UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORP., EDWARDS LIFESCIENCES LLC, AND EDWARDS LIFESCIENCES AG	)	
Petitioners,	)	
v.	)	CASE IPR 2017-00060
BOSTON SCIENTIFIC SCIMED, INC.,	)	
Patent Owner	)	

Deposition of NIGEL P. BULLER, M.D., taken pursuant to notice, at the law offices of Morris Nichols Arsht & Tunnell, LLP 1201 Market Street, Wilmington, Delaware, beginning at 8:40 a.m., on Thursday, June 15, 2017, before Terry Barbano Burke, RMR-CRR and Notary Public.

Edwards Lifesciences v. Boston Scientific Scimed
IPR2017-00060, U.S. Patent 8,992,608
Exhibit 2028

APPEARANCES:

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ALSO PRESENT:
VICTORIA BROWN, Legal Intern

- - -

NIGEL P. BULLER, M.D.,

the deponent herein, having first been duly sworn on oath, was examined and testified as follows:

BY MR. COHN:

Q. Good morning, Dr. Buller.

A. Good morning.

Q. You submitted an expert report in this inter partes review proceeding; is that right?

A. Yes.

Q. An expert declaration?

A. That's why I was hesitating. Yes, I think it was a declaration.

Q. And you signed that declaration under oath to give the truth and nothing but the truth so help you God in that declaration; is that right?

A. Yes, correct.

Q. Now, you also gave testimony recently in a United Kingdom litigation about the European counterpart to the patent that is at issue in this inter partes proceeding; is that right?

MR. EGAN: Objection. Relevance.

THE WITNESS: Earlier this year.

BY MR. COHN:

Q. That was January this year; correct?

A. Correct.

Q. And in that proceeding, you swore to tell the truth so help you God, is that right, when you testified in court?

A. Yes.

Q. And the oath that you took in that proceeding, you take that oath as seriously as

you took the oath that you just gave this morning; is that right?

A. Of course, yes.

Q. And you stand by your testimony in the UK in January?

A. I do.

Q. Is there anything that you recall saying in that proceeding that you want to correct or clarify right now?

A. Not as I sit here. I mean I may have misspoken. I hope I would have corrected it at the time if I said the wrong words, because I do remember something got mixed up.

But, no, essentially I'm sticking completely behind the testimony I gave. But wrong words and things, I might have misspoken.

Q. How many depositions have you given in the last five years?

A. I honestly don't know. Half a dozen. Half a dozen, I would guess. There were no depositions for the UK case. The only depositions I've given are in the US.

Q. When you say "in the US," you mean for

proceedings in the United States?

A. I mean both in the United States and court procedures. I haven't done any depositions outside the United States, but, yes, being full proceedings in the United States.

Q. How many of those depositions were in your capacity as an expert for Edwards Life Sciences?

A. Several of them. In the last five years, I believe I've only acted for two companies. One is CR Bard. And there was a trial earlier this year against Gore, and for that I gave -- I can't remember if it was one or two depositions, but I certainly did a deposition. And then I gave live testimony here in Delaware earlier this year.

And the other ones are, to the best of my recollection, all for Edwards.

Q. What was the subject matter? And let me just preface this by saying I don't want you to reveal any confidential information of Bard or the parties in that case, but what was the general subject matter of the testimony

you gave in the Bard case?

A. About ePTFE to cover stents. So it's about what is often called Gortex. It's a tradename for Gore, and it was about ePTFE thickness or covering stent grafts.

Q. Did you represent the patent owner in that case?

A. No. The patent owner was Gore and they were suing Bard, CR Bard for infringement, and I was acting for Bard saying the patent was invalid and not infringed. And this was in Delaware a few months back.

Q. Did your testimony discuss the Gore extruder? Is it called the extruder?

A. No, excluder. If that is what you mean.

Q. I misspoke.

A. The AAA device.

Q. Let me ask a clean question.

Did your testimony for Bard at the trial earlier this year in Delaware cover the Gore excluder?

A. No.

Q. Did you discuss in that testimony any

of the prior art that you have discussed in your declaration in this inter partes review?

A. No. I don't believe as I sit here, but, obviously, there are a lot of documents. I don't believe so.

By prior art, I'm sorry, can I correct that? There were a few general medical references, things like Lawrence, which is something I talked about. I think was talked about

There are a few, obviously my background as an interventional cardiologist, there's things in that, medical things. But the patents, the prior art, were not the same as in this case.

Q. Roughly, what was the priority date in the Gore case, the Bard/Gore case?

A. Much earlier. Approximately ten years earlier, I think, from memory. I may be wrong on this. It was around '93.

Q. In your capacity as an expert for Edwards in this inter partes reviews proceeding, are you being compensated?

A. Yes.

Q. Are you being compensated on an hourly basis?
A. Yes.
Q. What is your hourly rate?
A. Pound sterling, 480 pounds. I charge and am paid in sterling.
Q. Are you being paid by the hour for today's testimony?
A. Yes.
Q. Same rate?
A. Yes, exactly the same.
Q. Over the past five years, approximately how much compensation have you received from Edwards Lifesciences for all of your expert work for them?
A. I honestly don't know.
Q. Within 500,000 pounds?
A. Yes, I think probably more than 500,000 pounds, but I haven't added it up.
Q. Let's just establish some quick shorthands, mostly for the court reporters.
The patent at issue in this inter partes review proceeding, can we call it the '608 patent?

A. Yes.
Q. And you understand what patent I am talking about?
A. I do. I mean it is obviously the one, if you give me a copy, there will be no -- but yes, it is the '608. I have been in a case where there was another patent with the same numbers, but I know exactly what you are talking about, and I am talking about the '608 patent.
Q. The acronym T-A-V-R, TAVR, just for the record, what does that stand for?
A. Transluminal aortic valve replacement.
Q. Can we also call it transcatheter aortic valve replacement?
A. Yes, you can.
Q. That is an equally valid interpretation of that acronym, transluminal versus transcatheter?
A. Yes, yes. But the A, you gave the acronym, I thought you said "A", T-A-V-R.
Q. T-A-V-R?
A. Yes.
Q. So the "T" can be either transluminal

or transcatheter, it doesn't matter?
A. Yes.
Q. And TAVI, what does that mean?
A. Just change the replacement for implantation. Again, it's essentially the same. It's a slightly different acronym. There are a whole range of these acronyms which are used interchangeably for the same sort of procedure. Transcatheter aortic valve replacement is probably one of the more common ones.
Q. TAVR and TAVI are used interchangeably for essentially the same procedure?
A. I think they are, yes.
Q. Today can we just use TAVI?
A. I'm happy.
Q. Generally speaking, what is a TAVR procedure?
A. Today, or meaning as of today?
Q. Yes.
A. It's a procedure in which a replacement valve is put inside the body, typically into the heart, using a catheter and is most often used to treat aortic stenosis.

So that's the most common TAVR procedure. There are other ones used in other locations.

Q. Like in the pulmonic valve, for example?

A. Yes. The device, if you like, even though it is called aortic, they are occasionally put in other places and inside other valves. But the vast majority of them are put in to replace aortic valves in patients that have degenerative process and old age referred to as calcific stenosis. That would be the majority of ones that are done today.

Q. Now, when I asked you what is a TAVR procedure and you said, you asked me when I was referring to, would your definition change if I had said what is a TAVR procedure in 2004?

A. Well, yes, because by then it wasn't commercialized, and I would probably talk about the very few individuals you had experience of, and most notably Alain Cribier. A-L-A-I-N, Cribier.

Q. C-R-I-B-I-E-R?

A. Correct.

So it would change in that this procedure is in medical terms a fairly new procedure, and at the time that he did the first TAVR procedure, he was the only person that had done it and it wasn't a commonly used procedure. Therefore, I am not sure people would be using the term. It was something that he did first in the early 2000's.

Q. Do you know if the acronym TAVR was in common use by 2004?

MR. EGAN: Objection to form.

THE WITNESS: It depends what you mean by "common" really. I don't think I know whether that particular acronym was being used commonly. It probably was used, but, I mean, it depends what you mean by commonly, because in 2004 these procedures are very new and people are interested in them, such as myself, may well have come across it. But it wouldn't necessarily be something that was in the wider domain.

BY MR. COHN:

Q. So just make sure I understand what

you are saying. In June 2004, TAVR was a fairly new procedure; is that right?

A. Yes.

Q. And by that time, only one person in the whole world had performed TAVR procedures in human beings, is that right, and that is Dr. Cribier?

A. Yes, Dr. Cribier is the main one. I think by 2004 there may have been another person in the United States who had attempted them. But again, it's difficult to answer your question, what detail you go into.

The way Alain Cribier did the first ones was a very different route. He went up through the veins, across the septum. He went a route that we sometimes refer to as antegrade.

What I described to you earlier is, what's done today is almost always done retrograde, going against the flow of blood, coming up the aorta and into the valve. So there are things that have changed. And you can refer to them, and people might have, as TAVR, going back that far to 2004, but a lot

about the procedure, the devices has changed.

Q. In 2004, I think you said that Alain Cribier had performed TAVR procedures and possibly another person in the US?

A. Yes.

Q. Who was that other person?

A. I can't remember, but I think there was someone else by the US.

And there are other valve implantations done, pulmonary ones, by a gentleman called Bonhoeffer, which are, if you like -- if you take the "A" out of transluminal valve implantation, it was done by others, including Bonhoeffer.

So it's all around, the interest in putting heart valves in by percutaneous transcatheter techniques really came to life in the early 2000's and different people working on pulmonary valves, from aortic valves, and Alain Cribier was the first to perform an aortic valve implantation, but he did it by a different technique than the one that was commonly used.

Q. Now, if we expand our discussion

beyond just the aorta to talk about transcatheter valve replacement --

A. Yes.

Q. -- any valve in the heart, would you still have characterized that as a fairly new procedure by June of 2004?

MR. EGAN: Objection to form.

THE WITNESS: Yes. It was a fairly new -- as I say, there were other groups, including most notably Bonhoeffer's group. By 2004 I think he was in London. He's a French -- he was a French doctor. And he was putting in pulmonary valves using a different device which he had been involved in developing.

BY MR. COHN:

Q. By June 2004, had any regulatory body approved for the commercial sale a transcatheter replacement valve for any valve in the heart?

A. I don't believe so.

Q. Has there been any approval by a regulatory body for the commercial sale of a transcatheter pulmonic replacement valve?

MR. EGAN: Objection to the form.

THE WITNESS: Today?

BY MR. COHN:

Q. Today?

A. Yes.

Q. What approval is that, what valve is that for the pulmonary?

A. The Melody valve is the valve that was subsequently commercialized, which is related to the original work that Bonhoeffer did, and I think it is now, today, marketed by Medtronic.

Q. Are any of Edwards' transcatheter valve products approved by any regulatory body to be used in the pulmonic valve?

MR. EGAN: Objection to form and relevance.

THE WITNESS: The answer to that, there are so many different countries and regulatory authorities, I just don't know the answer.

BY MR. COHN:

Q. Are you aware of any that have

approved any Edwards' valve for the pulmonic valve?

MR. EGAN: Objection. Relevance, form.

THE WITNESS: As I just said, I'm not. But I don't know that, I don't know that there are not.

BY MR. COHN:

Q. Now, you talked about Dr. Cribier had performed an antegrade approach with his valve replacements in the aorta by June 2004; is that right?

A. Correct.

Q. What is the difference between an antegrade approach and a retrograde approach?

A. Well, in brief, to go antegrade, you're going with the flow of blood and, therefore, you go typically up a vein in the leg, and you go up to the heart the direction the blood returns to the heart. And then you have to cross over from the right side of the heart to the left side of the heart, and you make a hole with a needle and then stretch it up with a balloon to do that. Then you go

into the left side of the heart, and you go into the aortic valve from the direction of the ventricle towards the aorta.

So it is a more difficult, more complex procedure in some respects because you are traveling a lot longer distance, and you are putting the valve into the same position, into the subcoronary aortic position, but you're doing it via this so-called antegrade route.

And that is what Alain Cribier did for the first half dozen or so procedures that he performed.

Q. And the first half dozen or so procedures that Dr. Cribier performed were all before June 2004?

MR. EGAN: Objection to form.

THE WITNESS: I don't know the exact number. There were that sort of number of procedures that he and his group performed before 2004.

BY MR. COHN:

Q. As far as you are aware, had anyone in the world performed a retrograde approach for

a transcatheter aortic valve replacement before June 2004?

A. I don't know the answer to that, I'm afraid.

Q. You are not aware of any such procedures sitting here today?

A. Well, I'm talking about in my answer -- sorry, I should have prefaced it -- it is involved in patients, to treat patients.

In animals, yes, they had. Experimental work and animal work was definitely being done, and I'm aware of it, in that case right back to Andersen's work, Henning Rudd Andersen.

But I'm not, as I sit here today, aware as to whether anyone had performed a retrograde procedure before June 2004.

Q. Before June 2004, it is your testimony that retrograde TAVR procedures had been performed in animals?

A. Well, I don't know whether you call them TAVR procedures because they are experimental.

I mean, again, the terminology I'm not sure was used back then. But experimental work, put valves in going retrogradely in experimental procedures, you often don't start down the leg of the animal. You may go into the aorta. But they are being put in retrogradely, coming up the aorta and around into the aortic position, against the flow of blood. That had been done experimentally, yes.

Q. And when you said that these procedures were done not through the leg of the animal, how was the device implanted into the aorta and then into the heart valve?

A. Sometimes for ease it would be put directly into the aorta but down below the diaphragm. So to get in, because the devices were a certain size, animals have quite small blood vessels in the leg, so it would go into the aorta and then continue up the aorta.

Q. In your entire career, you have never performed a TAVR procedure on a human patient; is that correct?

A. Correct.

Q. And you have never performed any transcatheter or transluminal valve replacement procedure on a human patient?

A. Replacement procedure, no, I've never performed.

Q. And you have never performed a valve replacement procedure on an animal; is that correct?

A. Correct.

Q. And you have never deployed a TAVR device in a bench test or in any setting; is that right?

A. I have deployed TAVR devices in bench tests, yes. I've examined devices and equipment and I have deployed some. But I have never treated a patient and I have never implanted one in an animal. But I have inspected and looked at devices, including deploying some.

By "deploy," I mean on the bench. I mean not into an animal or human tissue.

Q. When you say "on the bench" -- well, let's back up.

In the devices that you have deployed, TAVR devices on the bench, were they being deployed in air or were they in some sort of a fixture or a model or something like that?

MR. EGAN: Objection. Compound.

THE WITNESS: Water bath, I think. So under water, a water bath. But I'm not sure what you mean by a fixture. I didn't quite understand what you meant in the question by a fixture in a tank, which would be...

BY MR. COHN:

Q. How many times have you deployed a transcatheter valve replacement device?

A. Very few. I mean a couple.

Q. Twice?

A. Two, three, four.

Q. Less than five?

A. I think that is fair.

Q. And the times that you deployed a transcatheter valve device, it was always in a water bath?

A. No, it wasn't always in a water bath,

but the majority have been in a water bath to keep -- look at the valve and to do it with something approaching body temperature.

Q. And these deployments of a transcatheter valve device that you did on the bench -- is that how you characterize it, on the bench?

A. Yes, broadly. I mean, that's an expression, meaning outside a patient. Experimental, just inspecting it. So on a bench, yes, that's fair.

Q. The transcatheter valve devices that you deployed on the bench, was that in conjunction with your work as an expert in a litigation?

A. Some of it was and some of it wasn't. Just a medical meeting. So both.

Q. The deployment of a transcatheter valve device that you did as part of a medical meeting, was that in 2013?

A. I certainly did. That is the training course, the Edwards training course that I went to in New York. And, yes, certainly there was one I deployed during that meeting.

Q. Had you deployed a TAVR device on the bench prior to 2013 other than in your capacity as a litigation expert?
A. Yes, at a medical meeting.
Q. When was that medical meeting?
A. I honestly don't remember.
Q. Was it after 2007?
A. I would guess, sitting here, it was after 2010, I would guess.
Q. Do you agree it was certainly after 2007?
A. Well, I have agreed. I think I said after 2010, so that is by definition after 2007.
Q. What was the transcatheter valve device that you deployed at a medical meeting some time after 2010?
A. CoreValve device, the Medtronic CoreValve device is one I remember.
Q. At the time that you did that deployment, you had been retained as an expert in litigation for Edwards around the CoreValve; right?
MR. EGAN: Objection.

Foundation.

THE WITNESS: Yes. I'm trying to think how long, how far back that was, but that was around 2007, yes.

BY MR. COHN:

Q. Was that the first time, that CoreValve deployment that you just mentioned at the medical meeting, that you had deployed a TAVR device in your career?

A. I can't remember whether I deployed an Edwards one. Just as I sit here can't remember, so I can't answer that. I don't know.

Q. When was the first time that you recall deploying a transcatheter valve device in your entire life?

A. Well, as I say, I don't think the CoreValve one was before 2010, and I think I may well have deployed an Edwards one, bench-top deployment before then, but I honestly can't remember the year.

Q. It would have been after 2007 that you did that; right?

A. I can't remember the year.

Q. Could it have been before 2007?
A. I can't remember the year. I can't remember, so I can't give you a date.
Q. You have never deployed a transcatheter valve device that had had a seal around the outside of the device; is that right?
MR. EGAN: Objection. Foundation.
THE WITNESS: Depending on what you mean by a seal, no. I mean, obviously, the intent with the device is it didn't have fabric around the outside. It was still a seal. But I have not deployed one at all that has a fabric around the outside.
I've done a few stitches traveling around stents to actually secure what's inside the stent.
BY MR. COHN:
Q. Now, in your report you mention a hands-on training in 2013 regarding TAVR devices?
A. Yes.
Q. And that 2013 training was provided by

Edwards; is that right?

