair.
20 Now, when you consider the word
21 "safe," which you haven't defined, it's safer
22 than the alternative. That is not the case

1 for an iliac approach TAVI. There would have
2 been other options which would have been
3 considered safer, and that's why so few were
4 ever done.
5 Q And so assuming that the
6 transfemoral route is not available, what
7 other access routes do you think would have
8 been safer for a TAVR procedure than insertion
9 through the common iliac artery?
10 A So in 2012, it was pretty
11 straightforward. If you were doing an Edwards
12 valve, you did a transapical; and if you were
13 doing a CoreValve, it would have been
14 subclavian.
15 So pretty much -- as I say, there
16 was a binary distinction between the valves,
17 and although now -- I mean, the CoreValve
18 could never be done transapically, so the
19 majority of people would have selected
20 subclavian if they wanted to implant
21 CoreValve, and in 2012, the majority of people
22 would have selected transapical if they wanted

1 an Edwards.
2 Q And do you believe that the
3 transapical delivery procedure is less
4 invasive for patients than delivery through
5 the common iliac artery?
6 A Well, anything other than
7 transfemoral has been associated with
8 increased risks.
9 It has been quite difficult to
10 unpick how much of that relates to the actual
11 site of access and how much of it relates to
12 the comorbidities that those patients have
13 because, by definition, they can't have
14 transfemoral. But if it had been safe and
15 obvious to do iliacs, then in 2010, 2011,
16 2012, 2013, 2014, iliac approach would have
17 been done, and it wasn't.
18 When I say it wasn't, there were a
19 few isolated cases, a fraction of 1 percent --
20 fraction of a fraction of 1 percent in most
21 registries.
22 Q Do you believe that the six

1 coauthors that we read about in Exhibit 1101
2 were taking unnecessary risks by introducing
3 transcatheter heart valves through the iliac
4 approach?
5 MR. LOWENSTEIN: Objection, form.
6 THE WITNESS: So which paper are we
7 referring to now?
8 MR. STOWELL: That was the paper we
9 just looked at, Exhibit 1101.
10 MR. LOWENSTEIN: Sorry, did you say
11 six authors?
12 BY MR. STOWELL:
13 Q So in that paper we looked at, there
14 were six patients that were implanted via the
15 iliac approach; correct?
16 A Yes.
17 Q Do you believe that the surgeons
18 that selected the iliac approach or the
19 doctors that selected the iliac approach were
20 taking unnecessary risks in those procedures?
21 A Well, that question needs a little
22 bit of unpicking, because the implication is

1 they knew of those risks prior to doing the
2 procedure.
3 The fact is -- first of all, they
4 may or may not have been authors on the paper.
5 So there were a thousand implants, and you'll
6 see there's something like 25 authors. There
7 are vastly more operators than authors.
8 This relates to 2010 and 2011, and
9 several people had never done -- several of
10 the centers would never have done subclavian.
11 This is CoreValve, so there wasn't any other
12 alternative. And as I say, people tried, and
13 it's what they perceived the risk to be.
14 I wouldn't dream of saying they were
15 taking unnecessary risks because that implies
16 a level of knowledge and analysis at the time
17 that they did it, which may have been in 2010.
18 But just given the fact that it's
19 nearly a thousand patients, and in the whole
20 course of that study, only six were done, that
21 to me speaks volumes. And as I say, most
22 people never did more than one.

1 I don't know where these were done,
2 whether it was one person who wanted to try
3 doing three, or whether it was six people that
4 did one and discarded it, but clearly it was
5 proved to be unsuccessful; and clearly, after
6 this date, I certainly have never heard of it.
7 I mean, it's not something that I can ever
8 recall coming up in a meeting.
9 Q Why don't we take a look at
10 Exhibit 1043.
11 (Discussion held off the record
12 regarding retrieving the exhibit.)
13 BY MR. STOWELL:
14 Q Dr. Brecker, is this Exhibit 1043
15 one of the documents you've reviewed as part
16 of your work on this IPR?
17 A Yes. I last read this a little
18 while ago. I didn't read it in the last
19 couple of days.
20 Q Okay. And based on your reading of
21 this, do you understand that the doctors in
22 this particular instance shows the common

1 iliac artery because the external iliac
2 arteries were too narrow for transcatheter
3 valve delivery?
4 MR. LOWENSTEIN: Objection, form.
5 THE WITNESS: I don't understand
6 that as the reason. The external iliac
7 arteries were too narrow?
8 BY MR. STOWELL:
9 Q Correct. Is that your understanding
10 of why the left common iliac artery was used?
11 A No, I don't understand that logic.
12 Q Okay.
13 A What I can explain is that it says
14 calcifications in the peripheral arteries.
15 So, I mean, their option would have been to
16 use the femoral, but they couldn't because of
17 calcification.
18 Q Okay, thank you.
19 A It then says external iliac arteries
20 had stenoses, so what that means is that
21 narrowings within the lumen of the artery, of
22 the external artery, had narrowed it.

1 Q Okay. I'd like to ask you a bit
2 about the delivery through the femoral artery.
3 When a device, a transcatheter heart
4 valve, is inserted through the femoral artery,
5 is it accurate to say that the device will
6 then traverse the femoral artery, the common
7 iliac artery, and the aorta, before reaching
8 the aortic valve?
9 MR. LOWENSTEIN: Objection, form.
10 THE WITNESS: Yes. The route is
11 common femoral, external iliac, common iliac,
12 aorta.
13 BY MR. STOWELL:
14 Q And in your declaration,
15 Exhibit 2051, I understand that you have
16 acknowledged that a valve having a crimp
17 profile of 8 mm could be delivered through the
18 femoral artery in at least some patients; is
19 that fair?
20 A Well, the 8 mm is the size of the
21 vessel -- you couldn't -- sorry, could you ask
22 that question again?

1 Q Yes. Maybe I'll reword it here.
2 A It's okay, I've got the question
3 now. The answer is yes. In a femoral artery
4 of 8 mm, which is pretty unusual actually, you
5 could implant at least some patients --
6 I think that was your question -- via that
7 route.
8 Q And implant those patients with a
9 transcatheter heart valve; is that correct?
10 A Yes, but I think you talked about
11 the crimp profile of the valve, and I talked
12 about the vessel size.
13 Q Okay. So if the patient has a
14 vessel size that measures 8 mm in diameter,
15 that patient could receive a transcatheter
16 heart valve via the femoral route so long as
17 there weren't some other sort of problems with
18 the vessel. Is that fair?
19 MR. LOWENSTEIN: Objection, form.
20 THE WITNESS: Yes, so long as there
21 was no calcification on the vessel.
22

1 BY MR. STOWELL:
2 Q What is the largest device that you
3 have ever delivered through the femoral
4 artery?
5 A So it would have been the LOTUS.
6 There's a lot of difficulty in being
7 precise about this because the companies are
8 very reluctant to give true dimensions to
9 their devices.
10 So, for example, Boston Scientific
11 with LOTUS simply had two sheath sizes,
12 regular and large, and it was very difficult
13 to get the true size of it. Same with
14 Edwards' sizing, which is based on the lumen
15 rather than the external diameter.
16 And it gets even more complicated if
17 you have to talk about the device itself,
18 because the device has got to be a bit smaller
19 than the lumen. So there is a lot of smoke
20 and mirrors from the companies themselves
21 about precise sizing.
22 What we can say is -- what I can say

