

1 UNITED STATES PATENT AND TRADEMARK OFFICE

2 BEFORE THE PATENT TRIAL AND APPEAL BOARD

3 EDWARDS LIFESCIENCES)
4 CORP., EDWARDS)
5 LIFESCIENCES LLC, AND)
6 EDWARDS LIFESCIENCES AG)
7)
8 Petitioners,)
9) CASE IPR
10 v.) 2017-00060
11)
12 BOSTON SCIENTIFIC)
13 SCIMED, INC.,)
14)
15 Patent Owner)

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

21 *Edwards v. Aortic Innovations*
22 U.S. Patent 11,337,834
23 **Edwards Ex. 1133**

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

1 APPEARANCES:

2 BRIAN P. EGAN, ESQUIRE
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6 -and-

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11 For the Petitioner

12 MARC A. COHN, ESQUIRE
13 EDWARD HAN, ESQUIRE
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17 For the Patent Owner

18 ALSO PRESENT:

19 VICTORIA BROWN, Legal Intern

20 - - -

21 NIGEL P. BULLER, M.D.,

22 the deponent herein, having first been
23 duly sworn on oath, was examined and
24 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?

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

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

7 A. Yes, correct.

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

13 MR. EGAN: Objection.
14 Relevance.

15 THE WITNESS: Earlier this year.
16 BY MR. COHN:

17 Q. That was January this year; correct?

18 A. Correct.

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

22 A. Yes.

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

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

3 A. Of course, yes.

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

6 A. I do.

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

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

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

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

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

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

1 proceedings in the United States?

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

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

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

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

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

1 you gave in the Bard case?

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

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

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

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

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

17 Q. I misspoke.

18 A. The AAA device.

19 Q. Let me ask a clean question.

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

23 A. No.

24 Q. Did you discuss in that testimony any

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

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

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

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

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

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

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

24 A. Yes.

1 Q. Are you being compensated on an hourly
2 basis?

3 A. Yes.

4 Q. What is your hourly rate?

5 A. Pound sterling, 480 pounds. I charge
6 and am paid in sterling.

7 Q. Are you being paid by the hour for
8 today's testimony?

9 A. Yes.

10 Q. Same rate?

11 A. Yes, exactly the same.

12 Q. Over the past five years,
13 approximately how much compensation have you
14 received from Edwards Lifesciences for all of
15 your expert work for them?

16 A. I honestly don't know.

17 Q. Within 500,000 pounds?

18 A. Yes, I think probably more than
19 500,000 pounds, but I haven't added it up.

20 Q. Let's just establish some quick
21 shorthands, mostly for the court reporters.

22 The patent at issue in this
23 inter partes review proceeding, can we call it
24 the '608 patent?

1 A. Yes.

2 Q. And you understand what patent I am
3 talking about?

4 A. I do. I mean it is obviously the one,
5 if you give me a copy, there will be no -- but
6 yes, it is the '608. I have been in a case
7 where there was another patent with the same
8 numbers, but I know exactly what you are
9 talking about, and I am talking about the '608
10 patent.

11 Q. The acronym T-A-V-R, TAVR, just for
12 the record, what does that stand for?

13 A. Transluminal aortic valve replacement.

14 Q. Can we also call it transcatheter
15 aortic valve replacement?

16 A. Yes, you can.

17 Q. That is an equally valid
18 interpretation of that acronym, transluminal
19 versus transcatheter?

20 A. Yes, yes. But the A, you gave the
21 acronym, I thought you said "A", T-A-V-R.

22 Q. T-A-V-R?

23 A. Yes.

24 Q. So the "T" can be either transluminal

1 or transcatheter, it doesn't matter?

2 A. Yes.

3 Q. And TAVI, what does that mean?

4 A. Just change the replacement for
5 implantation. Again, it's essentially the
6 same. It's a slightly different acronym.
7 There are a whole range of these acronyms
8 which are used interchangeably for the same
9 sort of procedure. Transcatheter aortic valve
10 replacement is probably one of the more common
11 ones.

12 Q. TAVR and TAVI are used interchangeably
13 for essentially the same procedure?

14 A. I think they are, yes.

15 Q. Today can we just use TAVI?

16 A. I'm happy.

17 Q. Generally speaking, what is a TAVR
18 procedure?

19 A. Today, or meaning as of today?

20 Q. Yes.

21 A. It's a procedure in which a
22 replacement valve is put inside the body,
23 typically into the heart, using a catheter and
24 is most often used to treat aortic stenosis.

1 So that's the most common TAVR procedure.

2 There are other ones used in other locations.

3 Q. Like in the pulmonic valve, for
4 example?

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

14 Q. Now, when I asked you what is a TAVR
15 procedure and you said, you asked me when I
16 was referring to, would your definition change
17 if I had said what is a TAVR procedure in
18 2004?

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

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

1 A. Correct.

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

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

12 MR. EGAN: Objection to form.

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

23 BY MR. COHN:

24 Q. So just make sure I understand what

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

3 A. Yes.

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

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

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

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

1 about the procedure, the devices has changed.

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

5 A. Yes.

6 Q. Who was that other person?

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

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

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

24 Q. Now, if we expand our discussion

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

3 A. Yes.

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

7 MR. EGAN: Objection to form.

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

16 BY MR. COHN:

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

21 A. I don't believe so.

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

1 MR. EGAN: Objection to the
2 form.

3 THE WITNESS: Today?

4 BY MR. COHN:

5 Q. Today?

6 A. Yes.

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

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

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

17 MR. EGAN: Objection to form and
18 relevance.

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

23 BY MR. COHN:

24 Q. Are you aware of any that have

1 approved any Edwards' valve for the pulmonic
2 valve?

3 MR. EGAN: Objection.
4 Relevance, form.

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

8 BY MR. COHN:

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

13 A. Correct.

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

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

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

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

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

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

17 MR. EGAN: Objection to form.

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

22 BY MR. COHN:

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

1 a transcatheter aortic valve replacement
2 before June 2004?

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

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

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

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

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

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

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

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

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

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

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

24 A. Correct.

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

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

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

9 A. Correct.

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

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

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

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

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

6 MR. EGAN: Objection. Compound.

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

13 BY MR. COHN:

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

16 A. Very few. I mean a couple.

17 Q. Twice?

18 A. Two, three, four.

19 Q. Less than five?

20 A. I think that is fair.

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

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

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

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

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

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

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

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

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

1 Q. Had you deployed a TAVR device on the
2 bench prior to 2013 other than in your
3 capacity as a litigation expert?

4 A. Yes, at a medical meeting.

5 Q. When was that medical meeting?

6 A. I honestly don't remember.

7 Q. Was it after 2007?

8 A. I would guess, sitting here, it was
9 after 2010, I would guess.

10 Q. Do you agree it was certainly after
11 2007?

12 A. Well, I have agreed. I think I said
13 after 2010, so that is by definition after
14 2007.

15 Q. What was the transcatheter valve
16 device that you deployed at a medical meeting
17 some time after 2010?

18 A. CoreValve device, the Medtronic
19 CoreValve device is one I remember.

20 Q. At the time that you did that
21 deployment, you had been retained as an expert
22 in litigation for Edwards around the
23 CoreValve; right?

24 MR. EGAN: Objection.

1 Foundation.

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

5 BY MR. COHN:

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

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

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

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

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

24 A. I can't remember the year.

1 Q. Could it have been before 2007?

2 A. I can't remember the year. I can't
3 remember, so I can't give you a date.

4 Q. You have never deployed a
5 transcatheter valve device that had had a seal
6 around the outside of the device; is that
7 right?

