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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.,
Petitioner,
v.
INARI MEDICAL INC.,
Patent Owner.

Case IPR2024-01157
Patent 11,697,011

VIDEOTAPED DEPOSITION of PAUL J. ZALESKY, PH.D.
Monday, June 23, 2025
9:07 a.m.

Hilton Boston Logan Airport
One Hotel Drive
Boston, Massachusetts

Reported By: Michelle Keegan, RMR, CRR, CSR

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13

14 Also Present:

Bob Giannini, Videographer

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1 I N D E X

2 Videotaped Deposition of: Page

3 PAUL J. ZALESKY, PH.D.

4 By Mr. Barnes 5

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7 PREVIOUSLY MARKED EXHIBITS

8 Exhibit 1001 78

9 Exhibit 1005 128

10 Exhibit 1006 171

11 Exhibit 1007 175

12 Exhibit 1008 138

13 Exhibit 2001 15

14 Exhibit 2002 119

15 Exhibit 2003 120

16 Exhibit 2008 17

17 Exhibit 2009 111

18 Exhibit 1006 172

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1 P R O C E E D I N G S

2 THE VIDEOGRAPHER: Good morning. We are
3 on the record. This is the videographer speaking,
4 Bob Giannini, and I am with court reporter
5 Michelle Keegan. And we are with Digital Evidence
6 Group.

7 Today's date is June 23rd, 2025, and the
8 time is 9:07 a.m. Eastern Time. We are here at
9 the Hilton Boston Logan Airport to take the video
10 deposition of Paul Zalesky in the matter of
11 Imperative Care, Inc. versus Inari Medical Inc.

12 Will counsel introduce themselves for the
13 record.

14 MR. BARNES: This is Brian Barnes of
15 Knobbe Martens, representing the petitioner,
16 Imperative Care.

17 MR. HAMILTON: This is Joseph Hamilton of
18 Perkins Coie, representing patent owner.

19 THE VIDEOGRAPHER: Thank you. Will the
20 court reporter please swear in the witness.

21

22

1 PAUL J. ZALESKY, PH.D.,
2 having been satisfactorily identified and duly
3 sworn by the Notary Public, was examined and
4 testified as follows:

5 EXAMINATION BY COUNSEL FOR
6 PETITIONER IMPERATIVE CARE, INC.
7 BY MR. BARNES:

8 Q. Good morning, Dr. Zalesky.

9 A. Good morning.

10 Q. Could you please state your full name and
11 home address for the record.

12 A. Paul J. Zalesky, 125 Gilbert Stuart Drive,
13 East Greenwich, Rhode Island.

14 Q. And do you understand that today's
15 deposition concerns an inter partes review filed
16 by Imperative Care relating to U.S. Patent Number
17 11,697,011?

18 A. Yes.

19 Q. And can we agree to refer to inter partes
20 review by the shorthand "IPR" during today's
21 deposition?

22 A. Yes.

1 Q. Can we also agree to refer to U.S. Patent
2 Number 11,697,011 as "the '011 patent" in today's
3 deposition?

4 A. Yes.

5 Q. Are you aware that Imperative Care has
6 filed IPRs for several of Inari's other patents as
7 well?

8 A. I know only that that has occurred. I
9 don't have any real information, though.

10 Q. You've submitted expert declarations in
11 some of the IPRs challenging some of Inari's other
12 patents as well. Is that correct?

13 A. Yes.

14 Q. I understand that you've been deposed
15 before. Is that right?

16 A. I have.

17 Q. Do you recall how many times you've been
18 deposed before?

19 A. In the last seven or eight years, I would
20 say probably 15. Mostly on Zoom because of
21 conditions, as you know.

22 Q. So you're probably familiar with all of

1 this, but just at the outset I'm just going to go
2 over some ground rules to make sure we're on the
3 same page and to make sure everything goes
4 smoothly today.

5 Do you understand that you're under oath
6 and you must testify truthfully, accurately, and
7 completely, the same as if you were in court?

8 A. Yes.

9 Q. And do you understand that all of your
10 answers need to be verbal so that the court
11 reporter can take down a complete record of
12 today's deposition?

13 A. Yes.

14 Q. I'd just ask that you please do your best
15 to wait until I finish asking my question before
16 you begin your answer and I will also do my best
17 to wait until you complete your answer before I
18 ask my next question. Is that fair?

19 A. Yes, it is.

20 Q. And can you please let me know if at any
21 point today you don't understand one of my
22 questions? And I will do my best to clarify. If

1 you don't let me know that you don't understand a
2 question, I will assume that you've understood.
3 Is that fair?

4 A. Okay.

5 Q. And your counsel may make short objections
6 from time to time. However, you will still need
7 to answer my question even if he objects unless
8 Counsel instructs you not to answer. Is that
9 okay?

10 A. Right.

11 Q. And I'll do my best to go roughly about an
12 hour and we'll take several breaks throughout the
13 day. And if at any point you need a break, please
14 just let me know and we can go off the record.
15 The only thing I ask is that if we're in the
16 middle of a question and answer we just finish
17 that question before taking a break. Is that
18 fair?

19 A. Okay.

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

22 A. No.

1 Q. You were hired as an expert witness by
2 patent owner Inari Medical in relation to this
3 IPR. Is that correct?

4 A. Yes.

5 Q. Who were you contacted by to work on this
6 matter initially?

7 A. I can't recall her last name. She went by
8 "Benje." And it was via a phone call she made to
9 me to introduce herself and the potential case.

10 Q. Do you recall when that phone call took
11 place?

12 A. I want to say approximately a year and a
13 half ago, a little less than that, I think.

14 Q. Prior to that phone call, were you
15 familiar with Inari Medical?

16 A. I was not.

17 Q. And I assume that you had never done any
18 work for Inari in the past before this case?

19 A. That's correct.

20 Q. Outside of this IPR and the other IPRs,
21 have you done any work with Inari since that phone
22 call?

1 A. There's another case that's a patent
2 infringement case with a different law firm
3 representing -- and I've done a very brief sort of
4 introductory work on that case.

5 Q. Do you own any stock in Inari?

6 A. I do not.

7 Q. Are you familiar with Stryker Corporation?

8 A. Yes.

9 Q. How so?

10 A. I try to stay current in the medical
11 technology world, which is where I've been focused
12 on product development for most of my career. And
13 watching Stryker evolve over time and expand their
14 business areas has been something I have just
15 monitored periodically.

16 Q. Have you ever done any work for Stryker?

17 A. I have not.

18 Q. Have you spoken to anyone at Stryker about
19 this IPR?

20 A. No.

21 Q. Have you spoken to anyone at Stryker about
22 any of the other IPRs in which you've submitted

1 declarations?

2 A. No.

3 Q. Do you own any stock in Stryker?

4 A. No.

5 Q. Do you know Mr. Troy Thornton?

6 A. I know of him via the expert report that I
7 reviewed.

8 Q. Prior to reviewing his expert report, were
9 you familiar with him?

10 A. I was not. No.

11 Q. Do you have any opinion of Mr. Thornton?

12 A. Not really. I read his declaration. So
13 that's my extent of knowing him, if you will.

14 Q. Have you reviewed any of Mr. Thornton's
15 patents?

16 A. I have not.

17 Q. Are you familiar with Abbott's MitraClip
18 device?

19 A. I am.

20 Q. Were you aware that Mr. Thornton was one
21 of the inventors of Abbot's MitraClip device?

22 A. I recall seeing something, some reference

1 to that in his CV as an attachment to his
2 declaration.

3 Q. Do you agree that Mr. Thornton is an
4 expert in hemostasis valves in catheters?

5 A. Yes. I think so.

6 MR. HAMILTON: I just want to object for
7 that last question, objection, calls for legal
8 conclusion.

9 Q. Are you aware that there is a district
10 court litigation going on between Imperative Care
11 and Inari?

12 A. No.

13 Q. Did you do anything to prepare for today's
14 deposition?

15 A. I had a few hour sessions with Joe here to
16 review I guess what I would refer to as the
17 primary aspects of --

18 MR. HAMILTON: I just want to interject.
19 You can answer to the extent we met, but please
20 don't reveal any communications or the subject of
21 any of our communications, the topics.

22 THE WITNESS: Understood, understood.

1 MR. HAMILTON: Thank you.

2 Q. And again, without getting into any
3 attorney-client privileged information, generally
4 what did you do to prepare for the deposition?

5 A. About a week ago I reviewed my own
6 declaration just to remind myself of the points or
7 observations and conclusions I had made, and then
8 met with Joe a couple of times.

9 Q. Were your meetings with Joe in person?

10 A. We met once in person. It was mostly via
11 videoconference.

12 Q. And do you recall how many times you met
13 to prepare for this deposition?

14 A. If memory serves, I think we had two
15 videoconference calls addressing the deposition.

16 Q. Do you recall how long those calls were?

17 A. Approximately two hours each.

18 Q. And I believe you mentioned that you
19 reviewed your declaration that you submitted. Do
20 you recall roughly how long you reviewed your
21 declaration for?

22 A. Not very long, quite honestly. Probably

1 something like an hour and a half.

2 Q. Other than your declaration, did you
3 review any other documents to prepare for your
4 deposition?

5 A. I probably glanced at the '011 patent but
6 just briefly reminding myself again of figures and
7 legends.

8 Q. Did you review any of the prior art that
9 was asserted in Imperative Care's IPR petition?

10 A. I had done that prior to producing my
11 declaration.

12 Q. And you prepared and submitted two
13 declarations --

14 A. Yes.

15 Q. -- in connection with this IPR. Correct?

16 A. Yes.

17 Q. And when you were referring to reviewing
18 your declaration in your prior answer, were you
19 referring to the first declaration you submitted
20 or the second declaration?

21 A. The first.

22 Q. I'm going to hand you a document that has

1 been marked in this IPR as Exhibit 2001.

2 (Previously marked Exhibit 2001)

3 Q. Do you recognize Exhibit 2001?

4 A. Yes.

5 Q. Exhibit 2001 is a copy of the first
6 declaration that you submitted in this IPR. Is
7 that correct?

8 A. Yes.

9 Q. And if we go to page 104 of Exhibit 2001,
10 is that your signature on page 104?

11 A. Yes.

12 Q. And you signed this declaration on
13 October 29th, 2024. Is that correct?

14 A. Yes.

15 Q. And when you signed the declaration, you
16 declared that you believed all the statements in
17 the declaration were true. Is that correct?