A. Yes. It was a formal Edwards training session for physicians, which I attended, I requested to go and attend it. And I went along to listen and take part in the training session. It wasn't arranged for me. It was a routine session to train people who were going to potentially go ahead and implant Edwards' devices in the United States and outside, from memory.

Q. It was an Edwards training session?

A. Well, I don't know. It was certainly organized on behalf of Edwards, but it was at a hospital with physicians. So I'm not sure whether, but it was absolutely on behalf of Edwards, and it included a lot of physicians who were well known in the field of TAVR.

Q. Who was one of the physicians who was well known in the field of TAVR who was at the training session you attended in 2013?

A. Marty Leon.

Q. Anyone else?

A. There were lots, but I can't remember, as I sit here.

Q. Do you know if Marty Leon regularly attends and teaches at Edwards training sessions?

A. I don't know if he does now. I mean I think -- I don't know the answer to that. I mean you would have to ask him. I don't know.

Q. And at the training session, did you personally deploy a TAVR device on the bench or did you watch it be done?

A. Did I purposely arrange the thing? I honestly don't remember. I don't remember. There were lots of -- it was a question of different people looking and holding things. I don't remember.

Q. Do you remember which of the Edwards' TAVR devices you had hands-on training with at the 2013 hands-on training?

A. I don't, as I sit here now, I'm afraid.

Q. Was the Sapien 3 part of the hands-on training?

A. No, it wasn't. The Sapien 3 was not part of it at all.

Q. So it was either the XT or the

original Sapien?
A. Correct.
Q. And you can't remember which one?
A. I can't.
Q. And when you say "hands-on training," did you actually put your hands on the product?
A. Yes. There were products there to look at and examine and, yes, absolutely, hands on, touching the product.
Q. You touched the valve?
A. Yes. I can't remember if they were ones that were real valves in preservative -- I think some of them were -- and if there were gloves. But there were other ones, main ones, if you like, sort of a mock-up is the real stent and the real fabric, Dacron, but the valve is replaced by non-animal tissue so that you can look at them, and there were ones like that as well, I think.
Q. Just so we are clear, I used the word "valve." What I meant is the whole valve device. You picked up the whole Sapien or Sapien XT valve device and looked at it?

A. Yes.
Q. Did you do anything with it other than look at it?
A. Well, handle it, feel it, look at it. But I was already familiar with them, so that wasn't -- I mean I had already handled and touched and examined many before going to that meeting.
Q. In the course of your work as a litigation expert?
A. Mainly in the course of litigation expert acting for Edwards, but also at medical meetings.
Q. Can you identify the medical meetings where you actually put your hands on a transcatheter valve product?
A. I can't as I sit here. I mean meetings, a TCT meeting in the United States, it is one of the big interventional cardiology meetings.
Q. And those are attended by hundreds of cardiologists?
A. Thousands. I mean it started as hundreds. I went in the very early days when

it was a few hundreds, but it's grown and grown over the years, and I think it is now up above 10,000 delegates. They are not all interventional cardiologists, but it is now a very large meeting, annual meeting.

Q. How many other people were being trained with you at the 2013 Edwards training session that you attended?

MR. EGAN: Objection. Relevance.

THE WITNESS: On the order of a dozen, that sort of order. It was a small coach that picked us up from the hotel and took us to the hospital. So it was of the order of a dozen. But I can't be more precise than that.

BY MR. COHN:

Q. And that was the first time you received training in the use of a TAVR device?

MR. EGAN: Objection to form.

THE WITNESS: No. This was the first time I attended one of these formalized training sessions, but, obviously, I had been to lots of medical meetings, seen live

procedures, been to the stands of companies including Edwards, and read scientific articles, medical articles. So learning about these devices is an ongoing process which includes being up to date with literature, going to medical meetings, watching live demonstrations.

And then I wanted to go and I requested to go to a formal meeting to actually hear what was being told to people who were training so that I could sit in and find out what was actually being said to people who were getting ready to do their first implants.

BY MR. COHN:

Q. And that last bit about the formal meeting, you are referring to the 2013 training session with Edwards?

A. Yes.

Q. Now, other than attending medical meetings and reading medical articles, you had not received any training prior to 2013 on how to use a TAVR device, is that fair?

MR. EGAN: Objection.

Mischaracterizes testimony.

THE WITNESS: No, I mean I had become aware of and learned about it from the literature and from medical meetings and live demonstrations, medical meetings that included live demonstrations, and these days and back then on the internet. You can look at these things and get a certain amount of training online.

BY MR. COHN:

Q. Before 2013 you had not received any hands-on training in how to use a TAVR device?

MR. EGAN: Objection.

THE WITNESS: Booths at meetings, you can see devices and touch devices and receive direct communication from the salespeople, marketing teams, which are there at the medical meetings. They attend and they are very keen to interact with physicians. And I had been to many meetings of that sort before the 2013 formal training session that I went to.

BY MR. COHN:

Q. Prior to your training by Edwards in

2013, the only source of your knowledge about TAVR devices was from reading about them and talking to other people about them; is that right?

MR. EGAN: Objection to form.

THE WITNESS: No. I mean as I said, I've handled them at meetings, I've looked at demonstrations, I've watched ones being implanted in patients, so a whole range of things. But a range of things which is accessible to interventional cardiologists who are interested in the development of interventional cardiology.

BY MR. COHN:

Q. Now, when you say you have watched a TAVR being implanted in a patient, you are referring to broadcasts of implantations that are done at medical meetings; is that right?

A. Yes.

Q. You were never present in an operating room while a TAVR was being implanted in your career; is that right?

A. I was for -- I mean approximately that's true, yes.

Q. You have not at any time in your career had experience participating in the design of a TAVR device; is that correct?

MR. EGAN: Objection to form.

THE WITNESS: That's true.

Can I qualify that? I've talked so much to companies about designs of stents and technologies and things that I've had discussions about the design of these devices. But, I mean, I have personally not designed one that I've in any sense put my name to. But I have had discussions with companies involved in the field who are either interested in the area or looking at the area with great interest as a potential area for future development.

BY MR. COHN:

Q. And you have not had experience participating in the design of a TAVR device; correct?

MR. EGAN: Objection to form.

THE WITNESS: I mean I essentially agree with that, but, again, with the qualifications that I've talked to

companies about TAVR devices going back to really very early days and in broad terms about whether you think this is feasible, what it's going to require, how can it be done, will it work, those sort of level of discussions.

But I have not formally set to and designed one or been hired to set to and design a TAVR device by any company.

BY MR. COHN:

Q. When you say "the early days" in your last answer, what time period were you thinking about?

A. The 90's, and the early 2000's. There was obviously great excitement when the concept was first published by Andersen, which was in the early 90's. I was on advisory boards for companies and some advisory boards I served together with Alain Cribier. These were things that were talked about and could this really happen, could we do this in patients, what would this require. Those were things that were talked about at meetings that I was taking part in.

I was on the advisory board for most of the 90's for Boston Scientific, I was paid, and so was Alain Cribier. And these were the sorts of things, because they were highly topical and interesting to medical device companies, that these were things that were talked about: Would this come to fruition? What would this require? People are fascinated by Andersen's work. And then, obviously, the intensity of interest went up even more in the early 2000's when Alain Cribier actually performed the first human implants in patients.

Q. You have never performed any surgical valve replacements in a patient; is that right?

A. No, I'm not a surgeon. I've referred lots of patients for surgical replacement, but I'm a cardiologist, so I investigate people. I do the hemodynamics and assess the patient. And if I feel that they need a valve replacement, I then refer it to one of my surgical colleagues.

Q. When you would refer a patient for a

valve replacement, for an aortic valve replacement, is that because their aortic valve was diseased in some way?

A. Of course. I mean you wouldn't replace an aortic valve unless it was diseased in some way. That would not be ethical or sensible. So, yes, they are diseased. But certainly how it works in the UK is people with valve disease get referred to cardiologists. It's the cardiologist that investigates them, does all the hemodynamics, decides what exactly is wrong with the valve, the severity of it, quantitates it all and characterizes it all. And then if it is felt that the valve is bad enough to need replacing, then refers to a surgeon.

A surgeon will then, if they agree, go ahead and replace it. And then the patient comes back to the cardiologist, back to me, for instance, to then follow up, monitoring, checking the valve, the replacement valve is working properly for the long-term followup.

And then if there are further

problems, they then may go back for a second valve replacement to the surgeon. That's how it works. But the person who investigates the severity of valve disease and decides if they need to refer them for surgery is a cardiologist, and that was my bread and butter work or part of my bread and butter work throughout my career.

Q. Did you ever observe in the operating room a surgical valve replacement?

A. Oh, yes, lots.

Q. When was the first time you did that?

A. Oh, I was a medical student. I qualified first as a doctor in 1980, so it would have been the 70's.

Q. And you would watch a surgical valve replacement happen?

A. Yes, I assisted some, absolutely. I mean it was very interesting. I was interested in cardiology and cardiac surgery from the beginning, and I would go into the operating theater and watch these procedures, years and years before even the concept of TAVI-type replacement. Surgical replacement,

yes.

And then later in my career with my own patients, if there were particularly interesting cases, you wanted to see whether what you had imaged really looked like it, I would go into the operating theater with my colleagues in Birmingham and have a look.

Q. You would be in the gallery watching through the window?

A. No, scrubbed with a gown on in the operating theater.

Q. Were you doing that in the early 2000's?

A. I was doing it throughout. As I said, I have been scrubbed up in the operating theater back in the 1970's, intermittently ever since then.

Q. Did you observe surgical valve replacements in the operating room in the early 2000's?

A. Yes.

Q. I think you said in your report that you retired from medicine in 2008; is that right?

A. No. I retired from performing interventional cardiology procedures. So I stopped performing angioplasties, stent implantations, the procedures, I stopped doing any procedures that involved radiation in 2008. I continued working as a cardiologist. I retired completely from the practice of medicine last year.

Q. Are you a named inventor or co-inventor on any heart valve patent?

A. No.

Q. We talked about diseased aortic valves. Those are highly calcified; is that right?

MR. EGAN: Objection to form.

THE WITNESS: No, not necessarily. I mean they can be, but in old age there is a very common condition in old age, and we are all living older, which is sort of calcific degenerative aortic stenosis, and that's a common condition in old age where the valve calcifies. There are other valve conditions that occur at much younger ages where there may be no calcification and the

aortic valve may leak.

Sometimes you have to replace valves not because they are stenosed or narrowed, but because they are leaking. Other times people can develop stenosis at an earlier age. Other times they can get infections on valves and that may require valve replacement. But there are lots of different conditions.

But the calcific aortic stenosis, which is probably the most common substrate today for patients to have a TAVI procedure, it is a common condition and associated typically with old age.

MR. COHN: Why don't we take our first break.

MR. EGAN: Sure.

(Recess.)

BY MR. COHN:

Q. Welcome back.

A. Thank you.

Q. You had talked before the break about discussions you have had with companies in the 90's and early 2000's about TAVR.

A. Yes.

Q. And as part of that testimony, you said that you discussed what TAVR would require.

Do you remember that?

A. Yes.

Q. One of the things that a TAVR valve required was that it not migrate. Do you agree with that?

MR. EGAN: Objection to form.

THE WITNESS: Correct. I think I understand you. You mean where you put it, you want it to stay there, is that what you mean by migrate? Would be not staying where you want it to stay?

BY MR. COHN:

Q. That is what I meant.

A. Yeah.

Q. That word "migrate" is something that people in the TAVR field use to refer to the moving of the valve device; is that right?

MR. EGAN: Objection. Foundation.

THE WITNESS: Correct.

BY MR. COHN:

Q. That is not a term that I use uniquely today. You have heard that before; right?

A. Oh, yes, sure.

Q. What were some of the other features that you recall discussing about what a TAVR valve would require in the, let's say, early 2000's?

A. The design of the valve, the design of the stent, the size, strength of the stent, the attachment, the prevention of leaking, the likely durability of the device as a whole of all the components put together. All those sort of issues.

I mean the obvious issues that anyone will have to consider when they're considering this sort of device for human implantation.

Q. When you talk about attachment -- I think you used the word "attachment" in your last answer -- you mean the attachment of the flexible valve leaflets to the metal stent?

MR. EGAN: Objection. Foundation.

THE WITNESS: The attachment together of all the structures and one of the main ones will be the valve itself to the stent.

BY MR. COHN:

Q. You wouldn't want the valve to get torn while the stent was being collapsed or expanded; right? That was one of the obvious issues that you discussed in early 2000's?

MR. EGAN: Objection to the form.

THE WITNESS: I mean that is an obvious issue. I think I covered that when I talked about durability. You don't want the thing to be damaged because that would lead to either instantaneous or premature deterioration of the valve function. If it badly ripped and came off, you could potentially have a situation where the valve part would migrate, even though the stent might stay where you put it.

BY MR. COHN:

Q. Let's talk about for a moment abdominal aortic aneurysms, also known as AAA.

A. Yes.

Q. Just briefly, what is an abdominal aortic aneurysm?

A. It is a not uncommon condition in patients where there is an enlargement of the aorta in the abdomen, and that enlargement can get up to such a size that it is a risk of actually bursting, of rupturing and causing a catastrophe, very often fairly instantaneous death. So it is a condition that needs treating.

Originally it was treated by medical treatment, such as control of blood pressure and all those things. But then by surgery of cutting out the enlarged part and putting in a tube by conventional surgery, and then subsequently the concepts came about of using stent technology with covers on stents to isolate the aneurysm. That is, to put in a stent graft, as we call it now, and seal that in place such that the aneurysm, if you like, is excluded from the circulation. And that sort of device, which would go in to exclude the aneurysm section of the abdominal aorta

from the circulation is what we would today refer to as a AAA device.

Q. The cover around the stent of a AAA stent graft is meant to exclude the aneurysm from circulation pressure; is that right?

MR. EGAN: Objection to form.

THE WITNESS: It may be. I mean, as you know in this case, there are new designs that have extra bits of seals, as well as the cover. And when you say cover on the stents, covers can be on the inside or outside or both. So you can have the cover on the inside. But the idea, the concept is to exclude an aneurysm. Therefore, you are putting in a device which through some mechanism forms a seal at the top end and a seal at the lower end, and the aneurysm is excluded from the blood pressure, which is the driving force that will make it continue to grow in size and risk rupturing.

So you are trying to isolate it from the blood pressure which is in the rest of the aorta.

BY MR. COHN:

Q. You are trying to keep the blood inside the AAA stent graft from flowing outside the AAA stent graft into the aneurysm?

A. Absolutely right. So you are trying to exclude the aneurysmal sections, relatively short section, but maybe tens of centimeters, but you are trying to exclude that section, which is aneurysmal, from the circulation. So the pressure in that drops and the aneurysm is no longer exposed to blood pressure and, therefore, the concept is that you reduce the risk of it continuing to grow. Particularly, you reduce the risk of it rupturing, bursting.

Q. You have never put a AAA device into a patient; correct?

A. Not on my own, no, I have not.

Q. And you haven't put a thoracic aortic aneurysm device into a patient; is that right?

MR. EGAN: Objection. Foundation.

THE WITNESS: Yes, I have. It depends what you mean. I have used the excluder, that you mentioned earlier, device to treat what are called dissecting aortic

aneurysms. It's a different type of aneurysms. There are lots of different types of aneurysms. Some aneurysms are just swellings, fusiform. Other ones can include tearing of the wall, and that's sometimes referred to as a dissecting aortic aneurysm or an aortic dissection. And that's different from a fusiform aneurysm or a circular aneurysm. And I have used devices for the treatment of aortic dissection.

BY MR. COHN:

Q. You have used stent grafts for the treatment of aortic dissection but not for abdominal aortic aneurysm; correct?

A. Correct, I have not on my own treated abdominal aortic aneurysms. I have, again, referred lots of patients in my own hospital, Queen Elizabeth Hospital in Birmingham, was part of a big research study for treating abdominal aortic aneurysms, and it required that the operator was a particular person and that ran between '99 and 2004. So over this sort of priority date period, that was the EVAR 1 study, and I was referring patients to

go into that scientific research. It was the EVAR 1 trial which was subsequently published I think in the Lancet, and my hospital was part of it.

Q. Can you explain briefly what an aortic dissection is?

A. In simple terms, it's a tear in the wall. Another way that the aorta can enlarge in size, become aneurysmal is a tear in the wall. And the wall is made up of layers. But the main wall is muscle. That's called the media. And you get a tear that goes deep into the media, and then tracks along. And this is a very bad situation because not only can it enlarge the aorta and risk tearing the outside, so in a sense bursting the aorta, but it can also track along great distances and rip off side branches.

So patients with this condition can end up losing coronary arteries, for instance, because the tear can go along and compress side branches. And so it's a medical emergency. And it's a condition that I was involved in treating, as were many

cardiologists.

And there is slight confusion with terminology because I've always referred to it as a dissecting aortic aneurysm. And I know you were in the UK at the trial. Dr. Lutter, who is a cardiac surgeon, said he doesn't regard it as an aneurysm. It was completely different from an aneurysm. He regarded it as a completely different condition. But that is in a sense semantics. I mean the condition is aortic dissection. Whether you call it dissecting aortic aneurysm or aortic dissection, it is the same condition, and that is treated with aortic stent grafts, and I was involved in using it for that kind of condition.