8 MR. EGAN: Objection.
9 Foundation.

10 THE WITNESS: Depending on what
11 you mean by a seal, no. I mean, obviously,
12 the intent with the device is it didn't have
13 fabric around the outside. It was still a
14 seal. But I have not deployed one at all that
15 has a fabric around the outside.

16 I've done a few stitches
17 traveling around stents to actually secure
18 what's inside the stent.

19 BY MR. COHN:

20 Q. Now, in your report you mention a
21 hands-on training in 2013 regarding TAVR
22 devices?

23 A. Yes.

24 Q. And that 2013 training was provided by

1 Edwards; is that right?

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

11 Q. It was an Edwards training session?

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

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

21 A. Marty Leon.

22 Q. Anyone else?

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

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

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

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

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

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

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

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

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

24 Q. So it was either the XT or the

1 original Sapien?

2 A. Correct.

3 Q. And you can't remember which one?

4 A. I can't.

5 Q. And when you say "hands-on training,"
6 did you actually put your hands on the
7 product?

8 A. Yes. There were products there to
9 look at and examine and, yes, absolutely,
10 hands on, touching the product.

11 Q. You touched the valve?

12 A. Yes. I can't remember if they were
13 ones that were real valves in preservative --
14 I think some of them were -- and if there were
15 gloves. But there were other ones, main ones,
16 if you like, sort of a mock-up is the real
17 stent and the real fabric, Dacron, but the
18 valve is replaced by non-animal tissue so that
19 you can look at them, and there were ones like
20 that as well, I think.

21 Q. Just so we are clear, I used the
22 word "valve." What I meant is the whole valve
23 device. You picked up the whole Sapien or
24 Sapien XT valve device and looked at it?

1 A. Yes.

2 Q. Did you do anything with it other than
3 look at it?

4 A. Well, handle it, feel it, look at it.
5 But I was already familiar with them, so that
6 wasn't -- I mean I had already handled and
7 touched and examined many before going to that
8 meeting.

9 Q. In the course of your work as a
10 litigation expert?

11 A. Mainly in the course of litigation
12 expert acting for Edwards, but also at medical
13 meetings.

14 Q. Can you identify the medical meetings
15 where you actually put your hands on a
16 transcatheter valve product?

17 A. I can't as I sit here. I mean
18 meetings, a TCT meeting in the United States,
19 it is one of the big interventional cardiology
20 meetings.

21 Q. And those are attended by hundreds of
22 cardiologists?

23 A. Thousands. I mean it started as
24 hundreds. I went in the very early days when

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

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

9 MR. EGAN: Objection.
10 Relevance.

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

17 BY MR. COHN:

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

20 MR. EGAN: Objection to form.

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

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

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

15 BY MR. COHN:

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

19 A. Yes.

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

24 MR. EGAN: Objection.

1 Mischaracterizes testimony.

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

10 BY MR. COHN:

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

13 MR. EGAN: Objection.

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

23 BY MR. COHN:

24 Q. Prior to your training by Edwards in

1 2013, the only source of your knowledge about
2 TAVR devices was from reading about them and
3 talking to other people about them; is that
4 right?

5 MR. EGAN: Objection to form.

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

14 BY MR. COHN:

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

19 A. Yes.

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

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

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

4 MR. EGAN: Objection to form.

5 THE WITNESS: That's true.

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

17 BY MR. COHN:

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

21 MR. EGAN: Objection to form.

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

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

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

10 BY MR. COHN:

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

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

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

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

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

24 Q. When you would refer a patient for a

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

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

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

24 And then if there are further

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

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

11 A. Oh, yes, lots.

12 Q. When was the first time you did that?

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

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

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

1 yes.

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

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

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

12 Q. Were you doing that in the early
13 2000's?

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

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

21 A. Yes.

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

1 A. No. I retired from performing
2 interventional cardiology procedures. So I
3 stopped performing angioplasties, stent
4 implantations, the procedures, I stopped doing
5 any procedures that involved radiation in
6 2008. I continued working as a cardiologist.
7 I retired completely from the practice of
8 medicine last year.

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

11 A. No.

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

15 MR. EGAN: Objection to form.

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

1 aortic valve may leak.

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

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

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

17 MR. EGAN: Sure.

18 (Recess.)

19 BY MR. COHN:

20 Q. Welcome back.

21 A. Thank you.

22 Q. You had talked before the break about
23 discussions you have had with companies in the
24 90's and early 2000's about TAVR.

1 A. Yes.

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

5 Do you remember that?

6 A. Yes.

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

10 MR. EGAN: Objection to form.

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

16 BY MR. COHN:

17 Q. That is what I meant.

18 A. Yeah.

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

22 MR. EGAN: Objection.

23 Foundation.

24 THE WITNESS: Correct.

1 BY MR. COHN:

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

4 A. Oh, yes, sure.

5 Q. What were some of the other features
6 that you recall discussing about what a TAVR
7 valve would require in the, let's say, early
8 2000's?

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

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

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

23 MR. EGAN: Objection.

24 Foundation.

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

5 BY MR. COHN:

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

10 MR. EGAN: Objection to the
11 form.

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

22 BY MR. COHN:

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

1 A. Yes.

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

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

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

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

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

6 MR. EGAN: Objection to form.

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

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

24 BY MR. COHN:

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

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

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

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

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

19 MR. EGAN: Objection.
20 Foundation.

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

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

11 BY MR. COHN:

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

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

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

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

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

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

1 cardiologists.

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

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

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

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

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

8 Q. Did you ever implant a Gore excluder?

9 A. Yes.

10 Q. When was the first time you did that?

11 A. Early 2000.

12 Q. You did that to repair a dissection?

13 A. Yes.

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

16 A. I think only twice.

17 Q. In your whole career?

18 A. Whole career.

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

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

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

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

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

12 A. Less than 50.

13 Q. That is 1-5?

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

15 Q. How many had you done by the middle of
16 2004, approximately?

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

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

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

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

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

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

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

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

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

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

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

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

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

7 Q. GraftMaster?

8 A. I think so.

9 Q. Or monster?

10 A. Master. Not monster.

11 Q. Okay.

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

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

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

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

1 refer back to 20 years ago.

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

4 A. Well, I haven't done anything since
5 2008. I haven't done anything since 2008. I
6 can't remember how close it was, but the last
7 procedures I did were in 2008. So I haven't
8 put one in since then.

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

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

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

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

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

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

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

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

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

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

1 reporting on TAVR procedures in human beings?

2 A. I honestly don't know. It is a small
3 number. I mean I don't know how many
4 articles. I can think of three or four ones
5 that Alain Cribier had his name on. There are
6 abstracts as well. So if you include
7 abstracts and papers, peer review papers and
8 reviews, I mean probably less than a dozen.

9 Q. By June 2004, would you have
10 considered TAVR to have been a young field?

11 MR. EGAN: Objection to form.

12 THE WITNESS: Yes. I mean to a
13 degree, it is still a young field, yes. But
14 certainly in 2004, I think it's reasonable to
15 say it was a young field, yes.

16 BY MR. COHN:

17 Q. And same answer if I broaden that
18 question to include all transcatheter valve
19 replacements?

20 A. Same answer. Transcatheter valve
21 replacements, I think it's fair to say 2004
22 was a young field. I still consider it in
23 many ways to be a young field in 2017.