18 A. Yes.

19 Q. And was that an accurate statement when
20 you signed the declaration?

21 A. Yes.

22 Q. Do you still believe that all the

1 statements in the declaration are true?

2 A. I do.

3 Q. Are you aware of any errors in the

4 statements in the declaration?

5 A. I'm not aware of any.

6 Q. How much time did you spend preparing

7 Exhibit 2001?

8 A. It's frankly a hard thing to estimate

9 because I would do it piecemeal, not in one

10 sitting, of course.

11 Cumulatively, maybe 12, 15 hours total.

12 Q. Did you draft the declaration yourself?

13 A. I collaborated with another counsel.

14 Q. Do you recall who that was?

15 A. Matt Williams.

16 Q. What role did you play in drafting the

17 declaration?

18 A. What role did I play or did he play?

19 Q. Did you play.

20 A. I identified what I thought were the major

21 issues after reviewing the petition. And then we

22 went back and forth on those various issues.

1 Q. Do you recall how many drafts of the
2 declaration you reviewed before you signed it?

3 A. I'm guessing two or three.

4 Q. And other than counsel, did you speak with
5 anyone regarding your declaration?

6 A. Only my wife.

7 Q. And what did you and your wife discuss
8 regarding your declaration?

9 A. Very, very minimal, very high level, Here
10 is a case I'm working on as an expert.

11 Q. I'm now going to hand you a document
12 that's been marked as Exhibit 2008 in this IPR.

13 (Previously marked Exhibit 2008)

14 Q. Do you recognize Exhibit 2008?

15 A. Yes.

16 Q. Is Exhibit 2008 a copy of your
17 supplemental declaration that you submitted in
18 this IPR?

19 A. I believe --

20 MR. HAMILTON: If you could just wait for
21 a minute, give me a minute to review it.

22 Okay. You can go ahead and answer.

1 A. Yes.

2 Q. And if you'd turn to page 122 at the end
3 of the declaration, is that your signature on
4 page 122?

5 A. Yes.

6 Q. And you signed your supplemental
7 declaration on April 18th, 2025. Is that correct?

8 A. Seems to be so. Yes.

9 Q. And when you signed your supplemental
10 declaration, you declared that you believed all of
11 the statements in the declaration were true. Is
12 that correct?

13 A. Yes.

14 Q. Was that an accurate statement when you
15 signed the declaration?

16 A. Yes.

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

19 A. I do.

20 Q. Are you aware of any errors or
21 misstatements in your supplemental declaration?

22 A. No.

1 Q. Did you draft your supplemental

2 declaration?

3 A. There was a significant amount of material

4 common with the initial declaration. So drafting

5 or composition was fairly minimal compared to the

6 first.

7 Q. Do you recall roughly how long you spent

8 in preparing your supplemental declaration?

9 A. Significantly less time than the first.

10 Q. Did you work with the same counsel to

11 prepare your supplemental declaration as your

12 initial declaration?

13 A. I did.

14 Q. Do you recall how many drafts of your

15 supplemental declaration you reviewed before you

16 signed it?

17 A. Probably the same, two or three.

18 Q. Did you speak with anyone besides counsel

19 regarding your supplemental declaration?

20 A. No.

21 Q. Other than counsel for Inari, did you

22 speak with anyone regarding this IPR?

1 A. No.

2 Q. Other than counsel, have you spoken with
3 anyone at Inari regarding this IPR?

4 A. No.

5 Q. I understand you are charging your normal
6 hourly consulting rate for your work in this IPR.
7 Is that right?

8 A. That's correct.

9 Q. What is your normal hourly consulting
10 rate?

11 THE WITNESS: Is that pertinent?

12 MR. HAMILTON: You can answer.

13 A. \$300 an hour.

14 Q. And you're also being reimbursed for your
15 out-of-pocket expenses. Is that correct?

16 A. Yes.

17 Q. How many total hours have you billed to
18 Inari for this IPR?

19 A. I'd have to check my records, but I would
20 estimate somewhere in the neighborhood of 20,
21 perhaps 25.

22 Q. And do you know roughly how many total

1 hours you've billed to Inari for all of the IPRs
2 in which you've submitted declarations?

3 A. When I give you that number, that's for
4 all work related to the Inari case.

5 Q. I understand that in the last five years
6 you have testified in both depositions and court
7 settings. Is that correct?

8 A. Yes.

9 Q. I believe previously -- actually, let me
10 just reask the question.

11 Prior to today, do you recall how many
12 times you've testified in depositions?

13 A. I think I mentioned the number 15 or so.

14 Q. And were any of those depositions
15 involving patent cases?

16 A. Actually, most. Yes.

17 Q. Do you recall how many of those
18 depositions involved patent cases?

19 A. Probably 12 out of 15.

20 Q. For those patent case, what was your role
21 in the case?

22 A. Expert witness.

1 Q. Do you recall what technology was involved
2 in your prior patent cases?

3 A. Generally related to interventional
4 cardiovascular devices and methods of using those
5 devices.

6 Q. Did any of your prior cases involve
7 devices used to aspirate blood clots?

8 A. They did not.

9 Q. Did any of your prior cases involve
10 hemostasis valves?

11 A. I'm sorry. Involve?

12 Q. Hemostasis valves.

13 A. Not specifically.

14 Q. Did any of your prior cases involve
15 catheters used for interventional cardiology
16 procedures?

17 A. Yes. Many.

18 Q. And do you recall what specifically those
19 catheters were used for in those cases?

20 A. They were involved with balloon
21 angioplasty, other interventions such as
22 arthroectomy, stent delivery, followup stent

1 procedures, and something called guide extension
2 catheters.

3 Q. What is a guide extension catheter?

4 A. In a typical interventional cardiology
5 procedure to treat coronary artery disease, a
6 standard guiding catheter, which is basically just
7 a single lumen tube, is advanced from the groin to
8 the ostium of the coronary artery in the heart.

9 And then a guide extension catheter goes
10 inside that guide catheter and is advanced into
11 the coronary vasculature to gain access to the
12 difficult geometry or complex lesions.

13 Q. And for those procedure, what size of
14 standard guiding catheters are typically used?

15 A. Almost always between 6 French and
16 8 French.

17 Q. And what is the size of the guide
18 extension catheters in those procedures?

19 A. Necessarily smaller, so typically 4 to
20 5 French.

21 Q. And are any hemostasis valves typically
22 used for those procedures?

1 A. Hemostasis valves are used in virtually
2 all of those procedures. Yes.

3 Q. What kinds of hemostasis valves are
4 typically used?

5 A. Again, almost always Tuohy Borst has been
6 the standard for many years.

7 Q. Are there any other types of hemostasis
8 valves that you recall being used for those
9 procedures?

10 A. I've seen clamps. I've seen the use of
11 suture material. Different physicians have their
12 own different approaches to providing hemostasis
13 depending on the equipment they're using.

14 Q. And when you referred to the use of suture
15 material, what do you mean by that?

16 A. Simply wrapping a suture material around
17 an object or objects.

18 Q. Would the suture material be wrapped
19 around the standard guide catheter?

20 A. It could be. More often it would be
21 wrapped around some juncture of a guide catheter
22 with another device or with a needle or with an

1 introducer.

2 Q. And then would the physician place tension
3 on the suture material to close the juncture
4 around the catheter tool being inserted?

5 A. In some of those case, yes, that was the
6 purpose.

7 Q. And are you aware of any -- let me
8 rephrase.

9 For those procedures that used suture
10 material for the hemostasis valve, were any of
11 those included in a device that was used for the
12 hemostasis valve or were they just simply being
13 operated by the physician pulling on the suture
14 material?

15 A. The latter. Just operated by the
16 physician.

17 MR. HAMILTON: Just a reminder, if you'd
18 wait until he finishes the question. You're kind
19 of -- it's hard for the court reporter to get that
20 when you speak.

21 Q. Do you recall when you first became aware
22 of physicians using suture material to apply

1 hemostasis to the catheter?

2 A. It would be quite a while ago.

3 Angioplasty took off really in the '80s, stents
4 took off in the '90s, so probably in that time
5 frame.

6 Q. Was that a common practice to use suture
7 materials to form hemostasis?

8 A. No, I wouldn't call it common. The Tuohy
9 Borst was the standard.

10 Q. Do you recall roughly how many times
11 you've seen physicians use suture materials to
12 form hemostasis valves?

13 MR. HAMILTON: Objection, vague.

14 A. Not many. So probably single digits.

15 Q. Do you know why the physicians would use
16 sutures to form hemostasis valves?

17 MR. HAMILTON: Same objection, vague.

18 A. I don't think I could represent the
19 interventional cardiologist in that. My
20 observation was there was some seepage that wasn't
21 being controlled well enough by the Tuohy Borst.

22 Q. So in your experience, did the suture

1 material work better than the Tuohy Borst valves?

2 A. It appeared to.

3 Q. Do you know why that was?

4 A. I think it's simple mechanics of exerting
5 an additional source of constriction.

6 Q. And when you say "additional source of
7 constriction," what do you mean by that?

8 A. At the percutaneous entry site, you
9 typically have a device inside of a device, a tube
10 within a tube, sometimes a tube within a tube
11 within another tube. And each of those annuli are
12 capable of having back bleeds.

13 There are some cases where you get more
14 than others, depending on what procedure you're
15 doing and what size devices you're using.

16 Q. So how would a suture material apply an
17 additional source of constriction compared to a
18 Tuohy Borst valve?

19 A. It's essentially ligation. You're
20 strangling what was otherwise an open space and
21 closing it.

22 Q. And does a Tuohy Borst valve not apply the

1 same type of closing mechanism as the suture

2 material did?

3 A. It's a different mechanism. The Tuohy

4 Borst uses a flexible silicone material but it

5 squashes, if you will, inside of a lumen. And in

6 the preponderance of cases, the Tuohy Borst works

7 fine.

8 Q. But there were some cases in which the

9 suture material was used because the Tuohy Borst

10 valves were not working well enough. Is that

11 accurate?

12 MR. HAMILTON: Objection, vague.

13 A. You know, I'm just an observer in these

14 cases, so I can't really definitively say that's

15 what was going on. That was my observation, but I

16 don't know for sure. It's not something I would

17 inquire or analyze.

18 Q. And so shifting gears again a little bit

19 back to your prior testifying experience, do you

20 recall how many times you've testified in court

21 settings?

