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

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Edwards v. Aortic Innovations
U.S. Patent 11,497,634
Edwards Ex. 1072

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Exhibit 1100 Declaration of Dr. Stephen Brecker IPR2017-00060 Patent 8,992,608.....86

Exhibit 1101 2014 European Heart Journal article, "Treatment of aortic stenosis with a self-expanding transcatheter valve: the International Multi-centre ADVANCE Study (13 pages).....146

Exhibits CON'T

PREVIOUSLY MARKED EXHIBITS REFERRED TO

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P R O C E E D I N G S

THE VIDEOGRAPHER: We are on the record. This is the remote video deposition of Dr. Stephen Brecker, in the matter of Edwards Lifesciences Corporation and Edwards Lifesciences LLC v. Aortic Innovations, LLC, in the United States Patent and Trademark Office, before the Patent and Appeal Board.

My name is Billy Fahnert. I am the video technician today. The court reporter is Dawn Jaques. We are here on behalf of Digital Evidence Group.

Today's date is August 30th, 2022. The time is 8:34 a.m. Pacific Daylight Time.

All parties have stipulated to the witness being sworn in remotely. The appearances of counsel are noted on the stenographic record, and the witness can now be sworn in.

THE REPORTER: If you'll raise your right hand, sir, to be sworn.

(The witness was administered the oath.)

Whereupon,

STEPHEN J.D. BRECKER, M.D.,

was called as a witness, after having been first duly sworn by the Notary Public, was examined and testified as follows:

EXAMINATION BY COUNSEL FOR THE PETITIONERS

BY MR. STOWELL:

Q Good morning, Dr. Brecker. I introduced myself off the transcript. My name is Josh Stowell. I will be deposing you on behalf of Edwards today.

Do you understand that you are under oath just as if you were testifying in a court of law and that you are required to tell the truth today?

A Yes, I do.

Q The court reporter is writing down everything that we say, so all of your answers will need to be verbal today.

Do you understand?

A I do.

Q We'll try to avoid talking over each other today so that we get a clean transcript. Please wait until I finish my question before answering, and I will try to wait for you to answer before I ask my next question.

Is that understood?

A Yes, it is, yes.

Q If you don't understand one of my questions at any point today, please let me know. If you don't speak up, the assumption will be that you have understood the question.

Is that fair?

A Yes, I understand.

Q Your counsel, Mr. Lowenstein, may make short objections during today's deposition. However, you will still need to answer all of my questions unless you are specifically instructed not to answer.

Do you understand?

MR. LOWENSTEIN: Objection, form.

THE WITNESS: I do understand.

BY MR. STOWELL:

Q I'll try to go about an hour between breaks today. If you need a break in the interim, just let me know. The only thing I'll ask is that we finish the question we're on before we take a break. Is that fair?

A Yes, that sounds good.

Q And this deposition is being done remotely, so please let me know if you encounter any technical difficulties. If you don't say anything, we will assume that the technology is working okay. Is that fair?

A Yes, that's fair.

Q Is there any reason you can't provide truthful and accurate testimony today?

A There is not.

Q Have you had any food, drink, or medication that would inhibit your ability to testify truthfully today?

A No, no.

Q And where are you sitting for today's deposition?

A I am in the offices of Lowenstein & Weatherwax in Santa Monica.

Q And did you come to the United States exclusively for this deposition?

A I did, yes.

Q And when did you arrive in the United States?

A I arrived late on Thursday evening, the 25th.

Q And did you travel to the United States directly from the UK?

A I did.

Q Are you required to take any special precautions while you are traveling due to your position as an interventional cardiologist?

A The hospital I work at has not had any specific restrictions.

The precautions are that I'm fully vaccinated. I've had COVID quite recently, and I wear a mask when I can.

So those are the restrictions.

There's no specific restrictions in my role as an interventional cardiologist.

Q Other than the standard travel difficulties that are all too common today, did you encounter any hurdles in traveling to the United States for this trip?

A Yes, I did.

Q And what were the hurdles?

A So the flight was delayed quite a lot because the flight that was due to depart prior to my flight to Los Angeles was canceled, and so they had to off-load all of those passengers and their luggage and put them onto our flight.

Q Okay. So I consider that within the umbrella of typical standard difficult -- standard travel difficulties today.

Did you encounter any other hurdles in traveling to the United States?

A I can't think of anything, no. It was quite a long and delayed journey, but there were no hurdles as such.

I mean, there was a very, very long line at Los Angeles Airport through immigration checks, but apart from that, no.

Q So in the future, if you need to come to the U.S. for another deposition in these matters, I take it that should not be a problem. Is that fair?

MR. LOWENSTEIN: Objection, form.

THE WITNESS: I don't think anyone can predict what's going to happen with the next wave. Certainly at our hospital, we are gearing up for a major wave in the autumn, that's despite a booster program.

So I don't think anyone can predict what's going to happen even in two or three months' time, but if this autumn and winter are smooth and there are no restrictions on travel and no new variants, it's anyone's guess, frankly.

BY MR. STOWELL:

Q Okay. But if conditions remain as they are today, is it fair to say that you

would have no problems traveling to the U.S. in the future for another deposition?

MR. LOWENSTEIN: Objection, form.

THE WITNESS: If the conditions are as we are today, then no.

BY MR. STOWELL:

Q What is your setup, technology setup, for today's deposition?

A Well, I have two computer screens in front of me. I can see your image as a small image on the right of the screen. There's then a lot -- this is on the screen that's directly in front of me. Then there is an exhibit window screen.

And then there is a separate monitor to the left, which I believe is on a -- an uploaded image, uploaded pieces of evidence.

Q Okay. So you have two desktop monitors set up today; is that fair?

A Yes.

Q Okay. And there's an exhibit window on one of the monitors; is that right?

A Yes. The one that's directly in front of me, it says "Exhibit Window," and then there is a -- as I say, there's a monitor off to the left which has the word "Box" in blue on the top, which I think is like a dropbox type interface.

Q Okay. So as we go through the deposition today, if we use exhibits, the exhibits should be placed in that second screen that you have, the drop screen, where you can download them and review them in full if you want to, okay?

The hot seat operator will also pull up the exhibits in the exhibit window so you can view them.

Does that make sense?

A Yes.

Q Okay. I understand that Mr. Lowenstein is in the room with you today; is that correct?

A He is. He's on my left.

Q Is anyone else in the room with you

today?

A Yes. Mr. Hsieh.

Q And where is Mr. Hsieh sitting in relation to you?

A He is on Mr. Lowenstein's left.

Q And is there anyone else in the room with you today?

A There's no one else in the room.

Q Did you bring any materials with you to the deposition today?

A Yes.

Q What did you bring with you?

A So I have clean printed copies of my declaration of the AI patents, and of some of the other patents. I can go through the ones that I've got in front of me.

The Spencer 2, Levi, Walther, and Spencer 1 I have as hard copy, and I have the AI patents.

Q And when you refer to the AI patents, are you referring -- do you have the U.S. patent number 10,792,172 in front of

you?

A Yes, '172, I have that one.

Q And do you have U.S. patent number 10,857,011?

A I do.

Q And do you have U.S. patent number 10,881,538?

A I do.

Q Do you have U.S. patent number 10,966,846?

A I do.

Q And you probably know this from your prior patent work, but we typically refer to the patents by the last three digits of the patent number. So, for example, we would refer to U.S. patent number 10,792,172 as the '172 patent.

Are you familiar with that naming nomenclature?

A Yes, I am.

Q Okay. And so if I refer to the '172 patent today, will you know what patent

I'm referring to?

A Yes, I will.

Q You mentioned your declarations. What exhibit number is on the declaration or declarations you have in front of you today?

A 2051.

Q Do you have any other declarations in materials with you today?

A I have hard copies of Exhibit 2002.

Q And what IPR is Exhibit 2002 from that you have in your --

A I'm sorry, I overspoke you. I don't think you finished.

Q Yeah. What IPR is Exhibit 2002 from that you have in your materials?

A So I have two. One is IPR2022-00549, and IPR2022-00556.

Q Now, you have submitted two additional declarations that are not in your materials in these IPRs that are the subject of the deposition today, correct?

MR. LOWENSTEIN: Objection, form.

THE WITNESS: So there were some declarations before the one Exhibit 2051, which is a consolidated declaration, and I think there were more than two.

BY MR. STOWELL:

Q Right. So for today's deposition, in total, you have submitted five declarations; is that fair?

MR. LOWENSTEIN: Objection, form.

THE WITNESS: Yes. There were four initial, and then --

MR. LOWENSTEIN: Objection, form.

Go ahead.

THE WITNESS: There were four initial declarations, and then one second declaration that was a consolidated declaration.

BY MR. STOWELL:

Q And of the four initial declarations, you have two of those declarations with you today; is that correct?

MR. LOWENSTEIN: Objection, form.

THE WITNESS: No. I think the two that I have with me relate to other matters, not -- they're not two of the four that the consolidated declaration encompasses.

BY MR. STOWELL:

Q Okay. So you have two declarations that you had submitted in other IPRs with you today; is that fair?

A Yes, that's correct.

I gave you those IPR numbers.

Q And with the declarations, do you have all of the exhibits that you attached to those declarations?

MR. LOWENSTEIN: Objection, form.

THE WITNESS: I do not. I do not have hard copies of those exhibits.

The only hard copies that I have in front of me are the ones that I've specified, the AI patents and the patents that -- or, rather, the documents, the exhibits which I itemized, starting with Spencer 2.

BY MR. STOWELL:

Q With your declaration, Exhibit 2051, there were two exhibits: an Exhibit A, which looked to be your CV, and an Exhibit B that was a listing of your patent cases.

Do you have those exhibits with you today?

A I do not. Those have not been printed out.

Q Have you made any notes on the materials that you have brought with you today?

A I have not.

Q Have any of the materials you brought with you today been highlighted?

A They have not. Actually, there are some highlights that I think I recalled seeing, yes, but they're not highlights that I made.

So these were printed out copies, but I think they may have just been copies that had like one highlight. So there are

some highlights on one/two of them, but they're not highlights that I've made or have attached significance to.

Q Do you know who made the highlights?

A I do not.

Q Have any sticky tabs or other indicators been added to the materials that you have in front of you today?

A So I had some sticky tabs on one of them, which they're basically just tabs for markers for where I had got up to reading, but I'm happy to remove those. They were literally just like bookmarks for me. They don't highlight anything in particular.

Those have been removed.

Q Other than those sticky tabs, are there any other tabs on the materials today?

A No, there is not.

Q And so other than the highlighting that was mentioned, is it fair to say that you have clean copies of documents in front of you today?

A Yes, I do. Yes, that is correct.

Q Do you have any devices set up to communicate with people during today's deposition?

A I do not.

MR. LOWENSTEIN: Objection, form.

BY MR. STOWELL:

Q Are you aware that now that the deposition has started, that you may not speak to anyone about your deposition testimony until we conclude the deposition, which will likely be tomorrow?

MR. LOWENSTEIN: Objection, form.

THE WITNESS: I am aware that I'm not able to speak to anyone.

Can I just make a request that I get completely clean copies? So it's only two of the patents that have any highlights on. All of the others are completely clean.

There are two patents, which I will give, with your permission, to Mr. Hsieh to give me completely clean copies of.

MR. HSIEH: I believe those highlightings were in the original exhibits as submitted.

THE WITNESS: Oh, okay. So I've just been told that these highlights were in the original submitted exhibits. I can show you them if you would like.

BY MR. STOWELL:

Q Why don't you just tell me what exhibits are you looking at there that have the highlights?

A Okay. So there is the '011 patent and the '172 patent, and for each of those IPRs, they are Edwards Exhibits 1001. So these highlights would appear to be were on the original exhibit.

Q Okay, thank you.

And other than patent '011 and patent '172, you haven't seen any highlights on any of the other documents you have in front of you today; is that correct?

A That's correct. I haven't been

through every page, but I have done a skim through, and I can't see any other highlights.

Q Thank you. You were hired by Patent Owner, Aortic Innovations, in this matter, correct?

A My engagement was through Lowenstein & Weatherwax, and I'm aware that their client is Aortic Innovations.

I had no direct contact with Aortic Innovations initially.

Q And who contacted you to work on this matter?

A That's a good question. I think it must have been Mr. Lowenstein, but it could have been somebody else who sent the original email, it was via email, and I don't recall exactly who the first contact was made from.

Q Okay. But you recall that the first contact was made through email?

A Yes, I think so. I think so. It wouldn't have been via -- well, I think it was

via email. I can't be 100% sure.

It's potentially possible that there was a phone message, but I don't recall that. There's so many -- I get so many emails and messages every day, I can't remember where the initial contact came from. My recollection is that it was an email.

Q And do you remember when you were first contacted for this matter?

A I can't remember the date. I could look it up, but I can't -- I would have to go to look at my emails.

Q Can you provide an estimate of roughly when you were contacted?

A Well, it would have been last year, obviously, and I just can't. Last year was such a -- well, for everyone, such a crazy year. Honestly, if I tried to give you the month, I would be wrong I think.

I could find out. I would be able to find out quite easily, but it would mean me looking at emails.

Q Before being contacted to work on this matter, were you familiar with Aortic Innovations?

A I was not.

Q So it's fair to say that before being contacted on this matter, you had not done any work for or with Aortic Innovations?

A Certainly I have not.

Q Outside of working on this matter, do you currently have any other relationship with Aortic Innovations?

A I do not.

MR. LOWENSTEIN: Objection, form, but go ahead.

BY MR. STOWELL:

Q The inventor on all of the patents today is Dr. Ali Shahriari; is that correct?

A Yes, that is correct.

Q Were you familiar with Dr. Shahriari before you were contacted to work on this matter?

A I was not.

Q Since you have been retained to work on this matter, have you spoken to Dr. Shahriari?

A Yes.

Q And how many times have you spoken to Dr. Shahriari?

A Well, it would be a small number, and typically only in meetings with other people. It's possible only once or twice.

So I've never had an individual meeting with him. I have only been in an online meeting where we have had a conversation with others present, and my recollection is that might only be a very small number of times.

Q So your recollection is you may have had one or two online meetings in which Dr. Shahriari was present?

A Yes, more than one.

Q And what were the purposes of the meetings that you participated in with Dr. Shahriari?

A So I think one of them would have been after Dr. Buller's deposition, possibly during the deposition.

I don't recall other meetings, but it's possible. I just don't have any recollection of any other specific meeting.

I have had a very brief conversation in which he was involved in the last day or two as well.

So my recollection is that it would have been around the time of Dr. Buller's deposition, and then just literally a three-minute, four-minute conversation in the last day or two.

Q And why were you speaking to Dr. Shahriari around the time of Dr. Buller's deposition?

A So Dr. Shahriari was also present at Dr. Buller's deposition online, and there would have been a group discussion about the testimony.

Q And you mentioned other people were

present for that conversation.

Who else was present?

A I mean, I think -- I can't give you the exact list. My sense is that Mr. Nifong would have been there, possibly Mr. Lowenstein.

It's online, and it's sometimes difficult to remember. So it's -- yeah, I don't recall the chapter and verse of who was there.

Q So what about Dr. Buller's testimony was being discussed with Dr. Shahriari?

A Well, my recollection is there was quite a lot of issues raised, but you're asking me about a conversation that was several months ago.

It would have been about aspects of the testimony that was being given, so I can recall issues of vascular access were being discussed.

I can recall there were issues about the number of patients with aortic stenosis

who would die untreated; that was discussed.

There may have been other issues as well.

Q And why was Mr. Nifong participating in your conversation with Dr. Shahriari?

A Well, it wasn't my conversation with Dr. Shahriari as such. That would mischaracterize the meeting.

The meeting was the sort of meeting that I'm sure you have, which is a debrief type meeting after an expert's testimony is completed.

Q Did anything from the discussion with Dr. Shahriari around the time of Dr. Buller's deposition influence the opinions you've given in this case?

A Not at all.

Q You mentioned that --

A Sorry, if I could just -- sorry, I had paused, but it didn't influence my opinions. I'll leave it at that. It didn't influence my opinion.

Q You also mentioned you had a brief conversation with Dr. Shahriari in the last day or two. What was the purpose of that conversation?

A We were discussing the patents, we were discussing Dr. Shahriari's background, but it was a very, very brief conversation.

Q What did you discuss about the patents?

A So, obviously, there's been a lot of discussion. I can't recall the exact content of what point we had discussed.

Q Do you remember the general content of what you discussed?

A Well, I know we discussed the fact that Dr. Shahriari was a cardiovascular surgeon. I've had a lot of discussions about the patents in the last three days, so I cannot recall what it was that we -- honestly, I just can't recall what we discussed specifically with respect to the patent.

I believe we may have -- we may have

discussed some aspect, but it may have been that we were discussing that, and then Dr. Shahriari came on the call, and we certainly clarified his experience as a cardiovascular surgeon.

Q You also mentioned that you talked about Dr. Shahriari's background. What did you discuss with respect to his background?

A Exactly what I've just said, his experience as a cardiovascular surgeon.

Q So based on your experience in the industry, are you aware of anything that Dr. Shahriari had done to advance the field of transcatheter heart valves?

MR. LOWENSTEIN: Objection, form. Objection, scope.

THE WITNESS: Yes, quite a lot.

BY MR. STOWELL:

Q And what are you aware of?

MR. LOWENSTEIN: Same objections.

THE WITNESS: So I'm aware that Dr. Shahriari has been an innovator in

previous technologies. I'm not familiar with those technologies, but I am aware that they relate to the field of endovascular stent graft type technology and repair technology for aortic disease.

I am aware of the patents that are being discussed currently, and the innovative and inventive ideas that those patents contain in the field of transcatheter heart valve technology.

BY MR. STOWELL:

Q And are you aware of any other contributions by Dr. Shahriari to the field of transcatheter heart valves?

MR. LOWENSTEIN: Objection, form. Objection, scope.

THE WITNESS: Sorry, could you repeat that question? Because I think I had just answered it, but I might have missed an extra bit that you wanted.

BY MR. STOWELL:

Q Yeah. So you spoke about, I believe

you said Dr. Shahriari's contributions to stent graph technology, and that you are aware of the patents that are at issue in this deposition.

Are you aware of any other contributions that Dr. Shahriari has made to the field of transcatheter heart valves?

MR. LOWENSTEIN: Objection, form. Objection, scope.