24 Q. Would you agree that in 2004 there was

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

5 MR. EGAN: Objection to form.

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

11 BY MR. COHN:

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

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

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

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

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

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

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

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

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

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

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

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

12 A. Yes.

13 Q. What causes the valve to close?

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

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

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

8 A. Yes.

9 Q. What is that?

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

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

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

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

11 MR. EGAN: Objection to form.

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

19 BY MR. COHN:

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

1 MR. EGAN: Objection to form.

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

8 BY MR. COHN:

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

13 MR. EGAN: Objection to form.

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

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

1 velocity of blood going out through the valve.

2 The valve is very loose. Wash it in the
3 direction of the aorta.

4 BY MR. COHN:

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

8 A. Yes.

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

11 A. I mean, sadly, many.

12 Q. That is a horrible thing when it
13 happens?

14 MR. EGAN: Objection to form.

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

1 point in time.

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

5 BY MR. COHN:

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

10 MR. EGAN: Objection to form.

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

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

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

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

6 BY MR. COHN:

7 Q. Is it fair to say that in June 2004
8 persons of ordinary skill in the art of the
9 '608 patent knew that it was critically
10 important that a TAVR device not migrate?

11 MR. EGAN: Objection to form.

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

1 for in the new field of TAVR.

2 BY MR. COHN:

3 Q. So the force on the leaflets from the
4 pressure and flow of the blood is significant
5 enough to dislodge even a surgically implanted
6 valve?

7 A. Yes. It has happened. I mean often
8 this occurs when the whole suture line
9 dehisces, is the word we call, dehiscence at
10 the suture line. It often is associated with
11 infection. And luckily it is a very rare
12 complication. But surgical valves have come
13 out. Perhaps even more importantly, sometimes
14 the valve, piece in the valve has come out,
15 and you are probably aware because your
16 profession was very involved in litigation.
17 There was some disastrous surgical valves, the
18 Shiley valve, where pieces of the valve fell
19 apart and tears occurred in valves. And there
20 are well reported problems with surgical
21 valves, migration, if not of the entire
22 device, of parts of the device.

23 Q. Were there concerns among persons of
24 ordinary skill in June 2004 that a TAVR valve,

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

3 A. Yes, of course. Of course.

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

6 BY MR. COHN:

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

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

15 BY MR. COHN:

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

18 A. Yes.

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

21 A. I do.

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

1 leaflets inside of an aortic annulus.

2 Do you understand that from this
3 drawing?

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

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

12 A. Got it. Okay.

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

16 MR. EGAN: Objection to form.

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

1 BY MR. COHN:

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

4 A. Yeah.

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

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

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

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

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

21 MR. EGAN: Objection to form.

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

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

7 BY MR. COHN:

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

10 A. Correct.

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

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

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

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

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

4 A. Yes.

5 Q. Can you identify any of those?

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

9 COURT REPORTER: Can you repeat
10 that, please.

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

16 BY MR. COHN:

17 Q. Dr. Cribier's TAVR device in the early
18 2000's was held in place due to its interface
19 with the aortic annulus; is that right?

20 MR. EGAN: Objection to form.

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

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

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

13 BY MR. COHN:

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

17 A. Yes. Do you have a red pen?

18 Q. My colleague seems to.

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

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

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

21 A. Can I?

22 Q. Yes.

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

1 And then initial it?

2 Q. Thank you.

3 A. (Indicating.)

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

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

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

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

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

24 Q. Can you indicate with your finger the

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

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

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

12 BY MR. COHN:

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

15 A. Yes.

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

19 A. Yes.

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

22 Do you see that?

23 A. I do.

24 Q. One way that a TAVR valve as shown in

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

3 MR. EGAN: Objection to form.

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

8 BY MR. COHN:

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

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

16 Q. I asked a different question.

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

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

1 of the anchor.

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

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

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

24 It can flow wherever blood can

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

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

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

11 A. Leakage?

12 (Indicating.)

13 Q. That is an appropriate label?

14 A. Yes, if you like it, yes.

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

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

24 Q. So the red arrows on Buller Exhibit 2

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

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

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

11 A. Fine.

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

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

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

22 A. I understand that.

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

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

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

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

8 A. (Indicating.)

9 MR. COHN: Can we mark this,
10 please.

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

13 BY MR. COHN:

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

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

1 Do you understand that?

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

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

6 BY MR. COHN:

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

12 Do you see that in the figure?

13 MR. EGAN: Objection to form.

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

16 BY MR. COHN:

17 Q. And does that make sense?

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

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

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

10 A. Fine.

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

13 A. Yes.

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

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

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

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

5 Does that make sense?

6 A. Yes.

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

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

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

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

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

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

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

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

16 A. Correct.

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

19 A. Yes (indicating).
20 Initial it?

21 Q. Yes, please.

22 A. (Indicating.)

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

1 without disturbing the schematic?

2 A. Should I just label one on this side?

3 There is leaflets on both sides as the record
4 will show. This is a leaflet where I can,
5 (indicating), that's a leaflet. Or I can put
6 an arrow across to there. The trouble with
7 arrows, they start looking -- the record will
8 get confused.

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

12 A. Here?

13 Q. Yes.

14 A. (Indicating.)

15 Q. Thank you.

16 Why don't we take a break right
17 now.

18 MR. EGAN: Sure.

19 (Recess.)

20 BY MR. COHN:

21 Q. Welcome back, Dr. Buller.

22 A. Thank you.

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

24 A. Yes.

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

7 MR. EGAN: Objection to form.

8 BY MR. COHN:

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

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

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

15 A. Yes.

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

19 A. Yes.

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

1 Do you understand me?

2 A. So there is no valve inside it?

3 Q. No valve.

4 A. Okay.

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

10 MR. EGAN: Objection to form.

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

14 BY MR. COHN:

15 Q. Thank you.

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

22 A. That's my understanding, yes.

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

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

3 MR. EGAN: Objection to form.

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

8 BY MR. COHN:

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

12 MR. EGAN: Objection to form.

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

17 BY MR. COHN:

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

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

3 THE WITNESS: It sounds proper
4 and true, yeah.

5 BY MR. COHN:

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

9 MR. EGAN: Objection to form.
10 Relevance.

11 THE WITNESS: Which one?

12 BY MR. COHN:

13 Q. The Sapien?

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

20 Q. Same question for the Sapien XT?

21 MR. EGAN: Objection to form and
22 relevance.

23 THE WITNESS: Same answer.

24 MR. COHN: Counsel, do you want

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

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

5 MR. COHN: I think so too.

6 BY MR. COHN:

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

9 Have you seen this before?

10 A. I have.

11 Q. What is it?

12 A. It's a PCT.

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

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

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

20 A. Fine.

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

23 A. On the cover.

24 Q. -- on the cover?

1 A. Yes.

2 Q. And that is a transcatheter valve
3 replacement device; is that right?

4 A. Yes.

5 Q. And that is meant to be implanted in a
6 diseased heart valve; is that right?

7 A. Yes, potentially it would be.

8 Q. Now, if we could turn to Figure 1 of
9 Spenser.

10 A. Can I say, this is a patent drawing.
11 It represents, it is a diagram. It is a
12 patent drawing. It relates clearly to a
13 design which you could build as a device that
14 you could put in. But it is a diagram.

15 Q. The Spenser patent is directed to a
16 TAVR device that is meant to be implanted in a
17 diseased heart valve; right?