22 A. In terms of the court with a jury

1 involved, really only one time. And that was a
2 patent litigation case, patent infringement case.

3 I testified in front of arbitration judges
4 several times. So those are probably the two main
5 court testimony experiences.

6 Q. And for the patent infringement case that
7 was in front of a jury, do you recall what type of
8 technology was at issue there?

9 A. It was a balloon angioplasty catheter.

10 Q. And do you recall whether hemostasis
11 valves were at issue in that case at all?

12 A. They were not.

13 Q. Do you recall what size of balloon
14 angioplasty catheters were at issue in that case?

15 A. These were typically 7 or 8 French
16 devices.

17 Q. I assume that case did not involve
18 aspirating blood clots. Is that correct?

19 A. That's correct.

20 Q. And for the arbitrations that you've
21 testified in, were any of those patent matters?

22 A. Patents were involved only tangentially.

1 The case was really about contract violation.

2 Q. And were you acting as an expert witness
3 in any of those cases?

4 A. I was.

5 Q. Were you testifying regarding patents in
6 any of those cases?

7 A. In the arbitration cases, no.

8 Q. Do you recall -- let me rephrase.

9 Do you recall what type of technology was
10 at issue in those arbitrations?

11 A. It was an area called tissue augmentation
12 conducted by plastic surgeons.

13 Q. I assume that didn't involve aspirating
14 blood clots. Is that right?

15 A. That's right.

16 Q. For any of your prior depositions that
17 you've testified in, were any of those related to
18 IPRs?

19 A. Yes. I can recall one in particular --
20 actually, two in particular that were IPR cases.

21 Q. Do you recall what the technology at issue
22 was in those prior IPRs?

1 A. One was a very sophisticated mathematical
2 algorithm associated with cardiac arrhythmias, and
3 the other involved the guide extension catheters
4 that I just described.

5 Q. I understand that you have a Ph.D. in
6 biomedical engineering from the University of
7 Michigan. Is that right?

8 A. Yes.

9 Q. When did you obtain your Ph.D.?

10 A. In the late '70s.

11 Q. And I understand your Ph.D. research
12 focused on the prediction of optimal surgical
13 timing for the repair of congenital heart defects.
14 Is that right?

15 A. Yes.

16 Q. Did your Ph.D. work involve designing any
17 intravascular catheters?

18 A. It did not.

19 Q. Did you use any intravascular catheters
20 during your Ph.D. project?

21 A. No.

22 Q. I assume your Ph.D. research did not

1 involve aspirating blood clots. Is that right?

2 A. That's correct.

3 Q. Your industrial career has focused on the
4 development and commercialization of medical
5 devices for diagnosing and treating heart disease.
6 Is that right?

7 A. Yes. I've been involved in other
8 categories, but that's been the primary
9 experience.

10 Q. What types of heart disease have you
11 focused on during your career?

12 A. Pretty much all, including congenital
13 heart disease, valvular disease, coronary artery
14 disease, and heart failure.

15 Q. Do you consider pulmonary embolism to be a
16 heart disease?

17 A. No. Different category.

18 Q. Have you ever worked on developing any
19 medical devices for treating pulmonary embolism
20 during your career?

21 A. Yes, indirectly. One example is what's
22 called intravascular ultrasound for imaging within

1 a vessel, which can be used to identify and
2 characterize things like pulmonary emboli.

3 Q. Did your work on the intravascular
4 ultrasound devices involve aspirating any
5 pulmonary emboli?

6 A. So some of the cases, some of the patients
7 in fact were treated for aspirating thrombus.

8 Q. Were you involved in designing any of the
9 devices used to aspirate the patient's pulmonary
10 embolism?

11 MR. HAMILTON: Objection, vague.

12 A. I wasn't directly involved in the actual
13 product development, but I was involved in
14 recommendations, observations, and testing.

15 Q. And for those devices that were used to
16 aspirate pulmonary embolisms, do you recall the
17 size of catheters that were used?

18 A. Depending upon the anatomy involved, they
19 could be larger for things like deep veins or the
20 pulmonary artery, so 10 French, 9 French. For the
21 coronaries, about half that size, typically 4 or
22 5 French.

1 Q. Do you recall whether any hemostasis
2 valves were used with those devices that were used
3 to aspirate the pulmonary embolisms?

4 A. Yeah. As I said earlier, the Tuohy Borst
5 has been the standard and was used in virtually
6 every case that I saw or was involved with
7 thrombectomy.

8 Q. Do you recall any other types of
9 hemostasis valves being used for those devices?

10 MR. HAMILTON: Objection, vague.

11 A. I didn't personally observe that. No.

12 Q. For the devices that you've helped develop
13 in your career, were any of those devices used to
14 treat deep vein thrombosis?

15 A. Again, not under my direct purview but
16 certainly in association with ancillary products.

17 Q. And were any of those devices that you've
18 worked with used to aspirate deep vein thrombosis
19 from a patient?

20 A. Aspiration was involved in some of the
21 cases that we were using other technology in as
22 part of the patient treatment.

1 Q. Do you recall what size of catheters were
2 used to aspirate the deep vein thrombosis?

3 A. Some larger. There was quite a bit of
4 variability depending upon the individual patient
5 anatomy. In general, between 8 and 14 French is
6 what I observed.

7 Q. And I assume that hemostasis valves were
8 used with those deep vein thrombosis aspiration
9 devices as well. Is that right?

10 A. A hemostasis valve was involved in
11 absolutely every case. Again, typically Tuohy
12 Borst.

13 Q. Other than a Tuohy Borst valve, were there
14 any other types of hemostasis valves that you can
15 recall being used with deep vein thrombosis
16 devices?

17 A. Not that I observed. No.

18 Q. Have you ever been involved in the -- let
19 me rephrase.

20 Have you ever designed a hemostasis valve
21 yourself during your career?

22 A. Over time I've made -- had to make or

1 manage variations or modifications to the size, to
2 the geometry of a Tuohy Borst valve or similar
3 construction.

4 Q. Other than a Tuohy Borst valve, have you
5 ever had to make any variations or modifications
6 to any other type of hemostasis valve?

7 A. Only prototypical and for controlled
8 clinical studies, not for commercial distribution.

9 Q. And for those prototypical or clinical
10 studies, what types of hemostasis valves other
11 than Tuohy Borst valves were you working on?

12 A. So these were handmade, if you will,
13 versions of clamps or clips that would assure
14 hemostasis in difficult situations.

15 And by that, I mean some procedures,
16 especially going into arteries such as the
17 coronary artery, is a much higher pressure,
18 inducing back bleed or leakage.

19 And in other cases you're applying high
20 pressures of fluid injection. They require
21 special considerations, hence a stronger, if you
22 will, valve.

1 Q. So in those cases, you would use a clamp
2 or a clip to compress the hemostasis valve. Is
3 that accurate?

4 A. You'd compress --

5 MR. HAMILTON: Hold on. Objection, vague
6 and ambiguous.

7 A. You wouldn't compress the Tuohy Borst.
8 You'd compress some other portion of the tubing
9 proximal to the patient.

10 Q. Did you ever use any suture material to
11 constrict tubing for providing hemostasis valves
12 in your prior work?

13 A. Only that equivalent on the bench for
14 doing certain studies but not in the clinic.

15 Q. And so in those bench studies that you
16 did, why did you use the suture material in those
17 cases?

18 A. I'm honestly not sure it was even suture
19 material. It was just basically a very convenient
20 way of shutting down back bleed or back flow via
21 tying something around a tube within a tube.

22 Q. Why was that convenient?

1 A. I could grab a suture material or a string
2 or some version thereof and simply wrap it in a
3 bench setting.

4 Q. And would you wrap the string material
5 around the catheter in a loop?

6 A. Typically you'd wrap it around a catheter
7 that had another device or catheter within it.

8 Q. Do you recall when you did those benchtop
9 tests whether you used the string or suture
10 material to form a hemostasis valve?

11 MR. HAMILTON: Objection, mischaracterizes
12 the testimony.

13 A. You know, I don't honestly recall what
14 material variations we used. It looked a lot like
15 suture material. We may have actually used dental
16 floss in some cases.

17 Q. And do you recall when that was?

18 A. It's been multiple settings. Certainly
19 with TherOx where we were infusing very
20 high-pressure oxygenated solutions. We did that
21 in the late 1900s and early-to-mid 2000s.

22 Q. Is it fair to say that all of that work

1 that you were referring to in your prior answers
2 took place before 2017?

3 A. Yes.

4 Q. And in one of your previous answers, I
5 believe you referenced the higher pressures that
6 are involved with implanting a catheter into an
7 artery. Is that correct?

8 A. Yes, as opposed to a vein.

9 Q. And that higher pressure is being supplied
10 by the relatively higher blood pressure that's
11 present in the artery. Is that right?

12 A. Yes.

13 Q. And I believe you also referred to
14 catheters that you've worked with being used to
15 inject a fluid at high pressures into the
16 patient's vascular system. Is that right?

17 A. Yes.

18 Q. Have you ever worked on interventional
19 catheters that were used to apply vacuum pressure
20 to a patient's vascular system?

21 A. In some procedures, the removal of
22 thrombus via syringe and simple single lumen

1 catheter would be involved in a procedure that we
2 were doing something else at the same time, such
3 as intravascular imaging.

4 Q. Were there any particular design
5 considerations that you had to take account for in
6 those cases where vacuum or aspiration were being
7 applied to the catheter?

8 A. The main issue was always size. Smaller
9 is better, especially in coronary arteries, which
10 are quite small. You don't want to occlude the
11 vessels for any period of time.

12 Q. And what about for the hemostasis valves
13 that were used with those catheters applying
14 vacuum pressure? Were there any special
15 considerations for designing the hemostasis
16 valves?

17 A. None that I observed.

18 Q. Is it fair to say that using hemostasis
19 valves to prevent back bleed during interventional
20 cardiology procedures was a common practice in the
21 field prior to 2017?

22 A. Yes.

1 Q. Have you ever worked with any rotating
2 hemostasis valves?

3 MR. HAMILTON: Objection, vague.

4 A. The Tuohy Borst is a rotating hemostasis
5 valve. So yeah.

6 Q. Are there any drawbacks to using a Tuohy
7 Borst valve as opposed to another type of
8 hemostasis valve?

9 MR. HAMILTON: Objection, vague.

10 A. I guess based on observation, I think
11 larger catheters were more challenging to attain
12 effective hemostasis.

13 Q. Why is that?

14 A. You've got a larger lumen, and you've got
15 more bulk material in the wall because of the size
16 of the catheter.