Q. When you would treat an aortic dissection, did the patient present with a dissection or did the dissection arise due to an interventional procedure that was going on?

A. Both. And sometimes it is difficult to tell, but you can cause dissections as a complication of a procedure. Catheters can poke in the wall and trigger a dissection.

Certainly some of those, I was involved in ones that that has occurred to my colleagues and I was involved in that.

I was also involved in ones where it occurred what we call spontaneous. Not with having tubes inside the patient, but it occurred spontaneous.

Q. Did you ever implant a Gore excluder?

A. Yes.

Q. When was the first time you did that?

A. Early 2000.

Q. You did that to repair a dissection?

A. Yes.

Q. How many times have you implanted a Gore excluder?

A. I think only twice.

Q. In your whole career?

A. Whole career.

Q. When was the second time after 2000 you implanted a Gore excluder?

A. It was around the same time. It could have been late 90's, but I think it was -- it could have been late 90's, but I think it was most probably in the early 2000's.

Q. And were both of those times to treat a dissection that had occurred during an intervention?

A. One of them that I can remember. I can't remember. I think one of them was a dissection that occurred in a procedure I think at another hospital and then the patient was transferred to us.

Q. How many times have you implanted a stent graft in a patient other than the two that you just mentioned?

A. Less than 50.

Q. That is 1-5?

A. 50, 5-0. Less than 50.

Q. How many had you done by the middle of 2004, approximately?

A. I mean less than 50, the same sort of number. We had one stent graft used in the coronary arteries. They came about in the late 90's. I was one of the early users of those. I can't give you an exact date, but it was late 90's, '97, that sort of time. I put some in the periphery, peripheral arteries, but not many. Less than 50, I mean a very

small number compared with the number of coronary stents, drug eluting stents and bare metal stents that I put in, which would be thousands.

Q. How many times have you implanted a stent graft in a patient's aorta other than the two Gore excluder instances that you mentioned?

A. I think there was another one where we tried to, with my colleague to make one. I mean back in those sort of days there were ones made. I think we tried to, but I didn't think it was successful. So I think, as I sit here today, I think it's only sort of two, three times.

Q. The third time that you implanted a stent graft in an aorta, was that a covered stent graft?

A. Yes, it was a stent graft, so by that I mean with a cover associated with it. But I think that's when we tried to make, put together, which wasn't uncommon back in those days to put coverings on stents, put Dacron on the stent and sew it in place.

Q. When you say "those days," what is the timeframe in which you did this third attempt to implant a stent graft in the aorta?

A. That would have been, I think, the first, so that would be in the late 90's.

Q. When you implanted a stent graft in the coronary arteries, was that to treat a dissection?

A. Quite possibly, yes, but when we have put them in would typically be when the dissection or direct rupture has occurred. So there would actually be what we call extravasation, blood coming out of the artery, and you put in a fairly small size diameter, small size stent graft to actually stop it bleeding. So you use it for rupture. But that rupture could well have been caused by a dissection, as I described earlier. Dissections can lead to ruptures.

Q. Do you know the brand names of any of the stent grafts that you implanted in the coronary artery?

A. Yes. It was one made by -- I don't know -- I am not sure I know what it was

called back then. It was made by a company called Jomed, I think it was then, or is now called the GraftMaster. I think it was subsequently after then bought by Abbott, and I think it is still sold today as the GraftMaster.

Q. GraftMaster?

A. I think so.

Q. Or monster?

A. Master. Not monster.

Q. Okay.

Any other stent grafts that you worked with in the coronary artery besides the Jomed device that you can recall?

A. There was another one. I'm afraid the name escapes me. There was another one and -- afterwards, the Jomed one was the first and that's why I remember. There was another one that came about later, which I also used, but I can't remember the name.

Q. When was the first time you installed a stent graft in the coronary artery?

A. I think I said, I think around '97, I think. I think that sort of timeframe. But I

refer back to 20 years ago.

Q. When was the last time you recall doing that?

A. Well, I haven't done anything since 2008. I haven't done anything since 2008. I can't remember how close it was, but the last procedures I did were in 2008. So I haven't put one in since then.

Q. Do you recall doing any stent graft procedures in 2008?

A. I don't, as I sit here. I can't remember.

Q. I guess my question is, you had said less than 50, and I am wondering if most of them occurred at the beginning, around '97, or if they were evenly distributed throughout the time period during which you were doing that, or if they were concentrated in some period of time?

A. I can't really answer that. None of them for the coronary ones are planned. They are to treat adverse events that occur, ruptures, bleeding from the artery. And, therefore, that is why they are small in

numbers compared with the number of stents, and they are not done as a planned procedure.

Q. So the stent grafts that you implanted in coronary arteries were not done as a planned procedure because they were meant to treat a rupture that occurred during an intervention?

A. I think that's true for the vast majority. I think I do remember one that we put in for a very large aneurysm. Occasionally, like I described, the aorta, coronary arteries do get aneurysms, and I remember putting one in for a very large aneurysm. So that was done electively. But the majority of them were done for leaking from the artery.

Q. By June of 2004, do you know roughly how many articles had been published reporting on actual TAVR procedures?

A. By 2004? What do you mean by "actual"? Including animal studies? What do you mean by "actual TAVR procedures"?

Q. I will break it down. By 2004, roughly, how many articles had been published

reporting on TAVR procedures in human beings?
A. I honestly don't know. It is a small number. I mean I don't know how many articles. I can think of three or four ones that Alain Cribier had his name on. There are abstracts as well. So if you include abstracts and papers, peer review papers and reviews, I mean probably less than a dozen.
Q. By June 2004, would you have considered TAVR to have been a young field?
MR. EGAN: Objection to form.
THE WITNESS: Yes. I mean to a degree, it is still a young field, yes. But certainly in 2004, I think it's reasonable to say it was a young field, yes.
BY MR. COHN:
Q. And same answer if I broaden that question to include all transcatheter valve replacements?
A. Same answer. Transcatheter valve replacements, I think it's fair to say 2004 was a young field. I still consider it in many ways to be a young field in 2017.
Q. Would you agree that in 2004 there was

not much of an experimental basis on which to rely for making predictions about how well a new transcatheter valve design might perform in situ?

MR. EGAN: Objection to form.

THE WITNESS: It is very difficult to answer these sort of questions because, obviously, there was stuff known which you would use and take into account. I really can't answer that question.

BY MR. COHN:

Q. Let's talk about the actual native aortic valve. When the left ventricle of the heart contracts, blood flows up through the valve. The valve opens and allows the blood to flow through; is that right?

A. In a normal heart that's how it is supposed to work, absolutely.

Q. And that cycle is called systole, is that right, when the left ventricle contracts?

A. Yes, when the left ventricle contracts, it is called systole. When the left ventricle relaxes, it is called diastole. That occupies, if you like, all the time,

systole/diastole, systole/diastole. Each heartbeat contraction is systole.

Q. Systole is when the blood pressure is maximal in the aorta, and diastole is when it is minimal?

A. No, no. Because systole is the contraction of the heart. So if you like, systole starts when the blood pressure is at its lowest. And it is systole that pushes the blood pressure up. I'm not on video, so I apologize. But, I mean, the blood pressure inside you and me is going up and down all the time. A bit like a sign wave, but, I mean, it is going up and down. And systole starts when the blood pressure is at its lowest. Because it is the contraction that pushes it back up. So systole starts when your blood pressure is at its lowest and pushes it up to its highest.

And then diastole is, if you'd like, when it is falling down again. And then the next systole pushes it up. So you can't say that systole is when it is at its highest. It pushes it up to its highest from its lowest.

Q. I see. Systole ends when the pressure is at its highest, and diastole begins at that point?

A. Approximately. I mean things are slightly more complex. Blood pressure can go up.

Things are slightly more complex. Blood pressure can go up after the end of systole.

Q. After systole, a healthy native aortic valve closes; right?

A. Yes.

Q. What causes the valve to close?

A. The blood pressure and stored energy in the aorta, and the direction of the flaps, closure of the valve is completely passive. The valve is not an active thing. But the pressure above is still high and the pressure in the ventricle drops very rapidly during diastole. When the heart relaxes, pressure drops down and, therefore, the column of blood in the aorta would otherwise come back into the ventricle, and that closes the valve because of the direction of the valve flaps.

They have pockets associated with them, and so the valve closes down because the column of blood is pushing them shut.

Q. Do you know what the magnitude is generally of the pressure differential above a closed aortic valve and below it when the valve is closed during diastole?

A. Yes.

Q. What is that?

A. Well, it varies all the time. Pressure above and below is changing all of the time. So you have to draw it as a graph. There isn't a one pressure. The pressure in the ventricle is falling during diastole, and as soon as the pressure gets lower in the aorta, the valve shuts. But at that moment, the pressure below is still fairly high and it goes on falling down. When it has fallen down to a level such that the mitral valve, the inflow valve can open, that valve opens and blood starts flowing in and the pressure starts going up again a little bit, and then you have systole. When systole occurs, the mitral valve closes, the pressure rises. Once

the pressure gets up to equal that in the aorta, the aortic valve opens.

So there is no single pressure. The pressures are all moving all of the time. The aortic valve opens when the pressure in the ventricle exceeds the aorta. And it closes when the pressure in the aorta exceeds the ventricle.

Q. During diastole there is a significant force on the valve leaflets; is that right?

MR. EGAN: Objection to form.

THE WITNESS: Yeah, and that varies all the time depending, as the pressure drops in the ventricle, then there is falls across that valve, which is varying. And again, you would have to draw it as a graph because it is not a constant pressure. It is varying all of the time.

BY MR. COHN:

Q. When a TAVR device is implanted in the aortic annulus, there would be a significant force on the device during diastole that would tend to push the device towards the heart, is that fair?

MR. EGAN: Objection to form.

THE WITNESS: Yes. When the valve is closed, for the TAVR device, which is where you have described, in the aorta when it is closed, there is a force pressing down on the leaflets in the direction of the left ventricle.

BY MR. COHN:

Q. And during systole, there is a force on a TAVR device that has been implanted in an aortic annulus that would tend to push the device into the aorta, is that fair?

MR. EGAN: Objection to form.

THE WITNESS: It is, but, obviously, the valve is open then, so what is happening is the blood is flowing through the open valve and, therefore, force is exerted, if you'd like, on the frame, but it is rather different from when the valve is closed with the force pushing down into the ventricle.

When valves migrate, the words you used earlier, in the direction of the aorta, it is mainly driven by the blood flow rather than -- the flow of blood, the fast

velocity of blood going out through the valve. The valve is very loose. Wash it in the direction of the aorta.

BY MR. COHN:

Q. You say "when valves migrate." Are you aware of reported instances of the migration of a TAVR valve in patients?

A. Yes.

Q. How many times have you heard about that happening?

A. I mean, sadly, many.

Q. That is a horrible thing when it happens?

MR. EGAN: Objection to form.

THE WITNESS: Yes, it is a horrible thing when it happens. It can be catastrophic. Obviously, if it happens then and there in the catheter lab, when the doctors are putting the valve in, at least they are in a position where they can quickly try and put another valve in and do something. It is better if it happens at that stage where the whole team around the patient is in the catheter lab than if it happens at a later

point in time.

But it is a terrible thing. But it is well reported and, unfortunately, it has occurred on many occasions.

BY MR. COHN:

Q. By June 2004, do you recall whether Dr. Cribier reported any migrations of his TAVR devices in the patients that he implanted?

MR. EGAN: Objection to form.

THE WITNESS: You would need to show me the articles. I don't remember a mass migration. There was one unsuccessful patient, and I can't recall what happened, whether he was actually able to put the thing in at all. There could have been a migration. But we're also interested, obviously, in small movements.

I mean, in a sense what I was describing was catastrophic where it completely moves out of position. We're also interested in small movements where the device is rocking a bit and moving a little bit because that can be a marker for the fact it

is not sufficiently fixed and may be at risk of greater movement in the future.

But I'd need to look at the articles to give you a definite answer to your question.

BY MR. COHN:

Q. Is it fair to say that in June 2004 persons of ordinary skill in the art of the '608 patent knew that it was critically important that a TAVR device not migrate?

MR. EGAN: Objection to form.

THE WITNESS: Well, yes. And long before. I mean, we were aware that conceptually the idea of putting a heart valve in was they shouldn't migrate. We knew that from surgical valves. Because all of the questions you have asked also apply to surgical valves. Unfortunately, on occasion, surgical valves come adrift and migrate. And so all of these concepts of stability, migration, leaking, paravalvular leak were already well known from the field of surgical valve replacement. And, therefore, all of these problems were known about and looked out

for in the new field of TAVR.
BY MR. COHN:
Q. So the force on the leaflets from the pressure and flow of the blood is significant enough to dislodge even a surgically implanted valve?
A. Yes. It has happened. I mean often this occurs when the whole suture line dehisces, is the word we call, dehiscence at the suture line. It often is associated with infection. And luckily it is a very rare complication. But surgical valves have come out. Perhaps even more importantly, sometimes the valve, piece in the valve has come out, and you are probably aware because your profession was very involved in litigation. There was some disastrous surgical valves, the Shiley valve, where pieces of the valve fell apart and tears occurred in valves. And there are well reported problems with surgical valves, migration, if not of the entire device, of parts of the device.
Q. Were there concerns among persons of ordinary skill in June 2004 that a TAVR valve,

which is not sutured into the aortic annulus, would migrate?

A. Yes, of course. Of course.

(Buller Deposition Exhibit No. 1 was marked for identification.)

BY MR. COHN:

Q. I am going to hand you what I have marked Buller Exhibit 1, which is a slide that I made. I intend this to be schematic. But I want to try to set it up with you and then maybe ask you a few questions about it.

MR. EGAN: I am going to object to this line of questions as outside of the scope of this declaration.

BY MR. COHN:

Q. Do you see the blue part of the diagram labeled "annulus"?

A. Yes.

Q. And then a gray anchor with a tan valve inside. Do you see that?

A. I do.

Q. What I am trying to depict schematically is a basic TAVR device having a stent anchor with flexible valve tricuspid

leaflets inside of an aortic annulus.

Do you understand that from this drawing?

A. If that's what you say it is, yes, then I understand what you are saying. But this is a TAVR device. This isn't a surgical valve. Because this could equally diagrammatically be a surgical valve.

Q. So diagrammatically with Buller Exhibit 1, I would like to discuss this in the context of a TAVR valve.

A. Got it. Okay.

Q. Just for orientation, during systole, there is a force on the valve that would tend to push it up on this page; is that right?

MR. EGAN: Objection to form.

THE WITNESS: Yes. If I understand your diagram. This isn't drawn in systole. Because if I understand your diagram, what you have shown is the valve is closed and they have come together. So this is drawn in what I take to be diastole, because it appears that you've drawn a closed valve, if I'm understanding your diagram.

BY MR. COHN:

Q. Let's be a little clearer. I want to be clear, the two of us.

A. Yeah.

Q. So in the diagram, the heart is at the bottom and the aorta is at the top?

A. Yes. And that's why the valve is facing in that direction, yes.

Q. And I want you to assume the valve is closed. So that would depict a valve in diastole; is that correct?

A. Yes. That's what I would take. Clearly, it's very diagrammatic, but this looks like a valve in diastole, if the aorta is above and the ventricle is below. The valve is closed, and it is sitting in its anchor or straddling the annulus.

Q. And during diastole, there would be a downward force on the valve, according to this schematic; is that right?

MR. EGAN: Objection to form.

THE WITNESS: Yes, one would expect the blood pressure, a living patient, so the blood pressure above is going to be

higher. It will vary all of the time throughout diastole, but it will be higher above than below, and so the force that the higher blood pressure above is exerting on it is tending to push it downwards towards the ventricle.

BY MR. COHN:

Q. TAVR valves are not sutured in place; is that right?

A. Correct.

Q. So the TAVR valve is held in place by its interface between the anchor and the annulus; is that right?

A. Some are. On this one, on your diagram, that's what it appears to be because it is not touching anyone else. There are ones that interface at other places as well, like higher up in the aorta, like the CoreValve.

But what you have drawn appears to only be interfacing with the annulus in your schematic.

Q. By 2004 did persons of skill in the art, were they aware of TAVR designs in which

the anchor was held in place by something other than an interface with the aortic annulus?

A. Yes.

Q. Can you identify any of those?

A. Well, Andersen taught what he called a higher embodiment, which would interface with higher up in the aorta.

COURT REPORTER: Can you repeat that, please.

THE WITNESS: Andersen taught an embodiment which had a higher stent and would interface with the aorta above the annulus. That was taught in the Andersen patent, which was way prior to 2004.

BY MR. COHN:

Q. Dr. Cribier's TAVR device in the early 2000's was held in place due to its interface with the aortic annulus; is that right?

MR. EGAN: Objection to form.

THE WITNESS: Yes, the device that he used in patients was a relatively short device, and its main interface was certainly with the diseased native valve.

But can I be clear, because what you haven't drawn on here is the native valve leaflets. I mean, what it would actually be interfacing with in the main part of its length would be the diseased valve leaflets, which, if you'd like, the annulus is underneath, beneath the diseased valve leaflets, at their lower end.

What you have drawn doesn't seem, in your schematic, to include native valve leaflets at all. You've just got the annulus.