THE WITNESS: So I think those areas that I've talked about contain a huge amount.

There's a lot of crossover technology in delivery systems between endovascular stent graph technology, aortic repair, and transcatheter heart valves.

So all of that technology is of value in advancing the field of transcatheter heart valve technology.

I'm aware of the patents that we are discussing. I'm also aware that there are other developments and innovations, but I'm not aware of the details of those.

BY MR. STOWELL:

Q You had mentioned you were aware that he was an innovator on previous technologies relating to stent graph technology.

Did the technology you're referring to in that instance include a transcatheter heart valve?

MR. LOWENSTEIN: Objection, form. Objection, scope.

THE WITNESS: I'm not aware of that.

BY MR. STOWELL:

Q Have you ever read any papers by Dr. Shahriari relating to transcatheter heart valves?

MR. LOWENSTEIN: Objection, scope.

THE WITNESS: I have read all of the patents.

BY MR. STOWELL:

Q Aside from the patents, have you read any other --

MR. LOWENSTEIN: Hold on.

Josh, you've been asking a lot of questions that are obviously for your litigation case. I've let it go on a little bit, but it's going on a little long.

If you intend to keep trying to ask questions about your trial testimony, why don't we get on a call with the Board so we can clarify the scope of this deposition, which is the declaration that Dr. Brecker has offered in these cases.

MR. STOWELL: Would you like me to repeat the question?

MR. LOWENSTEIN: Excuse me. Should we have a call with the Board? Because you're obviously asking questions that have no relevance to these IPRs.

MR. STOWELL: Nathan, you know that's not correct. You know Dr. --

MR. LOWENSTEIN: It is correct. If you like to get on a call with the Board, let's call the Board.

MR. STOWELL: Okay. If you would

like to put the deposition on hold and go off the record and you would like to initiate a call with the Board, we can do that.

As you're aware, in his declaration, Dr. Brecker has made statements about Dr. Shahriari's alleged contribution to the art. We are entitled to ask about the scope of the contribution.

MR. LOWENSTEIN: You're obviously asking questions for your litigation, not this IPR. We have a standing objection.

If you continue in this vein, I think we may have to have a call with the Board. Please continue.

BY MR. STOWELL:

Q Okay. Dr. Brecker, sorry for the interruption.

Have you ever read any other publications besides the patents that are at issue in this deposition by Dr. Shahriari relating to transcatheter heart valves?

MR. LOWENSTEIN: Objection, scope.

THE WITNESS: I may have done.

BY MR. STOWELL:

Q Do you recall any as you sit here today?

MR. LOWENSTEIN: Objection, scope.

THE WITNESS: So I have not prepared any type of analysis at this point on that.

I may well have read material. I read five or six scientific papers per week. It is quite possible that I have read something by Dr. Shahriari.

Sitting here now, I cannot give you chapter and verse. I don't -- I could find out, but I can't tell you now.

BY MR. STOWELL:

Q Have you ever seen Dr. Shahriari speak at any conferences on the topic of transcatheter heart valves?

MR. LOWENSTEIN: Objection, scope.

THE WITNESS: It's possible.

BY MR. STOWELL:

Q Do you recall any instances of that

as you sit here today?

MR. LOWENSTEIN: Objection, scope.

THE WITNESS: I would have to give the same answer, that I go to a very large number of scientific meetings, sessions, speakers. I could not tell you, sitting here now, whether I have seen Dr. Shahriari speak.

BY MR. STOWELL:

Q And you're aware that this deposition covers four different IPRs involving four Aortic Innovations patents, correct?

A I am aware of that, yes.

Q Do you understand that all four patents share the same specification?

A I had understood that, but I would have to have a look through the patents to confirm it.

Q When you say you had understood that, what do you mean?

A That is my understanding.

Q Were you familiar with any of the

four patents at issue in this deposition before you were contacted to work on this matter?

A I was not.

Q Are you aware that there is also a district court litigation pending between Aortic Innovations and Edwards?

A I am aware of that.

Q And what do you know about the district court litigation?

A I don't know anything about it at this point.

Q Do you know which party is the Plaintiff and which party is the Defendant in the litigation?

A Sitting here now, I do not.

Q Do you know which patents are involved in the litigation?

A I do not.

Q Do you know if any of the patents that are the subject of today's deposition are at issue in the litigation?

A I do not.

Q Do you have any intention right now to provide testimony in the district court litigation?

A So my understanding is today was about the IPRs and the declaration that I've submitted. I'm not aware if I'm able to go into the details of the question you've answered -- you've asked me.

Q And why is that?

MR. LOWENSTEIN: Objection, form. Objection, scope.

THE WITNESS: Well, my understanding is that today is a deposition about the IPRs, the four IPRs on which I've submitted the declaration.

I have not come today prepared to discuss the issues of litigation.

BY MR. STOWELL:

Q Right. And to clarify, I'm not asking you to discuss the issues in the litigation.

I'm just asking have you agreed to provide testimony in the district court litigation on behalf of Aortic Innovations?

MR. LOWENSTEIN: Objection, form. Objection, scope.

THE WITNESS: So I may have done, but I cannot tell you, sitting here now, if I will be the expert in the district court litigation.

BY MR. STOWELL:

Q And why is that?

MR. LOWENSTEIN: Objection, form. Objection, scope.

THE WITNESS: Well, there are several reasons. The first is I don't know if I'm permitted to answer.

The second is I have not had any communication about the district court litigation for quite a long time, so I have no sense of the status of it, nor my involvement in it.

BY MR. STOWELL:

Q You mentioned you hadn't had any conversations about the district court litigation for quite a long time.

When was the last time you had some exposure to the district court litigation?

MR. LOWENSTEIN: Objection, scope.

THE WITNESS: I have not had any exposure to the district court litigation.

BY MR. STOWELL:

Q When was the last time you discussed the district court litigation with someone?

MR. LOWENSTEIN: Objection, form. Objection, scope.

THE WITNESS: I have not discussed the district court litigation. I haven't had any discussion about the detail of it.

BY MR. STOWELL:

Q When you said I have not had any communication about the district court litigation for quite a long time, what did you mean?

A I meant exactly what --

MR. LOWENSTEIN: Objection, form. Objection, scope.

THE WITNESS: I meant exactly what I said. I had had some communication about a potential district court litigation between Aortic Innovations and Edwards a long time ago. I can't tell you the date.

Again, it's something I could look up and I could give you an accurate answer, but I can't do that sitting here now. It's not something I had prepared for for today.

That communication was from a law firm, not this law firm that I am in at the moment --

MR. LOWENSTEIN: Hold on. I'm going to caution you not to reveal anything that may be subject to some sort of privilege or confidentiality in that litigation.

THE WITNESS: Yeah, so I don't think I can answer your question. I don't think I'm permitted to.

BY MR. STOWELL:

Q Okay. But it's fair to say you were contacted by another law firm not present today regarding the district court litigation, is that fair?

MR. LOWENSTEIN: Okay, I've let this go on far enough. All you're asking are questions about the district court litigation. That's not what this deposition is about.

I've already raised this. You've asked 15, 20 minutes in a row exclusively about the district court litigation. This is extremely improper.

Can we please get back to the subject of this deposition and not your hunting and fishing for testimony in the district court litigation, please?

MR. STOWELL: Nathan, we are entitled to explore the information that Dr. Brecker has been exposed to that is relevant to these IPRs. This is part of that exploration. Obviously, we can ask

him questions.

MR. LOWENSTEIN: No, no. I have been involved in hundreds of IPR depositions. I've never had anyone go this deep into an irrelevant litigation that is not the topic of this IPR.

BY MR. STOWELL:

Q Dr. Brecker, can you answer my last question?

MR. LOWENSTEIN: Objection, form. Objection, scope. I'm sure he has no idea what your last question was.

MR. STOWELL: Nathan, you can limit your objections to a single word, as required by the rules.

MR. LOWENSTEIN: Well, you can limit your questioning to the subject of this deposition as opposed to your trying to hunt for information in the district court, which is completely improper.

MR. STOWELL: Nathan, your objection is improper. You can limit it to a single

word.

BY MR. STOWELL:

Q Dr. Brecker, is it fair to say you were contacted by another law firm not present today regarding the district court litigation?

MR. LOWENSTEIN: Objection, form. Objection, scope.

I will caution the witness not to reveal any information that he may be prohibited from doing so under some confidentiality or privilege.

THE WITNESS: I was contacted. Let me be clear and let me clarify it, and then hopefully we can move on.

Sitting here today, I know nothing about the details of the district court litigation.

I could not tell you which party is Plaintiff and which is Defendant. I could not tell you which patents are involved. I could not tell you anything because I don't know.

BY MR. STOWELL:

Q Okay, thank you.

Did you prepare for today's deposition?

A Yes, I did.

Q And what did you do to prepare?

A I read through my declaration, so the consolidated declaration; and I read through, in part, a lot of the AI patents; and I've read through a number of pieces of the prior art, including the exhibits, Spenser, Spenser II, Walther, Levi, et cetera. I've had discussions with Mr. Hsieh mostly over the past few days.

Q How much time --

A Sorry. I'm sorry. I've also had some briefer discussions with Mr. Lowenstein.

Q How much time do you estimate you've spent preparing for the deposition today?

A So I've done my own reading. I did that -- I did quite a bit of reading before I came.

I didn't do very much on the day after I arrived because it was a very late arrival and jetlag.

And then over the Saturday, Sunday and Monday, I've been in the office for a few hours each of those days, not full days.

So I couldn't give you a number, but that is the -- that's the preparation: that I did some reading on days before coming, and then the meetings that we've had here.

Q So you met with counsel in the office on Saturday, Sunday, and Monday; is that correct?

A Yes, I think those were the -- yes. They were not full days because, obviously, with the 8-hour time difference, it's difficult to keep going.

Q Understood.

And those meetings in the office, you said those were primarily with Mr. Hsieh; is that correct?

A Primarily, yes.

Q And you mentioned that you also had some meetings with Mr. Lowenstein; is that correct?

A That is correct.

Q And did you meet with anybody else to prepare for your deposition today?

A No, I've had no interactions on the content of this with anyone else. I'm trying to think. No.

Q Other than the materials that you have in front of you today, did you review any other documents to prepare for your deposition today?

A Well, there are a large number of exhibits. There's a large number of declarations, there's a lot of patents.

I've looked at a number of documents. I've looked at Dr. Buller's declarations, I've looked at some of the exhibits that he submitted.

I've tried to review as much as possible, but I have not looked through in

detail every single document pertaining to this case. There are probably tens of thousands of pages.

Q But you did look at other documents that are not in front of you today as part of your preparation for today's deposition; is that fair?

A Yes, I've certainly been looking at other documents.

Q And did any of the documents that you reviewed in preparation for your deposition refresh your recollection regarding any of the facts or issues in this IPR?

A I mean, that's a very general question, and if I said yes, you would ask me which documents and which facts, and I can't answer that.

I mean, when I review documents, some of it is familiar. Some of the things -- some things you read through a document you've read before and you see something different.

I can't give you a list of each fact

from each document that may have refreshed my memory on something, but --

Q But you -- sorry, go ahead.

A Sorry, yes. I have no doubt that in reading one or more of the documents, I noticed something that had not been emphasized before.

Q Earlier we discussed that you had prepared four initial declarations for the IPRs that are the subject of the deposition today; is that correct?

A Yes, that's correct.

Q How much time did you spend preparing those initial four declarations?

A I couldn't really give you an estimate sitting here now. I'd have to go back and look through the diary of the time that I've spent.

I mean, it's an iterative process, as you know, and you spend time reading, and then meeting, and then writing. It's tens of hours. I can't tell you how much on each

declaration and whether one was more than another, for example.

Q What about collectively for those first four declarations? Can you give an estimate of the time you spent preparing those four?

A I can't. I hadn't prepared that type of information. It's something I could find out, but I can't tell you sitting here now.

Q Do you believe it was more than 10 hours?

A For the four declarations, yes.

Q More than 100 hours?

A No.

Q More than 50 hours?

A For those four declarations, I would be very surprised if it was anything close to 50 hours, but it depends what you're asking me, because prior to the declarations, I would have done quite a bit of reading. Prior to even starting a declaration, there would have

been meetings.

So it really depends what you include in the time taken to write a declaration, whether you include time that you've spent reading the patent in general terms. So I can't give you the detail of the answer that you want.

Q And so do you remember that prior to working on the four declarations, the four initial declarations, that you had meetings and you reviewed a lot of documents before working on those declarations?

A I would definitely have read.

Q Do you recall having meetings before you worked on the declarations?

A There would have been. I wouldn't have started a declaration without having a discussion.

Q And walk me through the process of how the declarations were created.

A So there would have been reading, there would have been discussions, there would

have been a draft prepared. I would have written parts of the draft, the lawyers write other parts, and then a draft document is prepared, which I then edit and review.

As I say, it's an iterative process, and there would have been more discussion. I would have pushed certain elements that I feel are very important. I would have had discussion about other elements.

That's the process. It's no different for this case than other cases I've been involved in. There was no difference.

Q And who did you work with on preparing the four initial declarations?

A It was a different lawyer in this firm who has now left, and I haven't had any communication, obviously, with him for a number of months, and I'm sure the two people on my left know his name, and I just cannot recall sitting here now. I'm sorry, I just -- because, of course, you never meet the individual. You only ever do it online and

with Zoom calls. So I'm sorry, I can't give you his name. He was a lawyer in the firm who -- and then, obviously, there were meetings with Mr. Lowenstein as well.

Q And when you say it was a lawyer in the firm, you're referring to a lawyer at Lowenstein & Weatherwax?

A Yes, that's correct.

Q Okay, we've been going about an hour. Why don't we take our first break.

MR. LOWENSTEIN: How long?

MR. STOWELL: Why don't we go for 10 minutes.

MR. LOWENSTEIN: All right.

THE VIDEOGRAPHER: Okay, going off the record. The time is 9:32.

(A break was taken.)

THE VIDEOGRAPHER: We are back on the record. The time is 9:42.

BY MR. STOWELL:

Q Welcome back, Dr. Brecker.

Did you speak to anyone regarding

your deposition testimony during the break?

A I did not.

Q If I could ask our hot seat operator to pull up Exhibit 2051.

Dr. Brecker, can you see Exhibit 2051 on your screen?

A I can.

Q And you also have a copy in front of you today, correct?

A I do, yes.

Q What is Exhibit 2051?

A This is entitled Second Declaration, and this is a consolidated declaration relating to four IPRs.

Q And if we turn to page 150 of the declaration, is that your signature that we see on page 150?

A It is.

Q And did you sign this declaration on or about July 11th, 2022?

A Yes.

Q And when you signed the declaration,

you declared that you believe that all the statements in the declaration were true.

Was that an accurate statement when you signed the declaration?

A Yes, it was.

Q Do you still believe all the statements in the declaration are true?

A I do.

Q Are you aware of any errors or misstatements in Exhibit 2051?

A I'm not.

Q And how was this declaration created?

A Well, this is a consolidated declaration from my four prior declarations.

Q And what role did you play in preparing Exhibit 2051?

A So, obviously, I had a major role in the original declarations from which this is consolidated.

In terms of the cutting, pasting, and reformatting, that was done by

Lowenstein & Weatherwax.

Q So Exhibit 2051 incorporates some of the portions of your earlier declarations; is that correct?

A That is correct.

Q And did you play any role in selecting the portions from your earlier declarations that are incorporated into Exhibit 2051?

A Well, yes, because there would -- again, the whole process is one of back and forth, so discussions and --

Q So do you -- sorry, go ahead.

A So discussions, and then review.

Q And so do you remember selecting portions from your prior declarations for inclusion in Exhibit 2051?

A I don't remember a process where I or anyone else said, right, this paragraph must go in. It is a consolidated declaration of the opinions I gave.

Q And I'm just trying to figure out

who made the decision of which portions to consolidate.

Were you involved in the decision of which portions from the prior declarations to include in Exhibit 2051?

MR. LOWENSTEIN: Objection, form.

THE WITNESS: Yes, I would have been involved because I was involved in the discussions.

BY MR. STOWELL:

Q Okay. So you recall being involved in deciding which portions of prior declarations should be included in Exhibit 2051?

MR. LOWENSTEIN: Objection, form.

THE WITNESS: I cannot go through each paragraph and say this paragraph I specifically said should go in, and one other bit should not.

It was an iterative process by which the initial declarations were made, and then the relevant sections from those declarations

were put into a consolidated declaration.

I was involved throughout the process, obviously, but I can't tell you which specific -- if you're going to take me to a specific paragraph and say did I specifically say that this paragraph should or should not go in, I can't give you that detail.

I read through all the declarations and documents and made edits, and that's the process.

BY MR. STOWELL:

Q And my question was more general.

Just do you recall identifying any portions from the prior declarations for inclusion in Exhibit 2051?

MR. LOWENSTEIN: Objection, form.

THE WITNESS: Well, insofar as clearly the opinions I've expressed in the previous declarations had to go into this declaration.

BY MR. STOWELL:

Q Right, but we've discussed that

Exhibit 2051 is a consolidated version of the prior declarations.

Did you have any role in selecting which portions of the prior declarations were included in Exhibit 2051?

MR. LOWENSTEIN: Objection, form.

THE WITNESS: I would have had a role in the discussions that we had.

BY MR. STOWELL:

Q And did you identify any portions of the prior declarations that should be included in Exhibit 2051?

MR. LOWENSTEIN: Same objection.

THE WITNESS: Well, it would have been fairly obvious from the discussions as to the opinions I've given, and therefore I had to put those into the declaration.

I don't understand. You're asking me in general terms, and in a general answer, my answer is yes.

BY MR. STOWELL:

Q Okay. So you recall identifying

paragraphs in the prior declarations that you wanted included in Exhibit 2051?

MR. LOWENSTEIN: Objection, form.

THE WITNESS: Well, that's not a general question because you're taking me down to paragraph level, and the answer to that question is I can't give you paragraph detail.

All I can state is that it was essential that the opinions I had expressed in the initial declarations were put into this consolidated declaration, and I was involved in discussions and review throughout.

So I just -- I'm struggling. If you're going to take me to a particular paragraph and say did I specifically say that this paragraph must go in? The answer to that question is I can't tell you.

BY MR. STOWELL:

Q And that's not a question I have asked. I'm just asking whether you remember specifically identifying any paragraphs in the original declarations that should be included

in Exhibit 2051?