1 is that LOTUS was certainly the large valve
2 with the largest that I had delivered, and I
3 can't give you the dimensions of it.
4 I can also tell you that it was only
5 a minority of patients who would have
6 qualified for a femoral approach for the LOTUS
7 valve. "Minority," I mean the smallest
8 proportion out of Edwards, CoreValve, and
9 LOTUS, you would have a smaller proportion of
10 LOTUS patients being able to go femorally,
11 then Edwards, and then CoreValve, which was
12 the smallest system available, so much so that
13 we used to have a term within the cath lab of
14 these are "LOTUS size vessels," which meant
15 they were great big drainpipes, 8 mm.
16 Q So if I understand correctly, the
17 LOTUS valve with the large sheath is the
18 largest device you've implanted through a
19 femoral artery?
20 A Yes.
21 Q And as we sit here, I understand
22 that you don't know the diameter of the large

1 sheath that was used with the LOTUS device?
2 A I think it would have been around
3 21 French.
4 Q Is that a guess?
5 A Yes, it was that sort of size. It
6 was certainly a bigger sheath than the sheath
7 we typically used, which was an 18 French.
8 Q And have you encountered patients
9 with femoral arteries having diameters larger
10 than 8 mm?
11 A Very few. It's pretty rare. Yeah,
12 I mean I have, but I have to think about it.
13 Q I understand that the diameter of a
14 person's blood vessels typically increase with
15 age. Is that consistent with your experience?
16 A Not at all. No, that's incorrect.
17 I mean, you might be referring to
18 the development of aneurysmal formation, which
19 is pathological increase.
20 Q So in your experience, the typical
21 or average diameter of a patient in their 30s
22 of their femoral artery would not be smaller

1 than the average diameter of a femoral artery
2 of a patient in their 70s or 80s?
3 A My clinical experience is the other
4 way around. There's no -- I'm really
5 surprised that you -- that that's a -- I don't
6 know where you would have got that
7 information.
8 I mean, typically, on the rare
9 occasions we've had to do very young patients,
10 and certainly in the low-risk patients, who
11 tend to be younger, the vessels are bigger and
12 they're cleaner.
13 The typical 90-year-old patient has
14 muscle loss, which means their bulk gets
15 smaller, vessels get atheromatous and
16 calcified. It's completely the opposite to
17 what you suggested.
18 The only example I can imagine
19 you're referring to is the development of
20 aneurysms, which does increase with age.
21 Q What is the average age of a TAVR
22 patient?

1 A That's an interesting question. For
2 many years, it was low 80s. So for the first
3 several years, typically the average age would
4 be around -- I mean, I can just remember study
5 after study that showed it at 83. I'd have to
6 have a look at what it was in the
7 ADVANCE Study. I wouldn't be surprised if it
8 was in the low 80s in years.
9 The average age now has probably
10 come down because -- well, there's two
11 reasons. We're doing lower risk patients,
12 doing intermediate risk patients, and we're
13 also treating patients with what's known as a
14 bicuspid aortic valve. They were not included
15 in the early trials or studies or cohorts of
16 patients. They are now included, and they
17 tend to be younger.
18 Q And as of 2012, what would your
19 estimate be of the average age of a TAVR
20 patient?
21 A So that's what I was referring to
22 earlier. The average would have been in the

1 low 80s. That is my sense.
2 Q When you perform or the heart team
3 performs a TAVR procedure, are the diameters
4 of the arteries measured before the procedure?
5 A Yes, they are.
6 Q Are measurements made of the femoral
7 artery?
8 A Yes.
9 Q Are measurements made of the
10 diameter of the common iliac artery?
11 A Yes.
12 Q Are measurements made of the
13 diameter of the aorta?
14 A Very rarely the aorta itself, if you
15 mean descending aorta. If there's an
16 aneurysm, then yes, but not in the same way as
17 the iliofemorals. In other words, the reason
18 you're measuring the iliofemorals is to ensure
19 that they're large enough.
20 Q And in your experience, what is the
21 average diameter of the femoral artery?
22 MR. LOWENSTEIN: Objection, form.

1 THE WITNESS: So I have not done an
2 analysis of that, and I haven't given an
3 opinion of that.
4 I can give you my sense of my own
5 clinical experience because I do several of
6 these types of analyses all the time.
7 I mean, we see quite a high -- we
8 have a high proportion of patients with small
9 arteries, so we see femorals at 5.5, 6. It's
10 that sort of order, maybe 6.5 mm, would be the
11 average in my experience, but I'm giving you
12 that answer on the hoof, and I would have to
13 go and have a look at my own -- I haven't got
14 a database of the femoral artery sizes, but
15 I've got a lot of CT scans on my laptop.
16 BY MR. STOWELL:
17 Q Do you typically review the
18 measurements before performing a procedure?
19 A Every case.
20 Q What about a typical common iliac
21 artery, what is the typical diameter of a
22 common iliac artery for the patients you see?

1 MR. LOWENSTEIN: Objection, form,
2 scope.
3 THE WITNESS: So I have never
4 perceived a major increase in size. The
5 reason we measure them is because they are
6 usually much smaller than that.
7 If you look at a typical normal
8 patient, the size of the iliacs is never much
9 bigger than the common femoral. I mean, I
10 have not got an anatomical database to give
11 you the numbers, but I think it's really
12 nicely illustrated in one of Cribier's papers
13 where he's got a picture of a
14 three-dimensional volume-rendered image of a
15 patient's vessels, and you can see very
16 clearly that there is not this great big
17 step-up into the iliacs, not typically anyway.
18 I mean, sometimes they are, but my
19 typical experience is maybe a little bit
20 bigger, but sometimes they're smaller.
21 MR. STOWELL: Okay, we've been going
22 about another hour. Why don't we take a

1 10-minute break here.
2 MR. LOWENSTEIN: So we'll get back
3 at 2:00?
4 MR. STOWELL: Yes, two o'clock.
5 THE VIDEOGRAPHER: Okay, going off
6 the record. The time is 1:49.
7 (A break was taken.)
8 THE VIDEOGRAPHER: We are back on
9 the record. The time is 2:01.
10 BY MR. STOWELL:
11 Q Dr. Brecker, I understand that
12 you've known Dr. Buller for a long time; is
13 that fair?
14 A Yes, that is fair.
15 Before we start, could I just say
16 something for the record, because I took the
17 opportunity to look through that paper that
18 you showed me.
19 MR. LOWENSTEIN: Just for the
20 clarity of the record, I believe you're
21 referring to Exhibit 1101?
22 THE WITNESS: Exhibit 1101. You

said I should use the break to have a look at it, and I did, so I do just want to make a comment.

MR. STOWELL: Why don't we let your counsel ask you about that at the end of the deposition?

MR. LOWENSTEIN: No, no, no. You said he could look at it during the break. He took you up on that. Let him speak.

BY MR. STOWELL:

Q Okay, Dr. Brecker, what would you like to clarify with respect to Exhibit 1101?

A So you recall when we had the discussion, I hadn't seen this paper for the better part of nine years, and I wasn't sure what other information about the iliac reference was in the paper.

You may correct me, but as far as I can see, there is literally just one short line in the 13 pages of the paper about it.

There's no explanation of why it was used, whether it was an inadvertent external

1 iliac puncture, whether it was a cutdown,
2 whether it was simply the way they chose to do
3 it. There's no explanation, and I have no
4 recollection of it being an issue.
5 Your question to me was, I think,
6 was I familiar with it, and my answer, having
7 seen this paper now in full, is I'm still not
8 familiar. I was not familiar with the iliac
9 approach for TAVR, I've never done it, and to
10 the best of my recollection and knowledge, it
11 was never done in the hospitals I did TAVR in.
12 I didn't go to many of the hospitals that were
13 in the ADVANCE study.
14 So I wanted to clarify that for the
15 reported.
16 BY MR. STOWELL:
17 Q Okay, thank you.
18 And did you speak with anybody about
19 your deposition testimony during the break?
20 A I did not.
21 Q Okay. Let's see, so I was asking
22 about Dr. Buller.