18 MR. EGAN: Objection to form.

19 THE WITNESS: Yes. It is
20 broader because the TAVR is specifically
21 aortic, and I think Spenser is slightly
22 broader than that. But, yes, it can be
23 implanted in a diseased aortic heart valve.

24 BY MR. COHN:

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

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

9 A. Yes.

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

12 A. Yes.

13 Q. Figure 1 shows a transcatheter
14 replacement heart valve with a cuff labeled
15 21.

16 Do you see that?

17 A. I do.

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

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

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

24 MR. EGAN: Objection to form.

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

3 BY MR. COHN:

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

7 MR. EGAN: Objection to form.

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

11 BY MR. COHN:

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

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

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

23 BY MR. COHN:

24 Q. And the Spenser patent says that the

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

3 MR. EGAN: Objection to form.

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

8 BY MR. COHN:

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

12 MR. EGAN: Objection to form.

13 BY MR. COHN:

14 Q. Spenser says that specifically, right?

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

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

19 A. Yes.

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

23 A. Yes.

24 MR. EGAN: Just so the record is

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

3 MR. COHN: Thank you, counsel.

4 BY MR. COHN:

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

7 A. Yes.

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

10 A. Yes.

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

16 Do you see that?

17 A. I do.

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

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

24 Q. Now, between the fourth paragraph on

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

3 A. Yes.

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

6 A. Yes.

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

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

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

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

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

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

23 A. Yes.

24 Q. It says: "To prevent leakage from the

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

5 Do you see that?

6 A. Yes.

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

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

11 Q. Now, if we continue to Page 24.

12 A. Yes.

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

16 Do you see that?

17 A. Yes.

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

24 Do you see that?

1 A. I do.

2 Q. Is it true that when Spenser discusses
3 sealing the device at the valve inlet, it uses
4 the word "sleeve," and when it talks about
5 stability, it uses the word "cuff"? That's
6 true, right?

7 A. That's true, that's what you read out.
8 I don't read anything into that.

9 Q. The sleeve that is discussed with
10 respect to Figure 2 --

11 A. Yes.

12 Q. -- that prevents leaks of blood from
13 inside the anchor through the wall of the
14 anchor and back into the heart; correct?

15 A. Does it say that?

16 Q. I am asking you.

17 A. Oh, one sort of movement of blood
18 could be through and it could prevent that at
19 least over the position that it occupies. But
20 that's just one.

21 Q. But Spenser doesn't say that
22 specifically, does it?

23 A. No. That's what I was saying. He
24 doesn't say that specifically. He talks more

1 generally about it preventing leaks.

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

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

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

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

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

1 MR. EGAN: Objection. Asked and
2 answered.

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

5 BY MR. COHN:

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

7 A. The front cover again?

8 Q. Yes.

9 A. Yep.

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

13 A. Yes.

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

17 A. Yes.

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

23 MR. EGAN: Objection to form.
24 Relevance.

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

3 BY MR. COHN:

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

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

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

1 BY MR. COHN:

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

8 MR. EGAN: Objection to form and
9 relevance.

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

13 BY MR. COHN:

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

17 Have you read any patents that
18 talk about Exhibit 1004?

19 MR. EGAN: Objection.
20 Relevance.

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

23 BY MR. COHN:

24 Q. Either before or after exhibit --

1 well, it couldn't have been before it.

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

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

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

9 A. Yes. Yes.

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

13 Do you see that?

14 A. I do.

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

17 MR. EGAN: Objection to form.

18 THE WITNESS: Yes, they are.

19 BY MR. COHN:

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

24 A. Not necessarily, no. But I mean the

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

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

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

1 and closes and it moves with every heartbeat.

2 Q. If you look at Page 23 of Spenser.

3 A. Yes.

4 Q. The first paragraph, six lines down,
5 do you see the sentence that begins "The valve
6 assembly"?

7 A. Yes.

8 Q. And it says: "The valve assembly is
9 attached to the support stent at the support
10 beam." Do you see that clause?

11 A. I do.

12 Q. The phrase "valve assembly," what does
13 that refer to in Spenser?

14 A. The opening and closing bit of the
15 valve, the valve. For instance, the tissue
16 valve part of the device.

17 Q. The valve assembly refers to the
18 leaflets?

19 A. Yes. I mean the -- yes. And if they
20 are made from tissue, tissue, if that's what
21 they are made from.

22 Q. And that sentence continues with, "And
23 due to their constant length, there is no need
24 for slack material." Do you see that?

1 A. I do.

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

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

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

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

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

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

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

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

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

16 A. It does, correct.

17 Q. And the same for the cuff?

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

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

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

1 A. Yes, I do.

2 Q. We can call this "Elliot" for purposes
3 of our discussion?

4 A. Of course.

5 Q. Elliot describes a stent graft for use
6 in treating abdominal aortic aneurysm;
7 correct?

8 MR. EGAN: Objection to form.

9 THE WITNESS: One of the
10 teachings, yes.

11 BY MR. COHN:

12 Q. And it doesn't mention heart valves at
13 all, does it?

14 A. It mentions generally using it in
15 medical devices, general teaching. But the
16 example it gives is for treatment of an
17 aneurysm.

18 Q. Elliot doesn't mention heart valves,
19 does it?

20 A. Not specifically, no.

21 Q. There is no valve shown in any of the
22 embodiments depicted in Elliot; correct?

23 A. That is true, he doesn't specifically
24 example using it for a heart valve. He

1 teaches generally that it can be used for
2 medical devices.

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

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

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

11 MR. EGAN: Objection to form.

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

15 BY MR. COHN:

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

18 A. Yes.

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

20 A. Yes.

21 Q. -- and particularly Figure 3B.

22 A. Yes.

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

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

3 MR. EGAN: Objection to form.

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

9 BY MR. COHN:

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

12 A. Okay.

13 Q. Let's look at Figure 3C.

14 A. Yes.

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

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

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

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

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

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

14 MR. EGAN: Objection to the
15 form.

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

24 BY MR. COHN:

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

3 A. Sure.

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

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

12 A. Yeah.

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

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

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

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

4 I mean, it's attached --

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

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

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

12 A. Look, you can see it.

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

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

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

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

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

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

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

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

7 BY MR. COHN:

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

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

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

15 BY MR. COHN:

16 Q. If you can go to Figure 3B and use the
17 red pen on Exhibit 5 and mark where in Figure
18 3B the skirt is attached to the tube in
19 Elliot.

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

23 Do you want me to label it?

24 Q. If you could, please.

1 A. What should I label it?

2 Q. Is "attached" appropriate?

3 A. "Attached," yes.

4 And initial?

5 Q. Yes, initial, please.

6 A. (Indicating.)

7 Q. Now, does Elliot say anything in the
8 text about how the skirt is attached? Strike
9 that.

10 Does Elliot say in the text
11 where the skirt is attached to the tube in
12 Figure 3B?

13 A. I can't remember.

14 I can look at 3B.

15 Q. Why don't you take a look and see if
16 you can find any discussion in Elliot
17 describing how the skirt in Figure 3B is
18 attached to the tube?

19 A. I don't see anything saying how it is
20 attached. It is just describing that it is
21 attached. It is collapsed in 3A, and then it
22 expands out in the subsequent drawings.