MR. LOWENSTEIN: Objection, form.

THE WITNESS: Well, again, you're asking me specifics. You've said do I remember a discussion about specific paragraphs, and the answer to that question is I don't know. I can't tell you about a specific paragraph.

I can tell you that I was involved in the discussion regarding the opinions that I needed to express in this consolidated declaration.

BY MR. STOWELL:

Q Did you speak with anyone besides counsel in preparing Exhibit 2051?

A I didn't speak to anyone other than the lawyers. When you say "counsel," are you referring to a specific individual?

Q Did you speak to anyone besides lawyers at the Lowenstein firm in preparing Exhibit 2051?

A No.

Q I understand you are charging £625 per hour for your work on this case; is that accurate?

A Yes, that's correct.

Q And how many total hours have you billed for your work on these matters so far?

A I haven't added it up.

I should state that I'm not on an hourly rate for the time I'm in the U.S. I have a daily rate that relates to a certain number of hours, but it's not like 24 hours. I mean, it's a daily charge.

I can't tell you the number of hours, the exact number of hours. I haven't added it up.

Q Can you provide an estimate?

A Well, again, it's tens of hours. I'd be surprised if it was more than 100 hours prior to coming to the United States. I don't think it's anything like that, but I don't know, I haven't added it up. I could be surprised if I looked it through, but I don't

know.

Q And you mentioned a daily rate for time in the U.S. What is your daily rate for the time you're in the United States?

A It's 8 hours a day.

Q And what is the compensation for 8 hours per day?

A It's £625 per hour.

Q So for each day --

A I'm sorry, multiplied by 8.

Q So for each day you're in the United States, you charge for 8 hours regardless of how many hours you put into the case; is that accurate?

A Yes.

Q How much income have you received from your work on these matters thus far?

A I have not added that up.

Q Can you give an estimate?

A Well, the estimate is based on the number of hours, and prior to coming to the states, I've said that think it's less than

100 hours. But I have to be completely honest, I have not added it up in preparation for this.

Q I noticed in your declaration that you use the abbreviation T-A-V-R, or TAVR.

What does TAVR stand for?

A So TAVR stands for transcatheter aortic valve replacement.

Q And is that a -- sorry, go ahead.

A The terminology, and the evolution of the terminology, and the way in which it differs in different parts of the world is an interesting bit of the history to this.

Q Is TAVR a term you regularly use in your practice?

A So in the United Kingdom, it is generally referred to as TAVI, T-A-V-I, and that is relating to transcatheter aortic valve implantation.

There is a reason why in the United States it changed from TAVI to TAVR. Prior to that, it had been known as PAVR or

PAVI.

Q And so if we use the term "TAVR" today, will you understand that that term means transcatheter aortic valve replacement?

A Yes.

Q I also noticed in your declaration you used the abbreviation "PVL."

What does PVL stand for?

A Paravalvular leak.

Q And is PVL a term that you use regularly in your practice?

A It is.

Q And so is it okay if we use the term "PVL" during today's deposition to refer to paravalvular leak?

A Yes, it is.

Q I also noticed in your declaration that you used the abbreviation "POSITA," P-O-S-I-T-A. What does POSITA stand for?

A So there are a couple of spellings, but it's a person of ordinary skill in the art.

Q And is POSITA a term you are familiar with from your work on patent cases?

MR. LOWENSTEIN: Object to the form.

THE WITNESS: I'm familiar with the term in any event, but yes, from patent cases.

BY MR. STOWELL:

Q Okay. So is it okay if we use the term "POSITA" today during the deposition to refer to a person of ordinary skill in the art?

A Yes, it is.

Q I may also use the term "THV" today to refer to transcatheter heart valves. Are you familiar with the term "THV"?

A I am. That is not a term that is in sort of current colloquial use.

Q Is it a term that's commonly used in the art to refer to transcatheter heart valves?

A THV? It's not an abbreviation that many people use, the abbreviation. Transcatheter heart valves is understood.

Q Okay. So for the purpose of today's deposition, we'll do our best to refer to transcatheter heart valves rather than THV. Is that okay?

A Yes.

Q If our hot seat operator could go to page 210 of 210 in Exhibit 2051. It's actually the last page of Exhibit 2051.

Dr. Brecker, can you see what you've called Exhibit B here in your declaration, Exhibit 2051?

A Yes.

Q And is this a list of the patent cases in which you have served as an expert?

A Yes. It obviously doesn't include the current ones.

Q Now, have you been involved in other types of legal cases besides patent cases?

A Yes.

Q And what types of cases, aside from patent cases, have you been involved in?

MR. LOWENSTEIN: Objection, scope.

THE WITNESS: So I have been involved in clinical negligence cases in the United Kingdom, and as part of my role at St. George's, I undertake serious instant review at St. George's, at the hospital.

BY MR. STOWELL:

Q What is a serious instant review?

A So that's where some activity has had an adverse outcome, and it's necessary to assess whether there were avoidable factors, and to address learning from those potentially avoidable factors that may have led to an adverse outcome. And I've also undertaken that for other hospitals.

Q Is the serious instant review part of a legal proceeding?

A Often it would involve a coroner and an inquest, so yes. They're not synonymous with that.

Q You mentioned that you have participated in clinical negligence cases in the UK.

Have you ever participated in any negligence cases in the United States?

A I have not.

Q How many clinical negligence cases would you estimate you've participated in over the years?

A I couldn't give you a number.

Q Can you provide an estimate?

A So it depends what you mean by an involvement. Quite often I would get asked to review a case, either for an external hospital or a patient's family, and I do quite a lot of those reviews. In fact, they don't lead to anything beyond the review. So it's a one-off review of a case, and then there is no further involvement.

Q In any of the clinical negligence cases, do you submit sworn testimony, either in court or through a declaration or affidavit?

A Yes. Typically, there would be a report on the case.

Q And is that a report that you would prepare?

A Yes.

Q And roughly how many reports do you think you've prepared over the years?

A I can't give you an answer to that.

Q Are you ever deposed as part of the clinical negligence cases?

A There is no deposition type process for them. Clinical negligence is a civil matter. Once an expert report has been submitted, there will then be negotiation between the parties. Each party will have an expert report, although increasingly there would be what is known as a joint expert report, where an individual is appointed by both parties.

Once the report has been put in, then there's no deposition type process. The only proceeding would be if the case then proceeded to court. That is increasingly rare. So nearly always there is either no

case to answer, or the case would settle, and so there would be no further involvement from myself other than the report.

Q How many times have you testified in court for a clinical negligence case?

A So as I said, it's a very rare scenario. Not for several years, let me put it like that. Possibly a total of 30 years, 25 years of doing it, maybe half a dozen times, maybe a few more, maybe a few less.

It's exceptionally rare for a case to go to court. It does happen, but as I say, I have not been called as an expert witness in a clinical negligence trial for several years.

Q Turning back to Exhibit B to Exhibit 2051, the first case listed there is AGA v. Occlutech UK.

Which party did you serve as an expert for in that case?

A I served for AGA.

Q And what was the technology at issue

in that case?

A This was a medical device to close what is known as a septal defect, so holes in the heart. And the devices are made with like a Nitinol mesh with a fabric.

Q And when you served as an expert on that case, had you had experience with septal defect devices prior to the case?

A Oh, yes, huge amount.

Q It says "Trial" next to the case name there. What does "Trial" indicate on your list?

A So this was a court case of patent infringement, and it was a case held in the high court in London.

Q And AGA was the Patent Owner in that case; is that correct?

A Well, you're asking details of something from a long time ago, and I believe so, but I don't -- I can't remember the details of it. I don't remember the specific details.

I think it would have been an AGA patent, and Occlutech had infringed. So that is my recollection, but beyond that, I really haven't looked at that since 2009.

Q And did you testify at trial in that case?

A Yes. Yes, I would have done.

Q And did you prepare any sort of written declaration or report for that case?

A I would have done.

Q And do you recall the outcome of the case?

A So there were two trials, and I just can't remember the nuances, whether there was a license, whether the patent wasn't infringed. I just don't remember all of the outcomes. I don't remember the two outcomes.

My recollection is that one did not -- was not successful for AGA and one was, but I honestly, sitting here now, I cannot recall the details, and I certainly haven't had any involvement since 20- -- well, since

the latter trial. I don't remember the details.

Q And so the second one on your list here is labeled as 2014, AGA v. Occlutech.

Did that case also involve septal defect devices?

MR. LOWENSTEIN: Objection, form.

THE WITNESS: Yeah, so they were both septal -- they were the same device.

My recollection was one was to do with the design; and the other, my recollection -- and you'll have to forgive me because, as I say, this is not anything I reviewed in preparation for today.

My recollection is that the discussion centered on whether or not the procedure that had been done as part of a live case demonstration of the technology many years earlier, whether that had disclosed the technology, something like that.

So that was the type of issues. As I say, it was a septal defect closure device.

It is a device that is put in through the groin into the heart to close a hole. I did, still do, a very large number of those procedures.

It's a device of self-expanding Nitinol with fabric in it, and as I say, I've done a lot of those procedures, written a book on it, and done research on it, so yes.

BY MR. STOWELL:

Q The second case on your list is Edwards v. CoreValve. I take it you were an expert for CoreValve in that matter; is that correct?

A So I wouldn't say I was an expert.

I was asked as a user of CoreValve to give an impact statement -- this is my recollection, and again, I haven't looked at this for 10 years.

My recollection is that Edwards were -- and I may be wrong, so I want to preface my remarks by that -- but my recollection on this specific issue was what

would be the impact if CoreValve were to be removed from the market? What would the impact of that be on patients in terms of the harm that would come to those patients with aortic stenosis who would die as a result of not having CoreValve available.

That is my recollection, but as I say, I haven't looked at it for 10 years.

Q Is it fair to say you submitted that impact statement on behalf of CoreValve in that case?

A So I can't recall if it was at that point still CoreValve or Medtronic, but yes, it was not on behalf of Edwards because it was the impact of removing CoreValve, which I believe Edwards were attempting to do, but I don't recall. I don't -- honestly, I just don't recall the details.

I was not an expert witness in the case, so I was not an expert witness in the trial that had led to that, and I was not involved in anything other -- I was one of

many people who had given impact statements.

So perhaps it's incorrect to list it there as a patent expert. I was giving a statement as a user of one of the valves, but in full transparency, I feel I should declare that.

Q I appreciate that. Thank you.

If we go down to the fourth entry, that entry says 2018 Boston v. Edwards.

A Yes.

Q You were an expert on behalf of Boston in that matter; is that correct?

A That's correct.

Q And Boston refers to Boston Scientific; is that right?

A That's correct.

Q And you served as an expert in both an IPR and at a trial in that case; is that correct?

A Yes. Dr. Buller and I were both -- I think we were both experts for both parts of that.

Q And Dr. Buller was one of the experts for Edwards in that matter, correct?

A That's correct.

Q The fifth entry there is Abbott v. Edwards. Did you provide testimony on behalf of Abbott in that matter?

A I did not. I was asked -- I think I was asked, again, to give advice, and I was not involved in that case, so I did not give -- I may have written a statement, but I did not participate as an expert witness.

I was approached, do you know initially by Edwards. So I was initially approached by Edwards, but I had already declined. So, again, I can't remember the precise timeline of this.

I know I was approached by Edwards' lawyers in one of the cases, either that one or the Meril case. I think it was the Abbott case, but again, I don't recall.

Either way, the most that I would have done is written a statement for Abbott,

and that was the sum total of my involvement. I was then not involved at all.

Q And so did you prepare a statement for Abbott?

A It would have been a very, very short statement, I think. It would have been a very short piece of advice about the technology.

Q And do you know if that statement was ever filed with a court?

A I do not, and I don't think it was. I wasn't involved in the case after that statement. So it may have been, but I don't -- I certainly had no further involvement. It was a very short involvement.

Q You also have listed here a 2020 case between Edwards and Meril. You served as an expert for Meril in that case; is that correct?

A That is correct. My recollection is that that was the case that Edwards had approached -- or that Edwards approached me

on, but I had already reviewed information from Meril, so I immediately declared the conflict and was engaged by Meril.

Q And did you testify at trial in that case?

A I did.

Q And then next you have two IPRs, 2020 and 2021, between Medtronic and Teleflex.

Which party were you serving for as an expert in those IPRs?

A So I was engaged by Medtronic.

Q And what is the technology at issue in those IPRs?

A This is an interventional cardiology device known as an extension catheter.

Q And is that a device that you used in your practice prior to becoming involved in the IPRs?

A I had.

Q And did you submit declarations in both of the IPRs that are listed in Exhibit B?

A Yes.

Q And because Medtronic is listed first there, I take it you were challenging the patentability of some Teleflex patents in those IPRs; is that correct?

A Yes.

Q I'm going to ask our hot seat operator to pull up an exhibit that should be listed as Edwards v. Boston, IPR2017-00060.

THE VIDEOGRAPHER: I'm sorry -- oh, yeah, I see it. Sorry, my bad.

BY MR. STOWELL:

Q Dr. Brecker, do you recognize this document?

A Yes. It's one of a declaration that I had submitted in this case.

Q Okay. And to be clear, this is a declaration you submitted in one of the Edwards v. Boston IPRs; is that correct?

A Yes.

Q And if we turn to page 45 of the document (PDF page 47), is that your signature on page 45?

A Yes, it is.

Q And did you sign this declaration on or about June 23rd, 2017?

A So I would have done.

Q And did you believe that the statements in the declaration were true and correct when you signed the declaration?

A I would have done.

Q Are you aware of any mistakes in this declaration?

A So you're asking me about something from five years ago. I have no doubt there are some errors, but I can't sit here -- I haven't looked at this for some time, so I can't answer your question. I don't -- I'm not aware. I don't know.

Q Do you remember ever making any corrections to this declaration?

A I don't know.

Q And we're going to mark this with a new exhibit number so that it's clear for the record. My colleague is just pulling that up,

so give me a second here.

MR. LOWENSTEIN: Can you email me any new exhibits that you enter in this deposition?

MR. STOWELL: Sure, we can send you a copy. So let's mark this declaration of Stephen Brecker as Exhibit 1100 in this IPR -- or in the four IPRs, okay?

(Exhibit 1100 was marked for identification.)

BY MR. STOWELL:

Q This declaration was submitted --

MR. LOWENSTEIN: I'll object just to preserve my objection. Go ahead.

MR. STOWELL: Sorry, Counsel, what was the objection?

MR. LOWENSTEIN: Hearsay. At least hearsay, possibly others, but we'll see.

BY MR. STOWELL:

Q So as we sit here today, Dr. Brecker, you don't recall making any corrections to this declaration at any point

in time; is that fair?

A I haven't said that. I just don't recall. I have not -- I may well have not looked at this document since the -- since the date or during that IPR.

So there were a lot of documents in that case. You're showing me the front page of one of them. I can't answer your question. I don't know.

Q Do you remember the patent that was issued in this IPR? It's listed there on the front page, 8,992,608.

MR. LOWENSTEIN: Objection, scope.

Go ahead.

THE WITNESS: Yes, I recall the patent.

BY MR. STOWELL:

Q And was the patent referred to as the Haug, H-A-U-G, patent during this IPR?

A I referred -- we referred to it as the '608 patent.

Q Do you recognize the '608 patent as

having an inventor by the name of Haug, H-A-U-G?

MR. LOWENSTEIN: Objection, scope.

THE WITNESS: So I haven't looked at that patent for a long time. I believe that is the name of the inventor.

BY MR. STOWELL:

Q Do you recall the technology that the '608 patent dealt with?

A So the '608 patent is a complex and long patent. This case related to the paravalvular leak solution that was innovative in the '608 patent.

Q And when you say the paravalvular leak, was that paravalvular leak around a transcatheter heart valve?

A Yes, it was.

Q And was one of the solutions for paravalvular leak that was described in the '608 patent a fabric seal on the outside of the valve?

MR. LOWENSTEIN: Objection. I'm

going to also add that this exhibit is untimely. Objection, form. Objection, scope.

THE WITNESS: So I have not looked at this patent and all the language for some time. I'm aware that this included a paravalvular leak solution with a bunched up seal.

BY MR. STOWELL:

Q What do you mean by "bunched up"?

A So you may well be asking me about claim construction in this case, and I just don't -- I'm not prepared to do that. By "this case," I mean the Boston IPR case.

I'm aware of the invention and how this device worked, and the device worked by bunching up and creating flaps and pockets.

Q And when you say "bunching up," what was bunched up?

MR. LOWENSTEIN: Objection, form, scope.

THE WITNESS: Yeah, I've not reviewed this patent or my declaration in

sufficient detail to go through this.

I'm happy to do that now, but I would need time to read through the patent and read through my declaration.

BY MR. STOWELL:

Q So when you referred to something that was bunched up, what structure were you referring to?

A Well, that's what I say. I'm very happy to read through the patent and read through my declaration and answer your questions accurately.

MR. LOWENSTEIN: I'd just like to state for the record that the only thing that Dr. Brecker can see is the cover page of this exhibit, and nothing more, and it has not been sent to counsel for Aortic, so we preserve all of our objections.

BY MR. STOWELL:

Q Why don't we turn to page 24 of what we have marked as Exhibit 1100.

MR. LOWENSTEIN: Same objections.

THE WITNESS: So I would like to make a request, and that is that I have time to read that document.

MR. STOWELL: Let's go to page 24, please. This is page 22.

MR. LOWENSTEIN: Excuse me, can you please send us the document? I've asked three times.

THE VIDEOGRAPHER: The document --

MR. LOWENSTEIN: There's a Box document. Please allow us to see the entire document. We're not going to answer any more questions until you give us the document in a form that Dr. Brecker can look at.

THE VIDEOGRAPHER: There's a folder. The documents are in the Box folder that can be downloaded.

(Discussion held off the record.)

THE WITNESS: So this is a document of 113 pages that I haven't looked at for several years.

If you're going to ask me questions

about it, I'm going to need to have time to read it.

BY MR. STOWELL:

Q Well, let's start with paragraph 48 that's on page 24.

MR. LOWENSTEIN: Objection, form. Objection, scope. Objection --

MR. STOWELL: Mr. Lowenstein, please allow me to finish my question before you object.