1 When did you first meet Dr. Buller?
2 A A long time ago. I'm not even sure
3 Nigel would remember. I think it's when he
4 was a senior house officer on the intensive
5 care unit at St. George's -- at St. Thomas',
6 and I was a medical student, but that was
7 probably a fleeting visit, fleeting encounter.
8 I think the time where we knew each
9 other best was when we were both at the
10 Brompton Hospital.
11 Q And did you work with each other at
12 the Brompton Hospital?
13 A Yes, yeah. He was a newly appointed
14 senior lecturer, and I was a registrar --
15 yeah, registrar. Actually, I was a research
16 fellow with another consultant.
17 So I didn't work directly with him
18 in terms of being like one of the residents,
19 as you would call it, on the clinical service.
20 I was doing research then, and we certainly
21 interacted, and you could call it work
22 together, yes.

1 Q Did you ever receive training from
2 Dr. Buller?
3 A I think I did.
4 Q And what training do you recall
5 receiving?
6 A Well, to be honest, you're asking
7 about something from 30 years -- more than
8 30 years ago. I can't remember.
9 I can recall him giving a tutorial
10 once. You have these little -- I have these
11 little snippets of memory.
12 I can't -- I can't -- you are
13 talking about more than 30 years ago.
14 Q And at what point in time did you
15 stop working together at the Brompton
16 Hospital?
17 A I would have to look at my CV. I
18 can't tell you a date, and I haven't got my CV
19 here, but if you look on my CV, it will tell
20 you the dates I stopped at the Brompton.
21 Q Looks like 1994.
22 Does that sound right?

1 A Yes, that could be when I went to
2 the London Chest.
3 Q Did you continue to follow
4 Dr. Buller's work after the two of you stopped
5 working together at the Brompton Hospital?
6 A So I don't think we overlapped in
7 terms of research projects. It's possible we
8 did. Again, I haven't looked at my CV with
9 that in mind.
10 Obviously, I knew Nigel, and in the
11 years that followed, but we didn't have a -- I
12 wouldn't say we had -- we never worked
13 together again after that, I don't think, in
14 the same hospital.
15 Q And did you follow the projects he
16 was working on and the types of work he did
17 after the two of you left Brompton -- or after
18 you left Brompton?
19 A I'm not sure what you mean by
20 "follow." Certainly I was aware of some of
21 the projects he was involved in with coronary
22 stents.

1 I mean, it wasn't like I was
2 following his work closely for any reason
3 other than I would follow anyone's work, as it
4 were.
5 It's possible we have an abstract or
6 were named on a publication. I honestly just
7 don't remember.
8 MR. STOWELL: Okay, I'd like to ask
9 our hot seat operator to pull up Exhibit 2009.
10 MR. LOWENSTEIN: Give us a moment.
11 Okay, it's just open now.
12 THE WITNESS: Could I just add one
13 thing, obviously, to the last question you
14 asked?
15 Obviously, we've been involved in
16 some patent litigation since then, so we've
17 obviously come into contact and had -- you
18 could call it working together.
19 BY MR. STOWELL:
20 Q Okay. I'm not sure anybody would
21 characterize it as working together, but yes,
22 I understand what you mean.

1 MR. LOWENSTEIN: We are all together
2 on a call.
3 THE WITNESS: Yeah. So, I mean,
4 we -- well, I think we all understand, yeah.
5 Obviously, I mean, it goes without saying,
6 but ...
7 BY MR. STOWELL:
8 Q Okay. Dr. Brecker, do you recognize
9 Exhibit 2009?
10 A Yes, I do.
11 Q Okay. Is this one of the
12 publications that you relied upon in your
13 expert declaration, Exhibit 2051?
14 A Yes.
15 Q Okay. And is this a document that
16 you studied and reviewed in preparation for
17 your deposition today?
18 A Yes, not in the last few days. This
19 is one I would have read a little while ago,
20 not too long, but not in the last couple of
21 days.
22 Q And Exhibit 2009 describes the

1 replacement of a mitral valve, correct?
2 A Yes.
3 Q This article does not describe
4 aortic valve replacement, correct?
5 A It does not.
6 Q And this paper describes --
7 A I'm sorry, could I just finish?
8 Q Sure, yeah. Sorry, I thought you
9 were done.
10 A It doesn't describe aortic valve
11 replacement, but it describes using a
12 transcatheter aortic valve.
13 Q Right. And the transcatheter aortic
14 valve that's used in this procedure is a
15 Sapien 3 transcatheter heart valve, correct?
16 A No -- oh, I see. They describe use
17 of the XT, and in this one they say we have
18 recently modified an open transatrial
19 technique utilizing Sapien 3, correct.
20 Q So it's your understanding that the
21 valve that's implanted and described in this
22 publication was a Sapien 3 valve; is that

1 correct?
2 MR. LOWENSTEIN: Objection, form.
3 THE WITNESS: So it states that, but
4 could I just have a minute to just quickly
5 look through this?
6 BY MR. STOWELL:
7 Q Sure, take a minute.
8 A Yes, it is a Sapien 3 valve.
9 Q And the procedure that's described
10 in this paper is an open heart procedure,
11 correct?
12 A Yes.
13 Q Now, there is some material that was
14 added to the outside of the Sapien 3 valve in
15 the procedure that's described in
16 Exhibit 2009, correct?
17 A Yes, that's correct.
18 Q And are you familiar with the
19 structure of the Sapien 3 valve?
20 A Yes.
21 Q And the Sapien 3 valve has an outer
22 skirt, correct?

1 A Yes.
2 Q And so when the -- let me start
3 over. In this particular paper, Exhibit 2009,
4 a felt strip is added to the outside of the
5 Sapien 3 valve, correct?
6 A That is correct.
7 Q And the felt strip, is that applied
8 to the Sapien 3 valve on top of the existing
9 outer skirt?
10 A Yes, that's my understanding.
11 Q And the felt strip that's used --
12 MR. LOWENSTEIN: Were you done with
13 your answer?
14 THE WITNESS: I was done with my
15 answer.
16 BY MR. STOWELL:
17 Q Sorry, you're just a bit off camera,
18 so it's hard to tell if --
19 A Sorry, the reference is on the other
20 screen, so I have to just angle my neck.
21 Maybe I -- yeah, like that.
22 Q The material that's wrapped around

1 the outside of the Sapien 3 valve in
2 Exhibit 2009 is a teflon felt strip, correct?
3 MR. LOWENSTEIN: Objection, form.
4 THE WITNESS: So it just says
5 Bard PTFE felt, and with a reference.
6 BY MR. STOWELL:
7 Q What page are you reading on,
8 Dr. Brecker?
9 A 1440.
10 Q So if you go over to page 1442,
11 right about the middle of the first column,
12 there's a description of a Teflon felt strip.
13 A It's very blurry and small on the
14 image in front of me, so I do have to look at
15 the other image.
16 (Image blown up on Zoom screen.)
17 A Yeah, so that's a lot better.
18 So which are you taking me to? "We
19 prepare the valve with a Teflon felt strip,"
20 and the felt strip is PTFE felt, yes.
21 Q And how is felt manufactured?
22 MR. LOWENSTEIN: Objection, form,