23 Q. In Figure 4 of Elliot.

24 A. Yes.

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

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

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

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

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

18 A. Yes.

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

20 A. Yes.

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

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

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

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

15 Q. In the thoracic or the abdominal
16 aorta --

17 A. Yes.

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

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

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

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

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

24 Q. If you had a patient and you were

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

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

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

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

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

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

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

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

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

23 A. I see.

24 Q. And I guess my question is: Does

1 healthy aortic tissue generally have calcium,
2 have calcifications?

3 MR. EGAN: Objection to the
4 form.

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

11 BY MR. COHN:

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

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

1 example, and you would regard them as healthy.

2 But in old age, which we are
3 dealing with increasingly in medicine, we have
4 to recalibrate. I mean, it wouldn't be an
5 expected finding in a ten-year-old but it
6 would be almost a universal finding in an
7 80-year-old.

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

10 I think that is enough of that
11 question for now.

12 A. Okay.

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

15 A. Yes.

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

18 A. Yes, it is.

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

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

24 Q. There is no valve depicted in any of

1 the embodiments shown in Thornton; is that
2 right?

3 A. Correct.

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

6 A. In Figure 1?

7 Q. Yes.

8 A. Yes.

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

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

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

16 A. Yes. I will take that.

17 Q. If you look at Column 7.

18 A. Column 7?

19 Q. About Line 24, 25.

20 A. I see cuff.

21 Q. Keep going. 26, element 26?

22 A. Element 26, flange 26, yes.

23 Q. Back to Figure 1, do you see flange
24 26?

1 A. I do.

2 Q. Thornton does not provide that flange
3 26 performs a stabilizing function; correct?

4 MR. EGAN: Objection to form.

5 THE WITNESS: No. It's a
6 sealing function.

7 BY MR. COHN:

8 Q. So I am correct, right?

9 A. Yes. I believe so.

10 Q. Now, if you look at Figure 3 of
11 Thornton.

12 A. Yes.

13 Q. There is no calcification depicted on
14 the inside of that vessel; is that correct?

15 A. I don't know. I am not sure what the
16 lines are supposed to represent. I mean, they
17 are squiggles inside the wall. But it is a
18 diagram, it's a patent diagram, and I don't
19 think anything is labeled as calcification.
20 They are squiggles shown in the wall, a
21 cross-hatched wall of the blood vessel that
22 has an aneurysm.

23 Q. Now, I believe you say in your
24 declaration that flange of Thornton was

1 commercialized in a product, in the Gore
2 excluder product?

3 A. Yes.

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

6 A. Yes.

7 MR. EGAN: Objection. Asked and
8 answered.

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

13 BY MR. COHN:

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

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

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

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

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

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

15 (Recess.)

16 BY MR. COHN:

17 Q. Let's go back to Thornton.

18 A. Yes.

19 Q. If we look at Figure 1.

20 A. Yes.

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

24 A. Where the flange is attached? It is

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

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

5 A. Yes.

6 Q. Can you indicate that as well?

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

10 Do you want me to be label them
11 attachment?

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

14 A. And it would be all the way around.

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

17 A. (Indicating.)

18 Done.

19 Q. And then on Figure 3.

20 A. Yeah.

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

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

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

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

7 A. Yes.

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

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

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

24 A. Yeah.

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

4 And "attached"?

5 Q. Yes, please.

6 A. (Indicating.)

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

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

11 BY MR. COHN:

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

15 A. Thank you.

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

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

20 BY MR. COHN:

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

24 A. Yes.

1 Q. And the Cook patent does not mention
2 heart valves; correct?

3 A. Correct.

4 Q. And in the devices described in Cook,
5 there is no valve depicted in any of them; is
6 that right?

7 A. That I believe is correct.

8 Q. If you look at Figure 1 of Cook, do
9 you see cuff portion 15?

10 A. I do.

11 Q. The Cook patent does not provide that
12 the cuff portion 15 performs any stabilizing
13 function; is that right?

14 MR. EGAN: Objection to form.

15 THE WITNESS: No. It's teaching
16 it is as a seal.

17 BY MR. COHN:

18 Q. So I am correct; is that right?

19 MR. EGAN: Objection to form.

20 THE WITNESS: Yes. I mean you
21 are correct. It is teaching it as a seal.

22 BY MR. COHN:

23 Q. Do you see the proximal anchoring
24 stent 18 in Figure 1?

1 A. I do.

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

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

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

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

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

22 A. 3?

23 Q. Yes.

24 A. Yes.

1 Q. And do you see --

2 A. Oh, this is exactly what I was --
3 yeah, this is good. This is what I was
4 already trying to describe. So the proximal
5 anchoring stent 18, you will see it is
6 overlapping the two renal arteries, the two
7 branches coming off the aorta at the top of
8 Figure 3, or a little way down from the top of
9 Figure 3 going to the left and right. They
10 are the renal arteries, and the so-called
11 anchoring stent 18 is there overlapping the
12 renal arteries.

13 Q. Do you see the cuff portion 15 at the
14 top of Figure 3?

15 A. Yes.

16 Q. The direction of any leakage of blood
17 past cuff portion 15 would be from the top to
18 the bottom of Figure 3; is that right?

19 A. Yes. So it is heading into the
20 aneurysm, which is shown below, which is the
21 big dilated part of the aorta.

22 Q. You can put that aside for now.

23 Now, back in 2004, mild PVL was
24 something that persons of ordinary skill

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

3 MR. EGAN: Objection to form.

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

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

23 BY MR. COHN:

24 Q. Back in 2004, very mild paravalvular

1 leak was something that persons of ordinary
2 skill thought would not have had a bad effect
3 on mortality, and then that changed later.

4 But that was correct in 2004; right?

5 MR. EGAN: Objection to form.
6 Compound.

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

18 BY MR. COHN:

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

22 In the context of TAVR, back in
23 2004, mild PVL was something that persons of
24 ordinary skill thought would not have had a

1 bad effect on mortality, correct?

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

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

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

1 Cribier was using.

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

5 A. Yes.

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

13 Did I get that right?

14 A. Sure, absolutely.

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

18 BY MR. COHN:

19 Q. Did I get that right generally?

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

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

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

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

18 MR. EGAN: Objection to form.
19 Compound.

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

24 But these were incredibly ill

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

14 Whether or not that's true will
15 come out in some of the data that is still
16 being produced. But certainly there was a
17 concern that even very mild PVL might have an
18 adverse effect. But that was years after
19 2004.

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

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

6 BY MR. COHN:

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

10 MR. EGAN: Objection to form.
11 Relevance.

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

19 BY MR. COHN:

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

24 MR. EGAN: Objection to form.

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

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

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

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

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

14 BY MR. COHN:

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

17 A. Yes.

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

21 A. No.

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

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

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

8 MR. EGAN: Objection to form.
9 Relevance.

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

12 BY MR. COHN:

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

17 MR. EGAN: Objection to form.
18 Relevance.

19 Q. -- in forming your opinions?

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

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

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

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

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

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

1 outside. So yes, external.

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

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

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

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

1 delivery profile.

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

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

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

15 A. I'm sorry.

16 Q. That is fine.

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

21 A. Yes.

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

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

3 A. Well, they can be.

4 Q. They can be?

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

18 So there are many
19 considerations.

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

23 MR. EGAN: Objection to form.

24 THE WITNESS: I don't like the

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

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

13 BY MR. COHN:

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

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

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

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

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

6 If you're adding an extra
7 component, all other things being equal, then
8 you are going to have to do durability testing
9 and try it out in the clinical setting.