Let's start with paragraph 48 on page 24. Can you review this paragraph, and you're welcome to review the paragraphs before and after, and let me know if this is an accurate description of your understanding of what the '608 patent --

MR. LOWENSTEIN: Excuse me. You can review whatever you want.

MR. STOWELL: Hold on. Dr. Brecker, just a second.

Mr. Lowenstein, please allow me to ask my question. You spoke over me again

there.

MR. LOWENSTEIN: I did not, but you're not here to tell the witness what he can and cannot look at in the document.

He already explained to you that this is a five-year-old document, so don't tell him he can only look at such and such paragraphs.

MR. STOWELL: Mr. Lowenstein, this is not an objection that you are making. You are instructed to simply make a one-word objection. You are coaching the witness.

MR. LOWENSTEIN: I am happy to move forward. Can we please get along with the deposition? Let's move on with the --

THE WITNESS: So you're asking me about the '608 patent that I have not looked at for a very long time, and in order to answer your questions, I am going to need to have time to review the '608 patent.

BY MR. STOWELL:

Q Okay. So you would be unable to

answer the question regarding paragraph 48 without reviewing the entire declaration and the '608 patent; is that fair?

MR. LOWENSTEIN: There is no question pending about paragraph 48. Objection.

THE WITNESS: That is not -- that is not fair. What you have just said is not fair.

You're saying -- I don't know what question you're going to ask me, and what I'm saying is I need time to review a five-year-old declaration that runs to 113 pages, and the '608 patent, that my recollection is it runs to a very large number of pages.

(Beeping sound.) Sorry, I don't know what -- there was some kind of alert.

What you're asking me to do, I think, I need to have time to review the '608 patent and my declaration, and then I would be very happy to answer your question on

paragraph 48.

BY MR. STOWELL:

Q Okay. But as we sit here right now, can you tell me whether paragraph fairly summarizes what the '608 patent was about?

MR. LOWENSTEIN: Objection, form. Objection, scope.

THE WITNESS: Sitting here now, you're asking me does paragraph 48 summarize the '608 patent? And without reviewing the patent that runs to something like -- and this is off the top of my head -- 80 pages, I can't answer your question. I need to review the patent and review my declaration.

BY MR. STOWELL:

Q Do you have any reason to believe that the material in paragraph 48 of Exhibit 1100 is inaccurate?

MR. LOWENSTEIN: Objection, form. Objection, scope. Objection to the exhibit.

THE WITNESS: So you're asking me about a document that runs to 113 pages and is

five years old that I have not looked at.

You're asking me about a patent that I have not reviewed for the purposes of this deposition.

In order to answer your question, I need to review the patent and review my declaration, and then I would be very happy to answer your question.

BY MR. STOWELL:

Q In this IPR2017-0060 that we've marked as Exhibit 1100, you were arguing that the challenged claims of the Haug patent were valid, correct?

MR. LOWENSTEIN: Objection, form. Objection, scope. Objection to the exhibit.

THE WITNESS: You're asking about detail of the case that I simply am not prepared to answer on the hoof without having reviewed the documents that I need to answer your questions accurately.

BY MR. STOWELL:

Q So you don't recall what your

position was with regard to the validity of the '608 patent in this IPR?

MR. LOWENSTEIN: Objection, form. Objection, scope. Objection to the exhibit.

THE WITNESS: This was a very complex case that involved both IPR and trial. I gave a number of declarations, a number of depositions, and testified at trial.

You're asking me about something from five years ago. I need to review the patent and my declaration, and I need to have the time to do that, and then I would be happy to answer your questions.

BY MR. STOWELL:

Q Okay. But as we sit here, is it fair to say you don't recall what your position was with respect to the validity of the '608 patent in this IPR?

MR. LOWENSTEIN: Objection, form. Objection, scope.

THE WITNESS: No, that's not fair to say for the reasons I gave earlier. It is not

fair to characterize what I have said by saying I can't give you an answer.

I am saying I can give you an answer, but I would need to review my declaration and the patent and know what question you're asking.

BY MR. STOWELL:

Q Okay. So in order to provide a response, you would need to review the patent and the declaration?

MR. LOWENSTEIN: Objection, form.

MR. STOWELL: Is that your testimony?

MR. LOWENSTEIN: Objection, scope.

MR. STOWELL: Just a second. Mr. Lowenstein, you spoke over me once again. Please wait on your objections until the question is complete.

MR. LOWENSTEIN: Sorry. When the question is so objectionable, I can't restrain myself.

THE WITNESS: Could you ask your

question again because I've forgotten it.

BY MR. STOWELL:

Q So your testimony is that in order to provide a response to my question regarding your position in this IPR, you would need to review the patent and the declaration first?

MR. LOWENSTEIN: This IPR? What IPR? Can you please be more precise?

MR. STOWELL: Mr. Lowenstein, that is an inappropriate objection.

MR. LOWENSTEIN: No, it's not.

MR. STOWELL: It's happened numerous times.

MR. LOWENSTEIN: You're saying "this IPR." Are you talking about the Boston Scientific five-year-old IPR, or are you talking about the present IPR?

MR. STOWELL: Mr. Lowenstein, you are coaching this witness. This is inappropriate.

MR. LOWENSTEIN: Okay. Objection, form, scope.

THE WITNESS: I'm sorry, I've lost my train of thought here. Could you repeat the question?

BY MR. STOWELL:

Q I will. So your testimony today is that in order to provide a response to my question regarding your position on validity in the Boston IPR, you would need to review the patent and the declaration first?

MR. LOWENSTEIN: Objection, form. Objection, scope.

THE WITNESS: You are asking me about something from five years ago. I think it is only reasonable that I am given time to review the material on which you wish me to provide an accurate answer.

I could give you an answer on the hoof. I don't think that's very sensible for me to do.

BY MR. STOWELL:

Q In this IPR, do you recall that Dr. Buller argued that the challenged claims

of the '608 patent were invalid?

MR. LOWENSTEIN: Objection, scope.

THE WITNESS: You're asking me about a case from five years ago in which there was an IPR and a trial. There were complex issues. My recollection is there were four-way arguments. There were arguments both in each direction, both on this and on other patents.

I would need to review material to answer questions that you are asking me about a case from five years ago. I've not prepared to review this material. I was not asked to review this material in preparation for this deposition.

BY MR. STOWELL:

Q Do you recall what the outcome of this particular IPR in the Boston case was?

MR. LOWENSTEIN: Objection, form. Objection, scope.

THE WITNESS: I cannot recall -- I can recall the outcome of the trial, but

simply to try to give you a one-word answer, I can't do that.

As I said, this was a very complex case, it involved a lot of issues, and I don't recall all of the details from five years ago. A lot has happened in the last five years, and I have not reviewed any material relating to this case in preparation for my deposition today.

BY MR. STOWELL:

Q Do you recall whether the Board in this Boston IPR involving the '608 patent found the challenged claims of the '608 patent invalid?

MR. LOWENSTEIN: Objection, form. Objection, scope.

THE WITNESS: So you're asking me about a case from five years ago, and in the interim period, a lot has happened.

I'm very happy to prepare answers to all of your questions on this case, and I could give you an answer on the fly, but I

want to be accurate, and therefore I'm going to need to review material, and it's only fair that you give me time to review the material in order to determine my answers.

BY MR. STOWELL:

Q And to be clear, I'm just asking for your best recollection today. If you don't have a recollection, that's fine.

MR. LOWENSTEIN: Objection, form. Objection, scope.

THE WITNESS: So I simply think it's inappropriate for me to give a vague recollection on something from five years ago that could potentially have importance.

You're asking me very important questions, very interesting questions actually, and I'd like to answer those accurately.

BY MR. STOWELL:

Q I understand from your declaration that you have performed over 1300 TAVR procedures; is that correct?

MR. LOWENSTEIN: Are you talking about the declaration in the current case, or are you still asking about the Boston Scientific case?

MR. STOWELL: Mr. Lowenstein, it is up for the witness to ask for clarification if he needs that.

MR. LOWENSTEIN: No.

MR. STOWELL: It is an improper objection.

MR. LOWENSTEIN: Look, can we please be adults? You just asked 10, 20 minutes of questions about one IPR, then you're switching to the other, and you said "this IPR."

Can you just clarify your question? That's it.

MR. STOWELL: Mr. Lowenstein, you are continuing to make inappropriate objections.

MR. LOWENSTEIN: Let's move on with our lives. Please ask a question.

BY MR. STOWELL:

Q Dr. Brecker, I understand from Exhibit 2051 that you have performed over 1300 TAVR procedures; is that correct?

A Yes, that's correct.

Q And I understand that you have also proctored over 600 TAVR procedures; is that correct?

A Yes.

Q And are the proctored cases separate from the 1300 cases that you have performed?

A There's some overlap, and I can explain that. 1300 cases -- and it's more than that now. We're doing lots of cases every week. My hospital is doing up to 10 cases a week, so the numbers are a moving target.

In proctoring, there are three different kind of models. One is that you would stand behind the patient -- sorry, stand behind the doctors who are doing it. You would not even touch the catheter or the

device or the patient.

There's another model where you stand in the copilot seat. So the two operators would stand by the bed, the first operator closest to the access site, the second operator on their right, and a lot of the proctoring I would have done I would have done like that. You know, holding the wire, moving the wire, assisting, and that's a procedure that I would have done.

And then a much smaller number would be where, as a proctor, you actually do the procedure. You're the first operator.

So in assessing the numbers, I mean, I've been involved in -- "been involved in" -- a very large number, and it just depends how you define the first operator, second operator, or proctor. So I could say that some of the proctored cases were in addition to the 1300. There's inevitably a bit of overlap, but it's more than 1300 now.

Q And I understand that you have

performed TAVR procedures with Medtronics, CoreValve, THV, and the follow-on iterations of that; is that correct?

A Yes, that is correct.

Q How many of the 1300 TAVR procedures were with Medtronic THV?

A Well, more than 50%, probably more than 60%, but I couldn't give you the exact number. Could be more than that.

Q Sorry, go ahead.

A So my current practice is probably 60% Medtronic, 40% Edwards Sapien.

Q And how many of the proctored cases were with a Medtronic product?

A Oh, so all of the proctoring I did was -- is with Medtronic.

Q I also understand that you have performed TAVR procedures with Boston Scientific's LOTUS valve; is that correct?

A Yes.

Q And how many of your 1300 TAVR procedures were with the LOTUS valve?

A So that would be a small percentage. Obviously, that valve is no longer around. I can't give you the exact number.

Q What about an estimate of how many implantations you've done with LOTUS?

A Could be less than 100. Could be high tens, like 60, 70, something like that.

Q Okay. And then I also understand that you have performed TAVR procedures with Edwards' Sapien line of valves; is that correct?

A Yes.

Q And how many of your 1300 TAVR procedures were with the Sapien line of valves?

A So I haven't done the calculation. The most accurate thing I can tell you now is I'm doing, I would say between 30- and 40%. I think I said 40% Edwards before. So, you know, it could be 36%. I haven't looked recently, but certainly we're using Edwards every week. I can't give you the exact

number.

Q And is your current usage of Edwards higher than it's been in the past?

A Yes.

Q Did you ever implant the original Sapien valve?

A The first one we would have implanted would have been the -- yes, the Sapien, prior to the XT.

Q And can you estimate how many Sapien valves you have implanted?

A I can't. I can't give you the exact number.

Q Can you give an estimate of the number?

MR. LOWENSTEIN: Object to the form.

THE WITNESS: So for that particular valve, we were predominantly implanting self-expanding valves then. So for the original Edwards Sapien, some tens of valves. Again, less than 100. I can't give you the exact number.

BY MR. STOWELL:

Q Have you ever implanted the Sapien XT valve?

A Yes, I think I have. Again, we wouldn't necessarily have documented it on spreadsheets as XT.

Q Can you provide an estimate of how many XT valves you think you may have implanted?

A I can't.

Q What about Edwards' Sapien 3 valve? Have you had an opportunity to implant the Edwards' Sapien 3 valve?

A Yes, I have.

Q And can you provide an estimate of how many Sapien 3 valves you've implanted?

A I can't give you the number. I can give you our current numbers at St. George's where I work to give you a sense, but we are doing between 5 and 10 procedures per week, of which between 30- and 40% is Sapien. The majority of those now would be Sapien 3 Ultra,

but the largest size would be Sapien 3.

Q Has your hospital been implanting Sapien 3 since it became available in the United Kingdom?

A I can't give you the exact dates.

Q Roughly how many years do you remember implanting the Sapien 3 valve now?

A 3 or 4 years, something like that.

Q And you mentioned your hospital is using the Sapien 3 Ultra valve. Have you actually implanted the Sapien 3 Ultra valve?

A Yes. That's the commonest type of valve that we now use for the balloon-expandable.

Q Okay, we've been going about another hour. Why don't we take a break, 10 minutes again.

MR. LOWENSTEIN: Sounds good. Thank you.

THE VIDEOGRAPHER: Okay, going off the record. The time is 10:48.

(A break was taken.)

THE VIDEOGRAPHER: We are back on the record. The time is 11:00 a.m.

BY MR. STOWELL:

Q Dr. Brecker, did you talk to anybody about your deposition testimony during the break?

A I did not.

Q Would you agree with me that Edwards is a pioneer in the field of transcatheter heart valves?

A I would.

Q And why would you agree with that statement?

A They were able to introduce one of the first two transcatheter valves that have proved to be successful solutions to the problem of the transcatheter valve.

Q When you say the problem of a transcatheter valve, what problem are you referring to?

A Sorry, I misspoke.

To dealing with the problem of

aortic stenosis in patients who are not suitable for open heart surgery by the development of the transcatheter valve.

Q Have you ever worked with Edwards aside from implanting Edwards' valves?

A It's possible, although I can't recall. I have done meetings with them and educational activities, but I've not worked with the company under a contract, if that's your question.

If I could just go back to the previous question about pioneering. Of course, the real pioneer was PVT, who developed the valve. Of course, it was then taken over by Edwards. So I kind of think of PVT and Edwards as one entity, although it started with PVT.

Q And you mentioned that Edwards launched one of the first two THVs that were on the market. The company that launched that was Edwards at the time, correct, not PVT?

A That's correct. The very first

implant would have been done I think before the acquisition, but that would have been with the original Cribier valve.

Q Before the break we were discussing some of the different THVs that you have implanted, and we were discussing the Medtronic THV.

Were all of the Medtronic THVs that you've implanted self-expanding valves?

A Yes, they were. Yes, they are.

Q And do you understand what I mean by "self-expanding"?

A I do.

Q And what do you understand that term to mean?

A Well, within the field of transcatheter valves, there is an understanding of a binary division between two methods of deployment, and I'm talking about the time period between 2000 and 2010 perhaps, so not including the LOTUS valve.

But when transcatheter valve

implants started, when I started doing them in 2007, it was pretty much a binary distinction between balloon-expandable and self-expandable.

Now, there are different methods of self-expansion, and certainly outside of the field of transcatheter valves, self-expansion could mean something different, but effectively those terms were used almost synonymously with the type of valve, where people wanted to refer to the valve without naming the company or brand name.

So they would say I think this patient would do well with a self-expanding valve, and the understanding was that that was a Medtronic valve; and someone might say this patient would do better with a balloon-expandable valve, and at the time, it was understood that meant Edwards.

So there is an understanding of what "self-expanding" means, but that is -- it's limited to perhaps the experience of what

transcatheter valves were available at the time that the term is being used.

Q You had mentioned the LOTUS valve may not fit into one of the buckets.

What did you mean by that?

A Yes, the LOTUS valve was a very interesting design, and it was called "mechanically expanded."

So it was not -- it was neither balloon expandable -- you could blow a balloon up in it afterwards, and you could expand it after deployment, but it was referred to, perhaps in order to try to differentiate it, as mechanically expanded.

And what that meant was that quite a long frame was shortened, and as it shortened, it expanded, as frames do. So as it shortened, it expanded outwards. And then there was a complex locking mechanism whereby the valve would be locked so that it wouldn't unspring. Now, in fact, that could happen, which was one of the difficulties with the

device.

But it was called "mechanically expanded" because the deployment was a very deliberate and active process of rotating an activator that would shorten the device and expand it at the same time.

Q And when did the LOTUS valve become available for physicians to use?

A So I don't have a clear recollection of the date, although 2014 is in my mind as to when I may have done the first implant. It's possible I did some implants before that with very early versions. I don't recall.

It was available before that, so it would have been available before then. So I can't remember exactly the date.

Q In 2012, what THV devices were commercially available in the UK?

A Well, certainly the Medtronic and Edwards. I don't recall if LOTUS was commercially available in 2012. It may have been in clinical trial then.

And, of course, the commercial date is less relevant than when valves were starting to be used because all of them were used in clinical research and registries prior to regulatory approval.

I'm trying to think when -- the Direct Flow was probably available then. The Symetis valve may have been available then.

I don't have an absolute recollection of other valves that were commercialized. All of these valves I mentioned were in clinical trial usage, maybe not all in the UK. Maybe some of them were in other countries.

Q You mentioned Direct Flow. Which of the two buckets would the Direct Flow valve fit into?

A Well, again, I can't -- I never used -- I never deployed it and I never used it, so I can't answer that question.

Q Did you ever use the Symetis valve?

A I did not.

Q Do you know which bucket, self-expanding or balloon-expandable, the Symetis valve would fit into?

A That would be self-expanding.

Q Do you have any experience with balloon-expandable THVs besides the Sapien line of products?

A So I have not used other balloon-expandable valves myself in my own practice other than the Sapien line of products.

Q Are you aware of any other balloon-expandable THVs that were in clinical trials or on the market prior to 2012?

A Not prior to 2012. No, I don't think so. It's possible that there was, but I can't recall at this point.

Q Earlier you mentioned that doctors would talk about patients being better suited for a self-expanding valve or a balloon-expandable valve.

What conditions would make a self-expanding valve better for a patient?

A So it's difficult to answer your question without giving it more context, because the way this whole field has evolved is fascinating and exciting, and we've learned a lot along the way.

So an answer that I might give to you now, we have a very good idea of which types of patients' anatomy are better suited to a self-expanding valve, and that knowledge has really been acquired over a long period of time.

To give you some examples, there is a general view that the type of gradients that you are left with when undertaking valve-in-valve TAVI -- so that's where you are putting a transcatheter valve in a previously placed, but now degenerated surgical valve -- there is a view that self-expanding technology is better in that setting because the design of the valve is supra-angular -- in other

words, the functioning part of the valve lies above the annulus, that's the bit that actually opens, not the base of the leaflet, just the opening is above the annulus -- and you are able to achieve higher valve areas. That was known quite early on.