17 Q. In those cases using larger catheters, was
18 there a different type of hemostasis valve that
19 was more effective, in your experience?

20 MR. HAMILTON: Objection, vague,
21 incomplete hypothetical.

22 A. So not that I was aware of.

1 Q. What about the hemostasis valves that use
2 the suture material? Weren't those more effective
3 for the larger catheters?

4 MR. HAMILTON: Objection, vague,
5 mischaracterizes prior testimony.

6 A. I wasn't aware of any studies that had
7 been done in that regard. What I related earlier
8 were anecdotal observations during certain cases.

9 Q. But in those certain cases, it was your
10 experience that the suture material was more
11 effective at sealing around a larger catheter. Is
12 that right?

13 MR. HAMILTON: Objection, vague,
14 mischaracterizes the testimony.

15 A. Again, observation from a distance, if you
16 will. It appeared to enhance, without any direct
17 measurements.

18 Q. Let me rephrase.

19 Could the Tuohy Borst valves that you
20 worked with be operated with one hand?

21 A. With a skilled interventionalist, yes;
22 with younger, in-training cardiologists, not as

1 much.

2 Q. Did the Tuohy Borst valves that you worked
3 with require the operator to manually open and
4 close the valve?

5 A. Yes.

6 Q. In your experience, did the Tuohy Borst
7 valves have limited sealing capabilities compared
8 to other types of hemostasis valves?

9 MR. HAMILTON: Objection, vague.

10 A. Yeah. I really, really can't say.
11 Nothing I have any recollection about.

12 Q. Did you ever use any static hemostasis
13 valves in your prior work?

14 A. I've seen them used in certain cases.
15 Yes.

16 Q. What types of cases would use the static
17 hemostasis valve?

18 A. Typically right side of the heart, which
19 is lower pressure.

20 Q. Do you know why static hemostasis valves
21 would be used for those cases involving lower
22 pressures?

1 A. I honestly didn't interrogate that. I
2 just -- that was something that a physician would
3 decide on.

4 Q. So was it common for the physicians
5 performing the procedures to select the type of
6 hemostasis valves that would be used with the
7 devices?

8 A. Yes. As I said, in almost all cases the
9 standard Tuohy Borst was used. If there were
10 exceptions, it was absolutely the physician's
11 decision.

12 Q. During your work in designing medical
13 devices, did you ever work on selecting a
14 particular type of hemostasis valve to include
15 with the device?

16 A. In certain instances we explored with
17 manufacturers what variations they could introduce
18 to the Tuohy Borst, which was primarily
19 dimensional. In some cases material alternatives.
20 But primarily dimensional. And by that, I mean
21 both length and lumen size.

22 Q. What types of material alternatives would

1 you investigate with the manufacturers?

2 A. Almost exclusively high-density polymers.

3 Q. And would that be the material that was
4 used to form the lumen of the Tuohy Borst valve?

5 A. Yes.

6 Q. Is it correct that when investigating
7 these alternatives for hemostasis valves, you
8 would work with the outside suppliers or
9 manufacturers to provide the different types of
10 the Tuohy Borst valves? Is that right?

11 MR. HAMILTON: Objection, vague.

12 A. As an example, we would suggest some
13 dimensions that we preferred and see if they were
14 able to deliver, or if they could modify the
15 materials or modify some of the geometry.

16 Q. Would you ever modify the hemostasis
17 valves yourself?

18 A. In the lab, you know, we would do some
19 fairly crude things like perhaps cut a piece away
20 or gang them, if you will.

21 Q. What do you mean by "gang them"?

22 A. Use more than one in series with each

1 other.

2 Q. What would the purpose of that be?

3 A. It's effectively a two-stage hemostasis.

4 Q. Would that provide more effective sealing
5 than using just a single hemostasis valve?

6 A. That was clearly the objective in that
7 configuration on the bench to achieve that, yes.

8 Q. Did you ever use any devices in clinical
9 practice that used multiple hemostasis valves
10 placed in a series?

11 A. We did some limited clinical studies with
12 modified Tuohy Borsts that we had customized
13 because of the application.

14 Q. And how had you customized those Tuohy
15 Borst valves?

16 A. We simply modified the geometry.

17 Q. And when you refer to "the geometry," are
18 you referring to the size of the lumen for the
19 Tuohy Borst valves?

20 A. Primarily the length and the outside
21 diameter of the device.

22 Q. Do you recall what that diameter was,

1 roughly?

2 A. I don't.

3 Q. And do you recall what type of procedure
4 those modified Tuohy Borst valves were being used
5 for?

6 A. This was doing the infusion of very
7 high-pressure oxygenated solutions.

8 Q. Have you ever designed a hemostasis valve
9 that was used with an aspiration catheter?

10 A. Again, I've not specifically overseen that
11 design. We simply utilized the devices available
12 or observed what the physician chose in the cath
13 lab.

14 Q. In 1986, you were working as the director
15 of R&D for Boston Scientific. Is that right?

16 A. Yes.

17 Q. And during your time at Boston Scientific,
18 you supervised the development of guide catheters
19 used to diagnose and treat cardiovascular
20 disorders. Is that right?

21 A. Among others. Yes.

22 Q. Do you recall what cardiovascular

1 disorders the catheters you worked on at Boston

2 Scientific were used for?

3 A. The primary market target and the primary

4 clinical setting was coronary artery disease.

5 Q. Were any of those devices you worked on at

6 Boston Scientific used to aspirate blood clots?

7 A. Yes. You could use a simple standard

8 guide catheter, having its tip placed proximal to

9 a thrombus, and with simple syringe evacuation

10 accomplish thrombectomy.

11 Q. And when you referred to a simple standard

12 guide catheter, what size of catheter would that

13 be?

14 A. These were almost always between 6 and

15 8 French OD.

16 Q. And do you recall what types of blood

17 clots those were used to aspirate?

18 A. Consistent with the primary market target,

19 thrombi in the coronary arteries that led to or

20 would lead to acute ischemia or heart attack. But

21 also peripherally as in peripheral arteries and

22 also in pulmonary arteries.

1 Q. And based on your prior testimony, I
2 assume that those devices you worked on -- let me
3 rephrase.

4 Based on your prior testimony, I assume
5 that those catheter devices you worked on at
6 Boston Scientific also involved the use of
7 hemostasis valves. Is that right?

8 A. Again, the standard being Tuohy Borst.

9 Q. Were there any other types of hemostasis
10 valves besides Tuohy Borst that you used while at
11 Boston Scientific?

12 A. None that I recall.

13 Q. For those Tuohy Borst valves that you used
14 while at Boston Scientific, would you purchase
15 them from a supplier or would you design them and
16 manufacture them yourself?

17 A. We purchased from a supplier.

18 Q. In 1986, you founded a company called
19 Inter Therapy. Is that right?

20 A. Yes.

21 Q. Inter Therapy was focused on developing
22 intravascular ultrasound for assessment of

1 coronary and peripheral vascular disease. Is that
2 right?

3 A. Yes.

4 Q. And based on your prior testimony, is it
5 correct that that intravascular ultrasound device
6 could be used to assess the presence of pulmonary
7 embolism or deep vein thrombosis?

8 A. Yes.

9 Q. Was the Inter Therapy device used to
10 aspirate any blood clots?

11 A. The Inter Therapy device itself, no. It
12 was specifically an intravascular imaging device.
13 It was used in some cases in conjunction with
14 aspiration devices.

15 Q. The Inter Therapy device included a
16 5 French catheter that was passed through a guide
17 catheter into the patient's vasculature. Is that
18 correct?

19 A. Yes.

20 Q. Do you recall what the size of the guide
21 catheter was that was used with the Inter Therapy
22 device?

1 A. Most of the procedures involved either a 7
2 or 8 French guide.

3 Q. And did the Inter Therapy device include a
4 hemostasis valve?

5 A. The entire assembly of the IVIS device, as
6 it's called, inside of a guide catheter required a
7 Tuohy Borst.

8 Q. And was that Tuohy Borst valve that was
9 used purchased from a supplier or was that
10 something that you designed yourselves?

11 A. Purchased from a supplier.

12 Q. After Inter Therapy, you worked as a VP of
13 R&D at Baxter International. Is that right?

14 A. Yes.

15 Q. Did you work on the development of any
16 interventional catheters while at Baxter?

17 A. I worked primarily on cardiopulmonary
18 bypass equipment and accessories but was also
19 involved with a separate division developing
20 angioplasty devices.

21 Q. What were the angioplasty devices that you
22 worked on used for?

1 A. Again, these were balloon angioplasty
2 devices and/or related therapy devices for
3 coronary disease and peripheral artery disease.

4 Q. Were any of those devices used to aspirate
5 blood clots?

6 A. Baxter was not developing a thrombectomy
7 system or device.

8 Q. Did the angioplasty devices you worked on
9 include a hemostasis valve?

10 A. Again, necessarily. These are devices
11 within a guide catheter and that assembly requires
12 a hemostasis valve.

13 Q. Did you use Tuohy Borst valves for those
14 devices?

15 A. Yes.

16 Q. Did you use any other types of hemostasis
17 valves besides Tuohy Borst valves?

18 A. None that I recall. No.

19 Q. Do you recall whether those Tuohy Borst
20 valves were purchased from a supplier or whether
21 they were designed yourselves?

22 A. I wasn't directly involved in the

1 acquisition, but I believe they were purchased
2 from a supplier.

3 Q. After your work at Baxter, you founded a
4 company called TherOx in 1995. Is that right?

5 A. Yes.

6 Q. TherOx was focused on developing a device
7 for delivering oxygen supersaturated solutions to
8 a patient's coronary artery after a heart attack.
9 Is that right?

10 A. Yes.

11 Q. And the TherOx device included a
12 subselective catheter that was delivered through a
13 larger catheter. Is that right?

14 A. That's right.

15 Q. Do you recall what the size of the
16 subselective catheter was?

17 A. We had a bit of variation, but it was
18 typically 4 or 5 French.

19 Q. Do you recall what the size of the larger
20 catheter that was used with the TherOx device was?

21 A. Again, that would have been a standard
22 guide between the 7 and 8 French variety.

1 Q. And I assume that the TherOx device also
2 involved the use of a hemostasis valve. Is that
3 right?

4 A. Yes. I mean, basically every
5 interventional procedure requires a hemostasis
6 valve.

7 Q. And what kind of hemostasis valve did you
8 use with the TherOx device?

9 A. I can't recall which specific
10 manufacturer. We probably sampled a couple
11 different firms, but they are virtually identical.