BY MR. COHN:

Q. If I give you a pen, do you think you could draw schematically where the native valve leaflets would be in this diagram?

A. Yes. Do you have a red pen?

Q. My colleague seems to.

A. It is difficult fitting them on in this schematic. But the leaflets would be here. Your annulus is quite sort of big and bulky. But approximately the leaflets are originating from the annulus and coming up the outside (indicating).

So the device is interfacing mainly with the diseased leaflets, because in what Dr. Cribier did, he didn't remove the native valve leaflets. Now, there were plenty of people that thought perhaps you should or you needed to remove the native valve leaflets. But in Dr. Cribier's work in his early implants before 2004, there was no attempt to remove the leaflets. The device was pushing mainly against the diseased leaflets, and these diseased leaflets were heavily calcified and, therefore, craggy, and, therefore, it was in Dr. Cribier's mind a good substrate to push the valve into. He thought that you would take advantage of the diseased leaflets by locking the device into place in the diseased leaflets.

Q. Can you just label those for the record "leaflets," and then initial at the bottom.

A. Can I?

Q. Yes.

A. They are both. Do you want me to put arrows to both? "Leaflets."

And then initial it?

Q. Thank you.

A. (Indicating.)

Q. Just so the record is clear, the witness has used a red pen on Exhibit 1. The red pen markings are from the witness' hand.

Now, looking at Exhibit 1, one way that a TAVR device can leak is through the flexible valve itself, right, through the center of the valve, basically?

A. Yes. The valve may not close perfectly and you can get a leak directly through the valve. In an ideal world, the valve, once it closes and there is no leak through it, but you could get leaking straight through the valve itself.

Q. And another way that a TAVR valve could leak is that blood would flow, could flow inside the anchor and then through the mesh of the anchor and back into the heart; is that right?

A. Yes. And so it would be flowing around the outside of the valve.

Q. Can you indicate with your finger the

path of that flow? Before I ask you to draw it, I want to make sure we are on the same page.

A. Well, if the valve is your brown triangle, it is coming down either inside or outside or both, because blood will flow where it can, and coming around the outside of the valve. And that we would refer to as paravalvular leak.

(Buller Deposition Exhibit No. 2 was marked for identification.)

BY MR. COHN:

Q. I am going to hand you Buller Exhibit 2.

A. Yes.

Q. Which is the same schematic I handed you for Exhibit 1, but it doesn't have your red markings on it.

A. Yes.

Q. And I have drawn an additional red arrow dotted line on Exhibit 2.

Do you see that?

A. I do.

Q. One way that a TAVR valve as shown in

the schematic can leak is shown by this red arrow; is that right?

MR. EGAN: Objection to form.

THE WITNESS: Yes, if that's what it represents. If this is blood leaking, this is paravalvular leak going around the outside of the valve.

BY MR. COHN:

Q. Would you characterize that as leakage between the anchor and the leaflets?

A. Yes, it may well be, as I've drawn my leaflets on here in this diagram. But if you sort of put that on there, it is between the valve and the leaflets. The valve is your triangle marked "valve."

Q. I asked a different question.

Would you characterize the leakage shown in Buller Exhibit 2 as being between the anchor and the leaflets?

A. Yes, part of it is, because the bottom part -- some of it is into the anchor. Some of it is coming out. And some of it is around the outside of the anchor. Your arrow travels partly outside of the anchor and partly inside

of the anchor.

I mean to make it clear, obviously, blood flow occurs everywhere it can. It wouldn't follow your arrow. It would be trying to get anywhere there is potential to leak. The blood column above will leak. It will be going around. You could equally draw an arrow coming down here and then going around there (indicating).

Q. I am going to ask you to draw the other pathway that blood can leak that you see in Buller Figure 2. You just indicated with your finger. Can you draw with the red pen, please.

A. There are a lot. I mean blood from above will try and get to the bottom wherever there is a pathway to go through. So it can come, as you've drawn it here, I mean blood could be, for instance, coming down here and going just around the side. It could be coming down here and going in and joining this path. I'll put arrows so I am making sure everything is clear.

It can flow wherever blood can

flow, and assuming there is a gap that it can flow through, it will flow through that gap.

So one could color everything above red and everything below green and say that anywhere that could go from red to green it will go, depending on where gaps are, what size gaps. It won't follow any one of our arrows, including mine. It will go anywhere it can.

Q. Can you label what you drew "leakage"?

A. Leakage?

(Indicating.)

Q. That is an appropriate label?

A. Yes, if you like it, yes.

Q. Well, do you agree it is appropriate for what you drew?

A. Yes. But, I mean, it will fit in with what I have said. The point I am trying to make is that blood doesn't really follow arrows. Arrows are schematic to show one place it will go. But blood will flow around the device wherever it is able to, through the device wherever it is able to.

Q. So the red arrows on Buller Exhibit 2

show some of the paths by which the blood could leak from the top to the bottom in the schematic?

A. Yes. Assuming there is a gap there for it to go through, which your arrow presumably represents, there is a gap. If there is no gap there, then it can't flow through.

Q. Yes, and I do want you to assume that anchor is a mesh stent that has gaps.

A. Fine.

Q. And that is consistent with what we have been talking about? That has been your understanding throughout this discussion; right?

A. Yes. I didn't know there was a cover on it. But clearly, the cover isn't -- even if it is, it is not producing a seal because there's leak.

Q. I did not mean to include any cover on the mesh stent in Buller 1 and Buller 2.

A. I understand that.

Q. Does that change any of your answer so far?

A. No. They still apply. They would still apply even if there was a cover.

Obviously, there is a path for a leak to occur. Leak only occurs when there is a path for it to occur through.

Q. Can you just put your initials at the upper corner like you did the last one.

A. (Indicating.)

MR. COHN: Can we mark this, please.

(Buller Deposition Exhibit No. 3 was marked for identification.)

BY MR. COHN:

Q. Your mention of the cover was timely. I hand you Buller 3.

Dr. Buller, I am handing you Buller-3, which includes the same schematic from Buller-1, the dotted line from Buller-2, and then I've added the thick black lines, something labeled "cuff," and I want you to assume that that is an impermeable membrane that is wrapped tightly around the base of the entire circumference of the base of the anchor.

Do you understand that?

MR. EGAN: Objection to form and outside the scope of his declaration.

THE WITNESS: I think I understand what you are saying, yes.

BY MR. COHN:

Q. Such a cuff would stop the leakage from the inside of the anchor down into the heart, as shown by the dotted line, being the red dotted line being cut off by the black cuff.

Do you see that in the figure?

MR. EGAN: Objection to form.

THE WITNESS: That's what I understand you have illustrated, yes.

BY MR. COHN:

Q. And does that make sense?

A. Yes, it makes sense. But, clearly, there needs to be complete sealing around the circumference. This is a 2D representation. You would need to seal right around, and, clearly, the seal would need to be attached to the valve so there isn't any leak. There is continuity between your seal and the valve,

and there needs to be perfect apposition of the seal all around the annulus. And the difficult calcified leaflets are not there. I have added them clearly in 1, Buller-1, but they are not here in Buller-3.

Q. So let's take this a step at a time. I want you to assume in Buller-3 that the valve and the cuff are connected in such a way that blood can't flow between them.

A. Fine.

Q. And I want you to assume that the cuff is circumferential all around the anchor.

A. Yes.

Q. Can you draw the leaflets in on Buller-3 as you did on Buller-1?

A. I can try. There isn't as much space because of your cuff, but I mean -- with a red pen I am putting them on as close as I can to what I have drawn on Buller-1 (indicating). Done.

Q. Blood can still leak around that valve device. I just want to make sure my terminology is correct because I don't want to say valve and -- strike that.

When I say "valve," I will be referring only to the valve leaflets. When I say "valve device," I want to be referring to the anchor, valve and cuff all together.

Does that make sense?

A. Yes.

Q. Are there still means by which blood can leak from the top of the figure past the valve device in Buller-3 to the bottom of the figure during diastole?

A. Potentially, yes, because of the craggy valves. There could be leaks that can occur between or through the interface between your black cuff and my red diseased valve leaflets.

Q. Can you indicate that leakage path that you just described with the red pen using an arrow?

A. There isn't much room to put it in. If I put it sort of going to the top and then coming out the bottom, that arrow, which I put an arrow head in the ventricle, represents a potential leak if there is not perfect interface between your circumferential cuff

and the diseased valve leaflets, which I've drawn in.

Q. And you would call that paravalvular leak, the arrow that you drew?

A. I would call all the leaks I've drawn, all of them are paravalvular leaks because they are all going around the outside of the valve. They are not through the valve. So all of the arrows on -- there aren't any arrows on two of them. But on Buller-2 and Buller-3 are paravalvular leaks.

Q. And the arrow that you drew with the arrowhead on Buller-3 depicts leakage between the cuff and the native valve leaflets; correct?

A. Correct.

Q. Just for the record, can you label that arrow "leakage"?

A. Yes (indicating).

Initial it?

Q. Yes, please.

A. (Indicating.)

Q. Then can you label the leaflets in a somewhat unobtrusive manner as "leaflets"

without disturbing the schematic?

A. Should I just label one on this side? There is leaflets on both sides as the record will show. This is a leaflet where I can, (indicating), that's a leaflet. Or I can put an arrow across to there. The trouble with arrows, they start looking -- the record will get confused.

Q. The leaflet on your right side, what if you take an indicator line off to the right and then indicate it as a leaflet?

A. Here?

Q. Yes.

A. (Indicating.)

Q. Thank you.

Why don't we take a break right now.

MR. EGAN: Sure.

(Recess.)

BY MR. COHN:

Q. Welcome back, Dr. Buller.

A. Thank you.

Q. Looking at Buller-3, the schematic --

A. Yes.

Q. -- if there were no valve leaflets in that anchor, it was just an open stent, the path of least resistance for the blood to flow back into the heart during diastole would be through the hollow anchor and not around it; do you agree?

MR. EGAN: Objection to form.

BY MR. COHN:

Q. Assuming the anchor is pressed tightly against the annulus?

A. I am not understanding your question. So like this one? I am lost. Sorry, I don't understand the question.

Q. Sure. Let's look at Buller-3.

A. Yes.

Q. I want you to assume that anchor and the cuff are pressed tightly against the annulus.

A. Yes.

Q. And I want you to assume the valve is not there. There is no pliable valve leaflets. It is simply a hollow mesh stent anchor with a cuff around it pressed tightly against the annulus.

Do you understand me?

A. So there is no valve inside it?

Q. No valve.

A. Okay.

Q. The path of least resistance for the blood to flow from the top to the bottom of the page would be through the hollow anchor and not around it where it was pressed tightly against the annulus. Do you agree?

MR. EGAN: Objection to form.

THE WITNESS: Correct, the path of least resistance would be through the great big space in the middle.

BY MR. COHN:

Q. Thank you.

Now, we talked about migration earlier, and you had said that Dr. Cribier felt that the craggy calcifications on the inside of the native valve leaflets could actually help prevent migration; is that right?

A. That's my understanding, yes.

Q. And that was because the intermittent bars of the stent could lock together with

those craggy calcifications and fix the anchor in place; is that right?

MR. EGAN: Objection to form.

THE WITNESS: Yes, that you could lock the device, whatever it's made of, into the craggy, calcified, diseased native valve leaflets.

BY MR. COHN:

Q. And it would be the intermittent bars of the mesh stent could lock with those craggy calcifications; is that right?

MR. EGAN: Objection to form.

THE WITNESS: Or whatever the device was made from, because he taught this concept in patents that had various different designs.

BY MR. COHN:

Q. I could show you the transcript if we need to get to it, but do you recall testifying in the UK trial that the intermittent bars of the stent and the craggy, calcified valve can act to lock it together so that then it is fixed and it is not likely to move? Do you have testimony like that?

MR. EGAN: Objection to form. Lack of foundation.

THE WITNESS: It sounds proper and true, yeah.

BY MR. COHN:

Q. The Edwards Sapien TAVR device did not have any fabric around the outside of the anchor; is that right?

MR. EGAN: Objection to form. Relevance.

THE WITNESS: Which one?

BY MR. COHN:

Q. The Sapien?

A. The Sapien, yes. Other than the little bits of sutures, because some sutures around bars are made of fabric. But other than those very tiny bits of fabric, there was no significant piece of fabric wrapped around the outside of the stent.

Q. Same question for the Sapien XT?

MR. EGAN: Objection to form and relevance.

THE WITNESS: Same answer.

MR. COHN: Counsel, do you want

me to mark these with deposition exhibits if they are exhibits from your petition?

MR. EGAN: I think we can just use the petition exhibit number.

MR. COHN: I think so too.

BY MR. COHN:

Q. Dr. Buller, I am going to hand you what has been previously marked Exhibit 1004.

Have you seen this before?

A. I have.

Q. What is it?

A. It's a PCT.

Q. This is a patent invented by Spenser and others that you rely on in your declaration in this proceeding; is that right?

A. Correct. It is what I sometimes refer to as the Spenser PCT.

Q. We can call it "Spenser" for today, does that work?

A. Fine.

Q. Now, there is a picture on the first page of Spenser --

A. On the cover.

Q. -- on the cover?

A. Yes.
Q. And that is a transcatheter valve replacement device; is that right?
A. Yes.
Q. And that is meant to be implanted in a diseased heart valve; is that right?
A. Yes, potentially it would be.
Q. Now, if we could turn to Figure 1 of Spenser.
A. Can I say, this is a patent drawing. It represents, it is a diagram. It is a patent drawing. It relates clearly to a design which you could build as a device that you could put in. But it is a diagram.
Q. The Spenser patent is directed to a TAVR device that is meant to be implanted in a diseased heart valve; right?
MR. EGAN: Objection to form.
THE WITNESS: Yes. It is broader because the TAVR is specifically aortic, and I think Spenser is slightly broader than that. But, yes, it can be implanted in a diseased aortic heart valve.
BY MR. COHN:

Q. Actually in my head I was thinking merely TVR and not TAVR. Let me ask the question again. I meant my question to be broad.

The transcatheter valve of Spenser is meant to be implanted in a diseased heart valve, that is what this patent is about; right?

A. Yes.

Q. In Figure 1 of Spenser, why don't you turn to that, please.

A. Yes.

Q. Figure 1 shows a transcatheter replacement heart valve with a cuff labeled 21.

Do you see that?

A. I do.

Q. And you recall that that is called a cuff in the patent?

A. It is. 21 I think is a cuff.

Q. And in this figure, the cuff is depicted as being in contact with the outer surface of the anchor; is that right?

MR. EGAN: Objection to form.

THE WITNESS: It's around the outside of the anchor of this cuff.

BY MR. COHN:

Q. The cuff in Figure 1 is not shown as having any bunched-up portions, at least in this figure; is that right?

MR. EGAN: Objection to form.

THE WITNESS: No, it is a diagram, and it's shown, it's surrounding the anchor on its lower, on its lower half/third.

BY MR. COHN:

Q. And in this figure, the figure itself doesn't show the cuff as having flaps that extend into space as formed by native valve leaflets in this figure?

MR. EGAN: Objection to the form to the extent it calls for a legal conclusion.

THE WITNESS: Well, there is no native valve shown. This is a depiction of the device. It is not in anything. It's a diagram and it depicts a cuff around the outside of the lower part of the stent.

BY MR. COHN:

Q. And the Spenser patent says that the

purpose of the cuff in the embodiment of Figure 1 is to enhance stability; correct?

MR. EGAN: Objection to form.

THE WITNESS: That's one of the things it says. I think it says other things. I think it also says "sealing," as in stopping leaks, sealing.

BY MR. COHN:

Q. You would agree that one purpose of the cuff described in Spenser is to enhance the stability of the device; correct?

MR. EGAN: Objection to form.

BY MR. COHN:

Q. Spenser says that specifically, right?

A. Yeah, you can direct me. I can't remember the words. But if you say so, then I'll accept that.

Q. If you could turn to Page 22, please.

A. Yes.

Q. On Page 22 of Spenser, do you see the fourth paragraph down it says "Reference is now made to Figure 1"?

A. Yes.

MR. EGAN: Just so the record is

clear, you are referring to 22 of the PCT or the page of the exhibit number on the bottom?

MR. COHN: Thank you, counsel.

BY MR. COHN:

Q. I was referring to Page 22 of the PCT of the Spenser patent itself.

A. Yes.

Q. Do you see the fourth paragraph down begins "Reference is now made to Figure 1"?

A. Yes.

Q. Then in the next paragraph it says, "In the embodiment shown in Figure 1, a cuff portion 21 of the valve assembly 28 is wrapped around support stent 22 at inlet 24 to enhance the stability."

Do you see that?

A. I do.

Q. And then the discussion of Figure 1 continues onto Page 23 of Spenser for the next two paragraphs, and then you see there begins a discussion of Figure 2, correct?

A. The last paragraph on 23 starts "Figure 2," correct.

Q. Now, between the fourth paragraph on

Page 22 that begins "Reference is now made to Figure 1" --

A. Yes.

Q. -- and the discussion of Figure 2 that begins on the bottom of 23 --

A. Yes.

Q. -- is there any description in that text of leakage?

A. I need to read it all, but if you tell me there isn't, I will accept it. But it is talking about sealing, and that is on the previous page, on Page 21, I think.

As I scan it, I don't see any mention of leakage, but I'm just scanning the paragraphs you've asked me to look at.