Another example where a self-expanding would be preferable is where there is heavy calcification in the left ventricular outflow tract.

So one of the most feared complications of balloon-expandable transcatheter valve is aortic root rupture, and that is highly correlated to heavy calcification in the outflow tract. So many cardiologists feel that heavy calcification in the outflow tract is an indication for self-expanding technology.

To turn things around, there are certain anatomies that are much better suited to balloon-expandable technologies. Where you feel that you want to regain coronary access,

and your choice is between, for example, a Sapien and a Medtronic valve, many cardiologists feel there are benefits to having the lower frame of the Sapien valve rather than the tall frame of the Medtronic valve in order to regain coronary access. Now, there are exceptions to that rule as well. And I could go on.

There are other settings where, for example, in a valve-in-valve, you would want a balloon-expandable valve, and that is, for example, where you have a surgical valve that's failed in a young patient where you may want to have coronary access, but more importantly, where you may need another transcatheter valve in the future.

Now there's a big debate as to which type of technology you should put in first, and many people would say, well, if you've got a surgical valve that's failed -- and I had a patient like this just a short while ago, age 66, he's going to need another transcatheter

valve, so we had to think.

You kind of have to think about what are we going to do in 10 years' time or 15 years' time or, hopefully, 18 or 20 years' time with this guy, and we elected to put in a Sapien valve first, and there are methods that you can do to expand the surgical valve that's in there to make space.

The one final area that I would say you would favor a self-expanding technology is if your coronary height is very low. So if your coronaries are low, it's felt that the balloon-expandable valve may split the native leaflets and cause the other feared complication of TAVI, which is acute coronary occlusion.

And I should say, as my final remark on this, that coronary occlusion and aortic rupture are the two most feared complications of TAVI. Those are the ones where you have a high risk of mortality. There are others, like value embolization, but those are the two

more common ones.

Q Thank you for that explanation.

In this IPR, we're interested in roughly the 2012 time frame. Those, you know, benefits of self-expanding and balloon-expandable valves that you just described, would those have been known in 2012?

A Yes. The one that may not is the sequence of transcatheter valves that you would want to do in a patient who is young, because that's something where the indication has increased.

So now a patient in their 60s who's had a previous surgical valve, we have no worries about doing a transcatheter valve-in-valve implant. In 2012, I think the surgeons would probably have said we'll do a reoperation, we'll do another surgical valve, and then you can do a TAVI in 15 years' time.

But the other ones I mentioned — the valve-in-valve in general, coronary occlusion,

outflow tract calcification and rupture — that was all known in 2012.

Q And who at the hospital will make the decision about which type of valve to implant?

A So from the very beginning of this technology, unlike almost any other procedure, something called a heart team approach evolved, and it was very refreshing and it was very exciting, because prior to that, pretty much an individual physician would make an individual choice about a patient.

Now, things did change with coronary disease and the development of what was known as a multidisciplinary team meeting, but that's taken a long time to evolve, and it really was only evolving in 2012, I would say.

For transcatheter valves from the outset, there was a recognition that you had to have a multidisciplinary heart team approach, not just with interventional cardiologists and surgeons, but also imaging

cardiologists, intensive care unit doctors.

And so from the outset, the choice of valve has been made at a collaborative multidisciplinary team meeting where you review the echo and the CT scan and things like that.

Q So in 2012, who are the people at the hospital that would have been involved on the heart team?

A So that would include the people I just mentioned: interventional cardiologists, cardiovascular surgeon, imaging cardiologists, and often there was someone from the intensive care unit, not always.

And then for specific cases, you may call in other particular specialties to join the meeting, very commonly vascular surgeons if the cardiovascular surgeon was not a vascular surgeon. In the U.S., typically my experience was that the cardiac surgeons were also vascular surgeons. That's a very distinct separation, for example, in the UK;

and respiratory medicine for patients with lung disease, things like that.

Q Would you agree that TAVR procedures encompass many different delivery routes to the heart?

A Yes, there are many potential delivery routes. The overwhelming majority now are transfemoral. The vast, vast, vast majority are transfemoral, but many other potential routes have been tried over the years.

Q What are the potential routes that you're aware of as having been tried for a TAVR procedure?

A Okay, so there's a lot.

The ones that I have heard of people doing and/or done myself would include, firstly, transapical.

Now, at the start of transplant aortic valve implantation, for the Edwards, depending on which series of patients you look at and studies, but it was often a 50/50 split

between transfemoral arterial and transapical.

For the Medtronic valve, and now for Edwards as well, there is the so-called subclavian or axillary artery approach. They're anatomically different, there are slightly different entry sites, and those can be done either, as I say, subclavian or axillary. And then there are different methods of doing it either with a small incision and cutdown onto the vessel or a percutaneous needle being advanced into the vessel directly.

The original method, which was discarded quite quickly, was a transvenous approach, which went through the vein, but this was the original method that Cribier had tried because the devices were, frankly, too large for the femoral artery, and it was also felt that a venous rupture was less serious than an arterial rupture. That's not always the case.

But the method was extremely

complicated and very challenging technically of going up through the femoral vein into the right atrium, doing a transseptal puncture across the interatrial septum, and then going into the left ventricle, and then going up out through the aorta in an antegrade fashion.

So that was the transvenous transseptal. We've talked about transfemoral, we've talked about transapical, axillary, and subclavian.

Now, at later time points -- and those were really the only methods that would have been used at around 2012. There wouldn't have been any others.

I don't recall when I first heard about the carotid artery approach, but that was an approach where, for example, the femoral arteries couldn't be used. People felt, well, we could expose the carotid artery and put in a device through that way.

Oh, I've forgotten another important route, which was, in fact, very early on used,

so probably around 2010, maybe even earlier, would have been the direct aortic route. So that was a very important access route. I could go on about the reasons, but I won't unless you want me to.

But direct aortic was a very successful approach, predominantly because the surgeons were very used to do doing mini-thoracotomies and placing large catheters into the aorta, and this is exactly the method that was used to deploy the valve. So direct aortic, transapical, the carotid.

More recently, so post-2012, there has been another access route, which is not used very much, which is again, where the femoral arteries may not be usable, people have put a catheter into the -- we have not done this procedure, by the way -- a catheter into the femoral vein and the inferior vena cava, and the inferior vena cava and the aorta are like two big tubes that meet each other over a short distance, and believe it or not,

if you puncture from the inferior vena cava into the aorta, you can then dilate that tract and put a sheath cross. That's been used where the femorals, neither right nor left femoral, was available.

That has not gained wide usage. It's technically quite difficult, quite a high complication rate, as you can imagine, because you leave a big hole in the aorta; and in addition, it's technically quite challenging. It wasn't around in 2012, in any event.

So I'm sure I have left one or two out that I may have been exposed to, but I can't think of any immediately.

Q Let's see, we've got about three minutes. Why don't we go back through a couple of these. That was a lot of information.

Can you just explain for direct aortic, how that procedure was performed?

A Yes. This might take me three minutes, and then maybe we could break

after that.

So direct aortic is a procedure whereby the patient is put under a general aesthetic, and the surgeon performs a mini-thoracotomy. So a small incision -- and I'm showing an incision of a couple of inches -- either in the right upper thorax, or does an upper mini-sternotomy -- there's two approaches, pros and cons to both -- and a small section of the ascending aorta is exposed.

The surgeon then places a needle into the aorta, and a wire is put through the needle, the needle is removed, and then a small sheath is advanced over the wire into the aorta.

What happens then is a catheter is placed through that sheath, and the aortic valve is crossed. So the narrow aortic valve is crossed using a catheter through a sheath in the aorta, directly into the aorta, and a wire is placed into the left ventricle.

That's quite a tricky maneuver to do because your hands are all up. You're not working on a table. You haven't got -- the ergonomics of it are quite challenging.

You then put a stiff wire into the ventricle, and over the stiff wire, you then insert your large sheath into the aorta.

As I say, the reason surgeons quite like this is this is how they would -- not the percutaneous method I've described, but rather when they are operating on a patient, they would be very used to putting in a large sheath, a large bypass sheath, or a conduit for bypass into the aorta.

Once the sheath is there, I mean the big sheath, 18 or 22 French or bigger, you can then advance over the stiff preshape wire that's in the ventricle, you can advance your transcatheter valve.

You deploy your valve, and of course you're very close to the valve itself. The rest of the catheter is -- you need someone to

hold it because -- it would normally all be in the patient, but because you're so close to the valve, it's not.

But you deploy the valve, and you can do either self-expanding or balloon-expandable, and I've done both with this technique, and you then take the valve out -- sorry, the delivery system out, the valve is in place, and then it's down to the surgeon just to put a few stitches, which are already placed there, around the hole in the aorta and to close the sternotomy.

There were benefits to this in that you could use a much larger sheath. It was not -- obviously, you would do it in patients who an endovascular method wasn't feasible, there's no access from the femorals or subclavian. Some people used it in preference to the subclavian.

I would say now it's fallen out of practice. I haven't heard of anyone doing a direct aortic transcatheter valve procedure

for a rather long time.

Q Just a couple quick follow-up questions, and then we'll take our break.

So this direct aortic transcatheter valve implantation method was known and used prior to 2012; is that correct?

A Yes, it's correct. It was used with transapical.

Q And with --

A When I say "with," typically the surgeon would either say I think this is better for transapical or this is better for direct aortic, but the method was a surgical method, direct aortic.

Q Would you consider the direct aortic method to be an endovascular procedure?

A No, no.

Q And why not?

A It's not what anyone would understand to be endovascular.

Q And why wouldn't anyone understand it to be endovascular?

A Because endovascular is going via a peripheral vessel, advancing a method, so advancing a sheath and the device in that way.

So transfemoral, subclavian, those would be endovascular, but these are surgical. The direct aortic and transapical I would not consider to be endovascular.

Q And so in your opinion, are endovascular procedures limited to delivery through peripheral vessels?

MR. LOWENSTEIN: Objection, form.

THE WITNESS: So I've not given a definition in my declaration of endovascular, I don't think. I'm happy to have a look. If you think I have, then I'd appreciate you directing me to it.

I know that direct aortic transcatheter valve implantation has never been considered. No one ever considered it endovascular.

MR. LOWENSTEIN: Okay, so should we take our break?

MR. STOWELL: Yes, we can take a break now.

MR. LOWENSTEIN: When are we reconvening? Why don't we go off the record.

MR. STOWELL: Yeah, let's go off the record.

THE VIDEOGRAPHER: Going off the record. The time is 11:34.

(Lunch break taken.)

THE VIDEOGRAPHER: We are back on the record. The time is 12:51.

BY MR. STOWELL:

Q Dr. Brecker, did you speak to anyone about your deposition testimony during the break?

A I did not.

Q Before the break, we were talking about access routes for TAVR procedures, and you mentioned the subclavian delivery route.

Can you explain how a TAVR would be delivered through the subclavian route?

A So that is quite a complicated

procedure. There's a lot of procedural steps. I mean, I'm happy to go through them.

It typically would involve a surgical cutdown onto the vessel. It can be done under local or general anesthetic, more typically general. The vessel is entered with a needle, a wire is placed in the vessel, a sheath is placed in the vessel, a catheter is placed in the sheath, and the catheter is then used to advance a wire across the valve, a stiff preshaped wire is put in the ventricle.

And then you can either put a sheath into -- typically it won't take much more than an 18 sheath -- into the subclavian vessel, and then you advance your transcatheter valve through that. It then requires a surgical repair after the procedure.

There are quite a lot of complications to the procedure, or can be. The technique has been modified more recently to have a more distal approach than the subclavian artery, typically the axillary

artery, which is further distal.

Q And is delivery of a TAVR through the subclavian artery an endovascular procedure?

A So I haven't given an opinion on that. It is endovascular in as far as it's -- well, I have not really considered whether that would be endovascular, because the term "endovascular" -- for all purposes in terms of endovascular surgery, for example, everyone understands that's a femoral or -- femoral access, typically.

I would have to give some thought as to whether you would consider a subclavian approach endovascular. Certainly cardiologists have never referred to the alternative access as endovascular, any of the alternative access, but I can see how some people would consider subclavian endovascular.

Q You also mentioned the axillary route. Is that spelled A-X-I-L-L-A-R-Y?

A Yes, that's -- I have to spell it

out. Axillary, I think it's two Ls. I'll just write. Yes, A-X-I-L-L-A-R-Y.

Q And can you explain how a TAVR would be delivered through the axillary route?

A Well, that can be very similar. It can be done identically. It's just a different site of entry into the vessel.

Q Would delivery through the axillary route be considered endovascular delivery?

A So I would give the same answer as I've given before. I've not given an opinion on that in my declaration, and I'd have to give it some thought.

I've never heard of it as delivered endovascularly, but I can see why some people would consider the axillary approach endovascular.

Q Would you agree that, in 2012, TAVR procedures were considered an alternative to open heart surgery?

A So that's not completely correct.

TAVR was the only option for many

patients in 2012. There wasn't an alternative. They were patients who were not suitable for surgery.

It wasn't until the intermediate-risk trials and the low-risk trials where patients could have had either surgery that you would have considered it an alternative.

In 2012, there were certainly patients having TAVR who could have had surgery, and that contrasted to our earlier experience where we were undertaking TAVR only on those patients who would not have been surgical candidates, and therefore I wouldn't have characterized them as having an alternative.

Q So in 2012, would you agree that there was a group of patients that could only have their aortic valve replaced via a TAVR procedure?

A In 2012, there were patients who could not have surgery, and therefore could

only have had their procedure by TAVR, that is correct.

Q Why would a person of skill in the art in 2012 have used one of the delivery routes we've discussed other than the transfemoral route?

A If it was felt that the transfemoral route was completely unavailable, the alternative would be, if it was felt that going via the transfemoral route would carry highers risks than one of the other routes.

Q And what were some reasons why the transfemoral route might be completely unavailable?

A Well, typically, calcific atheromatous disease in either of the femoral vessels.

Q And what does that mean?

A Calcified plaques of atheroma overlie the vessel, and when you put in the sutures to the vessel prior to putting the sheath in, they can simply pull through it and

you can get uncontrolled hemorrhage.

You can rupture a vessel if you push too hard.

You can pull the artery out on the sheath. So if your sheath is slightly bigger than the artery, you could pull the artery out with the sheath and the patient could die as a result of catastrophic hemorrhage.

So a lot of the efforts in the early days of TAVR were all around assessing the vascular risk. This was one of the -- apart from the problems with the valve itself, which I've mentioned, aortic rupture and coronary occlusion, which thankfully were very rare, that contrasts with much, much more common vascular complications.

And particularly leading up to 2012, when cardiologists and cardiac surgeons had become more confident doing higher risk patients, we still saw a lot of vascular complications.

Q You also mentioned that there may be

situations where the transfemoral route carries higher risks than one of the alternative access routes.

What would be some situations where the femoral approach would carry higher risks than the other alternative access routes?

A Well, the same, calcified atheromatous plaques. You could have plaques that were -- there's a whole spectrum of disease that you can have.

If you have it at the entry site only, you might consider trying to put a big sheath in, but you'd have to accept the increased risks.

The other point I should make is that we certainly had patients where even though there was no disease, the vessels were simply too small; that would either preclude you or give you a higher risk of a vascular complication.

Q And when you say the vessels are too small, you're referring to that the femoral

arteries of some patients were too small for a delivery of a transcatheter valve through the femoral artery?

A The whole iliofemoral system typically. When the femoral artery is narrow caliber, you tend to have narrow caliber vessels everywhere, including the aorta.

So we certainly have had small patients, typically low body surface area women, where the vessels are just too small for any type of access for TAVR. So it's not just the femorals; it would be the iliacs, the subclavian, everything.

Q Now, are you familiar with delivery of transcatheter heart valves through the iliac approach?

A I'm not familiar with it other than having seen the Kainuma paper. I've never heard of it being done in any center that I have worked in for TAVR, and that must be over a hundred centers.

Q I'll ask our hot seat operator to

pull up a document titled -- it should be "Brecker treatment of aortic stenosis."

Okay, Dr. Brecker, can you see this exhibit?

MR. LOWENSTEIN: Can we pull up the entire exhibit? Is that possible on this thing?

MR. HSIEH: They haven't updated it yet, but once they update it --

THE VIDEOGRAPHER: Is this going to be Exhibit 1101?

MR. STOWELL: This will be Exhibit 1101, yes.

(Exhibit 1101 was marked for identification.)

MR. LOWENSTEIN: Can you email these documents or email the documents in realtime to Mr. Hsieh so we have them as well?

MR. STOWELL: They're also on the Box. If you all have computers, you can download there.

MR. LOWENSTEIN: Ed, do you have

access to this?

MR. HSIEH: I have access to the Box, but the Box is not yet updated with 1101.

THE VIDEOGRAPHER: Yeah, it should be updated. You've got to hit the refresh.

MR. HSIEH: Okay.

(Discussion held off the record regarding retrieving documents.)

BY MR. STOWELL:

Q Okay, Dr. Brecker, do you have access now to Exhibit 1101?

A Yes, I do.

Q Okay. So on the cover page of this document, there are a number of authors listed. It looks like the last one is you, Stephen Brecker; is that correct?

A That's correct.

Q And were you involved in the preparation of this paper?

A Yes, I was.

Q Okay. And what was your involvement in the preparation of the paper?

A So I haven't looked at this in a long time, and it's 2014.

This was a clinical study, so it was a registry study of patients having CoreValve. I can't remember my precise responsibilities or my precise role.

The ADVANCE Study was a large study. I can recall it was more than a thousand patients, and there were a large number of publications that came from it.

The senior author on this paper was the first author, Axel Linke, who was the principal investigator.

The sum of the papers, the authorship was ordered in terms of recruitment of patients. So I have not -- there was another paper where I know I wrote the paper. This one I did not write. I may have been put as the final author, which after the first author, it's an important position in a multiauthor paper, but it may well have been nothing more than our center recruited a very

high number of patients. And I do know that on different papers, different authors took -- the authorship was changed.

I cannot remember the details of this. You're showing it to me for the first time in many years, and it's not a paper that I've reviewed in preparing my opinions for this case.

Q Do you believe you would have reviewed this paper before publication?