1 scope.
2 THE WITNESS: Yeah, I've not given
3 any opinion on that.
4 BY MR. STOWELL:
5 Q Did you do any research on how felt
6 was manufactured when you were evaluating the
7 Russell reference?
8 A I have not analyzed how felt is
9 manufactured, no.
10 Q Would you agree that felt is made by
11 a different process than a woven or knitted
12 fabric?
13 A I have not done any analysis of how
14 felt is manufactured.
15 Q And have you done any analysis to
16 determine how compressible the felt described
17 in Russell is?
18 A I have not done any analysis of how
19 compressible the felt in Russell is, no.
20 Q And did you do any comparison of the
21 compressibility of the felt in Russell with
22 the other references that are in this case,

1 such as Walther?
2 A I have not done a comparison of
3 their compressibility. There is no
4 information as to the compressibility as far
5 as I'm aware.
6 Q The article itself does not describe
7 any bunching of the felt that's on the outside
8 of the Sapien 3 valve, does it?
9 A Well, it shows it. Do you mean
10 there's no verbal description of it?
11 Q Correct. There's no verbal
12 description of bunching of the felt, is there?
13 A If I could just have a minute to
14 just -- so I don't think there's a verbal
15 description of it bunching visible to me.
16 Q And what -- what material -- sorry.
17 A I'm sorry, I was saying I think it's
18 clearly visible.
19 Q And what figures are you relying on
20 to show the alleged bunching?
21 MR. LOWENSTEIN: Objection, form.
22 THE WITNESS: So we could go to my

1 declaration, I think, where I deal with this.
2 So if you look at my declaration, we
3 could look at the original reference pictures,
4 they're a bigger and clearer I think, at least
5 on the images I'm looking at.
6 So in my declaration, on page 31,
7 top left, I think you can see bunching around
8 the top.
9 I think in the image below, I've
10 actually labeled it, and there are other areas
11 other than where the yellow line ends where
12 you can see what appear to be, amongst other
13 things, ridges and folds. That's more clearly
14 seen on the image on top of page 32. It's
15 evident on the image below that, and in the
16 images that follows on the next two pages.
17 So I think they're all showing a
18 very bulky, bunched up bulging cloth.
19 BY MR. STOWELL:
20 Q The pictures you're referring to,
21 you're in Exhibit 2051, correct?
22 A Yes.

1 Q So the picture on the top left of
2 page 31, that is an image of the valve in its
3 expanded configuration, correct?
4 A It's difficult to know whether
5 that's fully -- sorry, the top of page 31 on
6 the left, it looks expanded. Whether it's
7 fully expanded, it's difficult to know, but it
8 is in the expanded configuration.
9 Q And is it your position that this
10 figure shows bunching?
11 A Well, it clearly does.
12 Q And can you explain how the valve in
13 Exhibit 2009 is implanted in the patient?
14 MR. LOWENSTEIN: Objection, form.
15 THE WITNESS: So this is an open
16 procedure, and the access is directly via --
17 I'd like to go to the actual description of
18 the procedure so I can get it accurate.
19 So the patient is put onto
20 cardiopulmonary bypass, and the approach to
21 the mitral valve is via an opening in the left
22 atrium. The surgeon removes the anterior

1 leaflet of the mitral valve.
2 There is some further detail which I
3 could read, but it's itemized there by
4 Dr. Bibak (ph), who did this surgery.
5 BY MR. STOWELL:
6 Q So in this procedure, how does the
7 doctor gain access to the heart to make the
8 incision in the left atrium?
9 A Well, it's open heart.
10 So let me just read this through,
11 because I know that -- could I just have a
12 moment to just read through the surgical
13 technique here?
14 Q Sure.
15 A Okay, so -- sorry, what was your
16 question again? The surgical procedure used?
17 Q Correct.
18 A So I'm not a cardiac surgeon. My
19 understanding is that this patient would have
20 had a median sternotomy, an open surgery.
21 Q And you mentioned that the anterior
22 leaflet is removed. How is the leaflet

1 removed?
2 A You're asking me techniques of
3 cardiac surgery, the detail of which I
4 wouldn't try to go beyond saying what I've
5 seen and assisted with, is the surgeon uses a
6 scalpel and forceps and scissors.
7 Q And then cuts the leaflet out of the
8 heart valve?
9 A Well, I can only read Dr. Bipak's
10 description, which is the anterior leaflet is
11 excised, leaving a standard room of tissue at
12 the aortomitral curtain that will be used to
13 place pledgeted anchoring sutures, and that is
14 described -- or that is shown in FIG. 4A.
15 So just looking at FIG. 4A, the
16 surgeon is using what looks like forceps,
17 could be scissors. This is surgical
18 technique.
19 Q What are the pledgeted sutures for?
20 A So you're asking a level of detail
21 of cardiac surgery that really a cardiac
22 surgeon would have to answer.

1 I can give you a response as an
2 interventional cardiologist, so there is a
3 limit to my expertise in this area.
4 Typically, a pledgeted suture is to
5 stabilize the suture and stop it cutting
6 through the material -- stop it cutting
7 through the tissue. So it's placing sutures;
8 "pledgeted" are the little white bits.
9 Q And is it your understanding that
10 this valve that's described in Exhibit 2009 is
11 eventually sutured in place in the mitral
12 valve?
13 A Yes, the sutures -- well, again, I
14 would have to go through all of the surgical
15 detail. I'm just reading through.
16 Yes, so those pledgeted sutures
17 encircle the base of the mitral leaflets, and
18 then pass through the felt ring and the stent
19 frame. They're secured on the inside of the
20 valve frame. These sutures are critically
21 important in preventing PVL.
22 So that's the answer --

1 Q So the sutures --
2 A -- to your question.
3 Q Sorry, I apologize. Were you done?
4 A Yes.
5 Q So the sutures are passed through
6 the felt strip that's been added to the
7 outside of the valve, and then they are tied
8 off on the inside of the valve?
9 Is that accurate?
10 A I don't know where they're tied off.
11 Q Would you agree that they are passed
12 through the felt strip that's been added to
13 the outside of the valve?
14 A Yes, I think that's exactly what I
15 read out, that they're passed through the felt
16 ring and the stent frame. They're secured on
17 the inside of the valve frame, I'm sorry.
18 So, yes, they go through the felt,
19 and they're secured on the inside.
20 Q I think you had your declaration,
21 Exhibit 2051, out. I'd like to go to page 10
22 of that document, specifically paragraph 20.