10 That's normal development of a medical device.

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

16 MR. EGAN: Objection to form.
17 Compound.

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

20 BY MR. COHN:

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

23 A. Sure.

24 Q. But I will read it again.

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

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

12 MR. EGAN: Objection to form.
13 Compound.

14 BY MR. COHN:

15 Q. -- in forming your opinions.

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

1 considered those in my report.

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

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

9 A. Yes.

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

13 A. Yes.

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

18 MR. EGAN: Objection to form.

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

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

11 BY MR. COHN:

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

17 MR. EGAN: Objection to form.
18 Relevance.

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

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

5 BY MR. COHN:

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

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

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

20 MR. EGAN: Objection to form.

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

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

4 BY MR. COHN:

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

9 MR. EGAN: Objection to form.

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

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

4 BY MR. COHN:

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

10 A. Okay.

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

13 MR. EGAN: Objection to form.

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

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

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

6 BY MR. COHN:

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

11 MR. EGAN: Objection to form.
12 Relevance.

13 BY MR. COHN:

14 Q. True?

15 A. Not for my declaration, no. I mean I
16 didn't consider Sapien 3 at all. I didn't
17 know it had any relevance in my declaration.
18 I didn't consider Edwards' Sapien 3 product at
19 all for my declaration that I signed on the
20 10th of October of last year.

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

1 MR. EGAN: Objection to form.
2 Relevance.

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

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

9 BY MR. COHN:

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

13 MR. EGAN: Objection to form.
14 Relevance.

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

21 BY MR. COHN:

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

1 before the Sapien 3?

2 MR. EGAN: Objection to form.

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

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

1 before putting the device in.

2 BY MR. COHN:

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

7 What did you mean by that?

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

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

19 MR. EGAN: Objection. Form,
20 foundation.

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

1 leak. That's before TAVR implant.

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

14 BY MR. COHN:

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

19 MR. EGAN: Objection to form.

20 BY MR. COHN:

21 Q. Either experimentally or commercially?

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

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

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

14 MR. EGAN: Objection to form.
15 Relevance.

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

20 BY MR. COHN:

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

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

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

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

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

14 MR. EGAN: Objection to form and
15 relevance.

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

24 BY MR. COHN:

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

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

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

13 MR. EGAN: Objection to form.

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

1 even in 2017.

2 BY MR. COHN:

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

6 MR. EGAN: Objection to form.

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

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

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

10 BY MR. COHN:

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

13 A. Yes.

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

16 MR. EGAN: Objection to form.

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

20 BY MR. COHN:

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

24 MR. EGAN: Objection to form to

1 the extent it calls for a legal conclusion.

2 THE WITNESS: I don't know that.

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

13 BY MR. COHN:

14 Q. Have you ever seen a Lotus valve?

15 A. Oh, yeah.

16 Q. In real life?

17 A. Yes.

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

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

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

24 MR. EGAN: Objection to form to

1 the extent it calls for a legal conclusion.

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

9 BY MR. COHN:

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

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

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

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

1 Q. The Lotus valve had been sold in
2 Europe for a time; right?

3 A. Yes, absolutely right.

4 Q. So clinicians had been using the Lotus
5 valve in Europe for a time?

6 A. Yes.

7 Q. And you did not undertake an
8 investigation of whether any of those
9 clinicians had praised the external seal on
10 the Lotus valve in coming to your opinions in
11 this case; is that right?

12 A. I've heard some of them praise it.
13 For this case, I didn't consider that. I
14 didn't think it important to consider it. I
15 haven't considered the Lotus valve for my
16 declaration at all.

17 Q. Did you attempt to determine whether
18 Boston Scientific's Lotus product was an
19 embodiment of Claims 1 through 4 of the '608
20 patent in the course of your analysis?

21 A. No.

22 Q. If it were and if it had been praised
23 by the industry, wouldn't that have been
24 relevant to your analysis?

1 MR. EGAN: Objection to form.

2 Compound.

3 THE WITNESS: No, it wouldn't.

4 BY MR. COHN:

5 Q. Did you undertake any effort to
6 determine whether Edwards' Sapien 3 product
7 was an embodiment of Claims 1 through 4 of the
8 '608 patent in the course of your analysis in
9 your declaration?

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

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

18 MR. EGAN: Objection to form.

19 THE WITNESS: No, it wouldn't.

20 BY MR. COHN:

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

24 A. Okay.

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

6 A. Yes, I believe that's true.

7 Q. Do you know what the other four are?

8 A. Oh, gosh.

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

16 Q. Queen Elizabeth is in Birmingham;
17 right?

18 A. Correct.

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

22 MR. EGAN: Objection.
23 Relevance.

24 THE WITNESS: It is very

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

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

20 BY MR. COHN:

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

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

24 Q. Do they have a comprehensive center

1 there?

2 MR. EGAN: Objection.
3 Relevance.

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

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

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

17 (Recess.)

18 BY MR. COHN:

19 Q. Welcome back.

20 A. Thank you.

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

24 A. Some of the time. I mean the team

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

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

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

21 A. I am.

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

23 A. Yes.

24 Q. And you are aware that the District

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

4 A. Yes, I've seen that.

5 Q. You have seen the order?

6 A. I've seen the order.

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

10 A. No.

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

16 A. I do.

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

20 A. That is true.

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

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

1 BY MR. COHN:

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

5 Do you see that?

6 A. I do.

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

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

14 Yes, it is.

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

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

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

22 A. Yes.

23 Q. And you turn in it to Paragraph 104.

24 Do you see Paragraph 104?

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

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

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

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

15 A. Yes.

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

18 A. Yes.

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

22 A. Yes, it is.

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

1 A. Yes.

2 Q. You see the paragraph at the bottom
3 that talks about "cuff portion 21"?

4 A. Yes.

5 Q. That is the same as Paragraph 109 in
6 Buller Exhibit 8, the US Spenser publication;
7 correct?

8 A. More or less. It seems to have
9 different numerals in it, but the words are.
10 Why are some of the numbers different?

11 Q. The numerals look the same to me.

12 A. It is different pagination. Yes, it
13 is the same.

14 Q. The paragraph at the bottom of Page 22
15 of Spenser Exhibit 1004 that starts, "In the
16 embodiment shown in Figure 1," and talks about
17 a cuff portion 21, that is the same as
18 Paragraph 109 in the US Spenser that is Buller
19 Exhibit 8; correct?

20 A. Correct.

21 Q. And then one more.

22 A. Yes.

23 Q. If we turn to Page 24 of Spenser
24 Exhibit 1004.

1 A. Yes.

2 Q. The last sentence of the top paragraph
3 that begins "a portion of the valve assembly."

4 Do you see that?

5 A. Yes.

6 Q. It talks about the rolled sleeve. Do
7 you see that sentence?

8 A. Rolled over the stent of the inlet,
9 yes.

10 Q. That is the same as the last sentence
11 of Paragraph 112 in the US Spenser publication
12 that is Buller Exhibit 8; correct?