Q. I want you to look at those paragraphs carefully. It is four paragraphs.

A. Well, I have. I can't see a direct mention of leakage.

Q. Now, let's turn back to the previous page you had mentioned on Page 21 at the bottom.

A. Yes.

Q. It says: "To prevent leakage from the

inlet, it is optionally possible to roll up some slack wall of the inlet over the edge of the frame so as to present rolled-up sleeve-like portion at the inlet."

Do you see that?

A. Yes.

Q. That paragraph does not use the word "cuff," does it?

A. No. It's describing how to form it, but it doesn't use the word "cuff."

Q. Now, if we continue to Page 24.

A. Yes.

Q. The top of Page 24, the paragraph that continues from 23, at the bottom, it says: "A portion of the valve assembly 34 at an inlet."

Do you see that?

A. Yes.

Q. And it says, I'll just read it: "A portion of the valve assembly 34 at an inlet zone 45 is optionally rolled over support stent 32 at the inlet, making up a rolled sleeve, which enhances the sealing of the device at the valve inlet."

Do you see that?

A. I do.
Q. Is it true that when Spenser discusses sealing the device at the valve inlet, it uses the word "sleeve," and when it talks about stability, it uses the word "cuff"? That's true, right?
A. That's true, that's what you read out. I don't read anything into that.
Q. The sleeve that is discussed with respect to Figure 2 --
A. Yes.
Q. -- that prevents leaks of blood from inside the anchor through the wall of the anchor and back into the heart; correct?
A. Does it say that?
Q. I am asking you.
A. Oh, one sort of movement of blood could be through and it could prevent that at least over the position that it occupies. But that's just one.
Q. But Spenser doesn't say that specifically, does it?
A. No. That's what I was saying. He doesn't say that specifically. He talks more

generally about it preventing leaks.

Q. The Spenser patent does specify the path of the leakage that is being discussed in those passages, fair?

A. Correct. He's talking about leaks because, as I've always understood it, I mean a patent isn't required to teach what's already known, and leaks around valves, paravalvular leaks were very well known.

Q. And Spenser does not describe leakage between the sleeve in Figure 2 and the native valve leaflets; correct?

A. No. He talked generally about leaks, and it's already known by a person of skill in the art where leaks can occur around replacement valves. This was well known. What he's talking about is putting a structure on to prevent leakage, which is obviously not through the valve, paravalvular leakage that he's addressing with this structure, this sleeve and cuff.

Q. But Spenser does not specifically mention leakage between the sleeve in Figure 2 and the native valve leaflets; correct?

MR. EGAN: Objection. Asked and answered.

THE WITNESS: Correct. He talks generally about leak and preventing leakage.

BY MR. COHN:

Q. If you look at the front of Spenser --

A. The front cover again?

Q. Yes.

A. Yep.

Q. Do you see there are four inventors listed on the face of Exhibit 1004 of the Spenser patent?

A. Yes.

Q. And one is Mr. Spenser, one is Mr. Benichu, one is Mr. Bash, and one is Mr. Zakai?

A. Yes.

Q. Have you seen any documents or testimony from any of these inventors that suggests that this Spenser patent does not address leakage between the cuff or the sleeve and the native valve leaflets?

MR. EGAN: Objection to form. Relevance.

THE WITNESS: No, I have not seen anything that I believe suggests that.

BY MR. COHN:

Q. If you saw a document or testimony from any of the inventors stating that this Spenser patent does not address leakage between the cuff or the sleeve and the native valve leaflets, that is something that you would want to consider in forming your opinions; right?

MR. EGAN: Objection to form. Relevance. Lack of foundation.

THE WITNESS: If it was prior to the priority date, then yes, potentially. But as a person of ordinary skill in the art, I am considering this reference, my purpose of considering it is considering it through the eyes of a person of skill in the art in 2004. And I don't look at things or consider things which are after that date. So I'm looking at it through the eyes of a person of ordinary skill in the art in 2004. That's how I've considered it and that's what my declaration is about.

BY MR. COHN:

Q. Have you ever seen a patent that includes some of these named, the same named inventors as the Spenser patent of Exhibit 1004 that suggests that Exhibit 1004 does not address leaks that occur around the cuff or the sleeve?

MR. EGAN: Objection to form and relevance.

THE WITNESS: As I sit here, I can't think of anything, no. You are talking about prior art 2004?

BY MR. COHN:

Q. I am asking any patent on which any of these inventors is a named inventor, have you seen any such patent in which -- strike that.

Have you read any patents that talk about Exhibit 1004?

MR. EGAN: Objection. Relevance.

THE WITNESS: I may have, but as I sit here, I can't think of any.

BY MR. COHN:

Q. Either before or after exhibit --

well, it couldn't have been before it.

Have you seen any patents that came out after Exhibit 1004 that discussed Exhibit 1004?

A. I may well have, but as I sit here, I can't even show you anything, but as I sit here, I can't recall any.

Q. If we go back to Figure 1 of Spenser.

A. Yes. Yes.

Q. There are structures in there called "support beams." I think they are labeled "23."

Do you see that?

A. I do.

Q. Those are designed so that their length stays constant; right?

MR. EGAN: Objection to form.

THE WITNESS: Yes, they are.

BY MR. COHN:

Q. And if the cuff 21 shown in Figure 1 were attached to the support beams and only to the support beams, then its length would stay constant too; right?

A. Not necessarily, no. But I mean the

bit attached to the support beam would remain constant. But clearly, even if it were attached to them, the vast majority of it is not attached to them, and they could be squashed or changed in length easily, because most of the 360 degrees around the entire circumference of the device is not the structure 23.

Q. Spenser provides that the valve assembly, the leaflets, is attached to the support stent at the support beams; is that right?

A. Part of it is. The commissure, the joining of the valve leaflets is attached to the support beam, but, obviously, most, I mean, the really important thing about the valve is that the middle bit is lax and free to use. That's how it can open and close. So my understanding of Spenser is what is actually attached to the support beam remains constant in length and can't move with any ease. But, clearly, the inside bit of the valve, particularly the outflow end is lax and free to move. That's how it works. It opens

and closes and it moves with every heartbeat.
Q. If you look at Page 23 of Spenser.
A. Yes.
Q. The first paragraph, six lines down, do you see the sentence that begins "The valve assembly"?
A. Yes.
Q. And it says: "The valve assembly is attached to the support stent at the support beam." Do you see that clause?
A. I do.
Q. The phrase "valve assembly," what does that refer to in Spenser?
A. The opening and closing bit of the valve, the valve. For instance, the tissue valve part of the device.
Q. The valve assembly refers to the leaflets?
A. Yes. I mean the -- yes. And if they are made from tissue, tissue, if that's what they are made from.
Q. And that sentence continues with, "And due to their constant length, there is no need for slack material." Do you see that?

A. I do.

Q. The slack material is referring to material of the valve assembly, right?

A. No. It's referring to part of it. It's referring to the part of it attached to the bar, because in other places in Spenser it emphasizes there is slack in the valve to enable it to open and close. And it is obvious, I think. I don't think I am saying anything which isn't apparent to all of us, that the most important part of the valve is free to open and its slack, and that's how it opens and closes with each heartbeat. Only the part attached to the bar is held constant in length.

Q. Now, the cuff 21 in Figure 1 is described as a portion of the valve assembly; is that right?

A. Yes. I mean, yes, it is a portion of a valve assembly which is wrapped up around the outside. But it's not the moving part. It's not the leaflets of the valve. It is a different part of the valve assembly, if you use that terminology.

Q. And the sleeve portion that we saw in Figure 2, that is also a portion of the valve assembly, right, in Spenser?

A. The sleeve portion of Figure 2, did you say?

Q. Yes. The sleeve portion of Figure 2 is described as a portion of the valve assembly?

A. It is a portion of the valve assembly, if by valve assembly you include all of the parts, not just the valve that opens and closes part.

Q. Well, the Spenser patent describes the sleeve-like portion of Figure 2 as being a portion of the valve assembly; is that right?

A. It does, correct.

Q. And the same for the cuff?

A. And same for the cuff and the sleeve I think are one and the same thing, but yes.

Q. I am going to hand you what has previously been marked 1005.

Do you recognize 1005 as the Elliot patent that you discuss in your declaration in this case?

A. Yes, I do.
Q. We can call this "Elliot" for purposes of our discussion?
A. Of course.
Q. Elliot describes a stent graft for use in treating abdominal aortic aneurysm; correct?
MR. EGAN: Objection to form.
THE WITNESS: One of the teachings, yes.
BY MR. COHN:
Q. And it doesn't mention heart valves at all, does it?
A. It mentions generally using it in medical devices, general teaching. But the example it gives is for treatment of an aneurysm.
Q. Elliot doesn't mention heart valves, does it?
A. Not specifically, no.
Q. There is no valve shown in any of the embodiments depicted in Elliot; correct?
A. That is true, he doesn't specifically example using it for a heart valve. He

teaches generally that it can be used for medical devices.

Q. Elliot describes a skirt around the outside of the tubular member; is that right?

A. Yes, that's one of the things that Elliot describes. He describes using a displaceable skirt to bring about sealing.

Q. Elliot does not describe that the skirt performs a stabilizing function; correct?

MR. EGAN: Objection to form.

THE WITNESS: No, I think that's fair. I mean the reason for the displaceable skirt, which is in the title, is for sealing.

BY MR. COHN:

Q. Now, if you turn to Figure 3 of Elliot --

A. Yes.

Q. -- which is on sheet 3 of 7 --

A. Yes.

Q. -- and particularly Figure 3B.

A. Yes.

Q. The direction of any leakage in the device of Elliot Figure 3B is shown as being

downward on the page; is that right? 3C as well.

MR. EGAN: Objection to form.

THE WITNESS: I'm not sure it shows the direction of leakage, does it? You will have to help me or let me have a look. What are you saying is the direction of leakage on 3C?

BY MR. COHN:

Q. Let me back it up and make the question a little clearer.

A. Okay.

Q. Let's look at Figure 3C.

A. Yes.

Q. The direction of leakage, if there were any, would be downward on the page; is that right?

A. Well, that's one of the ways, yes. This is illustrating an aneurysm, and they obviously only show the top half of it, and the leakage would be around that. There would be another end where there could be leakage in the other direction, if you are with me. What is illustrated in 3C is just the top half, and

this wavy line at the bottom I think is showing, is actually showing part of a device.

Q. So looking at Figure 3C, the direction of leakage at this end of the device would be downward on the page?

A. Yes. That top end, the direction of leakage of the aneurysm would be downward from the aorta above into the aneurysm sac, which is shown by the wall curving out on the left-hand side.

Q. In figures 3A, 3B and 3C, the skirt is attached to the tubular body at the top end of the tube; is that right?

MR. EGAN: Objection to the form.

THE WITNESS: I can't really tell on 3A because it is collapsed. I don't think you can tell that. But on 3B, yes, where it is flat-out, looking like almost a lady wearing a skirt, it looks like sort of a skirt coming out from the device from the top, and it clearly goes to a larger diameter in the underlying device.

BY MR. COHN:

Q. Now, I want you to use, let's use the blue pen, if we can.

A. Sure.

Q. And indicate somewhat like this, I want you to do it your way and accurately, but I am looking for something similar to this, where along the tube in Figure 3B the skirt is attached?

Let's break it down one step at a time. Let's start with your finger before we start marking up the diagram.

A. Yeah.

Q. Can you indicate for me where on Figure 3B of Elliot the skirt is attached to the tube?

A. Generally around the top. I'm not sure that level of detail is shown, but it is shown around the top. There is a dotted line so you see the tube is running roughly parallel. I'm taking that to be a dotted line. And it's attached around the top end.

Q. Okay. Can you indicate with the blue pen where the skirt in Figure 3B of Elliot is attached on the document?

A. How do you want me, draw a circle around? Obviously, it is attached all the way around.

I mean, it's attached --

Q. Just do the best you can and then you can indicate with an arrow and label it.

A. I'm sort of adding a blue circle to show that it is attached there onto the underlying -- is that right?

Q. Now I'm thinking the red would have been better.

A. Look, you can see it.

Q. Let's do the red just to be safe.

Counsel, can I ask you to give the witness your copy?

MR. EGAN: Let me make sure I haven't made any markings yet.

MR. COHN: Sorry, Doctor, I just want a clean.

MR. EGAN: I think to the extent we are going to mark up any of these, we should probably put another exhibit number so it is distinguished from what was actually submitted as part of the petition.

MR. COHN: That is a good idea. Let's do that.

Let me take the one you marked up. I am going to mark it Buller-4.

(Buller Deposition Exhibit No. 4 was marked for identification.)

BY MR. COHN:

Q. I marked Buller-4 the document you just marked with blue pen.

Now we are going to do that on Buller-5. Another clean copy of Exhibit 1005, the Elliot patent.

(Buller Deposition Exhibit No. 5 was marked for identification.)

BY MR. COHN:

Q. If you can go to Figure 3B and use the red pen on Exhibit 5 and mark where in Figure 3B the skirt is attached to the tube in Elliot.

A. I am just doing in red what I did in blue, and it will show you much better in red. But it's attached on that circle.

Do you want me to label it?

Q. If you could, please.

A. What should I label it?
Q. Is "attached" appropriate?
A. "Attached," yes.
And initial?
Q. Yes, initial, please.
A. (Indicating.)
Q. Now, does Elliot say anything in the text about how the skirt is attached? Strike that.
Does Elliot say in the text where the skirt is attached to the tube in Figure 3B?
A. I can't remember.
I can look at 3B.
Q. Why don't you take a look and see if you can find any discussion in Elliot describing how the skirt in Figure 3B is attached to the tube?
A. I don't see anything saying how it is attached. It is just describing that it is attached. It is collapsed in 3A, and then it expands out in the subsequent drawings.
Q. In Figure 4 of Elliot.
A. Yes.

Q. Figures 4A through 4E depict a cylindrical shaped skirt; is that right?

A. Yes, I think that's fair. Again, it has a free edge, which is 18, but this is a different shape, and it is like a sort of cylinder, which protrudes out from the underlying device.

Q. And the skirt in Figure 4 of Elliot is attached to the tube at a location that is spaced from the end of the tube; is that fair?

A. Yes. In this one it is shown below the end of the tube, below the upper end of the tube.

Q. If you look at Figure 5, the skirt in Figure 5 is shown as being attached to the tube at a location that is spaced from the end of the tube; correct?

A. Yes.

Q. The same for Figure 6 and 7; correct?

A. Yes.

Q. Would you consider calcified aortic tissue to be healthy?

A. There's degrees of it. I'm afraid you may have some calcification. I almost

certainly do. I'm 62 this year. So, I mean, there are degrees of it and there's a degree of calcification which, you know, is not how it is supposed to be and not how it is when you are born, at a young age, but you develop it before you've got significant valve problems. So there are degrees of calcification which are unimportant or trivial, if that is what you are asking. But by the time you've got clinically significant aortic stenosis, then it is not healthy.

Obviously, like most disease processes, it starts gradually and it starts at a much younger age than when it presents.

Q. In the thoracic or the abdominal aorta --

A. Yes.

Q. -- would you consider calcified tissue to be healthy?

A. Well, no. I think I've already answered it. It's not. But you develop it at an age before you have got an actual clinical problem or an underlying problem. So if you take healthy adults and look at them, a lot of

them will have calcification in the aorta. They will be fit and healthy, active, playing sports, things like that, and they will have calcification. So we know that in human beings they get calcification when they are still healthy. It would be better if they didn't have it, but it is a fact of life. The majority of people by the time they reach old age have calcification in their aorta.

Q. Some people can still appear healthy and active even though they may have diseased tissue in their body; is that fair?

A. Of course, of course. But what we realize, as I tried to describe, and, unfairly, is the disease processes for certain diseases start very early and you have a long period, a later period where you are fit and healthy by all sensible criteria. And even if people knew about it they wouldn't need to treat it or do anything about it. But, unfortunately, it develops and gets worse, and then it can lead to problems when it is advanced.

Q. If you had a patient and you were

investigating the health of their descending aorta and you found calcification in there, would you consider that to be healthy aortic tissue?

A. I think I've already answered. It depends on degree. If they are an octogenarian, they are in their 80's, it would be almost universal they may have some. And they may be completely healthy. And I would be more than happy to tell them they are healthy. There is no point in me drawing attention to something which is universal. It is part of getting older. Because it is not at a level that is causing them significant problems or harm or a diseased state that requires treatment.

If I can help further, because I am not sure that I am answering your question, but it is normal to have some calcification in the aorta by the time you are 80, and in that much it is normal to have some and it is not causing them any problem, active problem, then you could still regard them as healthy. And I would still tell them that they are healthy.

Does that help to answer? I am a bit lost with what you are asking me.

Q. I was asking a slightly different question, and I am trying to make a distinction between the overall health of a patient and whether a particular portion of the tissue is diseased. So just an example.

I will get to a question, counsel. But just to give some more context to this.

I hear anecdotes about people who have highly diseased coronary arteries and they are fine, they appear healthy for a time. But you would not describe the highly diseased coronary artery as healthy tissue.

So I am trying to draw a distinction between the patient seeming okay, being healthy and running around, and having this diseased tissue.

So my question is really focused on this healthy tissue aspect of my question and not so much the healthy patient aspect.

A. I see.

Q. And I guess my question is: Does

healthy aortic tissue generally have calcium, have calcifications?

MR. EGAN: Objection to the form.

THE WITNESS: It depends on how you are using the term, and you really can't answer that question. I mean, a lot of healthy tissue has minor degrees of abnormalities, including calcification, particularly in older patients.