1 A Paragraph 20, yes.
2 Q In this paragraph you state that you
3 believe the level of ordinary skill would be
4 an interventional cardiologist with experience
5 implanting, researching, or designing TAVRs in
6 the 2010 to 2012 time frame.
7 Do you see the portion I'm reading?
8 A Yes.
9 Q What did you mean here by
10 "researching"?
11 A Anything other than the purely
12 clinical aspect of looking after a patient,
13 that the research would be clinical research,
14 adding to the volume of acquired knowledge of
15 what at this time was a very new technology.
16 So clinical research, and it could take
17 several different forms.
18 Q And what are those forms that it
19 could take?
20 A So it could involve recruiting
21 patients to clinical trials or registries, and
22 submitting that data to multicenter trials or

1 registries, but it would be that you would be
2 a named investigator or one of those
3 individuals who was recruiting patients. So
4 you would go and speak to the patients and say
5 would you like to enter this research trial.
6 In fact, in the early days, every
7 patient was. The very early days, all the
8 patients were enrolled in trials or
9 registries.
10 It could have involved data analysis
11 of cohorts of patients from multiple different
12 hospitals.
13 It could have involved research on a
14 new valve material or function.
15 It could have involved developing a
16 new device.
17 It could have involved trialing that
18 new device.
19 It could have involved -- I mean,
20 there's a very, very wide range of research
21 activities, and to paint the picture in 2010
22 and 2012, my view is that the field was so

1 frenzied, in a way, that everyone who would
2 have been considered a person of ordinary
3 skill in the art would have been involved in
4 some of these activities, particularly so for
5 the 2012 time point. That was really a
6 pivotal period in the technology and the
7 clinical treatment. Things were really taking
8 off then.
9 So it had had a slow start, and with
10 all of these techniques, it's a bit like a
11 bell shape. You go up, and in 2012, we were
12 on the very rapid rise part of that curve.
13 Q Have you ever been involved in the
14 design of a transcatheter heart valve?
15 A Yes, I have.
16 Q Can you explain for me a little bit
17 your involvement in the design of a
18 transcatheter heart valve?
19 A Well, it's quite a lot to go
20 through. I mean, I can take some time to do
21 it.
22 So over this time period, I was

1 involved regularly in meetings with several
2 valve companies — mostly just Medtronic and
3 Boston Scientific, not with Edwards — where
4 there would be what are called a steering
5 committee of clinical trials where design
6 features of the valve are discussed, and in
7 particular, whether implant practice should
8 change or the design of the valve should
9 change. So that's one example.
10 There were advisory boards which I
11 participated in, and many others did as well.
12 Everyone, we all were involved in all of these
13 activities. It wasn't exclusively me. Almost
14 everyone that was involved in TAVR.
15 Those advisory boards would be
16 meetings with companies under non-disclosure
17 agreements where you would see the next
18 generation of device, and you would see
19 various options or iterations of the device,
20 and your feedback would shape the strategy for
21 how the device would change.
22 There were other types of activity

1 where I and many others would do what's called
2 usability testing. So usability testing is
3 where we take usually the new design or the
4 design that we've suggested tweaks to, and we
5 try it out -- not in patients, you'll be
6 pleased to know, but initially in silicon
7 models of beating hearts -- and that is done
8 in a mockup or a real cath lab with x-rays,
9 and as close as possible as you can get to the
10 femoral access, the arch, the aorta and the
11 heart, which is all created by 3D printing in
12 silicate, filled with fluid, it's warmed and
13 the heart beats, and it's as close as you can
14 imagine to doing a procedure in a patient
15 without the patient being there.
16 And then there's animal work, which
17 I did quite a lot of, testing new designs,
18 getting feedback on the performance. So all
19 of that I would quote as one big chapter of
20 design activity.
21 I did design a heart valve as well.
22 That is the patent application that is

1 recorded on my CV. It was a very long file
2 process, and it was a design of a
3 transcatheter mitral valve that would have
4 proceeded but for the fact -- I'm laughing,
5 but it breaks my heart -- that I delayed for
6 various reasons about a year before getting it
7 written up by a patent attorney, and the piece
8 of prior art that meant we couldn't proceed
9 with it was about two weeks after I would have
10 had that document submitted had I gone when I
11 thought I was going to go. Such is life.
12 So there is a patent application
13 where I designed a valve, and it did not
14 proceed beyond the patent application, but it
15 was looked at with interest by a number of
16 companies. In fact, a very similar -- very,
17 very similar design -- the owners of the
18 patent who I would have infringed, had I gone
19 forward with it, have moved to clinical trials
20 on their valve.
21 Q What company -- sorry.
22 A And I wish them the very best of

1 luck with it.
2 Q What company owned the patent that
3 you would have infringed?
4 A I cannot tell you. I don't
5 remember. I don't know. I could go and look
6 it up, but ...
7 Q What company has moved into
8 clinicals with the valve?
9 A They're not in clinicals. Well,
10 I think they may have done some.
11 I can only give you the name of the
12 valve as it was when I knew, but I think it's
13 been changed. Cephea was the name of the
14 valve.
15 Q You may have to spell that for our
16 court reporter.
17 A Yes. C-E-P-H-E-A, I think, but I
18 might be wrong. It's a while since I've
19 looked at this, and I can't really give you
20 any more information about it.
21 Q When you say that you designed that
22 heart valve, did you do your own design

1 drawings for the valve?
2 A Yes.
3 Q And did you make prototypes of the
4 valve?
5 A No. We tried to get funding, as I
6 say, and we had -- we were very, very close to
7 getting funding from an investment group, but
8 as I say, we could not proceed.
9 Q Have you made prototypes for any
10 other heart valves?
11 A I have not made prototypes. Or do
12 you mean have I had them made? I personally
13 have not done what Dr. Anderson did in the
14 early days of going into his garage with some
15 pliers and wire. No, I have not done that.
16 I have played with some existing
17 devices and tweaked them and done things like
18 that, but I have never from scratch built a
19 prototype.
20 Q Have you ever been involved in the
21 design of a transcatheter heart valve with an
22 outer seal?

1 A Yes, I would say that I have,
2 because much of that activity that I spoke to
3 you about would have been on, for example, the
4 LOTUS valve, the Evolut, Evolut PRO,
5 Evolut PRO+, and future valves that I can't
6 talk about.
7 Q So on the LOTUS valve, what was the
8 outer seal made of?
9 A Well, you're asking me now again
10 about the '608 patent, and I would have to
11 read through all of the materials that I was
12 involved in to answer your question.
13 I can tell you what it looked like.
14 The design issues that I was involved in were
15 more to do with the usability of it, how that
16 should affect the design of the device as a
17 whole, rather than the external seal.
18 Q And just to be clear, I'm not asking
19 about the '608 patent. I'm asking you about
20 the LOTUS valve that you have worked with.
21 Do you know what the outer seal on
22 the LOTUS valve was made of?

1 A Sitting here now, I can't tell you
2 the material name.
3 Q Can you describe the material on the
4 outer seal?
5 A All I can do is tell you how people
6 referred to it. This was a colloquial
7 description, and it was referred to rather
8 like clingfilm. That's the term we use in the
9 UK. I think you call it saran wrap.
10 Q And based on your observations of
11 the LOTUS valve, was that an apt description
12 of the outer seal on the valve?
13 A Well, I couldn't really say. I
14 mean, I know why people referred to it that
15 way.
16 I'm trying to think if I ever saw
17 the LOTUS valve in the expanded position --
18 I'm talking about in real life, I obviously
19 had seen pictures of it -- because it was
20 always given to me in the catheter.
21 When you said was I ever involved in
22 the design of a valve with an external skirt

1 I think was the question, the answer is yes,
2 but if you said to me was I involved in the
3 design of the skirt, the answer is no.
4 I was more involved with how the
5 design of the valve and the implant technique
6 might be altered as a result of issues that
7 arose during the use of the valve.
8 Q And I believe you said you worked on
9 the Evolut PRO valve; is that correct?
10 A Yes, I was involved in the types of
11 activities that I was describing earlier:
12 clinical trials, advisory boards, usability
13 testing, that sort of thing.
14 Q And does the Evolut PRO valve have
15 some sort of outer seal?
16 A It has a layer of pericardial tissue
17 around the outside.
18 Q What are the different factors that
19 contribute to whether or not PVL occurs with a
20 transcatheter aortic heart valve?
21 A So there's a lot of factors.
22 The first is sizing. So sizing the