12 Q. Were they Tuohy Borst valves?

13 A. Yes.

14 Q. And were those hemostasis valves that you
15 used with the TherOx device effective at
16 preventing leaks?

17 A. Yes, as far as I can recall.

18 Q. So if we -- if you'd turn to your
19 supplemental declaration, which is Exhibit 2008,
20 and if you'd turn to Paragraph 16, which I believe
21 is on page -- it begins on page 6.

22 So in Paragraph 16 of your supplemental

1 declaration, you list various guide catheter
2 configurations that were developed and tested by
3 different companies between 1995 and 2005. Is
4 that correct?

5 A. Yes.

6 Q. And one of those catheter configurations
7 you listed in Paragraph 16 is multihardness
8 bodies. Is that correct?

9 A. Yes.

10 Q. Did you work on the development of any
11 catheters with multihardness bodies between 1995
12 and 2005?

13 A. Yes. When we were exploring alternatives
14 for the high-pressure infusion catheter, one of
15 the options was a multihardness. And by that, I
16 simply mean stiffer proximally and more flexible
17 distally.

18 Q. What was the purpose of the multihardness?

19 A. To enhance manipulation or steerability.

20 Q. Other than your work for the infusion
21 catheters, did you investigate multihardness
22 catheters for any of the other devices you worked

1 on?

2 A. We certainly looked at it with guide
3 catheters for Boston Scientific. In some of my
4 consulting roles I looked at it for various
5 catheters, both arterial and venous procedures.

6 Q. And was a multihardness body considered to
7 be a new property for guide catheters at that
8 time, or was that something that was well known?

9 A. It had been well known for a number of
10 years.

11 Q. Do you recall roughly when that
12 development was first -- let me rephrase the
13 question.

14 Do you recall roughly when multihardness
15 bodies for guide catheters were first developed?

16 A. I don't honestly know when they were first
17 developed, but my first exposure would have been
18 in the mid 1980s.

19 Q. One of the other configurations that you
20 list in Paragraph 16 is multiflexibility
21 properties. Is that right?

22 A. Yes, which is a close relative of

1 multihardness.

2 Q. Did you work on development of any
3 catheters with multiflexibility properties between
4 1995 and 2005?

5 A. It's honestly a bit redundant with
6 multihardness. The way to accomplish multiple
7 flexibility would be to use different durometer
8 polymers at different points in the catheter.

9 Q. One of the other configurations you listed
10 in Paragraph 16 is various lumen geometries. Is
11 that right?

12 A. Yes.

13 Q. What types of lumen geometries were you
14 referring to in Paragraph 16?

15 A. Anything -- I mean, in general, lumens are
16 circular, but some catheters are multilumen,
17 meaning they have two or more lumens within the
18 walls of that device.

19 And when that happens during extrusion,
20 they assume a different geometry because of the
21 wall pressure on the lumens that is typically oval
22 or elliptical. So those were the two main

1 cross-sectional geometries of lumens.

2 Q. Did you work on any catheters that used
3 multiple lumens between 1995 and 2005?

4 A. Yes. We certainly explored combining
5 devices so that, for instance, in a procedure for
6 the coronary, you put in a guide catheter over a
7 guidewire and then you want to put in a
8 therapeutic catheter, either a balloon by itself
9 or a balloon with a stent crimped on it, that
10 you're going to deliver.

11 So we explored catheters where you could
12 put a guidewire in one lumen and the therapeutic
13 catheter in another lumen.

14 And even more complexity, an imaging
15 catheter, which was almost impossible because of
16 the restrictions of the coronary anatomy. But we
17 certainly looked at those possibilities.

18 Q. And what were the restrictions of the
19 coronary anatomy that made providing the imaging
20 catheter difficult?

21 A. It's simply a diameter. Yours and my
22 coronary arteries probably range for most of the

1 vasculature in the heart between 3 and 6 French
2 internal diameter. So you can't put anything
3 larger than a 5 or 6 French into those vessels.

4 I'm sorry. Millimeters. I didn't mean
5 French.

6 Q. And for those catheters that involve
7 multiple lumens within the catheter, were there
8 any special considerations for the hemostasis
9 valves you used with those devices?

10 A. No, not that I recall.

11 Q. Did any of the devices that you -- let me
12 rephrase.

13 In your prior work, did you use any
14 devices with multiple lumens in a catheter in
15 clinical use?

16 A. Yes. In almost all procedures it became
17 common to use what are called monorail catheters,
18 which have a single lumen for most of the length
19 but then a separate second lumen at the distal end
20 so that the guide catheter for the catheter can be
21 slid over, advanced, and retracted via the
22 monorail section.

1 Q. And in those procedures that use these
2 monorail catheters, would you typically use a
3 Tuohy Borst valve as the hemostasis valves?

4 A. Yes.

5 Q. In your experience, were the Tuohy Borst
6 valves effective at preventing leak, in those
7 cases that use the monorail catheters?

8 A. In my experience, yes.

9 Q. In Paragraph 16 of your supplemental
10 declaration, you also refer to variations on
11 thrombectomy that were developed and tested by
12 many different companies between 1995 and 2005.
13 Is that right?

14 A. Yes. That's my recollection.

15 Q. What kind of variations on thrombectomy
16 were developed and tested during that time frame?

17 A. Combination of geometry as in diameter, of
18 course, length for different indications, and port
19 or ports. So one extreme would be a single distal
20 port or opening and another would be a series of
21 side openings.

22 Q. And by a distal port, are you referring to

1 a port on the end of the device nearest the
2 operator?

3 A. No. The distal end in the patient.

4 Q. Were you involved in the development of
5 any of those variations in thrombectomy
6 procedures?

7 A. I'd indirectly manage product development,
8 but I did interact with developers as part of my
9 consulting roles.

10 Q. Did any of those variations in
11 thrombectomy involve aspiration procedures?

12 A. Yes.

13 Q. And do you recall what the variations in
14 those aspiration procedures that were developed
15 were?

16 MR. HAMILTON: Objection vague.

17 A. In that specific time period, they were
18 primarily simple syringe and tube arrangements
19 with a stopcock. And individual physicians had
20 their own methodology, if you will, for applying
21 suction pressure to accomplish the thrombus
22 aspiration.

1 Q. What were the types of methodologies that
2 you were aware of for applying suction pressure?

3 A. Pretty simple variations in how forcefully
4 to withdraw -- in other words, the plunger of the
5 syringe or other variations of handling a syringe.

6 Q. And you referred to a stopcock that was
7 used in those aspiration devices. What was the
8 purpose of the stopcock?

9 A. You typically had at least two different
10 lumens distal to the stopcock so that you could
11 segregate aspiration from infusion, infusion being
12 used to either do a contrast imaging or perhaps
13 pharmacologic infusion, whereas the suction lumen
14 would collect the thrombus and keep it segregated
15 from an infusion lumen.

16 Q. Were the stopcocks used to build up vacuum
17 pressure in the syringes?

18 MR. HAMILTON: Objection, vague and
19 ambiguous.

20 A. I recall seeing some cases where the
21 plunger and the syringe would be pulled back with
22 a stopcock in the closed position and then

1 released, presumably -- I didn't really get
2 involved directly in the physician's methodology,
3 but presumably to apply an abrupt pressure change.

4 Q. Do you recall when you first observed that
5 being done?

6 MR. HAMILTON: Objection, vague and
7 ambiguous, calls for speculation.

8 A. I don't recall specifically when, but it
9 was certainly in that time period mentioned in
10 Paragraph 16.

11 Q. So in 1995 to 2005, is that the rough time
12 period?

13 A. Yes.

14 Q. Do you recall roughly how many cases you
15 observed that methodology being done?

16 A. I don't recall specifically, but I would
17 guesstimate 10 or 15.

18 MR. HAMILTON: Objection, calls for
19 speculation.

20 Q. Were you done with your answer?

21 A. Yeah. I'm guessing.

22 Q. Was it more than five cases?

1 A. Sure. Yes.

2 Q. More than 10?

3 A. I'm guesstimating between 10 and 15.

4 Q. And I believe you also, in your prior
5 answer you referred to the catheter geometry as
6 one of the variations in thrombectomy procedures.
7 Is that right?

8 A. Yes.

9 Q. And what did you -- let me rephrase.
10 What types of variations in catheter
11 geometry were developed during that time for
12 thrombectomy procedures?

13 A. As we discussed a couple of minutes ago,
14 variations in the port geometry at the distal end
15 of the device as well as the diameter of the
16 device.

17 Q. What types of variations in the diameter
18 of the devices do you recall being developed?

19 A. So really simply consistent with the
20 indication. A coronary artery thrombectomy
21 requires a pretty small catheter. A distal venous
22 or even a main pulmonary artery thrombectomy can

1 accommodate a much larger catheter.

2 Q. And when you refer to much larger, what
3 range of size would that be?

4 A. In general, I would say larger than
5 8 French going up to the teens in French sizes.

6 Q. Do you recall any catheters that were
7 20 French being used for thrombectomy procedures?

8 A. I have seen that size catheter used in
9 distal veins.

10 Q. What's the largest catheter that you've
11 seen being used for aspirating blood clots?

12 A. Probably the one I just mentioned.

13 Q. And that would be 20 French?

14 A. Yes.

15 Q. Do you recall when you first saw a
16 20 French catheter being used for aspirating a
17 blood clot?

18 A. It was quite a while ago. I would say
19 late '80s, early '90s, with a vascular surgeon
20 colleague of mine.

21 Q. Would the physicians typically be the ones
22 to select the size of the catheters that were

1 being used for the procedures?

2 A. Always, yes.

3 Q. Was the size of the catheter being used
4 for the device something that you would take into
5 consideration during the design of the device?

6 A. The cases I observed were using
7 commercially available, simple catheters, quite
8 honestly.

9 Q. How would the size of the catheter being
10 used for the device impact the choice of a
11 hemostasis valve that you used with the device?