BY MR. COHN:

Q. The calcification would generally be minimal with healthy tissue and not minimal with diseased tissue?

A. Generally speaking, there will be a correlation, but you can have quite a lot of calcification without, for instance, an aneurysm, and, therefore, you might say they are absolutely fine, and you will tell them they are healthy, but they have got quite a lot of calcification. You will still regard them as healthy, and the caliber is normal, so they haven't developed a problem such as an aneurysm, but I am just using that as an

example, and you would regard them as healthy.

But in old age, which we are dealing with increasingly in medicine, we have to recalibrate. I mean, it wouldn't be an expected finding in a ten-year-old but it would be almost a universal finding in an 80-year-old.

Q. Without a camera, that's just easier than passing a note.

I think that is enough of that question for now.

A. Okay.

Q. I am going to hand you what has been marked 1019.

A. Yes.

Q. This is the Thornton patent that you discussed in your declaration; right?

A. Yes, it is.

Q. The Thornton patent does not mention heart valves; correct?

A. No. Again, it is broadly applicable to implantable medical devices, but it doesn't specifically mention a heart valve.

Q. There is no valve depicted in any of

the embodiments shown in Thornton; is that right?

A. Correct.

Q. In Figure 1 of Thornton, there is a skirt depicted; is that right?

A. In Figure 1?

Q. Yes.

A. Yes.

Q. Is that called a flange or skirt? Do you remember the word that is used?

A. I can't. It may well be a flange or a skirt, yes. But that's a fair, both are fair descriptions.

Q. No. 26 in Figure 1, that is described as a flange; right?

A. Yes. I will take that.

Q. If you look at Column 7.

A. Column 7?

Q. About Line 24, 25.

A. I see cuff.

Q. Keep going. 26, element 26?

A. Element 26, flange 26, yes.

Q. Back to Figure 1, do you see flange 26?

A. I do.
Q. Thornton does not provide that flange 26 performs a stabilizing function; correct?
MR. EGAN: Objection to form.
THE WITNESS: No. It's a sealing function.
BY MR. COHN:
Q. So I am correct, right?
A. Yes. I believe so.
Q. Now, if you look at Figure 3 of Thornton.
A. Yes.
Q. There is no calcification depicted on the inside of that vessel; is that correct?
A. I don't know. I am not sure what the lines are supposed to represent. I mean, they are squiggles inside the wall. But it is a diagram, it's a patent diagram, and I don't think anything is labeled as calcification. They are squiggles shown in the wall, a cross-hatched wall of the blood vessel that has an aneurysm.
Q. Now, I believe you say in your declaration that flange of Thornton was

commercialized in a product, in the Gore excluder product?

A. Yes.

Q. Now, did you, yourself, actually use the Gore excluder?

A. Yes.

MR. EGAN: Objection. Asked and answered.

THE WITNESS: You asked me about it and I said, from memory, two, I think, and the Gore excluder that I used had a flange just like as is illustrated in the patent.

BY MR. COHN:

Q. So if I asked you how many times did you, yourself, used the Gore excluder, you would say twice?

A. I think so. I thought I answered. I may have not been clear. But I thought I answered that before the last break.

But not the abdominal one. I mean, again, there is a thoracic one. Not the abdominal Gore excluder. They made, it is still called the excluder, but it is a thoracic Gore excluder.

Q. Let's be clear, then. The Gore excluder that you used twice was a thoracic?

A. Correct. I have never used the abdominal AAA Gore excluder. As I said, I've not on my own treated an abdominal aortic aneurysm. It is outside the territory. I was very interested in it. I was referring patients. My hospital was part of a big trial for the abdominal aortic aneurysm. But they are two separate devices. There is a AAA Gore excluder and there was a thoracic Gore excluder.

MR. COHN: Why don't we take a break.

(Recess.)

BY MR. COHN:

Q. Let's go back to Thornton.

A. Yes.

Q. If we look at Figure 1.

A. Yes.

Q. If you could take out the red pen and indicate on Figure 1 where the flange is attached to the tubular member, please.

A. Where the flange is attached? It is

attached over a fairly wide area. I am crosshatching, because it is a fairly...

Q. And is there a flange at the other end?

A. Yes.

Q. Can you indicate that as well?

A. Yes. It is facing the other direction because this is for an aneurysm (indicating). So to isolate it, there is the attachment.

Do you want me to be label them attachment?

Q. I just want to make sure we do it the same way.

A. And it would be all the way around.

Q. If you could label that as "attached," and then initial.

A. (Indicating.)

Done.

Q. And then on Figure 3.

A. Yeah.

Q. Is the device in Figure 3 the same device from Figure 1?

A. Well, it's the same sort of device. I mean it's a diagram. So I'm not -- I just

never know what you mean by -- it's a diagram. It is not actually a device. It's a diagram of the same device, the same sort of device. But it's a patent diagram and it's depicting it inside a diseased aneurysmal aorta.

Q. Do you see in Figure 3, flange 95?

A. Yes.

Q. Where is flange 95 attached to the tubular member? Why don't you just show me with your finger first just to make sure.

A. It is like I have drawn here with this hole, the white part. I mean, your terminology, it is the same device. It is attached all around here. I only see one end because half of it is off the picture. It is this band here, and that is why this wrinkle sort of comes to an end in this attachment, because this is attached across it. So the wrinkle comes to a blind end where the dotted line is shown.

Q. Can you now indicate with the red pen where the flange 95 is attached to the tubular body in Figure 3 of Thornton.

A. Yeah.

It is a big area of attachment on this particular photograph. So I am cross-hatching it (indicating).

And "attached"?

Q. Yes, please.

A. (Indicating.)

Q. Since you marked on that, I am going to mark it with a deposition exhibit.

(Buller Deposition Exhibit No. 6 was marked for identification.)

BY MR. COHN:

Q. I am taking a copy of Thornton that the witness marked up and I am labeling it Buller Exhibit 6.

A. Thank you.

MR. COHN: I am going to stamp this as Buller Exhibit 7.

(Buller Deposition Exhibit No. 7 was marked for identification.)

BY MR. COHN:

Q. This is a clean copy of Exhibit 1006, and that is the Cook patent that you discuss in your expert report in this case; right?

A. Yes.

Q. And the Cook patent does not mention heart valves; correct?
A. Correct.
Q. And in the devices described in Cook, there is no valve depicted in any of them; is that right?
A. That I believe is correct.
Q. If you look at Figure 1 of Cook, do you see cuff portion 15?
A. I do.
Q. The Cook patent does not provide that the cuff portion 15 performs any stabilizing function; is that right?
MR. EGAN: Objection to form.
THE WITNESS: No. It's teaching it is as a seal.
BY MR. COHN:
Q. So I am correct; is that right?
MR. EGAN: Objection to form.
THE WITNESS: Yes. I mean you are correct. It is teaching it as a seal.
BY MR. COHN:
Q. Do you see the proximal anchoring stent 18 in Figure 1?

A. I do.

Q. How would you describe what is depicted as proximal anchoring stent 18 in Figure 1?

A. It's a stent structure partly sticking out of the end of the stent graft. This was a common thing for aortic aneurysms because of the proximity of the renal arteries, kidney arteries, that come off the aorta and you didn't want to cover them with graft material. So in some devices you would have bare stent, uncovered stent sticking out, so you could put that either very close to or over the ring holes without blocking them.

Q. Would the proximal anchoring stent 18 perform a stabilizing function for the device shown in Figure 1?

A. Yes. As the word suggests, anchoring is meaning for that purpose, attaching, helping to anchor the graft.

Q. Now, if you look at Figure 3 of Cook.

A. 3?

Q. Yes.

A. Yes.

Q. And do you see --
A. Oh, this is exactly what I was -- yeah, this is good. This is what I was already trying to describe. So the proximal anchoring stent 18, you will see it is overlapping the two renal arteries, the two branches coming off the aorta at the top of Figure 3, or a little way down from the top of Figure 3 going to the left and right. They are the renal arteries, and the so-called anchoring stent 18 is there overlapping the renal arteries.
Q. Do you see the cuff portion 15 at the top of Figure 3?
A. Yes.
Q. The direction of any leakage of blood past cuff portion 15 would be from the top to the bottom of Figure 3; is that right?
A. Yes. So it is heading into the aneurysm, which is shown below, which is the big dilated part of the aorta.
Q. You can put that aside for now.
Now, back in 2004, mild PVL was something that persons of ordinary skill

thought would not have had a bad effect on mortality; is that fair?

MR. EGAN: Objection to form.

THE WITNESS: No, no. We wish to avoid any paravalvular leak because paravalvular leak can cause all sorts of problems, increased likelihood of what's called hemolysis, blood breaking down, red blood cells breaking down, infections and things. Obviously, the milder it is, the more you would consider leaving it. But you weigh that up against any signs of problems it is causing.

If I can add, surgeons, the common way for replacing any heart valve back in 2004 was surgery, and surgeons would go to great length to try and avoid any paravalvular leak, and they used devices that had squashy cuffs to form a seal, and they would do everything they could to make sure there was no PVL. They would consider it to be a significant downside to leave any PVL.

BY MR. COHN:

Q. Back in 2004, very mild paravalvular

leak was something that persons of ordinary skill thought would not have had a bad effect on mortality, and then that changed later. But that was correct in 2004; right?

MR. EGAN: Objection to form. Compound.

THE WITNESS: I'm trying to put it into context. But to a degree, surgeons try to avoid any PVL. PVL was known it could cause problems. If you knew that was PVL you would have to follow the patient very carefully to see if it was getting worse. But most of what we are talking about is surgical heart valve -- I'm assuming you are talking generally about PVL, not just a valve. There are -- perhaps I am completely misunderstanding your question?

BY MR. COHN:

Q. Maybe I should have given more context. I was talking in the context of TAVR.

In the context of TAVR, back in 2004, mild PVL was something that persons of ordinary skill thought would not have had a

bad effect on mortality, correct?

A. I think that is true, but really only because the sort of patients that were being treated were close to death's door. Many of them died within a short period anyway. Some of them were dying. Most of the use was compassionate and, therefore, it is true, because you're dealing with fantastically safe patients. That's the reality of what Alain Cribier was doing from 2003 to 2004.

So that is true. But would we want to avoid it or try to avoid it? Yeah, absolutely, we would.

But it wouldn't have an effect on mortality on these particular patients because these patients were so sick that you're trying to get into a procedure and they were dying from their valve disease. And therefore in almost any -- it is difficult to word, to repeat it, almost any improvement you achieve was going to greatly benefit these patients because of how sick they were. This was compassionate use in the very early days. That was the protocol that I think Alain

Cribier was using.

Q. So we can go to the UK transcript, but let's just see if we can set this up on our own first to get context.

A. Yes.

Q. At the UK trial, you testified that back in 2003/2004 timeframe very mild paravalvular leak was something that people thought would not have had a bad effect on mortality, and then later there was a surprising and disturbing finding ten years down the road that changed that.

Did I get that right?

A. Sure, absolutely.

MR. EGAN: Objection to form. If you need to look at your actual testimony, you can request it.

BY MR. COHN:

Q. Did I get that right generally?

A. Yes. And I thought that is what I said. If we are now in the context of TAVR and Alain Cribier, then because of what he was doing and who he was treating, the very mild PVL was thought not to be going to have an

effect on mortality because of who these, world's first patients were.

As we got more data and lots more people were using it, we learned a lot more, and there was a time, many, many, many years later, where we found out or at least the suggestion from the data was that even mild PVL could have a significant effect on mortality and, therefore, we became aware of that, and, therefore, more concerned about leaving even very mild paravalvular leakage.

Q. Now, in 2004, persons of ordinary skill in the art knew that moderate to severe paravalvular leakage was bad for patient mortality. That level of leakage was known to have an adverse effect on mortality at the time; is that right?

MR. EGAN: Objection to form. Compound.

THE WITNESS: Well, yes, but again, you've got to, in these very early patients -- absolutely. I mean the answer is yes, the simple answer.

But these were incredibly ill

patients you were trying to get it in. You would love to put in a valve where there was going to be no leak. A little bit of leak wasn't going to cause an adverse effect on these patients who were very ill and dying patients. As we expanded over the years and treated more, and the criteria got less, they went to aid from compassionate use, and these were done as elective procedures, you learn a lot more and then you pay more attention to things, and all of the data supported the fact that very mild PVL actually may have an effect on mortality.

Whether or not that's true will come out in some of the data that is still being produced. But certainly there was a concern that even very mild PVL might have an adverse effect. But that was years after 2004.

But if I can add, just for clarity on the record, we always wanted to produce as little PVL as we could achieve. I mean, the object in replacing a valve is to create a one-way flow of blood, not to leave a

two-way flow of blood. You want to put a valve in so that blood flows through the valve and then it closes and then there's no flow. That's the object, to create one-way flow. That is the purpose of putting a valve in.

BY MR. COHN:

Q. When did you first learn that the Edwards' Sapien 3 valve would have an external fabric seal?

MR. EGAN: Objection to form. Relevance.

THE WITNESS: I don't know when I first heard about it. I mean I can't remember when I first heard about it and saw pictures of it. But as soon as you would see a picture of it, you would see it as it's external cushion is a very apparent feature of the device.

BY MR. COHN:

Q. The outer skirt of the Sapien 3 was added in order to minimize paravalvular leakage by filling gaps between the stent wall and the native annulus; correct?

MR. EGAN: Objection to form.

Relevance. I don't see how this has any relevance to the IPR, counsel.

MR. COHN: There is a lot of relevance to the IPR.

MR. EGAN: To a product that was developed after 2004.

MR. COHN: I don't need to get into a speaking objection in front of the witness about this.

MR. EGAN: If you are going to continue asking him questions about the designs, the development of Sapien 3, we are going to shutdown that line of questions.

BY MR. COHN:

Q. Do you believe the Sapien 3 is a commercially successful product?

A. Yes.

Q. Did you consider that commercial success in rendering your opinions in this case?

A. No.

Q. Do you think the commercial success of the Sapien has any relevance to the issues in this IPR?

A. Not to my knowledge. I'm not a lawyer. It is not part of my analysis. I don't see that it has any relevance.

Q. In the course of forming your opinions, did you consider whether any products having an external fabric seal were commercially successful or not?

MR. EGAN: Objection to form. Relevance.

THE WITNESS: Not for the purpose of the IPR, no.

BY MR. COHN:

Q. Did you consider whether there was a long-felt need for an outer fabric seal that filled the gaps between the stent wall and the native annulus --

MR. EGAN: Objection to form. Relevance.

Q. -- in forming your opinions?

A. I considered motivation. And one of the things I considered is the need to create a seal. I mean, it was recognized from at least the 1960s in heart valve replacement, you needed to create a seal in surgical valves

initially, and that same desire to create a seal obviously extended through into the early development of transcatheter heart valves. So I considered all of that. But mainly as my consideration and motivation combined. There was great motivation to combine a better and different ways to seal with taught transcatheter heart valves.

Q. Did you consider whether there was a long-felt need for an external seal that extended from the anchor and filled the gaps between the anchor and the native valve leaflets?

A. Not in those words, I mean your words. But I've done what I just described in my words, which is motivation. There was great motivation to produce good sealing.

Q. Was there great motivation to use an external seal in particular?

A. Well, to produce a seal, and, therefore, an external -- I mean leaking occurs around the outside and, therefore, by external, meaning around the outside, yes. That's why you would want to seal around the

outside. So yes, external.

Q. So it is your opinion that in June 2004 there was a great motivation to use an external seal around the outside of the device?

A. It was one of the possibilities. You want to achieve a seal, and one of the ways you can achieve a seal would be with an external cuff, skirt, whatever you call it. There are obviously at the same time downsides to it such as profile. And in real-world development you're weighing the upside against the downside. And this is common in medical devices, that you have to weigh upside against downside.

Q. One of the downsides that were known by persons of ordinary skill in the art in June 2004 of having an external seal around a TAVR device was its effect on profile; correct?

A. Absolutely. By profile what I'm meaning is delivery profile. This is how small you can make the device to actually put it inside the body. So it's the collapsed

delivery profile.

Q. Any other downsides putting a seal around the outside of a TAVR valve that were known in June 2004 besides the effect on profile?

A. Well, yes, potentially you've got to consider how to attach it. You've got to consider what material it's made of and its thickness. Many of those also go into profile, like thickness. But you have to make sure it will achieve its purpose and it will have as little downside as possible.

Q. I am not sure that quite answered my question.

A. I'm sorry.

Q. That is fine.

One downside of having an external seal around the outside of a TAVR device in June 2004 was its negative impact on the profile of the device, correct?

A. Yes.

Q. Then you talked about, I asked you if there were any other downsides and you talked about how to attach it and the kinds of

material. Those aren't necessarily downsides, are they?

A. Well, they can be.

Q. They can be?

A. Clearly, it is an extra component. It's got to be secure. It must not migrate. You are putting an extra piece on, all other things being equal, and you've got to consider the effect it had. One effect, obvious effect, is on profile. Another effect is it has to be secure. Another effect would be whether it has any negative impact in securing the device. We talked early on about migration and things. You've got to weigh out whether it has any downside on other functions, such as securing the device in place.

So there are many considerations.

Q. And all of those effects in June 2004 were highly predictable by persons of ordinary skill in the art; is that right?

MR. EGAN: Objection to form.

THE WITNESS: I don't like the

highly predictable because there is no substitute to trying things. So in any idea, you have to develop it into a product, and you have to test it, including in man, and that takes time and a lot of expense.