1 valve to the appropriate degree of oversizing,
2 or interference fit, with the native anatomy
3 has to be done accurately.
4 So if you put in too small a
5 valve -- and on occasions, too large a
6 valve -- for that patient's anatomy, you may
7 get paravalvular leak.
8 The second consideration is the
9 implant depth. So valves have to be implanted
10 at a certain depth that is, in part, in large
11 part, related to their design in order to get
12 adequate sealing. Valves that are implanted
13 either too deep, and certainly too high, can
14 equalize to paravalvular leak.
15 The third factor is the design of
16 the valve itself. So it's well known that
17 some valves have a higher degree of
18 paravalvular leak than others.
19 So, for example, in the early days
20 of CoreValve versus Sapien, CoreValve had a
21 higher degree of paravalvular leak, and that,
22 in part, related to the degree of radial force

1 that was exerted by the valve on tissue, so
2 valve-related features.
3 And then the final area would be —
4 and perhaps this is the most important — the
5 patient's anatomy. So the degree of
6 calcification in the leaflets, whether there
7 is calcium that extends, as it typically does,
8 below the annular plane into the left
9 ventricular outflow tract, that can act as a
10 spur of calcium that would prevent the frame
11 expansion, and you could get a leak around the
12 edge.
13 The nature of the valve itself,
14 whether it's a bicuspid valve or a tri-leaflet
15 valve, would also affect that type of
16 consideration.
17 So there are many, many factors, and
18 they all interact with each other, and that is
19 why we have often said, and certainly I teach,
20 that the decisions you make prior to going
21 into the catheter lab are probably the most
22 important ones, and that is which valve you're

1 going to choose, your implant strategy, your
2 sizing, your depth of implant, and choosing a
3 valve with a particular type of design and
4 paravalvular leak solution that would guide
5 you.
6 Q You mentioned implanting a valve too
7 high. What does that mean in terms of the
8 anatomy?
9 A Oh, well, that can be -- that's
10 quite a serious complication if it occurs, and
11 it's -- I don't want to give you the
12 impression that -- I was going to call it a
13 feared complication, but that's adding to
14 annular rupture and coronary occlusion and
15 everything else, and I don't want to give you
16 the impression that it's a dangerous procedure
17 because it has changed out of all recognition
18 from the early days.
19 High implants I would say are still
20 feared because they can culminate in the
21 patient's death. If you implant the
22 transcatheter valve too high, then quite apart

1 from the fact that you may get a paravalvular
2 leak under the bottom edge, then -- it all
3 depends on how high, but you will get
4 inadequate anchoring. Certain types of
5 anatomy may cause anchoring within the
6 leaflets, but a lot of the time, if you
7 implant the transcatheter valve supra-annular,
8 by which I mean above what everyone knows to
9 be the annular plane, then you could embolize
10 that valve, and valve embolization is
11 associated with a significant risk of
12 morbidity and mortality. It's not a nice
13 thing when it happens, and frankly,
14 thankfully, it doesn't happen very often.
15 But high implants, by which I mean
16 implanting just a couple of millimeters below
17 the annulus, that can be quite advantageous.
18 For example, 3 mm, that can be exactly where
19 you want it.
20 Implanting at the annulus, or at
21 zero, you may get away with it, but you are
22 putting the patient at risk of embolization.

1 And implanting the valve above that,
2 no one would do that. No implanting
3 cardiologist would implant above the annulus.
4 It would be a very dangerous thing to do.
5 Q When you refer to implanting the
6 valve at the annulus, do you mean the tissue
7 portion of the valve is at the annulus, or do
8 you mean some other portion of the valve is at
9 the annulus? I'm just trying to understand
10 what you mean by that.
11 A So typically when we talk about
12 depth of implant, we talk about the
13 relationship of the bottom of the frame, or
14 the bottom of the valve, to the annular plane.
15 And for all the valves now, the typical target
16 depth is in the region of 3, maybe 3 to 4 mm
17 below the annular plane. So the bottom of the
18 frame would be that depth below the annulus.
19 Q You also mentioned radial force when
20 you were talking about the CoreValve device
21 and that it had a higher degree valve of
22 paravalvular leakage.

1 What did you mean by "radial force"?
2 A Radial force is a characteristic of
3 all transcatheter valves, but only after
4 implant.
5 Radial strength is a characteristic
6 that you could measure on an expanded valve
7 before you implant it.
8 It relates to the property that the
9 valve that is implanted has to be slightly
10 bigger than what it is being implanted into in
11 order to get a comfortable tight fit and,
12 therefore, there will be force exerted by the
13 valve on the tissues around it.
14 And on the very first iteration of
15 CoreValve, if you took it, for example, and
16 compared it to the Edwards valve, if you just
17 took an expanded valve outside the body and
18 tried to just gently squeeze the bottom, you
19 would need less force to deform the CoreValve
20 than the Sapien valve.
21 Q So is the radial force that you're
22 talking about the force required to deform the

1 frame, or is it the force that the frame
2 exerts on the surrounding tissue?
3 A Well, you're asking questions that I
4 haven't really made an opinion of for the
5 purposes of today.
6 They're pretty general questions,
7 and so it's not that I'm unhappy to answer,
8 but if, for example, radial force was
9 something that was going to be important in
10 the future, I don't want to give a definition
11 of it.
12 I can only give you what I
13 understand by it and what I think a POSITA
14 would understand, and it could be used in many
15 different ways, and both of those examples
16 that you gave could be used.
17 So it could be the amount of radial
18 force you need to compress is a use of the
19 term. The radial force that the device exerts
20 on surrounding tissue is another use of the
21 term.
22 It doesn't define the term. All it

1 is trying to convey is a property related
2 to -- and I'm using this term very loosely --
3 the strength, if you will, of the frame, the
4 amount of force that it can exert or can
5 resist.
6 Q How was the radial force of the
7 CoreValve device connected to the paravalvular
8 leakage, which is how we first got onto the
9 topic?
10 A Well, all I can do is give you some
11 examples.
12 If you've got a bottle of water, an
13 old-fashioned glass bottle of water with a
14 long neck, so sort of posh bottle of mineral
15 water in a glass bottle, you want to test how
16 the water will stay in the bottle, and you've
17 got a variety of plugs.
18 If you put in a plug that is smaller
19 than the diameter of the bottleneck, it's not
20 going to touch the edges, and when you turn
21 the bottle over, the first thing that will
22 happen is that will fall out and the water

1 will come out.
2 If you put in a stopper or bung that
3 is exactly the size of the bottle and turn it
4 upside down, it might stay in, but if you then
5 shake it and exert more force on it, it will
6 come out.
7 And if you put in a cork or a bung
8 that is bigger than the bottleneck, it will
9 exert radial force and it will stay in when
10 you turn it upside down.
11 So, I mean, I'm just giving that
12 example.
13 Q Okay. Would it be fair to say that
14 if the radial force of the frame of the
15 transcatheter heart valve is insufficient, it
16 may lead to paravalvular leakage?
17 A This is relating to the CoreValve
18 frame, and that is the example that I can
19 think of, yes.
20 That was the explanation of the
21 relatively high rates of paravalvular leak
22 with the original CoreValve, but there were