A Yes. I mean, it would have been -- I would have been reviewing it in 2013, nine years ago, because it takes -- for the European Heart Journal, it takes 6, 9 months for it to be published after review. So you're saying do I remember something from nine years ago.

Q No, I haven't asked that question. I was just asking if you thought you would have reviewed this paper prior to its publication.

A Well, that would have been at least

nine years ago. I think, in fact, it -- yeah. I mean, it would have been 2013 that I would have reviewed it.

Q Typically when you're listed as an author on a publication, do you review that publication before it is published?

A Yes.

MR. LOWENSTEIN: Objection, form.

THE WITNESS: Yes, I would have reviewed. I've reviewed every paper. I would have reviewed this paper before publication.

BY MR. STOWELL:

Q And in your ordinary practice, as you're reviewing papers that you're going to be listed as an author on, if you see an error, do you raise that with the authorship group?

A Yes. If you see an error, you would report it.

Q Let's go to the third page of this document. In the upper left-hand corner, it's 2674. And if we look down at the box

"Procedural characteristics," do you see where I'm at, Dr. Brecker?

A Yes. I'm going to move across to the larger version of it, yes.

Q And in this summary here, it's summarizing different information about the approaches that were used, and it specifically says "6 patients (0.6%) were implanted via the iliac approach." Do you see that?

A I do.

Q And do you know what it means by the iliac approach?

A I have not -- as I say, I have not reviewed this paper since 2013, so I would need to review all the procedural details to answer your question.

Q Do you believe that the statement "6 patients were implanted via the iliac approach" is factually correct?

MR. LOWENSTEIN: Objection, form.

THE WITNESS: I would have no reason to suspect that this was incorrect.

I want to point out that these patients were recruited between 2010 and 2011, so that's important. And the other important factor is it's almost a thousand patients in this study. So one has to put this into the context of a thousand patients having TAVI -- sorry, TAVR -- in 2010-11.

So I understand you asked me before was I familiar, I think your question was, with the iliac approach, and I said no, I was not, and sitting here today, since 2011, I've not been aware of any.

Clearly, there were some in this study, and having read that, I would have been aware of it, but you're asking me about an opinion from, as I say, nine years ago.

BY MR. STOWELL:

Q Why would the date of recruitment of the patients have been important, as you mentioned?

A Well, because it became pretty clear that that was not an appropriate approach.

Q And when you say it became pretty clear, when did it become clear?

A Well, my sense certainly was that no one ever did -- first of all, the vast majority of TAVI centers never did an iliac approach. Those that did typically did one and discarded it because of the complications and difficulties.

So this speaks to that. A thousand patients, of whom six had iliac, and I think that just actually supports the view that I've expressed.

The other -- and I haven't looked at the paper, but I can tell you with certainty that the reasons for doing this would not have been -- the reasons that the iliac would have been used would have been simply as an exploratory method of using an alternative access where the femoral was not available.

It wasn't being used because it was a bigger vessel, let me make that clear. It was being used because, like Kainuma, the

femoral would not have been usable at all due to calcification.

There is another -- I mean, I haven't looked at this paper, and I would like a little bit of time to read it through, if I may, because there is another point that I want to make, but I would like to have a look at the paper first.

Q I'm actually done asking you questions about the paper. If you'd like to -- we'll have a break here in a little bit. If you'd like to review it, and then come back and discuss it after the break, I'm happy to do that.

MR. LOWENSTEIN: Is it necessary to answer the last question that was pending, Dr. Brecker?

THE WITNESS: What I want to find out, because you're obviously asking me this for a reason, and what I want to see is if there is any further information about why the iliac was used.

And there is another important inference from the sentence. At this time, there was a real imperative for this to be a femoral procedure. It was very important for CoreValve that they had a very high femoral access rate, and you'll see it's 88.4. And this is in the very early days. This contrasted with Edwards' iliofemoral rate, which would have been significantly lower than that.

Now, I don't know if there was an intention to use the iliac. My sense is that it would almost certainly have been because the femoral wasn't used. That is assuming that it was done on purpose.

There were a number of cases, and I know this because I reviewed adverse instance, where the external iliac was punctured rather than the common femoral because there is -- basically, they just change their name as the vessel goes under the inguinal ligament, and some of those cases would have been classified

as an open inverted common iliac where you puncture the external iliac, and the reason is that that is a complication.

Now, I don't know, I can't -- that's what I wanted to review, and I was keen to see if there was any further narrative or explanation as to why the iliac had been used, whether this was an inadvertent puncture, or whether it was a purposeful reason because the femoral couldn't be used.

As I say, it was not being used as a method to use a larger device than would have gone in to a femoral had the femoral not been diseased.

Am I able to look at this document?

BY MR. STOWELL:

Q Well, why don't we do that at a break. I'm actually done asking questions about the document, and if you see something you would like to raise, we'll handle that how about when we come back from our next break?

A Okay.

Q Now, I understand from your declaration, Exhibit 2051, you have not implanted a transcatheter heart valve through the common iliac artery; is that correct?

A I have not.

Q Have you implanted any other medical devices through the common iliac artery?

A So I've been involved in vascular surgical endovascular procedures that have involved cutdowns to the iliac, a small number, and it would have been me doing it, or me assisting or observing with our vascular surgeons.

Q When you say "a small number," how many are you referring to?

A I can't give you the number. It's a small number.

Q Less than 10?

A Could be around that number, could be a bit less.

Q And what devices were being inserted into the patient through the common iliac

artery in these procedures?

A They would have been aortic stent grafts.

I can recall that we did have one case, I think, where we tried an endovascular repair of a dissection, but I haven't reviewed any of that experience in terms of numbers and detail.

Q Why was the common iliac artery selected as the site to introduce the aortic stent graphs that you inserted?

A I can't recall the details. These are often patients with severe peripheral vascular disease, or they are by definition.

Q Is there a reason that the aortic stent grafts weren't implanted in these patients through the femoral artery?

A I can't give you the exact details. I haven't got that level of detail.

Q Do you remember the French size of the aortic stent graph devices you were inserting through the common iliac artery?

A I do not.

Q Do you remember what the trade name or the commercial name of the aortic stent grafts you were inserting through the common iliac artery was?

A I cannot. It was a long time ago.

Q These devices that were inserted through the common iliac artery, why weren't they delivered through an open procedure?

A When you say an "open procedure," what do you mean?

Q Like an open chest procedure.

A Well, they were for the descending aorta, so you would never open the chest for that.

Do you mean why didn't these patients have open surgery?

Q Yes.

A Well, aneurysm repair became very predominantly endovascular. So there was a big move away from open surgery to endovascular.

Q And when did that move occur?

A Oh, a while ago. I can't give you the year. More than 10 years ago.

Q So the delivery of the aortic stent graphs through the common iliac artery that you did on these patients would have been considered an endovascular procedure; is that correct?

A Well, again, endovascular surgery can be done via the femoral or the iliacs, yes.

Q And do you recall the outcomes for the patients in these procedures where you inserted the aortic stent grafts through the common iliac artery?

A I can only remember that one was unsuccessful. Honestly, I just cannot remember the details.

Q Do you believe that the delivery of a transcatheter heart valve through the common iliac artery could be done safely?

A So what you have to understand is

that of all the patients in the hospital in 2012, those undergoing transcatheter aortic valve implantation were amongst the sickest. They typically had multiple comorbidities, and to have done an iliac approach, an iliac cutdown with surgery, was simply considered by the vast, vast majority of people untenable and too high risk.

I mean, this subset of patients, an iliac artery cutdown for an elective procedure would have been considered unsafe, in my opinion, and in the opinion of the vast majority of people at the time.

You know, it may have been used once as a trial technique by some people exploring alternative access, but in terms of a realistic safe approach, no.

Q Did you consider it a safe approach when you implanted the aortic stent grafts through the common iliac artery?

A Well, I didn't do that. That was -- when I say I didn't do it, I was not the

operator. This was being done by vascular surgeons, who had the immediate ability to convert to open surgery.

Now, that would apply if you were required -- when I say "convert to open surgery," convert to controlling the vessel with clamps, because if you are cutting down onto the common iliac artery, as I say, this is major invasive surgery in a patient who is vulnerable with multiple comorbidities.

So the vascular surgeons would always consider the risk of different alternatives. Now, for them, doing aneurysm repair, the alternative is open surgery.

Now, open surgery for aneurysm repair is amongst the highest risk surgery that occurs anywhere in the hospital for any indication, and that is why they sought an alternative of endovascular repair.

Now, when you consider the word "safe," which you haven't defined, it's safer than the alternative. That is not the case

for an iliac approach TAVI. There would have been other options which would have been considered safer, and that's why so few were ever done.

Q And so assuming that the transfemoral route is not available, what other access routes do you think would have been safer for a TAVR procedure than insertion through the common iliac artery?

A So in 2012, it was pretty straightforward. If you were doing an Edwards valve, you did a transapical; and if you were doing a CoreValve, it would have been subclavian.

So pretty much -- as I say, there was a binary distinction between the valves, and although now -- I mean, the CoreValve could never be done transapically, so the majority of people would have selected subclavian if they wanted to implant CoreValve, and in 2012, the majority of people would have selected transapical if they wanted

an Edwards.

Q And do you believe that the transapical delivery procedure is less invasive for patients than delivery through the common iliac artery?

A Well, anything other than transfemoral has been associated with increased risks.

It has been quite difficult to unpick how much of that relates to the actual site of access and how much of it relates to the comorbidities that those patients have because, by definition, they can't have transfemoral. But if it had been safe and obvious to do iliacs, then in 2010, 2011, 2012, 2013, 2014, iliac approach would have been done, and it wasn't.

When I say it wasn't, there were a few isolated cases, a fraction of 1 percent -- fraction of a fraction of 1 percent in most registries.

Q Do you believe that the six

coauthors that we read about in Exhibit 1101 were taking unnecessary risks by introducing transcatheter heart valves through the iliac approach?

MR. LOWENSTEIN: Objection, form.

THE WITNESS: So which paper are we referring to now?

MR. STOWELL: That was the paper we just looked at, Exhibit 1101.

MR. LOWENSTEIN: Sorry, did you say six authors?

BY MR. STOWELL:

Q So in that paper we looked at, there were six patients that were implanted via the iliac approach; correct?

A Yes.

Q Do you believe that the surgeons that selected the iliac approach or the doctors that selected the iliac approach were taking unnecessary risks in those procedures?

A Well, that question needs a little bit of unpicking, because the implication is

they knew of those risks prior to doing the procedure.

The fact is -- first of all, they may or may not have been authors on the paper. So there were a thousand implants, and you'll see there's something like 25 authors. There are vastly more operators than authors.

This relates to 2010 and 2011, and several people had never done -- several of the centers would never have done subclavian. This is CoreValve, so there wasn't any other alternative. And as I say, people tried, and it's what they perceived the risk to be.

I wouldn't dream of saying they were taking unnecessary risks because that implies a level of knowledge and analysis at the time that they did it, which may have been in 2010.

But just given the fact that it's nearly a thousand patients, and in the whole course of that study, only six were done, that to me speaks volumes. And as I say, most people never did more than one.

I don't know where these were done, whether it was one person who wanted to try doing three, or whether it was six people that did one and discarded it, but clearly it was proved to be unsuccessful; and clearly, after this date, I certainly have never heard of it. I mean, it's not something that I can ever recall coming up in a meeting.

Q Why don't we take a look at Exhibit 1043.

(Discussion held off the record regarding retrieving the exhibit.)

BY MR. STOWELL:

Q Dr. Brecker, is this Exhibit 1043 one of the documents you've reviewed as part of your work on this IPR?

A Yes. I last read this a little while ago. I didn't read it in the last couple of days.

Q Okay. And based on your reading of this, do you understand that the doctors in this particular instance shows the common

iliac artery because the external iliac arteries were too narrow for transcatheter valve delivery?

MR. LOWENSTEIN: Objection, form.

THE WITNESS: I don't understand that as the reason. The external iliac arteries were too narrow?

BY MR. STOWELL:

Q Correct. Is that your understanding of why the left common iliac artery was used?

A No, I don't understand that logic.

Q Okay.

A What I can explain is that it says calcifications in the peripheral arteries. So, I mean, their option would have been to use the femoral, but they couldn't because of calcification.

Q Okay, thank you.

A It then says external iliac arteries had stenoses, so what that means is that narrowings within the lumen of the artery, of the external artery, had narrowed it.

Q Okay. I'd like to ask you a bit about the delivery through the femoral artery.

When a device, a transcatheter heart valve, is inserted through the femoral artery, is it accurate to say that the device will then traverse the femoral artery, the common iliac artery, and the aorta, before reaching the aortic valve?

MR. LOWENSTEIN: Objection, form.

THE WITNESS: Yes. The route is common femoral, external iliac, common iliac, aorta.

BY MR. STOWELL:

Q And in your declaration, Exhibit 2051, I understand that you have acknowledged that a valve having a crimp profile of 8 mm could be delivered through the femoral artery in at least some patients; is that fair?

A Well, the 8 mm is the size of the vessel -- you couldn't -- sorry, could you ask that question again?

Q Yes. Maybe I'll reword it here.

A It's okay, I've got the question now. The answer is yes. In a femoral artery of 8 mm, which is pretty unusual actually, you could implant at least some patients -- I think that was your question -- via that route.

Q And implant those patients with a transcatheter heart valve; is that correct?

A Yes, but I think you talked about the crimp profile of the valve, and I talked about the vessel size.

Q Okay. So if the patient has a vessel size that measures 8 mm in diameter, that patient could receive a transcatheter heart valve via the femoral route so long as there weren't some other sort of problems with the vessel. Is that fair?

MR. LOWENSTEIN: Objection, form.

THE WITNESS: Yes, so long as there was no calcification on the vessel.

BY MR. STOWELL:

Q What is the largest device that you have ever delivered through the femoral artery?

A So it would have been the LOTUS.

There's a lot of difficulty in being precise about this because the companies are very reluctant to give true dimensions to their devices.

So, for example, Boston Scientific with LOTUS simply had two sheath sizes, regular and large, and it was very difficult to get the true size of it. Same with Edwards' sizing, which is based on the lumen rather than the external diameter.

And it gets even more complicated if you have to talk about the device itself, because the device has got to be a bit smaller than the lumen. So there is a lot of smoke and mirrors from the companies themselves about precise sizing.

What we can say is -- what I can say

is that LOTUS was certainly the large valve with the largest that I had delivered, and I can't give you the dimensions of it.

I can also tell you that it was only a minority of patients who would have qualified for a femoral approach for the LOTUS valve. "Minority," I mean the smallest proportion out of Edwards, CoreValve, and LOTUS, you would have a smaller proportion of LOTUS patients being able to go femorally, then Edwards, and then CoreValve, which was the smallest system available, so much so that we used to have a term within the cath lab of these are "LOTUS size vessels," which meant they were great big drainpipes, 8 mm.

Q So if I understand correctly, the LOTUS valve with the large sheath is the largest device you've implanted through a femoral artery?

A Yes.

Q And as we sit here, I understand that you don't know the diameter of the large

sheath that was used with the LOTUS device?

A I think it would have been around 21 French.

Q Is that a guess?

A Yes, it was that sort of size. It was certainly a bigger sheath than the sheath we typically used, which was an 18 French.

Q And have you encountered patients with femoral arteries having diameters larger than 8 mm?

A Very few. It's pretty rare. Yeah, I mean I have, but I have to think about it.

Q I understand that the diameter of a person's blood vessels typically increase with age. Is that consistent with your experience?

A Not at all. No, that's incorrect.

I mean, you might be referring to the development of aneurysmal formation, which is pathological increase.

Q So in your experience, the typical or average diameter of a patient in their 30s of their femoral artery would not be smaller

than the average diameter of a femoral artery of a patient in their 70s or 80s?

A My clinical experience is the other way around. There's no -- I'm really surprised that you -- that that's a -- I don't know where you would have got that information.

I mean, typically, on the rare occasions we've had to do very young patients, and certainly in the low-risk patients, who tend to be younger, the vessels are bigger and they're cleaner.

The typical 90-year-old patient has muscle loss, which means their bulk gets smaller, vessels get atheromatous and calcified. It's completely the opposite to what you suggested.

The only example I can imagine you're referring to is the development of aneurysms, which does increase with age.

Q What is the average age of a TAVR patient?

A That's an interesting question. For many years, it was low 80s. So for the first several years, typically the average age would be around -- I mean, I can just remember study after study that showed it at 83. I'd have to have a look at what it was in the ADVANCE Study. I wouldn't be surprised if it was in the low 80s in years.

The average age now has probably come down because -- well, there's two reasons. We're doing lower risk patients, doing intermediate risk patients, and we're also treating patients with what's known as a bicuspid aortic valve. They were not included in the early trials or studies or cohorts of patients. They are now included, and they tend to be younger.

Q And as of 2012, what would your estimate be of the average age of a TAVR patient?

A So that's what I was referring to earlier. The average would have been in the

low 80s. That is my sense.

Q When you perform or the heart team performs a TAVR procedure, are the diameters of the arteries measured before the procedure?

A Yes, they are.

Q Are measurements made of the femoral artery?

A Yes.

Q Are measurements made of the diameter of the common iliac artery?

A Yes.

Q Are measurements made of the diameter of the aorta?

A Very rarely the aorta itself, if you mean descending aorta. If there's an aneurysm, then yes, but not in the same way as the iliofemorals. In other words, the reason you're measuring the iliofemorals is to ensure that they're large enough.

Q And in your experience, what is the average diameter of the femoral artery?

MR. LOWENSTEIN: Objection, form.

THE WITNESS: So I have not done an analysis of that, and I haven't given an opinion of that.

I can give you my sense of my own clinical experience because I do several of these types of analyses all the time.

I mean, we see quite a high -- we have a high proportion of patients with small arteries, so we see femorals at 5.5, 6. It's that sort of order, maybe 6.5 mm, would be the average in my experience, but I'm giving you that answer on the hoof, and I would have to go and have a look at my own -- I haven't got a database of the femoral artery sizes, but I've got a lot of CT scans on my laptop.

BY MR. STOWELL:

Q Do you typically review the measurements before performing a procedure?

A Every case.

Q What about a typical common iliac artery, what is the typical diameter of a common iliac artery for the patients you see?

MR. LOWENSTEIN: Objection, form, scope.