12 MR. HAMILTON: Objection, vague.

13 A. Yeah. That's simply diameter matching on
14 the proximal end of the catheter.

15 Q. Were there any other considerations for
16 the design of the hemostasis valve other than
17 matching the diameter?

18 MR. HAMILTON: Same objection, vague.

19 A. Not that I was aware of.

20 Q. We've been going for almost an hour and a
21 half. Would you like to take a break?

22 A. Sure.

1 MR. BARNES: Can we go off the record,
2 please.

3 THE VIDEOGRAPHER: The time is 10:28.
4 We're off the record.

5 (Recess, 10:28 a.m. to 10:36 a.m.)

6 THE VIDEOGRAPHER: The time is 10:36.
7 We're back on the record.

8 BY MR. BARNES:

9 Q. Welcome back, Dr. Zalesky.

10 From 2007 to 2009, you worked as a vice
11 president of R&D at Volcano Corporation. Is that
12 right?

13 A. Yes.

14 Q. While at Volcano, you supervised the
15 development of coronary and peripheral artery
16 catheters. Is that right?

17 A. Yes.

18 Q. What were those catheters used for?

19 A. These were primarily continuation of
20 intravascular ultrasound, so internal imaging of
21 vessels.

22 Q. Were any of those catheters that you were

1 developing used to aspirate blood clots?

2 A. None that we were actually developing
3 internally, but many of our procedures were
4 associated with aspiration procedures.

5 Q. In those cases that also involved
6 aspiration procedures, would the imaging catheter
7 be introduced through the same guide catheter as
8 the aspiration catheter?

9 A. Almost always. Yes.

10 Q. Would they be introduced into the
11 patient's vasculature at the same time?

12 A. Quite a few variations on a theme there,
13 depending upon which vessel, size of that vessel,
14 and other procedures being done at the same time.

15 Q. Would there be situations in which both
16 the imaging catheter and the aspiration catheter
17 were introduced through the guide catheter at the
18 same time?

19 MR. HAMILTON: Objection, vague.

20 A. There were some cases where you could
21 accommodate within a guide catheter both devices
22 simultaneously.

1 Q. What types of hemostasis valves did you
2 use with those catheters?

3 A. I only recall Tuohy Borst's.

4 Q. Do you recall if you purchased those Tuohy
5 Borst valves from a supplier or did you design
6 them yourself?

7 A. We did not design them ourselves.

8 Q. I understand that in 2011 you served as
9 the interim CEO for a company called Keystone
10 Heart Ltd. Is that right?

11 A. Yes. I'm smiling because it was quite an
12 adventure.

13 Q. I understand that Keystone was focused on
14 developing cerebral protection devices for use
15 with transcatheter heart valve replacement
16 procedures. Is that right?

17 A. Yes.

18 Q. At a general level, can you explain how
19 the Keystone cerebral protection device worked?

20 A. It was basically a nitinol screen that
21 served as a filter. It was positioned at the arch
22 of the aorta where all three vessels that feed the

1 brain emanate. And the concept was to protect the
2 brain or cerebral vasculature from emboli that
3 would be broken loose while putting in a new heart
4 valve, an aortic root.

5 Q. It sounds like that device did not involve
6 implanting anything into the patient's cerebral
7 blood vessels. Is that right?

8 A. That's right.

9 Q. Do you have any experience with Inari's
10 ClotTrievers thrombectomy system?

11 A. I'm aware of the name, but I haven't
12 personally involved -- been involved.

13 Q. Do you know whether the ClotTrievers system
14 includes a hemostasis valve?

15 A. I honestly don't know. I can't recall
16 from looking at the website.

17 Q. Is it fair to say that you've never seen a
18 ClotTrievers system in person?

19 A. That's correct.

20 Q. For the hemostasis valves that you've used
21 in your industrial experience, did any of those
22 hemostasis valves include springs to help close

1 the valve?

2 A. Not that I recall.

3 Q. Did any of those hemostasis valves involve
4 buttons that were used to open and close the
5 valve?

6 A. Not that I recall.

7 Q. So if you could turn to -- it's page 37 of
8 your supplemental declaration, specifically
9 looking at the definition of a person of ordinary
10 skill in the art in Paragraph 68.

11 It's your opinion that a person of
12 ordinary skill in the art in 2017 would have had
13 an undergraduate degree in mechanical engineering
14 or a related engineering discipline and two to
15 four years of product design or engineering
16 experience designing medical devices in the field
17 of the '011 patent. Is that right?

18 A. That's part of the qualification. Yes.

19 Q. What is the other part of the
20 qualification?

21 A. If you continue to Paragraph 69, I add
22 some other requirements to that.

1 Q. What are those other requirements?

2 A. In particular, the sentence "having
3 experience in the relevant field," the field being
4 interventional vascular procedures or procedures
5 involving human anatomy and blood.

6 Q. So is it correct, then, that the field of
7 the '011 patent, in your opinion, is procedures
8 involving human anatomy and blood?

9 MR. HAMILTON: Objection, vague.

10 A. Yes.

11 Q. In your opinion, would a person of
12 ordinary skill in the art need to have experience
13 designing aspiration catheters?

14 MR. HAMILTON: Just one second.

15 Also, for the last question,
16 mischaracterizes the testimony.

17 A. I don't think the POSITA would necessarily
18 have direct experience with hemostasis valves but
19 would have experience with catheters and devices
20 involved in the bloodstream.

21 Q. So a person of ordinary skill in the art
22 does not need to have prior experience designing a

1 hemostasis valve. Is that right?

2 A. I think that's fair. Yes.

3 Q. Would a person of ordinary skill in the
4 art need to have prior experience designing an
5 aspiration catheter?

6 A. Same answer. Not specifically but general
7 experience with vascular devices and procedures.

8 Q. And when you say "general experience with
9 vascular devices and procedures," what do you mean
10 by that?

11 A. Anything from a simple drug infusion
12 catheter that goes into an artery or vein to a
13 complex interventional therapeutic device such as
14 a drug-eluting stent.

15 So quite a wide variety, but in each case
16 getting direct experience and knowledge of human
17 anatomy and blood properties.

18 Q. And so to qualify as a person of ordinary
19 skill in the art, someone would have had to
20 directly work in designing a device used for
21 vascular devices or procedures?

22 MR. HAMILTON: Objection, mischaracterizes

1 the testimony.

2 A. I wouldn't specify designing.

3 Q. So what type of work would a person of
4 ordinary skill -- let me rephrase.

5 What type of work would someone have had
6 to have done to qualify as a person of ordinary
7 skill in the art with respect to those vascular
8 devices and procedures?

9 MR. HAMILTON: Objection, vague and
10 ambiguous.

11 A. Be involved in the development. And
12 specifically, that could be as simple as bench
13 testing and looking at clinical data. It could be
14 an engineer involved in just one aspect of said
15 catheter or device. But obviously being cognizant
16 and learning to be aware of the requirements for
17 human anatomy and blood interaction.

18 Q. But they wouldn't specifically need
19 experience in designing the devices. Is that
20 correct?

21 MR. HAMILTON: Objection, asked and
22 answered.

1 A. Yeah. I think that's correct.

2 Q. You would agree that providing a strong
3 seal around a variety of instruments is an
4 important feature for a hemostasis valve to
5 possess. Is that right?

6 MR. HAMILTON: Objection, incomplete
7 hypothetical.

8 A. Hemostasis is preventing blood loss. So
9 in general, that's what a hemostasis valve is.

10 Q. And you would agree that providing easy
11 one-handed operation of the hemostasis valve is an
12 important feature for a hemostasis valve to
13 possess. Is that right?

14 MR. HAMILTON: Objection, incomplete
15 hypothetical.

16 A. I believe one-handed operation can be very
17 important depending upon the particular procedure.

18 Q. What types of procedures would one-handed
19 operation be important for?

20 A. In the case of advancing a catheter or a
21 guidewire into complex anatomy such as the
22 coronary vasculature or even the distal pulmonary

1 vasculature, he or she needs to be able to
2 manipulate as in steering, pushing, pulling,
3 rotating that device with a hand. If at the same
4 time that hand is required to hold a hemostasis
5 valve, he or she doesn't have that ability.

6 Q. Would aspirating deep vein thrombosis be
7 one of the procedures that's important to have a
8 hemostasis valve that can be operated by a single
9 hand?

10 MR. HAMILTON: Objection, incomplete
11 hypothetical.

12 A. I think in general a one-handed operation
13 of the hemostasis valve is advantageous, for the
14 same reason I just observed.

15 In the case of DVT, he or she is likely to
16 be manipulating the aspiration catheter to
17 different locations proximal and distal to the
18 thrombus material, as an example.

19 So if one hand is free to do that
20 manipulation while the other hand is handling the
21 hemostasis valve, that's an advantage to the time
22 and the safety of that procedure.

1 Q. Would those advantages have been something
2 that a person of ordinary skill would have
3 recognized prior to 2017?

4 A. I believe so. Yes.

5 Q. You believe that the design of the
6 hemostasis valve disclosed in the '011 patent
7 enables ease of use while maintaining an effective
8 and strong seal under the high pressure
9 differential caused by vacuum aspiration during
10 aspiration thrombectomy procedures. Is that
11 right?

12 MR. BARNES: Counsel --

13 MR. HAMILTON: You can answer.

14 MR. BARNES: -- while I'm fine with you
15 making objections on the record, I'm going to ask
16 that you refrain from the hand gestures.

17 MR. HAMILTON: I just want to stop the
18 witness until he gives me a chance to answer.

19 MR. BARNES: I would just ask that you
20 make your objections and, again, stop with the
21 hand gestures.

22 MR. HAMILTON: Would you prefer I just

1 tell him to wait until I get my objection, as
2 opposed to the hand?

3 MR. BARNES: That would be fine.

4 MR. HAMILTON: I can do that.

5 Q. Do you need me to repeat the question?

6 A. I recall the question. It's what I
7 recall -- I mean, we should probably go to the
8 patent itself. But that sounds like language in
9 the actual specification.

10 Q. I'll hand you what has been marked as
11 Exhibit 1001 in this IPR.

12 (Previously marked Exhibit 1001)

13 Q. Do you recognize Exhibit 1001?

14 A. Yes.

15 Q. Exhibit 1001 is a copy of the '011 patent.
16 Correct?

17 A. Yes.

18 MR. HAMILTON: If you could give me a
19 minute to review it before you answer.

20 Okay.

21 Q. And actually, if you could turn to
22 Paragraph 36 of your supplemental declaration.

1 A. Okay.

2 Q. So you see in the first sentence of
3 Paragraph 36 you stated, "The design and
4 functionality of this hemostasis valve enables
5 medical professionals to operate the valve with
6 one hand while maintaining a robust seal to
7 prevent blood loss during procedures." Do you see
8 that?