So many of the potential problems are predictable, I agree with that, but you still have to actually do it and do clinical research. You can never go to the FDA saying I understand I have not done it, but I can tell you everything that is going to happen. They wouldn't buy that.

BY MR. COHN:

Q. One of the potential problems of attaching an external fabric seal around a TAVR valve in June 2004 was that it might not be securely attached; is that fair?

A. You need to make sure it was securely attached.

Q. And one of the downsides would be that it wouldn't be? I'm trying to understand what you mean by a downside of doing that.

A. Well, I thought I described it as well as I can. If you add an extra component to a

device, you got to make sure that that component doesn't add any problems, and one of the problems for any extra component on the device is that it can break off, tear off, detach, and that's what I'm saying.

If you're adding an extra component, all other things being equal, then you are going to have to do durability testing and try it out in the clinical setting. That's normal development of a medical device.

Q. In forming your opinions set forth in your declaration in this proceeding, did you consider whether Edwards or any others tried and failed to solve the problem of PVL in the context of transcatheter valve replacement?

MR. EGAN: Objection to form. Compound.

THE WITNESS: Sorry, can you simplify it, reread it again.

BY MR. COHN:

Q. If you want to look at his screen next to you, you can see it.

A. Sure.

Q. But I will read it again.

A. Yes, it is very broad. People were trying to solve the problem of PVL, obviously. I've addressed many, many teachings of ways that you could potentially solve PVL. There were many people, and recognizing that leakage in the vascular system is an important thing, and there were many ideas to solve it.

Q. Did you consider whether any people undertook efforts to solve the problem but failed to solve the problem with those efforts --

MR. EGAN: Objection to form. Compound.

BY MR. COHN:

Q. -- in forming your opinions.

A. It is incredibly difficult to answer because when you say "any people," there were so few people that had actually done transcatheter aortic valve implantation, and namely Alain Cribier, that absolutely. He addressed in some of his articles that you need to solve it. I have looked at other articles that talk about the need to address PVL, prior to today, prior to 2004, and I've

considered those in my report.

But, I mean, the fact that PVL occurred was known, recognized and published, and people wanted to reduce it. And I have called out particular references that I think are relevant in this.

Q. So you say you considered the need to address PVL, correct?

A. Yes.

Q. And you considered possible solutions to the problem of PVL that was in the literature in the past, correct?

A. Yes.

Q. But did you consider any activities by Edwards or anyone in which the problem of PVL was actually attempted to be solved but was not?

MR. EGAN: Objection to form.

THE WITNESS: There was so few procedures done that you almost in a clinical -- there wasn't sufficient material to even look at that. We were dealing with less than ten procedures that are being done and we were evaluating that data. It was

recognizing that PVL was a problem. It was a complication that occurred, and it needed to be addressed. That was all known. But this was such an early day in transcatheter valve replacement, and specifically transcatheter aortic valve replacement, that the question doesn't resonate for me. It's really difficult to answer the question. You're at the very early stage and you're looking at the results and thinking, yes, we need to improve.

BY MR. COHN:

Q. When you were forming your opinions in this proceeding, did you ask from Edwards or its counsel for any information about Edwards' own attempts to solve the problem of PVL prior to the Sapien 3?

MR. EGAN: Objection to form. Relevance.

THE WITNESS: No, because of the date that I am considering is as of 2004, there wasn't even Sapien. I mean, it was so far back in the development. I mean, I'm dealing with basically what is sometimes referred to as the Cribier valve with PVT.

And one is looking at it through those eyes in that time. Edwards hadn't, as far as I'm aware, Edwards hadn't produced a commercial device by 2004.

BY MR. COHN:

Q. So in your view, events occurring after the June 2004 date in this case are irrelevant?

A. Well, I'm not a lawyer. I don't know if they are relevant, but I have not considered them. I have done my analysis looking through the eyes of a person of skill in the art at the priority date, as I understand it, of the '608 patent, and that's the analysis I have done. I have looked at it through those eyes in that timeframe.

Q. Are you aware of any praise in the industry directed at the Sapien 3's solution to paravalvular leakage?

MR. EGAN: Objection to form.

THE WITNESS: Yes, I think people like the device. I've seen what can be called praise for it. They like the device. It has produced good results. Some results

are published. None of that was in existence back in 2004. So I did not consider that as part of my analysis for this declaration.

BY MR. COHN:

Q. As part of your analysis for the declaration, were you instructed that events occurring after the June 2004 date were not relevant?

MR. EGAN: Objection to form.

THE WITNESS: I don't think I was instructed. I don't think I received that instruction, but I did the task if I was instructed, and that was looking at the time of 2004 and what would have been obvious and anticipated by the collection of references that I considered. I tried to be clear in my declaration of putting in my sort of legal instruction. And from memory -- you can give me my report -- but it was just obviousness and anticipation which was the legal instruction that I received, and I was looking through the eyes of the person of ordinary skill in the art as I saw it in the timeframe of 2004 and assessing what would have been

obvious or references that I considered anticipated the claims of '608, and that was the task I performed.

BY MR. COHN:

Q. I had asked you about industry praise for the Sapien 3 solution to PVL, and I think you had answered that the Sapien 3 itself had been praised. My question was a little more specific, so I will ask it again.

A. Okay.

Q. Are you aware of industry praise for the Sapien 3's solution to PVL?

MR. EGAN: Objection to form.

THE WITNESS: I am not sure I understand. What do you mean by "industry praise"?

I'm aware of clinicians that have praised the device, and one thing they report is that there is reduced PVL in some of the studies. But I have seen publications that there are other reasons other than the outside skirt that may have reduced PVL. I mean, there is, like is often the case in science, critical science, there are various

competing thoughts as to exactly what about the device leads to the benefits. But the benefits have been recorded. There's praise for the device as a whole, and there is debate as to exactly what brings about that benefit.

BY MR. COHN:

Q. In forming your opinions in this case, you did not undertake an investigation into whether there had been any praise by clinicians of the Sapien 3's outer skirt?

MR. EGAN: Objection to form. Relevance.

BY MR. COHN:

Q. True?

A. Not for my declaration, no. I mean I didn't consider Sapien 3 at all. I didn't know it had any relevance in my declaration. I didn't consider Edwards' Sapien 3 product at all for my declaration that I signed on the 10th of October of last year.

Q. You didn't look to see in the course of coming to your opinions whether there was an absence of praise by clinicians for the Sapien 3's outer skirt; correct?

MR. EGAN: Objection to form. Relevance.

THE WITNESS: Well, I think I've answered, I didn't consider Sapien 3, any aspect of it, in formulating my report. I didn't consider Sapien 3.

Obviously, I didn't do it because I didn't think it had any relevance.

BY MR. COHN:

Q. Before the Sapien 3 was launched, what had been done to try to solve the problem of PVL in commercial TAVR devices?

MR. EGAN: Objection to form. Relevance.

THE WITNESS: Patient selection, precise sizing. On occasions overexpansion. Increasing the volume of the inflation device for Edwards balloon-expandable device. All of these things singly or in combination have been done to try and improve clinical results.

BY MR. COHN:

Q. So you talked about patient selection. How would patient selection have addressed a problem of PVL with commercial TAVR devices

before the Sapien 3?

MR. EGAN: Objection to form.

THE WITNESS: Because the devices, the commercial devices that Edwards produced are labeled in their IFU to use a particular range of size, and I think in time clinicians became aware that that really is important. Even though there may be very strong compassionate reasons to give a patient that falls outside the range or if you don't have the right size on the shelf, people get more rigid about following the instructions that Edwards gave, so they would not try and put in a device which wasn't ideal in a way that they might have early on, before we fully recognized some of the problems.

And that is patient, that is what I am referring to as patient selection. So really making sure that you take a lot of notice and follow the IFU, making sure that you use really good, up-to-date imaging techniques to measure annular size, et cetera, before the procedure. All of those things. Fine tuning your decision-making process

before putting the device in.

BY MR. COHN:

Q. You had mentioned that overexpansion was one of the ways by which people had tried to solve the problem of PVL with commercial TAVR devices.

What did you mean by that?

A. That if you put a device in and it is leaking, and the device is in there, then you might need to make it a bit bigger to try and deal with the leak, and you may need to take it a bit bigger than is recommended in the IFU. And that is one of the things that is referred to as oversizing.

Q. What about calcification de-bulking before implantation, was that one means by which people would try to reduce PVL before putting a TAVR in?

MR. EGAN: Objection. Form, foundation.

THE WITNESS: Some people may have, but I'm not aware of any. I'm not aware of any commercialized product to perform de-bulking by removing calcification from the

leak. That's before TAVR implant.

People have talked about it in the scientific literature. People have talked about removing the leaflets by percutaneous techniques. Professor Lutter, who was one of the Boston witnesses in the UK, talked about does the UK have interest in it. But I don't believe that that has ever been commercialized. If it is being done, it is very, very small print, but I'm not aware that it has been done, and I'm not aware there is a commercialized product to perform such a procedure.

BY MR. COHN:

Q. How about adding a bunched-up fabric seal around the outside of a TAVR device, had that been done by anyone before the Sapien 3, to your knowledge?

MR. EGAN: Objection to form.

BY MR. COHN:

Q. Either experimentally or commercially?

A. Well, it depends what you mean by "bunched up"? I don't know whether that's what they refer to the Lotus valve

commercially. I mean the Lotus valve -- which Boston subsequently bought in the device I'm talking about -- but that has a seal. I don't know if it is Boston's official position that it practices the patents, and I don't know as I sit here, unless you show me something, that they refer to it as bunched up. I don't know. But that device I think was first implanted back in 2007/2008 time frame.

Q. Other than Boston Scientific's Lotus, can you think of any efforts to add a fabric seal around the outside of a TAVR device that had been done before the Sapien 3?

MR. EGAN: Objection to form. Relevance.

THE WITNESS: As I sit here now, I can't. That doesn't mean there isn't, but I can't think of a device that had that that was commercialized, at least.

BY MR. COHN:

Q. Sitting here today, do you know what, approximately, the rates of PVL were for the Sapien and Sapien XT after 12 months?

A. I don't remember. It's in the

publications, and it obviously depends on the severity, because it is classified as sort of mild, moderate and severe. And it's all there in the literature, but you can give me the publications. It's different in different publications.

But it is a measurable percentage and obviously the milder you go, the higher it is.

Q. Sitting here right now, do you have any reason to dispute that for the Sapien and Sapien XT there was over 20 percent rate of moderate to severe PVL after 12 months?

MR. EGAN: Objection to form and relevance.

THE WITNESS: I don't have any reason because you've got to show me. But you need to look at who the operators were, which study, what criteria were used. I mean one needs to evaluate the literature, and that is done, and reviews of it are done periodically. But you would need to put a paper in front of me for me to actually comment on it.

BY MR. COHN:

Q. Is it fair to say that in June 2004 persons of ordinary skill in the art did not know the long-term mortality associated with PVL in TAVR devices because TAVR had not been used long term by then?

A. Of course. That's absolutely true, and it has to be true because the longest surviving patients were very relatively short term in 2004.

Q. Would you agree there was a long-felt need to address paravalvular leakage from June 2004 all the way up to 2013?

MR. EGAN: Objection to form.

THE WITNESS: Such a legal term. Yes, there is a need to address paravalvular leak. There still is today. We haven't gotten to perfection yet with any devices, including Edwards Sapien 3 and Lotus. We are still developing this technology. And as was the case right at the beginning, paravalvular leak is one of the undesirable features that we are still addressing, and companies like Edwards, Boston Scientific are working in this area. But we haven't gotten a perfection yet,

even in 2017.

BY MR. COHN:

Q. In your opinion, would it be wrong to characterize the rate of PVL associated with the Sapien 3 as being virtually eliminated?

MR. EGAN: Objection to form.

THE WITNESS: It depends what you mean. I mean, again, it is slightly emotive words virtually eliminated. That suggests that it is not being eliminated, but you are getting close to eliminating it. But it depends how many patients you have done and in what hands.

If I can just say, in interventional cardiology procedures, part of the quest is to make the procedures easier and more and more safe so that less well-trained people can do it and get the same results. We're still at a stage where an awful lot of work and training and selection goes into maybe the patients and the operators, and we'd love to get to a procedure which becomes so good and reliable that lesser people can do it and a wider range of patients. At the minute

the range of patients is still very restricted and the range of operators is very restricted and there's a big learning curve for even operators. So I don't think we're at the stage I personally would want to say it is virtually eliminated because we want to treat a wider range of patients and we want to make it easier for operators to get as good as results as the current experts do.

BY MR. COHN:

Q. You had mentioned Boston Scientific's Lotus product earlier.

A. Yes.

Q. That has an external fabric seal around it; right?

MR. EGAN: Objection to form.

THE WITNESS: I believe it does. It's a polymer, but I think it is a fabric, yes, I think Boston does.

BY MR. COHN:

Q. You know that it creates flaps that extend into the gaps formed by native valve leaflets when it is deployed?

MR. EGAN: Objection to form to

the extent it calls for a legal conclusion.

THE WITNESS: I don't know that. I mean I don't -- I haven't yet seen it, and it may well be that they have as to whether Boston agrees that it practices the claims. But if Boston agrees that it practices the claims, then I guess they are characterizing it with these words that come straight out of the claims. But I don't know if Boston's position is that the Lotus practices, for instance, Claims 1 to 4 of the '608 patent, I'm just not aware of that.

BY MR. COHN:

Q. Have you ever seen a Lotus valve?

A. Oh, yeah.

Q. In real life?

A. Yes.

Q. Have you seen the seal of the valve when it has been in the expanded configuration?

A. Yes. I've handled it. I've seen it.

Q. And in your view, does that seal have flaps?

MR. EGAN: Objection to form to

the extent it calls for a legal conclusion.

THE WITNESS: Yes, I think it does. But what I was saying, and I thought I was very clear, I don't know whether that's Boston's position. But I've looked at it. I think it has flaps. They are very small ones. They run circumferentially. And what I think flaps should be it has.

BY MR. COHN:

Q. Did you undertake any analysis as to whether there had been industry praise for the external seal on BSC's Lotus valve?

A. No. And as I understand it, it is not even on the market. It had problems not necessarily related directly to the seal, but it is being withdrawn from the market. My understanding is it is not FDA approved. It is not on the market this side of the Atlantic. In Europe currently it's off the market.

Q. It was on the market for a time into Europe; correct?

A. Sorry, in Europe it was withdrawn from the market because of problems.

Q. The Lotus valve had been sold in Europe for a time; right?
A. Yes, absolutely right.
Q. So clinicians had been using the Lotus valve in Europe for a time?
A. Yes.
Q. And you did not undertake an investigation of whether any of those clinicians had praised the external seal on the Lotus valve in coming to your opinions in this case; is that right?
A. I've heard some of them praise it. For this case, I didn't consider that. I didn't think it important to consider it. I haven't considered the Lotus valve for my declaration at all.
Q. Did you attempt to determine whether Boston Scientific's Lotus product was an embodiment of Claims 1 through 4 of the '608 patent in the course of your analysis?
A. No.
Q. If it were and if it had been praised by the industry, wouldn't that have been relevant to your analysis?

MR. EGAN: Objection to form. Compound.

THE WITNESS: No, it wouldn't.

BY MR. COHN:

Q. Did you undertake any effort to determine whether Edwards' Sapien 3 product was an embodiment of Claims 1 through 4 of the '608 patent in the course of your analysis in your declaration?

A. No. I've already said -- I thought I answered very clearly -- I did not consider Sapien 3 at all for any purpose for my declaration.

Q. If the Sapien 3 product did practice Claims 1 through 4, if you came to that conclusion hypothetically, wouldn't that have been relevant to your obvious analysis?

MR. EGAN: Objection to form.

THE WITNESS: No, it wouldn't.

BY MR. COHN:

Q. Just some last questions, and then we will break. I will confer with my colleague and we may have more, we may not.

A. Okay.

Q. In your report you say that the cardiology department at Queen Elizabeth's is one of only five centers in the UK that provides the comprehensive adult cardiologic services; is that right?

A. Yes, I believe that's true.

Q. Do you know what the other four are?

A. Oh, gosh.

No. As I sit here, I need to sort of work it out again. But by saying that, I'm saying that ones that have all the services, grown up congenital heart disease, heart transplantation, the sort of range of things, and we are one of only five that has the full range.

Q. Queen Elizabeth is in Birmingham; right?

A. Correct.

Q. Are there any centers in London that have this comprehensive range of services you talked about?

MR. EGAN: Objection. Relevance.

THE WITNESS: It is very

difficult to answer because ones are being grouped together. And I worked at the Brompton Hospital. That's where I worked before I moved to Birmingham and it didn't, because it had its transplantation out at Harefield. But I think now it is combined with Harefield, and if you combine it, it is still geographically remote. But if you count them at one hospital, then I think they do. Now they are sort of a combined trust. This is what seems to have happened in the UK, along with smaller units are being grouped together, so it's difficult to answer.

But the point that I was trying to make is that Queen Elizabeth Hospital in Birmingham is a prestigious, large center offering the full range of adult cardiac services and there are few hospitals in the UK that have that.

BY MR. COHN:

Q. What about St. George's in London, do you know that hospital?

A. I do. That is where Steve Brecker is.

Q. Do they have a comprehensive center

there?

MR. EGAN: Objection. Relevance.