THE WITNESS: So I have never perceived a major increase in size. The reason we measure them is because they are usually much smaller than that.

If you look at a typical normal patient, the size of the iliacs is never much bigger than the common femoral. I mean, I have not got an anatomical database to give you the numbers, but I think it's really nicely illustrated in one of Cribier's papers where he's got a picture of a three-dimensional volume-rendered image of a patient's vessels, and you can see very clearly that there is not this great big step-up into the iliacs, not typically anyway.

I mean, sometimes they are, but my typical experience is maybe a little bit bigger, but sometimes they're smaller.

MR. STOWELL: Okay, we've been going about another hour. Why don't we take a

10-minute break here.

MR. LOWENSTEIN: So we'll get back at 2:00?

MR. STOWELL: Yes, two o'clock.

THE VIDEOGRAPHER: Okay, going off the record. The time is 1:49.

(A break was taken.)

THE VIDEOGRAPHER: We are back on the record. The time is 2:01.

BY MR. STOWELL:

Q Dr. Brecker, I understand that you've known Dr. Buller for a long time; is that fair?

A Yes, that is fair.

Before we start, could I just say something for the record, because I took the opportunity to look through that paper that you showed me.

MR. LOWENSTEIN: Just for the clarity of the record, I believe you're referring to Exhibit 1101?

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

iliac puncture, whether it was a cutdown, whether it was simply the way they chose to do it. There's no explanation, and I have no recollection of it being an issue.

Your question to me was, I think, was I familiar with it, and my answer, having seen this paper now in full, is I'm still not familiar. I was not familiar with the iliac approach for TAVR, I've never done it, and to the best of my recollection and knowledge, it was never done in the hospitals I did TAVR in. I didn't go to many of the hospitals that were in the ADVANCE study.

So I wanted to clarify that for the reported.

BY MR. STOWELL:

Q Okay, thank you.

And did you speak with anybody about your deposition testimony during the break?

A I did not.

Q Okay. Let's see, so I was asking about Dr. Buller.

When did you first meet Dr. Buller?

A A long time ago. I'm not even sure Nigel would remember. I think it's when he was a senior house officer on the intensive care unit at St. George's -- at St. Thomas', and I was a medical student, but that was probably a fleeting visit, fleeting encounter.

I think the time where we knew each other best was when we were both at the Brompton Hospital.

Q And did you work with each other at the Brompton Hospital?

A Yes, yeah. He was a newly appointed senior lecturer, and I was a registrar -- yeah, registrar. Actually, I was a research fellow with another consultant.

So I didn't work directly with him in terms of being like one of the residents, as you would call it, on the clinical service. I was doing research then, and we certainly interacted, and you could call it work together, yes.

Q Did you ever receive training from Dr. Buller?

A I think I did.

Q And what training do you recall receiving?

A Well, to be honest, you're asking about something from 30 years -- more than 30 years ago. I can't remember.

I can recall him giving a tutorial once. You have these little -- I have these little snippets of memory.

I can't -- I can't -- you are talking about more than 30 years ago.

Q And at what point in time did you stop working together at the Brompton Hospital?

A I would have to look at my CV. I can't tell you a date, and I haven't got my CV here, but if you look on my CV, it will tell you the dates I stopped at the Brompton.

Q Looks like 1994.

Does that sound right?

A Yes, that could be when I went to the London Chest.

Q Did you continue to follow Dr. Buller's work after the two of you stopped working together at the Brompton Hospital?

A So I don't think we overlapped in terms of research projects. It's possible we did. Again, I haven't looked at my CV with that in mind.

Obviously, I knew Nigel, and in the years that followed, but we didn't have a -- I wouldn't say we had -- we never worked together again after that, I don't think, in the same hospital.

Q And did you follow the projects he was working on and the types of work he did after the two of you left Brompton -- or after you left Brompton?

A I'm not sure what you mean by "follow." Certainly I was aware of some of the projects he was involved in with coronary stents.

I mean, it wasn't like I was following his work closely for any reason other than I would follow anyone's work, as it were.

It's possible we have an abstract or were named on a publication. I honestly just don't remember.

MR. STOWELL: Okay, I'd like to ask our hot seat operator to pull up Exhibit 2009.

MR. LOWENSTEIN: Give us a moment.

Okay, it's just open now.

THE WITNESS: Could I just add one thing, obviously, to the last question you asked?

Obviously, we've been involved in some patent litigation since then, so we've obviously come into contact and had -- you could call it working together.

BY MR. STOWELL:

Q Okay. I'm not sure anybody would characterize it as working together, but yes, I understand what you mean.

MR. LOWENSTEIN: We are all together on a call.

THE WITNESS: Yeah. So, I mean, we -- well, I think we all understand, yeah. Obviously, I mean, it goes without saying, but ...

BY MR. STOWELL:

Q Okay. Dr. Brecker, do you recognize Exhibit 2009?

A Yes, I do.

Q Okay. Is this one of the publications that you relied upon in your expert declaration, Exhibit 2051?

A Yes.

Q Okay. And is this a document that you studied and reviewed in preparation for your deposition today?

A Yes, not in the last few days. This is one I would have read a little while ago, not too long, but not in the last couple of days.

Q And Exhibit 2009 describes the

replacement of a mitral valve, correct?

A Yes.

Q This article does not describe aortic valve replacement, correct?

A It does not.

Q And this paper describes --

A I'm sorry, could I just finish?

Q Sure, yeah. Sorry, I thought you were done.

A It doesn't describe aortic valve replacement, but it describes using a transcatheter aortic valve.

Q Right. And the transcatheter aortic valve that's used in this procedure is a Sapien 3 transcatheter heart valve, correct?

A No -- oh, I see. They describe use of the XT, and in this one they say we have recently modified an open transatrial technique utilizing Sapien 3, correct.

Q So it's your understanding that the valve that's implanted and described in this publication was a Sapien 3 valve; is that

correct?

MR. LOWENSTEIN: Objection, form.

THE WITNESS: So it states that, but could I just have a minute to just quickly look through this?

BY MR. STOWELL:

Q Sure, take a minute.

A Yes, it is a Sapien 3 valve.

Q And the procedure that's described in this paper is an open heart procedure, correct?

A Yes.

Q Now, there is some material that was added to the outside of the Sapien 3 valve in the procedure that's described in Exhibit 2009, correct?

A Yes, that's correct.

Q And are you familiar with the structure of the Sapien 3 valve?

A Yes.

Q And the Sapien 3 valve has an outer skirt, correct?

A Yes.

Q And so when the -- let me start over. In this particular paper, Exhibit 2009, a felt strip is added to the outside of the Sapien 3 valve, correct?

A That is correct.

Q And the felt strip, is that applied to the Sapien 3 valve on top of the existing outer skirt?

A Yes, that's my understanding.

Q And the felt strip that's used --

MR. LOWENSTEIN: Were you done with your answer?

THE WITNESS: I was done with my answer.

BY MR. STOWELL:

Q Sorry, you're just a bit off camera, so it's hard to tell if --

A Sorry, the reference is on the other screen, so I have to just angle my neck. Maybe I -- yeah, like that.

Q The material that's wrapped around

the outside of the Sapien 3 valve in Exhibit 2009 is a teflon felt strip, correct?

MR. LOWENSTEIN: Objection, form.

THE WITNESS: So it just says Bard PTFE felt, and with a reference.

BY MR. STOWELL:

Q What page are you reading on, Dr. Brecker?

A 1440.

Q So if you go over to page 1442, right about the middle of the first column, there's a description of a Teflon felt strip.

A It's very blurry and small on the image in front of me, so I do have to look at the other image.

(Image blown up on Zoom screen.)

A Yeah, so that's a lot better.

So which are you taking me to? "We prepare the valve with a Teflon felt strip," and the felt strip is PTFE felt, yes.

Q And how is felt manufactured?

MR. LOWENSTEIN: Objection, form,

scope.

THE WITNESS: Yeah, I've not given any opinion on that.

BY MR. STOWELL:

Q Did you do any research on how felt was manufactured when you were evaluating the Russell reference?

A I have not analyzed how felt is manufactured, no.

Q Would you agree that felt is made by a different process than a woven or knitted fabric?

A I have not done any analysis of how felt is manufactured.

Q And have you done any analysis to determine how compressible the felt described in Russell is?

A I have not done any analysis of how compressible the felt in Russell is, no.

Q And did you do any comparison of the compressibility of the felt in Russell with the other references that are in this case,

such as Walther?

A I have not done a comparison of their compressibility. There is no information as to the compressibility as far as I'm aware.

Q The article itself does not describe any bunching of the felt that's on the outside of the Sapien 3 valve, does it?

A Well, it shows it. Do you mean there's no verbal description of it?

Q Correct. There's no verbal description of bunching of the felt, is there?

A If I could just have a minute to just -- so I don't think there's a verbal description of it bunching visible to me.

Q And what -- what material -- sorry.

A I'm sorry, I was saying I think it's clearly visible.

Q And what figures are you relying on to show the alleged bunching?

MR. LOWENSTEIN: Objection, form.

THE WITNESS: So we could go to my

declaration, I think, where I deal with this.

So if you look at my declaration, we could look at the original reference pictures, they're a bigger and clearer I think, at least on the images I'm looking at.

So in my declaration, on page 31, top left, I think you can see bunching around the top.

I think in the image below, I've actually labeled it, and there are other areas other than where the yellow line ends where you can see what appear to be, amongst other things, ridges and folds. That's more clearly seen on the image on top of page 32. It's evident on the image below that, and in the images that follows on the next two pages.

So I think they're all showing a very bulky, bunched up bulging cloth.

BY MR. STOWELL:

Q The pictures you're referring to, you're in Exhibit 2051, correct?

A Yes.

Q So the picture on the top left of page 31, that is an image of the valve in its expanded configuration, correct?

A It's difficult to know whether that's fully -- sorry, the top of page 31 on the left, it looks expanded. Whether it's fully expanded, it's difficult to know, but it is in the expanded configuration.

Q And is it your position that this figure shows bunching?

A Well, it clearly does.

Q And can you explain how the valve in Exhibit 2009 is implanted in the patient?

MR. LOWENSTEIN: Objection, form.

THE WITNESS: So this is an open procedure, and the access is directly via -- I'd like to go to the actual description of the procedure so I can get it accurate.

So the patient is put onto cardiopulmonary bypass, and the approach to the mitral valve is via an opening in the left atrium. The surgeon removes the anterior

leaflet of the mitral valve.

There is some further detail which I could read, but it's itemized there by Dr. Bibak (ph), who did this surgery.

BY MR. STOWELL:

Q So in this procedure, how does the doctor gain access to the heart to make the incision in the left atrium?

A Well, it's open heart.

So let me just read this through, because I know that -- could I just have a moment to just read through the surgical technique here?

Q Sure.

A Okay, so -- sorry, what was your question again? The surgical procedure used?

Q Correct.

A So I'm not a cardiac surgeon. My understanding is that this patient would have had a median sternotomy, an open surgery.

Q And you mentioned that the anterior leaflet is removed. How is the leaflet

removed?

A You're asking me techniques of cardiac surgery, the detail of which I wouldn't try to go beyond saying what I've seen and assisted with, is the surgeon uses a scalpel and forceps and scissors.

Q And then cuts the leaflet out of the heart valve?

A Well, I can only read Dr. Bipak's description, which is the anterior leaflet is excised, leaving a standard room of tissue at the aortomitral curtain that will be used to place pledgeted anchoring sutures, and that is described -- or that is shown in FIG. 4A.

So just looking at FIG. 4A, the surgeon is using what looks like forceps, could be scissors. This is surgical technique.

Q What are the pledgeted sutures for?

A So you're asking a level of detail of cardiac surgery that really a cardiac surgeon would have to answer.

I can give you a response as an interventional cardiologist, so there is a limit to my expertise in this area.

Typically, a pledgeted suture is to stabilize the suture and stop it cutting through the material -- stop it cutting through the tissue. So it's placing sutures; "pledgeted" are the little white bits.

Q And is it your understanding that this valve that's described in Exhibit 2009 is eventually sutured in place in the mitral valve?

A Yes, the sutures -- well, again, I would have to go through all of the surgical detail. I'm just reading through.

Yes, so those pledgeted sutures encircle the base of the mitral leaflets, and then pass through the felt ring and the stent frame. They're secured on the inside of the valve frame. These sutures are critically important in preventing PVL.

So that's the answer --

Q So the sutures --

A -- to your question.

Q Sorry, I apologize. Were you done?

A Yes.

Q So the sutures are passed through the felt strip that's been added to the outside of the valve, and then they are tied off on the inside of the valve?

Is that accurate?

A I don't know where they're tied off.

Q Would you agree that they are passed through the felt strip that's been added to the outside of the valve?

A Yes, I think that's exactly what I read out, that they're passed through the felt ring and the stent frame. They're secured on the inside of the valve frame, I'm sorry.

So, yes, they go through the felt, and they're secured on the inside.

Q I think you had your declaration, Exhibit 2051, out. I'd like to go to page 10 of that document, specifically paragraph 20.

A Paragraph 20, yes.

Q In this paragraph you state that you believe the level of ordinary skill would be an interventional cardiologist with experience implanting, researching, or designing TAVRs in the 2010 to 2012 time frame.

Do you see the portion I'm reading?

A Yes.

Q What did you mean here by "researching"?

A Anything other than the purely clinical aspect of looking after a patient, that the research would be clinical research, adding to the volume of acquired knowledge of what at this time was a very new technology. So clinical research, and it could take several different forms.

Q And what are those forms that it could take?

A So it could involve recruiting patients to clinical trials or registries, and submitting that data to multicenter trials or

registries, but it would be that you would be a named investigator or one of those individuals who was recruiting patients. So you would go and speak to the patients and say would you like to enter this research trial.

In fact, in the early days, every patient was. The very early days, all the patients were enrolled in trials or registries.

It could have involved data analysis of cohorts of patients from multiple different hospitals.

It could have involved research on a new valve material or function.

It could have involved developing a new device.

It could have involved trialing that new device.

It could have involved -- I mean, there's a very, very wide range of research activities, and to paint the picture in 2010 and 2012, my view is that the field was so

frenzied, in a way, that everyone who would have been considered a person of ordinary skill in the art would have been involved in some of these activities, particularly so for the 2012 time point. That was really a pivotal period in the technology and the clinical treatment. Things were really taking off then.

So it had had a slow start, and with all of these techniques, it's a bit like a bell shape. You go up, and in 2012, we were on the very rapid rise part of that curve.

Q Have you ever been involved in the design of a transcatheter heart valve?

A Yes, I have.

Q Can you explain for me a little bit your involvement in the design of a transcatheter heart valve?

A Well, it's quite a lot to go through. I mean, I can take some time to do it.

So over this time period, I was

involved regularly in meetings with several valve companies — mostly just Medtronic and Boston Scientific, not with Edwards — where there would be what are called a steering committee of clinical trials where design features of the valve are discussed, and in particular, whether implant practice should change or the design of the valve should change. So that's one example.

There were advisory boards which I participated in, and many others did as well. Everyone, we all were involved in all of these activities. It wasn't exclusively me. Almost everyone that was involved in TAVR.

Those advisory boards would be meetings with companies under non-disclosure agreements where you would see the next generation of device, and you would see various options or iterations of the device, and your feedback would shape the strategy for how the device would change.

There were other types of activity

where I and many others would do what's called usability testing. So usability testing is where we take usually the new design or the design that we've suggested tweaks to, and we try it out -- not in patients, you'll be pleased to know, but initially in silicon models of beating hearts -- and that is done in a mockup or a real cath lab with x-rays, and as close as possible as you can get to the femoral access, the arch, the aorta and the heart, which is all created by 3D printing in silicate, filled with fluid, it's warmed and the heart beats, and it's as close as you can imagine to doing a procedure in a patient without the patient being there.

And then there's animal work, which I did quite a lot of, testing new designs, getting feedback on the performance. So all of that I would quote as one big chapter of design activity.

I did design a heart valve as well. That is the patent application that is

recorded on my CV. It was a very long file process, and it was a design of a transcatheter mitral valve that would have proceeded but for the fact -- I'm laughing, but it breaks my heart -- that I delayed for various reasons about a year before getting it written up by a patent attorney, and the piece of prior art that meant we couldn't proceed with it was about two weeks after I would have had that document submitted had I gone when I thought I was going to go. Such is life.

So there is a patent application where I designed a valve, and it did not proceed beyond the patent application, but it was looked at with interest by a number of companies. In fact, a very similar -- very, very similar design -- the owners of the patent who I would have infringed, had I gone forward with it, have moved to clinical trials on their valve.

Q What company -- sorry.

A And I wish them the very best of

luck with it.

Q What company owned the patent that you would have infringed?

A I cannot tell you. I don't remember. I don't know. I could go and look it up, but ...

Q What company has moved into clinicals with the valve?

A They're not in clinicals. Well, I think they may have done some.

I can only give you the name of the valve as it was when I knew, but I think it's been changed. Cephea was the name of the valve.

Q You may have to spell that for our court reporter.

A Yes. C-E-P-H-E-A, I think, but I might be wrong. It's a while since I've looked at this, and I can't really give you any more information about it.

Q When you say that you designed that heart valve, did you do your own design

drawings for the valve?

A Yes.

Q And did you make prototypes of the valve?

A No. We tried to get funding, as I say, and we had -- we were very, very close to getting funding from an investment group, but as I say, we could not proceed.

Q Have you made prototypes for any other heart valves?

A I have not made prototypes. Or do you mean have I had them made? I personally have not done what Dr. Anderson did in the early days of going into his garage with some pliers and wire. No, I have not done that.

I have played with some existing devices and tweaked them and done things like that, but I have never from scratch built a prototype.

Q Have you ever been involved in the design of a transcatheter heart valve with an outer seal?

A Yes, I would say that I have, because much of that activity that I spoke to you about would have been on, for example, the LOTUS valve, the Evolut, Evolut PRO, Evolut PRO+, and future valves that I can't talk about.

Q So on the LOTUS valve, what was the outer seal made of?

A Well, you're asking me now again about the '608 patent, and I would have to read through all of the materials that I was involved in to answer your question.

I can tell you what it looked like. The design issues that I was involved in were more to do with the usability of it, how that should affect the design of the device as a whole, rather than the external seal.

Q And just to be clear, I'm not asking about the '608 patent. I'm asking you about the LOTUS valve that you have worked with.