9 A. Yes. That's a well-composed sentence.

10 Q. And then in the next sentence you stated,
11 "The design enables such ease of use while
12 maintaining an effective and strong seal under the
13 high pressure differential caused by vacuum
14 aspiration during aspiration thrombectomy
15 procedures." Do you see that?

16 A. Yes.

17 Q. So what features of the design described
18 in the '011 patent enable these benefits?

19 A. I think most importantly the mechanism of
20 garrote or strangling of the catheter that effects
21 very complete occlusion or closure.

22 Q. And how does the mechanism of garrote

1 effect very complete occlusion or closure of the
2 valve?

3 A. The flexible and small, very small,
4 flexible filament or filaments -- I guess filament
5 encompasses multiple filaments. That filament is
6 a very effective strangulation physics.

7 Q. And why do you believe that the filament
8 is a very effective strangulation physics?

9 A. Its inherent small size and flexibility
10 produces an essentially uniform circumferential
11 restriction or constriction for compression. And
12 that's the property or that result comes from the
13 property of the very flexible filament.

14 Q. Is there anywhere in the '011 patent that
15 states that the filament provides uniform
16 circumferential restriction?

17 A. I'd have to go back into both the body and
18 the claims. I'm sure circumferential constriction
19 is cited somewhere, perhaps more than one place.

20 Q. And you'd agree that there's no testing
21 data disclosed in the '011 patent for any of the
22 hemostasis valves that are described. Is that

1 right?

2 A. I don't recall seeing testing data. No.

3 Q. Would a person of ordinary skill in the
4 art have recognized that a filament would produce
5 uniform circumferential restriction of a
6 hemostasis valve prior to 2017?

7 MR. HAMILTON: If you could hold on for
8 just a minute.

9 Sorry. I put my hand up out of habit.

10 Would you just hold on and give me a
11 minute for an objection.

12 Objection, incomplete hypothetical.

13 A. I think a POSITA would have been exposed
14 to something as simple as the ligation of a
15 vessel, which is simply garroting a vessel, as an
16 example. If I think about it, I'm sure I could
17 come up with a number of others. But he or she
18 would likely have been exposed to that idea.

19 Q. And would a person of ordinary skill in
20 the art have recognized the benefits of garroting
21 that would be provided in the context of a
22 hemostasis valve prior to 2017?

1 MR. HAMILTON: Objection, vague,
2 incomplete hypothetical.

3 A. I don't believe a POSITA has to have
4 specific experience with different methodologies
5 of hemostasis. So he or she may well not know the
6 efficacy.

7 Q. Could the filament that is disclosed in
8 the '011 patent slide along the tubular member
9 when the actuators are depressed and the slack on
10 the filament is relaxed?

11 A. Would you repeat that?

12 Q. Sure. Could the filament that is
13 disclosed in the '011 patent slide along the
14 tubular member when the actuators are depressed
15 and the slack on the filament is relaxed?

16 MR. HAMILTON: Objection, vague,
17 incomplete hypothetical.

18 A. From my reading of the written description
19 and the figures, I don't think that's likely.

20 Q. Why wouldn't that be likely?

21 A. The properties of the filament essentially
22 keep it constrained.

1 Q. What properties of the filament would keep
2 it constrained?

3 A. Its small diameter and inherent
4 flexibility.

5 Q. So when you say that "the properties of
6 the filament essentially keep it constrained,"
7 what do you mean by "keep it constrained"?

8 A. Your question was could it slide, and I
9 interpreted that to mean axially. And I'm saying
10 I think that's unlikely based on the specification
11 and properties of the filament.

12 Q. How would the filament disclosed in the
13 '011 patent remain constrained when the actuator
14 buttons are depressed?

15 A. It's going to loosen, but necessarily
16 loosen in sort of a coaxial orientation because of
17 the actuator's attachment.

18 Q. When the filament loosens in that coaxial
19 orientation, if the valve were rotated by the
20 operator, tipped on its side, wouldn't the
21 filament potentially move along the tubular
22 member?

1 MR. HAMILTON: Objection, incomplete
2 hypothetical, vague.

3 A. Again, I think that's unlikely. Among the
4 main reasons for that would be the flexibility of
5 the filament is going to relax but stay coaptive
6 with the internal tube.

7 Q. So is it your opinion that the filament
8 disclosed in the '011 patent remains coapted to
9 the tubular member even when the actuator buttons
10 are depressed?

11 A. It is my understanding it would remain in
12 close proximity to the tubular member. Yes.

13 Q. Is that specified anywhere in the '011
14 patent?

15 A. I don't recall. I'd have to go read
16 through the entire description.

17 Q. Would the filament disclosed in the '011
18 patent remain in contact with the tubular member
19 when the actuator buttons are depressed and the
20 tension on the filament is relaxed?

21 MR. HAMILTON: Objection, vague,
22 incomplete hypothetical.

1 A. I think that's most likely. It's going to
2 be dependent on the size of the tubular member.

3 Q. Is it possible that portions of the
4 filament would disengage from the tubular member
5 when the actuator buttons are depressed?

6 MR. HAMILTON: Same objections.

7 A. I think the keyword "possible" is -- yes,
8 it's possible. But I'm purely speculating.

9 MR. HAMILTON: I just want to add one more
10 objection to that last question: calls for
11 speculation.

12 Q. The '011 patent doesn't require that the
13 filament remains in contact with the tubular
14 member even when the actuator buttons are
15 depressed. Correct?

16 A. I don't believe so.

17 Q. If you'd turn to Paragraph 50 of your
18 supplemental declaration. It's on page 26. Do
19 you see towards the middle of that Paragraph 50
20 the sentence that begins with, "A garrote valve"?

21 A. Uh-hmm.

22 Q. Do you see where you stated, "A garrote

1 valve that essentially cinches at a particular
2 point is necessarily more effective in this
3 setting than alternative valve configurations
4 imposing diffuse sealing force." Do you see that?

5 A. Yes.

6 Q. And the setting you were referring to in
7 that sentence is sealing large-bore catheters. Is
8 that right?

9 A. Yes.

10 Q. And would the effectiveness of cinching a
11 hemostasis valve for large-bore catheters have
12 been something that a person of ordinary skill in
13 the art would have known prior to 2017?

14 MR. HAMILTON: Objection, vague,
15 incomplete hypothetical.

16 A. They wouldn't have needed to have direct
17 experience with these larger devices or, in
18 particular, aspiration.

19 Q. So a person of ordinary skill would not
20 have known that cinching a hemostasis valve would
21 be more effective for a large-bore catheter?

22 MR. HAMILTON: Same objections.

1 A. I think most would. I don't know that
2 it's an absolute requirement. And when I say
3 "most would," from simple mechanical engineering
4 and physics.

5 Q. What did you mean by "diffuse sealing
6 force" in the sentence in Paragraph 50?

7 A. Spread out or not concentrated.

8 Q. Would a Tuohy Borst hemostasis valve apply
9 diffuse sealing force?

10 A. It's relative. It would be more diffuse
11 than a filament garrote.

12 Q. And why is that?

13 A. You're taking a force and spreading it
14 over some length as opposed to concentrated almost
15 at a point but certainly a much diminished length.

16 Q. In Paragraph 51, the next paragraph in
17 your supplemental declaration, in that paragraph
18 you explain that the ability of a hemostasis valve
19 to create a robust seal and provide quick
20 self-closing are critical to reduce patient blood
21 loss, which can be significant through a large
22 catheter. Is that correct?

1 A. I'm looking for those exact words. But
2 yes.

3 Q. Would that have been something that a
4 person of ordinary skill in the art would have
5 known prior to 2017?

6 MR. HAMILTON: Objection, vague,
7 incomplete hypothetical.

8 A. I'm not sure which characteristic you're
9 asking.

10 Q. So let's start with creating a robust
11 seal. Would the ability of -- let me rephrase.

12 Would a person of ordinary skill in the
13 art have known that creating a robust seal is
14 critical to reduce patient blood loss, which can
15 be significant through a large catheter, prior to
16 2017?

17 A. As I said earlier, I don't think that he
18 or she would necessarily have had experience with
19 large-bore catheters, but some experience with
20 almost any catheter in the blood system would give
21 that person innate understanding that robust seals
22 are important.

1 Q. Would a person of ordinary skill in the
2 art have known that providing quick self-closing
3 would be critical to reduce patient blood loss,
4 prior to 2017?

5 MR. HAMILTON: Objection, incomplete
6 hypothetical.

7 A. I don't think that's a very specific
8 requirement. No.

9 Q. The hemostasis valve that is described in
10 the '011 patent includes a biasing system that
11 biases the valve toward the closed position when
12 no force is being applied to the actuator. Is
13 that correct?

14 A. That's my understanding. Yes.

15 Q. Would that biasing system disclosed in the
16 '011 patent make it more difficult to insert a
17 tool through the hemostasis valve?

18 MR. HAMILTON: Objection, incomplete
19 hypothetical.

20 A. That's a user-controlled feature that he
21 would adjust consistent with whatever device he
22 was putting through the tubular element.

1 Q. Would the biasing system make it more
2 difficult for the operator to manipulate a tool
3 once it's been inserted through the valve?

4 MR. HAMILTON: Objection, incomplete
5 hypothetical.

6 A. Same answer to the last question. He or
7 she is going to know what manipulability he or she
8 requires for that procedure and would adjust the
9 biasing system accordingly.

10 Q. But the operator would have to adjust the
11 biasing system in order to manipulate the tool.
12 Is that right?

13 MR. HAMILTON: Objection, mischaracterizes
14 the testimony.

15 A. Not necessarily, but certainly optional.
16 Yes.

17 Q. Would the biasing system in the '011
18 patent require the operator to constantly engage
19 the actuator when inserting or manipulating a tool
20 that's been inserted through the valve?

21 MR. HAMILTON: Again, objection,
22 incomplete hypothetical.

1 A. No. I don't believe so.

2 Q. And why not?

3 A. The biasing system does exactly that. It
4 creates a stable bias. And so you have, if you
5 will, a static system now, not a moving system.