1 high rates of paravalvular leak with Sapien XT
2 as well, and that also related in a way to
3 radial force, but there may have been other
4 factors as well.
5 Q Does the geometry of the cell
6 structure in the frame of the transcatheter
7 heart valve have any impact on whether or not
8 the valve experiences paravalvular leakage?
9 A Do you mean the geometry of cell
10 design --
11 Q Correct, yes.
12 A -- or the geometry of the frame in
13 terms of its shape?
14 Q I'm talking about the geometry of
15 the cell design.
16 A So my understanding is that that
17 relationship is quite complicated.
18 So in all of my aspects of design,
19 there would always be an engineer in the room,
20 and that's the sort of question that I would
21 be asking the engineer or they would be
22 telling me, but I can't tell you that a

1 specific cell design would lead to
2 paravalvular leak.
3 What I can say is there was a change
4 in the cell, either size and/or geometry, of
5 the Evolut valve, and it was alleged that that
6 was one of the reasons why -- I mean, there
7 were several, actually -- but that was one of
8 the reasons why there was a reduction in PVL.
9 Q Can the total geometry of the valve
10 have an impact on paravalvular leakage?
11 MR. LOWENSTEIN: Objection, form,
12 scope.
13 THE WITNESS: So I think you're
14 asking an extremely general question, that
15 does the design of the valve as a whole affect
16 paravalvular leak, and the answer to that is
17 yes.
18 BY MR. STOWELL:
19 Q Maybe we'll -- sorry, go ahead if
20 you're still --
21 A It wasn't always predictable.
22 I mean, for example, as I was

1 mentioning before, the degree of paravalvular
2 leak with Sapien XT was higher than with the
3 previous iteration.
4 It wasn't until Sapien 3 that the
5 paravalvular leak really declined with that
6 frame -- with that valve, with Sapien I mean.
7 So the design of the valve does
8 affect paravalvular leak.
9 Q In your experience, do you recall
10 any specific instances where the overall shape
11 of the valve impacted paravalvular leakage?
12 MR. LOWENSTEIN: Objection, form.
13 Objection, scope.
14 THE WITNESS: The overall shape from
15 top to bottom, no, I don't recall anyone
16 saying this shape is associated with
17 paravalvular leak, no. It would be related to
18 the factors we've been discussing.
19 BY MR. STOWELL:
20 Q There are different degrees of
21 paravalvular leakage, correct?
22 A Yes, that is correct.

1 Q And is it fair to say that they're
2 typically referred to as mild, moderate, and
3 severe?
4 A Yes. There is also a grade even
5 below mild, which can be referred to as
6 "trace."
7 Q Would you agree that mild PVL is not
8 considered to significantly affect patient
9 mortality?
10 A That's a really interesting
11 question, and I could write a book chapter on
12 it, but I don't suppose you want me to do
13 that.
14 In the early days, we didn't pay any
15 attention at all to mild paravalvular leak,
16 and certainly paravalvular leak from the
17 surgical literature that was mild, no one
18 really worried about.
19 In the early days of TAVI --
20 I'm sorry, I'm using TAVI, T-A-V-I,
21 interchangeably with TAVR.
22 Again, we thought, oh, well, thank

1 goodness we got out of the cath lab with the
2 patient alive. We're not worried about mild
3 PVL. We're not even worried -- and I'm
4 talking about the 2007-2008 time frame --
5 we're really not worried about moderate PVL.
6 We're slapping each other on the back that
7 we've managed to deliver the valve and the
8 patient is alive.
9 Then there were one or two trials
10 that suggested that mild PVL may not be that
11 benign, and there was a lot of debate and a
12 lot of discussion about it. And, of course,
13 it doesn't only relate to the degree of the
14 PVL, it also relates to the patient's left
15 ventricular function, how well they can
16 tolerate, and other comorbidities that the
17 patient has got.
18 It also related to how the PVL was
19 measured. So some of the early trials relied
20 on self-reporting by the operators and the
21 hospital. You just had to fill out a case
22 report form, and you would mark, oh, mild PVL,

1 and human beings being human beings, there was
2 cognitive bias that led you perhaps to
3 underestimate the degree of PVL you'd left the
4 patient with.
5 And one of the trials that, if my
6 memory serves me correctly, suggested that
7 mild PVL may not be benign was with one of the
8 Sapien valves, probably I think the Sapien XT,
9 and the principal investigator at the time
10 probably correctly said, well, this is
11 because, if anything, we are rigorously
12 assessing the PVL, and we're being extremely
13 rigorous to it. So there was a lot of
14 discussion at the time about how accurate the
15 PVL was being reported.
16 And I think our feeling now is, for
17 the majority of patients, mild PVL doesn't --
18 really mild or trace -- doesn't matter, but
19 there is a subset of patients, you know, not a
20 sizeable proportion, in whom even mild PVL can
21 be very bad.
22 So it's a long answer, but it's a

1 complex area.
2 Q You mentioned that there were one or
3 two trials about mild PVL that kind of raised
4 or elevated mild PVL.
5 Do you remember when those trials
6 were published?
7 A So my recollection is it would have
8 been in the 2010, 2012 time frame.
9 PVL in general was becoming much
10 more of a concern, because of course, by 2010,
11 we'd been implanting valves for three years,
12 and we got over that emotion of just getting
13 the patient out of the room alive, and so we
14 wanted to improve the outcomes.
15 But as I say, prior to 2010, really
16 mild PVL would have been considered a pretty
17 good result.
18 Q And currently with your patients
19 that experience mild PVL after implantation of
20 a TAVR device, do you do any sort of
21 re-intervention with those patients to try to
22 improve the mild PVL?

1 A Well, that's another massive area to
2 discuss. I mean, the answer is sometimes, but
3 there's a lot of different interventions you
4 can do.
5 It depends on the type of valve
6 that's being implanted, and it depends on the
7 reason for the PVL, and all of that discussion
8 I gave you before about how PVL arises, all of
9 those have potential solutions.
10 Q Does mild PVL ever resolve over time
11 in patients that have a transcatheter heart
12 valve?
13 A Yes, it can. Certainly with Evolut,
14 some of the clinical trials showed that there
15 was a reduction in PVL over time.
16 Q And what causes the reduction in
17 PVL?
18 A So these are really complicated
19 questions. I mean, they're really -- they're
20 really -- they don't have short answers,
21 because each of these questions you're asking,
22 there have been huge meetings about.

1 You know, the discussion about why
2 PVL seemed to decrease in time in some
3 clinical trials, there were lots and lots
4 developments.
5 The truth is, I don't think anyone
6 knows for sure, but there are a few potential
7 explanations. One of them is that the mild
8 PVL was not mild, it was actually moderate,
9 and the patient died. So at follow-up, that
10 patient with moderate PVL no longer appears on
11 the list of patients who survive.
12 The other explanation, this applies
13 more to Evolut, was that ongoing expansion of
14 the valve may have enabled whatever the cause
15 of the PVL was, if there was a small gap, that
16 the frame expanded and put the skirt now into
17 contact with the tissue that then eliminated
18 the PVL.
19 And certainly we've seen patients
20 who had mild PVL, even mild plus PVL, after
21 the procedure, and when they have their
22 echocardiogram a week or two weeks later, the

1 PVL is gone. That has occurred more in those
2 patients with external seeding skirts than the
3 original CoreValve and Evolut, but ongoing
4 expansion of the frame may have contributed to
5 some of that.
6 Could I just mention that I'm
7 getting close to needing a toilet break.
8 MR. LOWENSTEIN: It's 12 minutes
9 left by my calculation. Do you want to go off
10 record for a minute or two, or what's your
11 preference?
12 THE WITNESS: Well, I just --
13 MR. LOWENSTEIN: Why don't we --
14 THE WITNESS: I've been drinking a
15 lot of water through the day, and it needs
16 to --
17 MR. LOWENSTEIN: Why don't we take a
18 two-minute break. Does that work?
19 MR. STOWELL: Sure, that's fine on
20 our end.
21 THE WITNESS: Okay.
22 THE VIDEOGRAPHER: Okay, going off