THE WITNESS: I don't know. I think their heart transplantation was stopped, but I may be wrong or it may have restarted. But I think for a period of time at least their heart transplantation was stopped. At least that's my memory. I may be wrong on that, but that's what I think.

But if you are asking me are they a good hospital, yes, they are a very good hospital. It is a very good cardiology department.

MR. COHN: Why don't we take our last break and see if we need to come back.

(Recess.)

BY MR. COHN:

Q. Welcome back.

A. Thank you.

Q. The team implanting TAVR valves often includes a cardiac or vascular surgeon, is that fair?

A. Some of the time. I mean the team

deciding whether a patient should be treated by TAVR always includes a surgeon. But the main role, as I understand it, of most of the surgeons is part of what's called the multi-disciplinary team. Actually sort of deciding is it sensible to do, should the patient actually have a surgical procedure. And so that's their main involvement.

Some of them, quite clearly, for instance, Professor Lutter who we spoke about earlier, actually does procedures. But the majority of the procedures I think are done by interventional cardiologists, the actual procedures, doing them. But the surgeons take part in the decision-making to make sure it is a sensible strategy.

Q. Now, you are aware that there is a District Court litigation between the same two parties that are involved in this inter partes review proceeding?

A. I am.

Q. And it is around the same '608 patent?

A. Yes.

Q. And you are aware that the District

Court in that litigation recently issued an order interpreting some of the claim terms in the '608 patent; is that right?

A. Yes, I've seen that.

Q. You have seen the order?

A. I've seen the order.

Q. Does the order change any of the opinions that you rendered in your declaration in this inter partes review proceeding?

A. No.

Q. In the course of the District Court proceeding, you submitted a declaration regarding the meaning of some of the claim terms of the '608 patent. Do you remember that?

A. I do.

Q. Is it fair to say the Court accepted some of your opinions and did not accept others?

A. That is true.

Q. I want to show you a patent. Let me mark it.

(Buller Deposition Exhibit No. 8 was marked for identification.)

BY MR. COHN:

Q. I am going to mark as Buller-8 US Patent Publication No. 2003/0153974 A1, published on August 14, 2003.

Do you see that?

A. I do.

Q. You see that this Spenser publication, Buller-8, has the same four inventors as the Spenser patent that was the subject of your declaration in this proceeding; correct?

A. I think from memory, yes. I was going to look as you were asking me questions comparing them.

Yes, it is.

Q. The second yes is based on your review of both patents; correct?

A. Yes. I have them both in front of me, so I was just checking if the names are the same, and they are.

Q. If you look at Buller-8, the one that I just gave you.

A. Yes.

Q. And you turn in it to Paragraph 104.

Do you see Paragraph 104?

A. Yes. A short paragraph, "to prevent leakage."

Q. That is the same paragraph from the Spenser patent that you reviewed in the course of this inter partes review proceeding regarding the rolled-up sleeve-like portion preventing leakage; right?

A. It looks to be, it looks to be very similar, if not the same. I can compare it if you want. If you say it is the same, I will accept it.

Q. Let's do it for good measure. Let's turn in the Spenser patent, Exhibit 1004, to Page 21 of the patent itself.

A. Yes.

Q. At the bottom do you see the paragraph that begins "to prevent leakage"?

A. Yes.

Q. And that is the same as Paragraph 104 in the Spenser patent that is Buller Exhibit 8; correct?

A. Yes, it is.

Q. And then if you turn to Page 22 of the Spenser patent, Exhibit 1004.

A. Yes.
Q. You see the paragraph at the bottom that talks about "cuff portion 21"?
A. Yes.
Q. That is the same as Paragraph 109 in Buller Exhibit 8, the US Spenser publication; correct?
A. More or less. It seems to have different numerals in it, but the words are. Why are some of the numbers different?
Q. The numerals look the same to me.
A. It is different pagination. Yes, it is the same.
Q. The paragraph at the bottom of Page 22 of Spenser Exhibit 1004 that starts, "In the embodiment shown in Figure 1," and talks about a cuff portion 21, that is the same as Paragraph 109 in the US Spenser that is Buller Exhibit 8; correct?
A. Correct.
Q. And then one more.
A. Yes.
Q. If we turn to Page 24 of Spenser Exhibit 1004.

A. Yes.
Q. The last sentence of the top paragraph that begins "a portion of the valve assembly."
Do you see that?
A. Yes.
Q. It talks about the rolled sleeve. Do you see that sentence?
A. Rolled over the stent of the inlet, yes.
Q. That is the same as the last sentence of Paragraph 112 in the US Spenser publication that is Buller Exhibit 8; correct?
A. Hang on.
Yes.
Q. And Figures 1 and 2 of both of these Spenser publications are the same; is that right?
A. I need to have a look at them.
Q. Go ahead.
A. Yes, they look to be the same.
Q. You can put the PCT aside.
A. Yes.
Q. But hang onto the US Spenser.
A. Okay.

Q. True or false: The US Spenser publication that is Buller-8 does not address leaks that can occur around the implanted valve?

MR. EGAN: Objection to form.

THE WITNESS: I'd need to read the -- I haven't in any sense prepared or read this before. I'd need to read the whole thing. You are asking me about a document that isn't in my declaration and I haven't considered for my declaration and I'd need to study it.

BY MR. COHN:

Q. Did the three passages that we just looked at address leaks that can occur around the implanted valve?

A. As you made me look at them, I didn't even consider that question as you are asking it now.

But the answers would be the answers I gave earlier.

Q. Let me ask it this way: Let's turn to Paragraph 104 of the US Spenser publication.

A. 104.

Q. Can I call Buller-8 the US Spenser publication?
A. Yes.
Q. Paragraph 104 of the US Spenser publication.
A. Yes.
Q. -- does not address leaks that can occur around the implanted valve; correct?
A. Yes, it does.
Q. What about Paragraph 109, does that address leaks that can occur around the implanted valve?
A. Well, it doesn't directly. It doesn't say anything about leaks.
Q. Okay. What about Paragraph 112, does that address leaks that can occur around the implanted valve?
A. Yes, because it teaches that it enhances the sealing of the device of the valve inlet.
Q. I am going to hand you Buller-9.
(Buller Deposition Exhibit No. 9 was marked for identification.)
BY MR. COHN:

Q. Buller-9 is a copy of US Patent No. 7,276,078.

Do you see that Mr. Spenser, Benichou, and Bash are inventors on Buller-9?

A. I do.

Q. And for shorthand today, can I call Buller-9 the "'078 Spenser"?

A. Yes.

Q. Mr. Spenser, Benichou and Bash are also inventors on the US Spenser publication we just looked at, Buller Exhibit 8; correct?

A. Yes.

Q. And if you look in the '078 Spenser patent, Column 2.

First of all, have you ever seen this document before?

A. I don't believe so. I mean I may have, but as I sit here now, I don't recollect it. I don't recollect the cover.

Q. Do any of the figures look familiar as you flip through them?

A. Some of them look very familiar. But no, I don't think I have studied this patent. No, it doesn't ring a bell.

Q. Now, if you look at Column 2.
A. Yes.
Q. Around Line 7 at the top.
A. Yes.
Q. Do you see it says, "Spenser, et al., in US Patent Application No. " And then it lists a number?
A. Yes.
Q. "20030153974"?
A. Yes.
Q. That is the US Spenser publication Buller Exhibit 8; right?
A. Yes, that's correct.
Q. And if you scroll down in the '078 Spenser Column 2, to Line 27, do you see it says, "Spenser, et al., also do not address leaks that can occur around the implanted valve"? Do you see that?
A. I do.
Q. Do you disagree with that description --
A. Yes.
Q. -- of the US Spenser publication?
A. Yes. I said I do. But I mean I

hadn't seen this, and I see no reason why I would have seen this for my analysis through the eyes of 2004.

Q. Do you believe that Mr. Spenser, Benichou and Bash are mischaracterizing the description of their own US publication?

A. I have no idea, because I never have spoken to them, or to the best of my knowledge met them. I would need to study the whole thing. As I said, I don't think I've seen this patent before. I haven't studied to see if I can work out what they are saying and what is different. I haven't considered it.

MR. COHN: I pass the witness.

MR. EGAN: I only have a few questions, Dr. Buller.

Counsel, on the PCT Spenser, we didn't mark that with a different exhibit number, did we? We just used Exhibit 1004?

MR. COHN: We did not remark it because it was not drawn upon.

BY MR. EGAN:

Q. Dr. Buller, if you could pull out Exhibit 1004, which is the Spenser PCT

publication?
A. Yes.
Q. Could you please turn to Page 23 of that publication.
A. Yes.
Q. If you could go about seven lines down in the first paragraph at the top of that page that starts with, "the valve assembly is."
A. Yes.
Q. Do you recall earlier today counsel asked you questions about portions of that sentence?
A. Yes.
Q. I just want to ask you questions about the entirety of the sentence. The sentence reads, "The valve assembly is attached to the support stent at the support beams, and due to their constant length, there is no need for slack material as the attachment points (25) remain at constant distances regardless of the position of the valve device (crimped or deployed)."
Do you see that?
A. Yes.

Q. What is your understanding of what the Spenser PCT publication is describing here?

A. Well, the consequence that because the support beams, support structures remain constant in length, then what is attached to it will not be required to change in length during crimping or deployment. And therefore there is no need for you to allow slack for that change in length to occur because it's not going to occur at the attachment site of the valve to the structures.

Q. What happens to the portions of the valve assembly that are not attached to the support beams?

MR. COHN: Objection. Form.

THE WITNESS: They are still free, as I think I talked about earlier today, they are still free and slack. So the valve can function to open and close. The bits that aren't detached are slack to allow the functions of a healthy opening and closing during the cardiac cycle.

BY MR. EGAN:

Q. And if you could go two sentences

following the sentence we were just looking at that starts with "in prior art."

A. Yes.

Q. It says, "In prior art, implantable valve devices, the entire support structure changes its dimensions from its initial first crimped position and final deployed position, and this means that in the attachment of the valve assembly to the support structure, one must take into consideration these dimension changes and leave slack material so that upon deployment of the device the valve assembly does tear or deform."

Do you see that?

A. Yes.

Q. What is your understanding of what is being described in that sentence in the Spenser PCT publication?

A. Well, they are pointing out several things. They are saying in prior art implantable valve devices, the entire support structure changes, and what they are describing is the change in length, the crimping and expanding. Therefore they are

saying slack would need to be left to allow for this in one of these prior art devices.

Also, they are saying where they are pointing out the entire -- I think they are contrasting it with their device, their inventive device, where parts of it remain constant, but my reading of it is the parts in between change in length.

So the parts in between the support structures change in length and they are pointing that out. The prior art ones had all changed length, whereas in their parts of it doesn't. But the parts in between do change in length.

MR. COHN: I am going to object to the form of the question.

BY MR. EGAN:

Q. You said that parts in between the support beams described in the Spenser PCT publication do change in length.

A. Yes.

Q. How do they change in length?

MR. COHN: Objection. Go ahead.

THE WITNESS: When it is

crimped, it is collapsed to a smaller size, the sections get longer. And when it's expanded, they get shorter. So I thought this was clearly apparent. If you look at other stent devices, you will see one where it isn't covered up. If you look at, for instance, Figure 40A -- the only reason I am picking this one is because there is no outside cuff or sleeve, so you can see the stent device. You will see that the bars will remain constant in length because they are solid bars. But the zigzag structure in between is clearly going to get much longer when it is collapsed. It is going to get longer top and bottom, and so the device as a whole is going to get longer from top to bottom, because as it they collapse, the peaks of the top and bottom will protrude beyond the fixed length bars.

And this process that we often refer to as shortening on expansion, the device gets shorter, often known as foreshortening, was very, very well known in stent art, and the invention here seems to be

putting in pieces that don't change in length into a device that otherwise does change in length.

MR. EGAN: No further questions.

BY MR. COHN:

Q. Looking at Figure 40A that you just pointed to.

A. Yes.

Q. You can see the support beams there with the holes through them where the commissures connect?

A. Yes.

Q. And then in between those there is a series of vertical longitudinal bars at the edge of each kind of zigzag pattern.

Do you see that?

A. I'm not sure exactly what you are describing. The straight bars that connect zigzagged pattern?

Q. Yes. The straight longitudinal bars that connect the zigzagged pattern. Do you see those?

A. I do.

Q. Do you see at the bottom of those

straight bars there is a dotted circumferential line?

A. I do.

Q. And that is the suture line at the bottom of the valve leaflets; right?

MR. EGAN: Objection. Form. Lack of foundation.

THE WITNESS: No.

BY MR. COHN:

Q. What is that suture?

A. I am looking at the wrong line. The dotted line which is going scallop line coming around appears to be the valve leaflet line, which is above that line. I may be looking at the wrong line.

There's a dotted line with sort of bigger dashes on it, and that to me is the suture line of the leaflets, which is above that dotted line closer to the bottom.

Q. So do you see the No. 549?

A. I do.

Q. If you could kind of keep your hand on that figure and turn also to Page 42 of the text.

A. Yes. I am there.
Q. At the bottom, the last sentence on that page actually begins, "PET skirt 543" --
A. Yes.
Q. -- "is sutured to the circumference of crimpable frame 540, at the bottom side 549."
A. Yes.
Q. "And at the top 542, using one of the commissural attachments that are described herein."
A. Yes.
Q. "Before describing other embodiments."
Do you see that sentence?
A. I do. I think that agrees with what I was saying. It is not the leaflets. It is the PET, that's polyethylene terephthalate, inner skirt. It is not the attachment of the leaflets, which is a higher level than that Line 549.
Q. Where do the leaflets attach?
A. Above that, the next line up, which isn't a straight line around the circumference. Do you see the dashed line, which is following the contour of the

scalloped inner skirt? That's what I think is the attachment of the leaflets.

Q. Why don't you take the red pen and we will mark this one.

A. Okay.

Q. And show me where the bottom of the leaflet in figure --

A. Hang on. But this is not an exhibit. I can mark this one?

Q. You can mark it and then we will put a sticker on it.

So let me make the question clear before you mark it.

A. Okay.

Q. To make sure we know what we are marking. I want you to mark on Figure 40A of the Spenser PCT where the bottom of the leaflet is sutured.

A. (Indicating.)

There.

Q. Now along that line is the bottom of the leaflet sutured to the frame or to something else?

A. Well, it's certainly, I can see

sutures where there are no frame bars. So it is sutured to the PET inner skirt there. It may also be sutured in places to the stent bars. Obviously there isn't a stent bar that's following this scalloped outline.

Q. Now, the longitudinal bars positioned between the support beams that we talked about earlier --

A. Yes.

Q. -- those do not foreshorten; right?

A. Those bars won't, no. No bars will actually foreshorten. It's the structure of the stent that will change in geometry.

Q. Only the zigzag portions will foreshorten; right?

A. Yes. But the whole, if you'd like, the whole section between the large bars with the holes in will foreshorten individual bits of it, like the straight longitudinal bars that you are pointing out, will not themselves. But then none of the bars will actually foreshorten. All the bars will remain the same length. But they just reorientate. The structure as a whole

foreshortens.

Q. Does Spenser indicate whether the bottom of the leaflets is sutured to any of the zigzag portions of the stent?

A. I can't remember. I need to read it all.

Shall I label this line?

Q. Why don't you do that, label the line -- what do you think would be appropriate?

A. "Leaflet attachment"?

Q. Yes.

A. (Indicating.)

And initial it like I have done before?

Q. Please.

A. (Indicating.)

Q. Then hand it to me.

MR. COHN: For the record, I am going to mark this copy of the Spenser PCT with Buller-10.

(Buller Deposition Exhibit No. 10 was marked for identification.)

MR. COHN: This is the one in

which the witness wrote with the red pen.

With that, I pass the witness.

Actually, I think I have nothing further.

MR. EGAN: Yes.

THE WITNESS: Thank you very much.

COURT REPORTER: Counsel, can I clarify orders on the record?

MR. EGAN: Rough tonight.

MR. COHN: We will take a rough tonight and we will take a final, did you say tomorrow?

COURT REPORTER: Yes.

Mr. Egan, the same?

MR. EGAN: We will ride their coattails.

(Witness excused.)

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(The deposition concluded at 1:24 p.m.)

I N D E X

E X H I B I T S

I N D E X (cont'd)

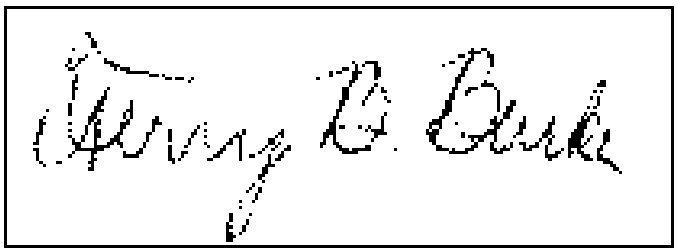
State of Delaware)
)
New Castle County)

CERTIFICATE OF REPORTER

I, Terry Barbano Burke, RMR-CRR and Notary Public, do hereby certify that there came before me on Thursday, June 15, 2017, 2013, the deponent herein, NIGEL P. BULLER, M.D., who was duly sworn by me and thereafter examined by counsel for the respective parties; that the questions asked of said deponent and the answers given were taken down by me in Stenotype notes and thereafter transcribed by use of computer-aided transcription and computer printer under my direction.

I further certify that the foregoing is a true and correct transcript of the testimony given at said examination of said witness.

I further certify that I am not counsel, attorney, or relative of either party, or otherwise interested in the event of this suit.



Terry Barbano Burke, RMR-CRR