13 A. Hang on.

14 Yes.

15 Q. And Figures 1 and 2 of both of these
16 Spenser publications are the same; is that
17 right?

18 A. I need to have a look at them.

19 Q. Go ahead.

20 A. Yes, they look to be the same.

21 Q. You can put the PCT aside.

22 A. Yes.

23 Q. But hang onto the US Spenser.

24 A. Okay.

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

5 MR. EGAN: Objection to form.

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

13 BY MR. COHN:

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

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

20 But the answers would be the
21 answers I gave earlier.

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

24 A. 104.

1 Q. Can I call Buller-8 the US Spenser
2 publication?

3 A. Yes.

4 Q. Paragraph 104 of the US Spenser
5 publication.

6 A. Yes.

7 Q. -- does not address leaks that can
8 occur around the implanted valve; correct?

9 A. Yes, it does.

10 Q. What about Paragraph 109, does that
11 address leaks that can occur around the
12 implanted valve?

13 A. Well, it doesn't directly. It doesn't
14 say anything about leaks.

15 Q. Okay. What about Paragraph 112, does
16 that address leaks that can occur around the
17 implanted valve?

18 A. Yes, because it teaches that it
19 enhances the sealing of the device of the
20 valve inlet.

21 Q. I am going to hand you Buller-9.

22 (Buller Deposition Exhibit No. 9
23 was marked for identification.)

24 BY MR. COHN:

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

3 Do you see that Mr. Spenser,
4 Benichou, and Bash are inventors on Buller-9?

5 A. I do.

6 Q. And for shorthand today, can I call
7 Buller-9 the "'078 Spenser"?

8 A. Yes.

9 Q. Mr. Spenser, Benichou and Bash are
10 also inventors on the US Spenser publication
11 we just looked at, Buller Exhibit 8; correct?

12 A. Yes.

13 Q. And if you look in the '078 Spenser
14 patent, Column 2.

15 First of all, have you ever seen
16 this document before?

17 A. I don't believe so. I mean I may
18 have, but as I sit here now, I don't recollect
19 it. I don't recollect the cover.

20 Q. Do any of the figures look familiar as
21 you flip through them?

22 A. Some of them look very familiar. But
23 no, I don't think I have studied this patent.
24 No, it doesn't ring a bell.

1 Q. Now, if you look at Column 2.

2 A. Yes.

3 Q. Around Line 7 at the top.

4 A. Yes.

5 Q. Do you see it says, "Spenser, et al.,
6 in US Patent Application No. " And then it
7 lists a number?

8 A. Yes.

9 Q. "20030153974"?

10 A. Yes.

11 Q. That is the US Spenser publication
12 Buller Exhibit 8; right?

13 A. Yes, that's correct.

14 Q. And if you scroll down in the '078
15 Spenser Column 2, to Line 27, do you see it
16 says, "Spenser, et al., also do not address
17 leaks that can occur around the implanted
18 valve"? Do you see that?

19 A. I do.

20 Q. Do you disagree with that
21 description --

22 A. Yes.

23 Q. -- of the US Spenser publication?

24 A. Yes. I said I do. But I mean I

1 hadn't seen this, and I see no reason why I
2 would have seen this for my analysis through
3 the eyes of 2004.

4 Q. Do you believe that Mr. Spenser,
5 Benichou and Bash are mischaracterizing the
6 description of their own US publication?

7 A. I have no idea, because I never have
8 spoken to them, or to the best of my knowledge
9 met them. I would need to study the whole
10 thing. As I said, I don't think I've seen
11 this patent before. I haven't studied to see
12 if I can work out what they are saying and
13 what is different. I haven't considered it.

14 MR. COHN: I pass the witness.

15 MR. EGAN: I only have a few
16 questions, Dr. Buller.

17 Counsel, on the PCT Spenser, we
18 didn't mark that with a different exhibit
19 number, did we? We just used Exhibit 1004?

20 MR. COHN: We did not remark it
21 because it was not drawn upon.

22 BY MR. EGAN:

23 Q. Dr. Buller, if you could pull out
24 Exhibit 1004, which is the Spenser PCT

1 publication?

2 A. Yes.

3 Q. Could you please turn to Page 23 of
4 that publication.

5 A. Yes.

6 Q. If you could go about seven lines down
7 in the first paragraph at the top of that page
8 that starts with, "the valve assembly is."

9 A. Yes.

10 Q. Do you recall earlier today counsel
11 asked you questions about portions of that
12 sentence?

13 A. Yes.

14 Q. I just want to ask you questions about
15 the entirety of the sentence. The sentence
16 reads, "The valve assembly is attached to the
17 support stent at the support beams, and due to
18 their constant length, there is no need for
19 slack material as the attachment points (25)
20 remain at constant distances regardless of the
21 position of the valve device (crimped or
22 deployed)."

23 Do you see that?

24 A. Yes.

1 Q. What is your understanding of what the
2 Spenser PCT publication is describing here?

3 A. Well, the consequence that because the
4 support beams, support structures remain
5 constant in length, then what is attached to
6 it will not be required to change in length
7 during crimping or deployment. And therefore
8 there is no need for you to allow slack for
9 that change in length to occur because it's
10 not going to occur at the attachment site of
11 the valve to the structures.

12 Q. What happens to the portions of the
13 valve assembly that are not attached to the
14 support beams?

15 MR. COHN: Objection. Form.

16 THE WITNESS: They are still
17 free, as I think I talked about earlier today,
18 they are still free and slack. So the valve
19 can function to open and close. The bits that
20 aren't detached are slack to allow the
21 functions of a healthy opening and closing
22 during the cardiac cycle.

23 BY MR. EGAN:

24 Q. And if you could go two sentences

1 following the sentence we were just looking at
2 that starts with "in prior art."

3 A. Yes.

4 Q. It says, "In prior art, implantable
5 valve devices, the entire support structure
6 changes its dimensions from its initial first
7 crimped position and final deployed position,
8 and this means that in the attachment of the
9 valve assembly to the support structure, one
10 must take into consideration these dimension
11 changes and leave slack material so that upon
12 deployment of the device the valve assembly
13 does tear or deform."

14 Do you see that?

15 A. Yes.

16 Q. What is your understanding of what is
17 being described in that sentence in the
18 Spenser PCT publication?

19 A. Well, they are pointing out several
20 things. They are saying in prior art
21 implantable valve devices, the entire support
22 structure changes, and what they are
23 describing is the change in length, the
24 crimping and expanding. Therefore they are

1 saying slack would need to be left to allow
2 for this in one of these prior art devices.

3 Also, they are saying where they
4 are pointing out the entire -- I think they
5 are contrasting it with their device, their
6 inventive device, where parts of it remain
7 constant, but my reading of it is the parts in
8 between change in length.

9 So the parts in between the
10 support structures change in length and they
11 are pointing that out. The prior art ones had
12 all changed length, whereas in their parts of
13 it doesn't. But the parts in between do
14 change in length.

15 MR. COHN: I am going to object
16 to the form of the question.

17 BY MR. EGAN:

18 Q. You said that parts in between the
19 support beams described in the Spenser PCT
20 publication do change in length.

21 A. Yes.

22 Q. How do they change in length?

23 MR. COHN: Objection. Go ahead.

24 THE WITNESS: When it is

1 crimped, it is collapsed to a smaller size,
2 the sections get longer. And when it's
3 expanded, they get shorter. So I thought this
4 was clearly apparent. If you look at other
5 stent devices, you will see one where it isn't
6 covered up. If you look at, for instance,
7 Figure 40A -- the only reason I am picking
8 this one is because there is no outside cuff
9 or sleeve, so you can see the stent device.
10 You will see that the bars will remain
11 constant in length because they are solid
12 bars. But the zigzag structure in between is
13 clearly going to get much longer when it is
14 collapsed. It is going to get longer top and
15 bottom, and so the device as a whole is going
16 to get longer from top to bottom, because as
17 it they collapse, the peaks of the top and
18 bottom will protrude beyond the fixed length
19 bars.