1 the record. The time is 3:12.
2 (A break was taken.)
3 THE VIDEOGRAPHER: We are back on
4 the record. The time is 3:16.
5 BY MR. STOWELL:
6 Q Dr. Brecker, what percentage of the
7 patients that you implant TAVR devices into
8 today end up with mild PVL?
9 A So it's pretty -- I would say it's
10 pretty small, but it's not insignificant.
11 So mild PVL is less common with
12 Sapien 3 than with Evolut/Evolut PRO+ at the
13 time of implant, and that relates to the fact
14 that there is some ongoing expansion of the
15 Evolut frame.
16 I would say -- you know, it depends
17 at what time you look: at implant, at 7 days,
18 at 30 days. But 30 days, a mild PVL, it could
19 be present in 20% even of Evolut patients, but
20 then if you look at a year, it's less, as I
21 say, and it's probably a smaller percentage,
22 maybe not 20%, smaller percentage with

1 Sapien 3.
2 And I'm including extremely mild.
3 I'm including in that trace as well, where you
4 literally just see a tiny, tiny amount going
5 back, and that would really be insignificant.
6 Q That raises a good question.
7 Is there a distinct measurement you
8 use to determine whether someone has trace or
9 mild PVL, or is it something that you're just
10 visualizing?
11 MR. LOWENSTEIN: Objection, scope.
12 THE WITNESS: So what you're asking
13 is grading a paravalvular leak, and that's,
14 again, a very complex area, and there are many
15 ways of grading it, both with angiography,
16 echocardiography, hemodynamics as well.
17 And so there is a -- there's no -- I
18 wouldn't say there is a distinction between
19 trace and mild, but everyone really knows what
20 that means. It's where you've got just a
21 tiny, tiny, tiny bit.
22 There are agreed criteria

1 echocardiographically for the distinction
2 between mild and moderate and moderate and
3 severe, and there are also criteria
4 angiographically, and there are hemodynamic
5 criteria as well.
6 BY MR. STOWELL:
7 Q For the patients that you perform
8 TAVR procedures on today that have mild PVL
9 after, say, 30 days, what percentage of those
10 patients do you have to do some sort of
11 additional intervention to correct the PVL?
12 MR. LOWENSTEIN: Objection, scope.
13 Are we ever going to ask any
14 questions that have anything to do with this
15 IPR?
16 No, no, hold on a second. Like,
17 seriously, for two hours now you've been
18 asking questions that have tangential, at
19 best, relevance to this IPR. I strenuously
20 object.
21 You've not asked a single question
22 about Levi, you haven't asked a single

1 question about Walther, Spenser II. You seem
2 to be digging for stuff in litigation.
3 I'm going to give you a very, very
4 short leash on this tomorrow, Josh. If you do
5 it, we're going to get on a call with the
6 Board, because this wasting my time, it's
7 wasting the witness's time. It's
8 inappropriate.
9 MR. STOWELL: Okay, Mr. Lowenstein,
10 I'll ask you to limit your objections to a
11 single word as required by the rules.
12 MR. LOWENSTEIN: You didn't dispute
13 anything I just said. I just want to point
14 that out.
15 MR. STOWELL: I'm not going to argue
16 with you on the record, Nathan.
17 BY MR. STOWELL:
18 Q Dr. Brecker, do you need me to reask
19 the question?
20 A No. Very, very, very, very few
21 patients with mild PVL will need further
22 intervention.

1 Q Thank you. So I think we've reached
2 a good stopping point on the outline.
3 Mr. Fahnert, can you give us a time?
4 THE VIDEOGRAPHER: Yes.
5 4 hours, 54 minutes.
6 MR. STOWELL: Okay.
7 MR. LOWENSTEIN: You don't get the
8 extra 6 minutes.
9 MR. STOWELL: Okay, so this would be
10 a good breaking point for today.
11 Dr. Brecker, thank you for your
12 time. We will pick up tomorrow morning at
13 8:30 a.m. Does that sound good?
14 THE WITNESS: Yes, that sounds good.
15 MR. LOWENSTEIN: And will you
16 actually ask questions about the IPR, or will
17 it just be another day of questions about
18 litigation?
19 MR. STOWELL: I think we can go off
20 the record now unless anybody else has any --
21 MR. LOWENSTEIN: I thought we were,
22 but we're meeting and conferring right now.

1 Completely inappropriate.
2 THE VIDEOGRAPHER: Going off the
3 record. This deposition is adjourned at 3:22.
4 (Whereupon, at 3:22 p.m. PDT, the taking
5 of the deposition was adjourned, to
6 be reconvened the following day.
7 Reading and signature were
8 RESERVED.)
9
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1 CERTIFICATE OF NOTARY PUBLIC

2 I, DAWN A. JAQUES, a Notary Public in and for
3 the Commonwealth of Virginia, before whom the
foregoing deposition was taken, do hereby certify
4 that witness whose testimony appears in the
foregoing pages was duly sworn by me; that the
5 testimony of said witness was taken by me in
shorthand at the time and place mentioned in the
6 caption hereof and thereafter reduced to typewriting
under my supervision; that said deposition is a true
7 record of the testimony given by said witness; that
I am neither counsel for, related to, nor employed
8 by any of the parties to the action in which this
deposition is taken; and, further, that I am not a
9 relative or employee of any attorney or counsel
employed by the parties thereto, nor financially or
10 otherwise interested in the outcome of the actions.
11
12
13
14
15
16
17 Dawn A. Jaques
Dawn A. Jaques, CSR, CLR
18 Notary Public in and for
the Commonwealth of Virginia
19
20 My commission expires:
21 August 31, 2023
22 Registration No. 132328

1 Stephen J.D. Brecker Vol I, c/o
LOWENSTEIN & WEATHERWAX LLP
2 1016 Pico Boulevard
Santa Monica, California 90405
3
4 Case: Edward Lifesciences Corp., et al., v. Aortic Innovations, LLC
Date of deposition: August 30, 2022
5 Deponent: Stephen J.D. Brecker Vol I
6
7 Please be advised that the transcript in the above
8 referenced matter is now complete and ready for signature.
9 The deponent may come to this office to sign the transcript,
10 a copy may be purchased for the witness to review and sign,
11 or the deponent and/or counsel may waive the option of
12 signing. Please advise us of the option selected.
13 Please forward the errata sheet and the original signed
14 signature page to counsel noticing the deposition, noting the
15 applicable time period allowed for such by the governing
16 Rules of Procedure. If you have any questions, please do
17 not hesitate to call our office at (202)-232-0646.
18
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5 Witness Name: Stephen J.D. Brecker Vol I
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7 I do hereby acknowledge that I have read
and examined the foregoing pages
8 of the transcript of my deposition and that:
9
10 (Check appropriate box):
( ) The same is a true, correct and
11 complete transcription of the answers given by
me to the questions therein recorded.
12 ( ) Except for the changes noted in the
attached Errata Sheet, the same is a true,
13 correct and complete transcription of the
answers given by me to the questions therein
14 recorded.
15
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18
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6 ERRATA SHEET

7

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

9 Witness Name: Stephen J.D. Brecker Vol I

10 Deposition Date: August 30, 2022

11 Page No. Line No. Change

12

13

14

15

16

17

18

19

20

21 _____ _____

22 Signature Date

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