Do you know what the outer seal on the LOTUS valve was made of?

A Sitting here now, I can't tell you the material name.

Q Can you describe the material on the outer seal?

A All I can do is tell you how people referred to it. This was a colloquial description, and it was referred to rather like clingfilm. That's the term we use in the UK. I think you call it saran wrap.

Q And based on your observations of the LOTUS valve, was that an apt description of the outer seal on the valve?

A Well, I couldn't really say. I mean, I know why people referred to it that way.

I'm trying to think if I ever saw the LOTUS valve in the expanded position -- I'm talking about in real life, I obviously had seen pictures of it -- because it was always given to me in the catheter.

When you said was I ever involved in the design of a valve with an external skirt

I think was the question, the answer is yes, but if you said to me was I involved in the design of the skirt, the answer is no.

I was more involved with how the design of the valve and the implant technique might be altered as a result of issues that arose during the use of the valve.

Q And I believe you said you worked on the Evolut PRO valve; is that correct?

A Yes, I was involved in the types of activities that I was describing earlier: clinical trials, advisory boards, usability testing, that sort of thing.

Q And does the Evolut PRO valve have some sort of outer seal?

A It has a layer of pericardial tissue around the outside.

Q What are the different factors that contribute to whether or not PVL occurs with a transcatheter aortic heart valve?

A So there's a lot of factors.

The first is sizing. So sizing the

valve to the appropriate degree of oversizing, or interference fit, with the native anatomy has to be done accurately.

So if you put in too small a valve -- and on occasions, too large a valve -- for that patient's anatomy, you may get paravalvular leak.

The second consideration is the implant depth. So valves have to be implanted at a certain depth that is, in part, in large part, related to their design in order to get adequate sealing. Valves that are implanted either too deep, and certainly too high, can equalize to paravalvular leak.

The third factor is the design of the valve itself. So it's well known that some valves have a higher degree of paravalvular leak than others.

So, for example, in the early days of CoreValve versus Sapien, CoreValve had a higher degree of paravalvular leak, and that, in part, related to the degree of radial force

that was exerted by the valve on tissue, so valve-related features.

And then the final area would be — and perhaps this is the most important — the patient's anatomy. So the degree of calcification in the leaflets, whether there is calcium that extends, as it typically does, below the annular plane into the left ventricular outflow tract, that can act as a spur of calcium that would prevent the frame expansion, and you could get a leak around the edge.

The nature of the valve itself, whether it's a bicuspid valve or a tri-leaflet valve, would also affect that type of consideration.

So there are many, many factors, and they all interact with each other, and that is why we have often said, and certainly I teach, that the decisions you make prior to going into the catheter lab are probably the most important ones, and that is which valve you're

going to choose, your implant strategy, your sizing, your depth of implant, and choosing a valve with a particular type of design and paravalvular leak solution that would guide you.

Q You mentioned implanting a valve too high. What does that mean in terms of the anatomy?

A Oh, well, that can be -- that's quite a serious complication if it occurs, and it's -- I don't want to give you the impression that -- I was going to call it a feared complication, but that's adding to annular rupture and coronary occlusion and everything else, and I don't want to give you the impression that it's a dangerous procedure because it has changed out of all recognition from the early days.

High implants I would say are still feared because they can culminate in the patient's death. If you implant the transcatheter valve too high, then quite apart

from the fact that you may get a paravalvular leak under the bottom edge, then -- it all depends on how high, but you will get inadequate anchoring. Certain types of anatomy may cause anchoring within the leaflets, but a lot of the time, if you implant the transcatheter valve supra-annular, by which I mean above what everyone knows to be the annular plane, then you could embolize that valve, and valve embolization is associated with a significant risk of morbidity and mortality. It's not a nice thing when it happens, and frankly, thankfully, it doesn't happen very often.

But high implants, by which I mean implanting just a couple of millimeters below the annulus, that can be quite advantageous. For example, 3 mm, that can be exactly where you want it.

Implanting at the annulus, or at zero, you may get away with it, but you are putting the patient at risk of embolization.

And implanting the valve above that, no one would do that. No implanting cardiologist would implant above the annulus. It would be a very dangerous thing to do.

Q When you refer to implanting the valve at the annulus, do you mean the tissue portion of the valve is at the annulus, or do you mean some other portion of the valve is at the annulus? I'm just trying to understand what you mean by that.

A So typically when we talk about depth of implant, we talk about the relationship of the bottom of the frame, or the bottom of the valve, to the annular plane. And for all the valves now, the typical target depth is in the region of 3, maybe 3 to 4 mm below the annular plane. So the bottom of the frame would be that depth below the annulus.

Q You also mentioned radial force when you were talking about the CoreValve device and that it had a higher degree valve of paravalvular leakage.

What did you mean by "radial force"?

A Radial force is a characteristic of all transcatheter valves, but only after implant.

Radial strength is a characteristic that you could measure on an expanded valve before you implant it.

It relates to the property that the valve that is implanted has to be slightly bigger than what it is being implanted into in order to get a comfortable tight fit and, therefore, there will be force exerted by the valve on the tissues around it.

And on the very first iteration of CoreValve, if you took it, for example, and compared it to the Edwards valve, if you just took an expanded valve outside the body and tried to just gently squeeze the bottom, you would need less force to deform the CoreValve than the Sapien valve.

Q So is the radial force that you're talking about the force required to deform the

frame, or is it the force that the frame exerts on the surrounding tissue?

A Well, you're asking questions that I haven't really made an opinion of for the purposes of today.

They're pretty general questions, and so it's not that I'm unhappy to answer, but if, for example, radial force was something that was going to be important in the future, I don't want to give a definition of it.

I can only give you what I understand by it and what I think a POSITA would understand, and it could be used in many different ways, and both of those examples that you gave could be used.

So it could be the amount of radial force you need to compress is a use of the term. The radial force that the device exerts on surrounding tissue is another use of the term.

It doesn't define the term. All it

is trying to convey is a property related to -- and I'm using this term very loosely -- the strength, if you will, of the frame, the amount of force that it can exert or can resist.

Q How was the radial force of the CoreValve device connected to the paravalvular leakage, which is how we first got onto the topic?

A Well, all I can do is give you some examples.

If you've got a bottle of water, an old-fashioned glass bottle of water with a long neck, so sort of posh bottle of mineral water in a glass bottle, you want to test how the water will stay in the bottle, and you've got a variety of plugs.

If you put in a plug that is smaller than the diameter of the bottleneck, it's not going to touch the edges, and when you turn the bottle over, the first thing that will happen is that will fall out and the water

will come out.

If you put in a stopper or bung that is exactly the size of the bottle and turn it upside down, it might stay in, but if you then shake it and exert more force on it, it will come out.

And if you put in a cork or a bung that is bigger than the bottleneck, it will exert radial force and it will stay in when you turn it upside down.

So, I mean, I'm just giving that example.

Q Okay. Would it be fair to say that if the radial force of the frame of the transcatheter heart valve is insufficient, it may lead to paravalvular leakage?

A This is relating to the CoreValve frame, and that is the example that I can think of, yes.

That was the explanation of the relatively high rates of paravalvular leak with the original CoreValve, but there were

high rates of paravalvular leak with Sapien XT as well, and that also related in a way to radial force, but there may have been other factors as well.

Q Does the geometry of the cell structure in the frame of the transcatheter heart valve have any impact on whether or not the valve experiences paravalvular leakage?

A Do you mean the geometry of cell design --

Q Correct, yes.

A -- or the geometry of the frame in terms of its shape?

Q I'm talking about the geometry of the cell design.

A So my understanding is that that relationship is quite complicated.

So in all of my aspects of design, there would always be an engineer in the room, and that's the sort of question that I would be asking the engineer or they would be telling me, but I can't tell you that a

specific cell design would lead to paravalvular leak.

What I can say is there was a change in the cell, either size and/or geometry, of the Evolut valve, and it was alleged that that was one of the reasons why -- I mean, there were several, actually -- but that was one of the reasons why there was a reduction in PVL.

Q Can the total geometry of the valve have an impact on paravalvular leakage?

MR. LOWENSTEIN: Objection, form, scope.

THE WITNESS: So I think you're asking an extremely general question, that does the design of the valve as a whole affect paravalvular leak, and the answer to that is yes.

BY MR. STOWELL:

Q Maybe we'll -- sorry, go ahead if you're still --

A It wasn't always predictable.

I mean, for example, as I was

mentioning before, the degree of paravalvular leak with Sapien XT was higher than with the previous iteration.

It wasn't until Sapien 3 that the paravalvular leak really declined with that frame -- with that valve, with Sapien I mean.

So the design of the valve does affect paravalvular leak.

Q In your experience, do you recall any specific instances where the overall shape of the valve impacted paravalvular leakage?

MR. LOWENSTEIN: Objection, form. Objection, scope.

THE WITNESS: The overall shape from top to bottom, no, I don't recall anyone saying this shape is associated with paravalvular leak, no. It would be related to the factors we've been discussing.

BY MR. STOWELL:

Q There are different degrees of paravalvular leakage, correct?

A Yes, that is correct.

Q And is it fair to say that they're typically referred to as mild, moderate, and severe?

A Yes. There is also a grade even below mild, which can be referred to as "trace."

Q Would you agree that mild PVL is not considered to significantly affect patient mortality?

A That's a really interesting question, and I could write a book chapter on it, but I don't suppose you want me to do that.

In the early days, we didn't pay any attention at all to mild paravalvular leak, and certainly paravalvular leak from the surgical literature that was mild, no one really worried about.

In the early days of TAVI -- I'm sorry, I'm using TAVI, T-A-V-I, interchangeably with TAVR.

Again, we thought, oh, well, thank

goodness we got out of the cath lab with the patient alive. We're not worried about mild PVL. We're not even worried -- and I'm talking about the 2007-2008 time frame -- we're really not worried about moderate PVL. We're slapping each other on the back that we've managed to deliver the valve and the patient is alive.

Then there were one or two trials that suggested that mild PVL may not be that benign, and there was a lot of debate and a lot of discussion about it. And, of course, it doesn't only relate to the degree of the PVL, it also relates to the patient's left ventricular function, how well they can tolerate, and other comorbidities that the patient has got.

It also related to how the PVL was measured. So some of the early trials relied on self-reporting by the operators and the hospital. You just had to fill out a case report form, and you would mark, oh, mild PVL,

and human beings being human beings, there was cognitive bias that led you perhaps to underestimate the degree of PVL you'd left the patient with.

And one of the trials that, if my memory serves me correctly, suggested that mild PVL may not be benign was with one of the Sapien valves, probably I think the Sapien XT, and the principal investigator at the time probably correctly said, well, this is because, if anything, we are rigorously assessing the PVL, and we're being extremely rigorous to it. So there was a lot of discussion at the time about how accurate the PVL was being reported.

And I think our feeling now is, for the majority of patients, mild PVL doesn't -- really mild or trace -- doesn't matter, but there is a subset of patients, you know, not a sizeable proportion, in whom even mild PVL can be very bad.

So it's a long answer, but it's a

complex area.

Q You mentioned that there were one or two trials about mild PVL that kind of raised or elevated mild PVL.

Do you remember when those trials were published?

A So my recollection is it would have been in the 2010, 2012 time frame.

PVL in general was becoming much more of a concern, because of course, by 2010, we'd been implanting valves for three years, and we got over that emotion of just getting the patient out of the room alive, and so we wanted to improve the outcomes.

But as I say, prior to 2010, really mild PVL would have been considered a pretty good result.

Q And currently with your patients that experience mild PVL after implantation of a TAVR device, do you do any sort of re-intervention with those patients to try to improve the mild PVL?

A Well, that's another massive area to discuss. I mean, the answer is sometimes, but there's a lot of different interventions you can do.

It depends on the type of valve that's being implanted, and it depends on the reason for the PVL, and all of that discussion I gave you before about how PVL arises, all of those have potential solutions.

Q Does mild PVL ever resolve over time in patients that have a transcatheter heart valve?

A Yes, it can. Certainly with Evolut, some of the clinical trials showed that there was a reduction in PVL over time.

Q And what causes the reduction in PVL?

A So these are really complicated questions. I mean, they're really -- they're really -- they don't have short answers, because each of these questions you're asking, there have been huge meetings about.

You know, the discussion about why PVL seemed to decrease in time in some clinical trials, there were lots and lots developments.

The truth is, I don't think anyone knows for sure, but there are a few potential explanations. One of them is that the mild PVL was not mild, it was actually moderate, and the patient died. So at follow-up, that patient with moderate PVL no longer appears on the list of patients who survive.

The other explanation, this applies more to Evolut, was that ongoing expansion of the valve may have enabled whatever the cause of the PVL was, if there was a small gap, that the frame expanded and put the skirt now into contact with the tissue that then eliminated the PVL.

And certainly we've seen patients who had mild PVL, even mild plus PVL, after the procedure, and when they have their echocardiogram a week or two weeks later, the

PVL is gone. That has occurred more in those patients with external seeding skirts than the original CoreValve and Evolut, but ongoing expansion of the frame may have contributed to some of that.

Could I just mention that I'm getting close to needing a toilet break.

MR. LOWENSTEIN: It's 12 minutes left by my calculation. Do you want to go off record for a minute or two, or what's your preference?

THE WITNESS: Well, I just --

MR. LOWENSTEIN: Why don't we --

THE WITNESS: I've been drinking a lot of water through the day, and it needs to --

MR. LOWENSTEIN: Why don't we take a two-minute break. Does that work?

MR. STOWELL: Sure, that's fine on our end.

THE WITNESS: Okay.

THE VIDEOGRAPHER: Okay, going off

the record. The time is 3:12.

(A break was taken.)

THE VIDEOGRAPHER: We are back on the record. The time is 3:16.

BY MR. STOWELL:

Q Dr. Brecker, what percentage of the patients that you implant TAVR devices into today end up with mild PVL?

A So it's pretty -- I would say it's pretty small, but it's not insignificant.

So mild PVL is less common with Sapien 3 than with Evolut/Evolut PRO+ at the time of implant, and that relates to the fact that there is some ongoing expansion of the Evolut frame.

I would say -- you know, it depends at what time you look: at implant, at 7 days, at 30 days. But 30 days, a mild PVL, it could be present in 20% even of Evolut patients, but then if you look at a year, it's less, as I say, and it's probably a smaller percentage, maybe not 20%, smaller percentage with

Sapien 3.

And I'm including extremely mild. I'm including in that trace as well, where you literally just see a tiny, tiny amount going back, and that would really be insignificant.

Q That raises a good question.

Is there a distinct measurement you use to determine whether someone has trace or mild PVL, or is it something that you're just visualizing?

MR. LOWENSTEIN: Objection, scope.

THE WITNESS: So what you're asking is grading a paravalvular leak, and that's, again, a very complex area, and there are many ways of grading it, both with angiography, echocardiography, hemodynamics as well.

And so there is a -- there's no -- I wouldn't say there is a distinction between trace and mild, but everyone really knows what that means. It's where you've got just a tiny, tiny, tiny bit.

There are agreed criteria

echocardiographically for the distinction between mild and moderate and moderate and severe, and there are also criteria angiographically, and there are hemodynamic criteria as well.

BY MR. STOWELL:

Q For the patients that you perform TAVR procedures on today that have mild PVL after, say, 30 days, what percentage of those patients do you have to do some sort of additional intervention to correct the PVL?

MR. LOWENSTEIN: Objection, scope.

Are we ever going to ask any questions that have anything to do with this IPR?

No, no, hold on a second. Like, seriously, for two hours now you've been asking questions that have tangential, at best, relevance to this IPR. I strenuously object.

You've not asked a single question about Levi, you haven't asked a single

question about Walther, Spenser II. You seem to be digging for stuff in litigation.

I'm going to give you a very, very short leash on this tomorrow, Josh. If you do it, we're going to get on a call with the Board, because this wasting my time, it's wasting the witness's time. It's inappropriate.

MR. STOWELL: Okay, Mr. Lowenstein, I'll ask you to limit your objections to a single word as required by the rules.

MR. LOWENSTEIN: You didn't dispute anything I just said. I just want to point that out.

MR. STOWELL: I'm not going to argue with you on the record, Nathan.

BY MR. STOWELL:

Q Dr. Brecker, do you need me to reask the question?

A No. Very, very, very, very few patients with mild PVL will need further intervention.

Q Thank you. So I think we've reached a good stopping point on the outline.

Mr. Fahnert, can you give us a time?

THE VIDEOGRAPHER: Yes.

4 hours, 54 minutes.

MR. STOWELL: Okay.

MR. LOWENSTEIN: You don't get the extra 6 minutes.

MR. STOWELL: Okay, so this would be a good breaking point for today.

Dr. Brecker, thank you for your time. We will pick up tomorrow morning at 8:30 a.m. Does that sound good?

THE WITNESS: Yes, that sounds good.

MR. LOWENSTEIN: And will you actually ask questions about the IPR, or will it just be another day of questions about litigation?

MR. STOWELL: I think we can go off the record now unless anybody else has any --

MR. LOWENSTEIN: I thought we were, but we're meeting and conferring right now.

Completely inappropriate.

THE VIDEOGRAPHER: Going off the record. This deposition is adjourned at 3:22.

(Whereupon, at 3:22 p.m. PDT, the taking of the deposition was adjourned, to be reconvened the following day. Reading and signature were RESERVED.)

CERTIFICATE OF NOTARY PUBLIC

I, DAWN A. JAQUES, a Notary Public in and for the Commonwealth of Virginia, before whom the foregoing deposition was taken, do hereby certify that witness whose testimony appears in the foregoing pages was duly sworn by me; that the testimony of said witness was taken by me in shorthand at the time and place mentioned in the caption hereof and thereafter reduced to typewriting under my supervision; that said deposition is a true record of the testimony given by said witness; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this deposition is taken; and, further, that I am not a relative or employee of any attorney or counsel employed by the parties thereto, nor financially or otherwise interested in the outcome of the actions.

Dawn A. Jaques

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Registration No. 132328

Stephen J.D. Brecker Vol I, c/o
LOWENSTEIN & WEATHERWAX LLP
1016 Pico Boulevard
Santa Monica, California 90405

Case: Edward Lifesciences Corp., et al., v. Aortic Innovations, LLC
Date of deposition: August 30, 2022
Deponent: Stephen J.D. Brecker Vol I

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