20 And this process that we often
21 refer to as shortening on expansion, the
22 device gets shorter, often known as
23 foreshortening, was very, very well known in
24 stent art, and the invention here seems to be

1 putting in pieces that don't change in length
2 into a device that otherwise does change in
3 length.

4 MR. EGAN: No further questions.

5 BY MR. COHN:

6 Q. Looking at Figure 40A that you just
7 pointed to.

8 A. Yes.

9 Q. You can see the support beams there
10 with the holes through them where the
11 commissures connect?

12 A. Yes.

13 Q. And then in between those there is a
14 series of vertical longitudinal bars at the
15 edge of each kind of zigzag pattern.

16 Do you see that?

17 A. I'm not sure exactly what you are
18 describing. The straight bars that connect
19 zigzagged pattern?

20 Q. Yes. The straight longitudinal bars
21 that connect the zigzagged pattern. Do you
22 see those?

23 A. I do.

24 Q. Do you see at the bottom of those

1 straight bars there is a dotted
2 circumferential line?

3 A. I do.

4 Q. And that is the suture line at the
5 bottom of the valve leaflets; right?

6 MR. EGAN: Objection. Form.
7 Lack of foundation.

8 THE WITNESS: No.

9 BY MR. COHN:

10 Q. What is that suture?

11 A. I am looking at the wrong line. The
12 dotted line which is going scallop line coming
13 around appears to be the valve leaflet line,
14 which is above that line. I may be looking at
15 the wrong line.

16 There's a dotted line with sort
17 of bigger dashes on it, and that to me is the
18 suture line of the leaflets, which is above
19 that dotted line closer to the bottom.

20 Q. So do you see the No. 549?

21 A. I do.

22 Q. If you could kind of keep your hand on
23 that figure and turn also to Page 42 of the
24 text.

1 A. Yes. I am there.

2 Q. At the bottom, the last sentence on
3 that page actually begins, "PET skirt 543" --

4 A. Yes.

5 Q. -- "is sutured to the circumference of
6 crimpable frame 540, at the bottom side 549."

7 A. Yes.

8 Q. "And at the top 542, using one of the
9 commissural attachments that are described
10 herein."

11 A. Yes.

12 Q. "Before describing other embodiments."

13 Do you see that sentence?

14 A. I do. I think that agrees with what I
15 was saying. It is not the leaflets. It is
16 the PET, that's polyethylene terephthalate,
17 inner skirt. It is not the attachment of the
18 leaflets, which is a higher level than that
19 Line 549.

20 Q. Where do the leaflets attach?

21 A. Above that, the next line up, which
22 isn't a straight line around the
23 circumference. Do you see the dashed line,
24 which is following the contour of the

1 scalloped inner skirt? That's what I think is
2 the attachment of the leaflets.

3 Q. Why don't you take the red pen and we
4 will mark this one.

5 A. Okay.

6 Q. And show me where the bottom of the
7 leaflet in figure --

8 A. Hang on. But this is not an exhibit.
9 I can mark this one?

10 Q. You can mark it and then we will put a
11 sticker on it.

12 So let me make the question
13 clear before you mark it.

14 A. Okay.

15 Q. To make sure we know what we are
16 marking. I want you to mark on Figure 40A of
17 the Spenser PCT where the bottom of the
18 leaflet is sutured.

19 A. (Indicating.)

20 There.

21 Q. Now along that line is the bottom of
22 the leaflet sutured to the frame or to
23 something else?

24 A. Well, it's certainly, I can see

1 sutures where there are no frame bars. So it
2 is sutured to the PET inner skirt there. It
3 may also be sutured in places to the stent
4 bars. Obviously there isn't a stent bar
5 that's following this scalloped outline.

6 Q. Now, the longitudinal bars positioned
7 between the support beams that we talked about
8 earlier --

9 A. Yes.

10 Q. -- those do not foreshorten; right?

11 A. Those bars won't, no. No bars will
12 actually foreshorten. It's the structure of
13 the stent that will change in geometry.

14 Q. Only the zigzag portions will
15 foreshorten; right?

16 A. Yes. But the whole, if you'd like,
17 the whole section between the large bars with
18 the holes in will foreshorten individual bits
19 of it, like the straight longitudinal bars
20 that you are pointing out, will not
21 themselves. But then none of the bars will
22 actually foreshorten. All the bars will
23 remain the same length. But they just
24 reorientate. The structure as a whole

1 foreshortens.

2 Q. Does Spenser indicate whether the
3 bottom of the leaflets is sutured to any of
4 the zigzag portions of the stent?

5 A. I can't remember. I need to read it
6 all.

7 Shall I label this line?

8 Q. Why don't you do that, label the
9 line -- what do you think would be
10 appropriate?

11 A. "Leaflet attachment"?

12 Q. Yes.

13 A. (Indicating.)

14 And initial it like I have done
15 before?

16 Q. Please.

17 A. (Indicating.)

18 Q. Then hand it to me.

19 MR. COHN: For the record, I am
20 going to mark this copy of the Spenser PCT
21 with Buller-10.

22 (Buller Deposition Exhibit
23 No. 10 was marked for identification.)

24 MR. COHN: This is the one in

1 which the witness wrote with the red pen.

2 With that, I pass the witness.

3 Actually, I think I have nothing
4 further.

5 MR. EGAN: Yes.

6 THE WITNESS: Thank you very
7 much.

8 COURT REPORTER: Counsel, can I
9 clarify orders on the record?

10 MR. EGAN: Rough tonight.

11 MR. COHN: We will take a rough
12 tonight and we will take a final, did you say
13 tomorrow?

14 COURT REPORTER: Yes.

15 Mr. Egan, the same?

16 MR. EGAN: We will ride their
17 coattails.

18 (Witness excused.)

19 - - -

20 (The deposition concluded at
21 1:24 p.m.)
22
23
24

I N D E X

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DIRECTIONS NOT TO ANSWER PAGE LINE

NONE

REQUESTS MADE FOR DOCUMENTS PAGE LINE

NONE

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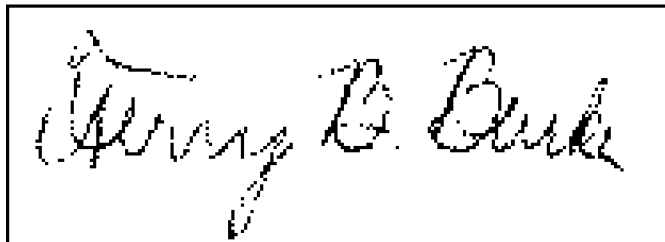
1 State of Delaware)
2 New Castle County)

4 CERTIFICATE OF REPORTER

5 I, Terry Barbano Burke, RMR-CRR and
6 Notary Public, do hereby certify that there
7 came before me on Thursday, June 15, 2017,
8 2013, the deponent herein, NIGEL P. BULLER,
9 M.D., who was duly sworn by me and thereafter
10 examined by counsel for the respective
11 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.

12 I further certify that the foregoing is a
13 true and correct transcript of the testimony
given at said examination of said witness.

14 I further certify that I am not counsel,
15 attorney, or relative of either party, or
16 otherwise interested in the event of this
17 suit.

18 

19
20 Terry Barbano Burke, RMR-CRR
21
22
23
24