6 Q. The biasing system keeps the valve in a
7 closed state when no force is being applied to the
8 actuator. Correct?

9 A. I think there's variability there. I'm
10 not sure if you mean complete closure.

11 Q. Isn't the purpose of the biasing system to
12 bias the valve toward its sealed state?

13 A. Or some state in between the two extremes.

14 Q. So let's take the example of when the
15 biasing system biases the valve to be in the
16 completely sealed state. Wouldn't that require
17 the operator to be constantly pressing on the
18 actuator buttons in order to insert a tool through
19 the valve?

20 MR. HAMILTON: Objection, incomplete
21 hypothetical.

22 A. Among other things, it would depend what

1 tool or device they're inserting through the
2 tubular element. And a guidewire is a fairly
3 robust semirigid axial structure whereas a soft
4 catheter does not have the innate axial strength,
5 so they would be handled differently.

6 Q. Would the operator have to constantly
7 apply pressure to the actuator buttons in order to
8 insert a soft catheter through the valve due to
9 the biasing system?

10 MR. HAMILTON: Objection, incomplete
11 hypothetical.

12 A. Not necessarily. I think that's an
13 option, but I think there would be a lot of
14 variability from physician to physician.

15 Q. Does the '011 patent explain how to design
16 a biasing system such that it would not inhibit
17 the introduction or manipulation of tools inserted
18 through the valve?

19 MR. HAMILTON: Objection, vague.

20 A. I don't believe it goes to that level of
21 detail. My interpretation of that is that's a
22 physician preference feature.

1 Q. How would a physician go about adjusting
2 the biasing system so that it would not inhibit
3 introduction of a tool when the actuator buttons
4 are undepressed?

5 MR. HAMILTON: Objection, incomplete
6 hypothetical.

7 A. He or she has familiarization with the
8 device that's being inserted and its properties,
9 and that would dictate the bias setting.

10 Q. And when you refer to "the bias setting,"
11 what do you mean by that?

12 A. The amount of constrictive force.

13 Q. The constrictive force is being applied by
14 a compression spring in the '011 patent. Is that
15 right?

16 MR. HAMILTON: Objection, incomplete
17 hypothetical, mischaracterizes the document.

18 A. The spring certainly is the primary source
19 of the compression force.

20 Q. So would the physician have to change out
21 the compression spring in order to adjust the bias
22 setting on the hemostasis valve?

1 MR. HAMILTON: Objection, incomplete
2 hypothetical.

3 A. I don't believe that's required. It could
4 be an option.

5 Q. How else would the physician adjust the
6 bias setting other than replacing the compression
7 spring?

8 MR. HAMILTON: Objection, incomplete
9 hypothetical.

10 A. By controlling the actuator buttons.

11 Q. And that would require the physician to be
12 applying force to the actuator buttons while the
13 tool is being inserted or manipulated through the
14 hemostasis valve. Correct?

15 A. From my experience, there's a lot of feel
16 and eye-to-hand coordination involved in these
17 procedures. And he or she would modify the
18 actuator force somewhat dependent on the friction
19 or resistance he's encountering while advancing a
20 device inside the tubular element.

21 Q. If you'd turn to Paragraph 72 of your
22 supplemental declaration, which is on page 39.

1 It's your opinion that the term "filament"
2 as used in the '011 patent means a thin flexible
3 length of material formed by one or more strands
4 of material. Is that right?

5 A. Yes.

6 Q. You agree that the filament that's claimed
7 by the '011 patent can be made from metal.
8 Correct?

9 A. Yes.

10 Q. You agree that the filament can be made
11 from stainless steel. Correct?

12 A. It's a qualified yes. And strands of
13 metal can be produced that are incredibly small in
14 diameter and therefore have significant inherent
15 flexibility, but far from ideal.

16 Q. You would agree at least that the '011
17 patent states that the filament could be made from
18 stainless steel. Correct?

19 A. That's my recollection. Yes.

20 Q. You'd agree that the filament can be made
21 from nitinol. Correct?

22 A. Same comment about stainless steel.

1 Q. You would agree that the filament could be
2 made from aluminum. Correct?

3 A. Same comment. Yes.

4 Q. It's your opinion that a filament that's
5 formed from a metal or polymeric material would be
6 manufactured by rolling or drawing. Is that
7 correct?

8 A. Those are the primary methodologies.
9 There may well be others.

10 Q. Are you aware of any other methodologies
11 for manufacturing a filament from metal or
12 polymeric material?

13 A. I believe injection molding is one.

14 Q. Any others?

15 A. Possibly modified extrusion.

16 Q. Any others?

17 A. That's all that comes to mind.

18 Q. Did the process of rolling a metallic
19 material to form a filament exist prior to 2017?

20 A. I believe so. Yes.

21 Q. That would have been something that a
22 person of ordinary skill in the art would have

1 been familiar with?

2 A. Not necessarily.

3 Q. Why not?

4 A. It's a relatively specialized fabrication
5 methodology specific to metals, not used commonly
6 with polymers. And polymers are the backbone of
7 medical devices, especially catheters and
8 therapeutic devices.

9 Q. So a person of ordinary skill in the art
10 would not have needed to be familiar with the
11 manufacturing processes used to make the
12 hemostasis valve that's disclosed in the '011
13 patent. Is that right?

14 MR. HAMILTON: Objection, mischaracterizes
15 the testimony.

16 A. The process you just described previously
17 was not the manufacture of the valve. It was the
18 production of a component, and that's what I was
19 responding to.

20 Q. The '011 patent doesn't describe how the
21 filament is manufactured. Correct?

22 MR. HAMILTON: Objection, the document

1 speaks for itself.

2 A. I don't believe so.

3 Q. So the claims of the '011 patent aren't
4 limited to filaments that are manufactured using
5 any specific technique. Would that be correct?

6 MR. HAMILTON: Objection, calls for a
7 legal conclusion.

8 A. That's my understanding.

9 Q. Did the process of using drawing to form a
10 metallic filament exist prior to 2017?

11 A. I believe so.

12 Q. Would that have been something that a
13 person of ordinary skill in the art would have
14 been familiar with?

15 A. My comment is the same as to the earlier.
16 The methodology of working with, you know, very
17 limited, very specific production methodologies
18 such as metal, not necessarily.

19 Q. What about the process of using drawing to
20 form a polymeric filament? Did that exist prior
21 to 2017?

22 A. I don't believe he or she would need to

1 have experience or knowledge specific to the
2 methodology of producing that material. But they
3 would, because of their engineering or other
4 technical expertise or perspective, understand the
5 properties associated with the resulting
6 component.

7 Q. Can a metallic filament be manufactured by
8 machine?

9 MR. HAMILTON: Objection, vague.

10 A. I haven't personally observed it, but I
11 think it's quite likely.

12 Q. What about a polymeric filament? Could
13 that be manufactured by machining?

14 MR. HAMILTON: Again, same objection,
15 vague.

16 A. Polymeric materials are typically extruded
17 or injection molded and sometimes machined.

18 Q. If we turn to the '011 patent, which is
19 Exhibit 1001, and if you turn to Figures 8 and 9,
20 those figures illustrate the filament being formed
21 into bights. Correct?

22 A. Yes.

1 Q. Is the filament that's depicted in
2 Figures 8 and 9 of the '011 patent flexible?

3 A. Yes.

4 Q. How do you know that?

5 A. From the written description.

6 Q. The written description of the '011 patent
7 doesn't use the word "flexible." Correct?

8 A. You know, I honestly am not sure if that
9 word is used in there. But the properties of the
10 filament necessarily require flexibility.

11 Q. What properties of the filament
12 illustrated in Figures 8 and 9 require
13 flexibility?

14 A. In particular, the ability to
15 circumferentially circumscribe or
16 circumferentially impose a force.

17 Q. Does the filament that's illustrated in
18 Figures 8 and 9 circumferentially circumscribe the
19 tubular member?

20 A. It would in the final configuration. This
21 is showing a -- one particular static positioning
22 of the filament.

1 Q. Could the filament depicted in Figures 8
2 and 9 be rigid?

3 A. No.

4 Q. Why not?

5 A. A rigid filament would not be able to
6 accommodate the circular circumference of the
7 internal tubular element.

8 Q. And as depicted here in Figures 8 and 9,
9 the shape of the bights doesn't change as the
10 filament is closed between Figures 8 and 9.
11 Correct?

12 A. It doesn't show that. No.

13 Q. And that doesn't suggest that those
14 filaments are rigid?

15 A. No. Again, as in the written description
16 specification and the needed properties for
17 circumferential constriction, flexibility is
18 absolutely essential.

19 Q. And that includes the embodiments where
20 the filament forms bights. Correct?

21 A. Yes.

22 Q. How flexible does a material need to be in

1 order to constitute a filament, under your
2 construction?

3 A. I'm laughing because the word "very" comes
4 to mind. I don't have a quantitative answer to
5 that.

6 Q. How would a person of ordinary skill in
7 the art measure the flexibility of a material to
8 determine whether it's a filament or not?

9 A. There are common methodologies. There are
10 instruments like the Instron device, which can be
11 used to measure the tension or the strength or the
12 flexibility of some configuration.

13 Q. Would there be a minimum amount of force
14 needed to bend a material in order for it to
15 constitute a filament under your construction?

16 A. I think that's one way of assessing
17 flexibility. I think more commonly would be its
18 conformativeness or its adaptability to
19 accommodate a structure that it's surrounding or
20 encountering.

21 Q. How would you test whether a material has
22 enough of an ability to conform to a structure

1 that it's surrounding to constitute a filament?

2 A. One way to do it would be simply wrap the
3 filament around a chosen structure, such as a
4 tubular element or a catheter, and observe its
5 compliance and its coaption to the external wall
6 of the device.

7 Q. How compliant would the material need to
8 be in order to constitute a filament?

9 A. Again, very. But I think it would be more
10 of a visual observation of its property.

11 MR. HAMILTON: I just want to put in for
12 that last question, incomplete hypothetical,
13 objection.

14 Q. How would a person of ordinary skill in
15 the art go about determining whether a given
16 material is compliant enough to be a filament or
17 to not be a filament?

18 MR. HAMILTON: Objection, incomplete
19 hypothetical.

20 A. Primarily trial and error.

21 Q. What specific properties would the person
22 of ordinary skill in the art be looking for in

1 order to determine whether something is a filament
2 or not?

3 MR. HAMILTON: Objection, asked and
4 answered.

5 A. As I responded a minute ago, both its
6 coaptability or its adaptability to a structure
7 it's circumscribing and its coaption to the
8 external surface of that structure.

9 Q. What about a paper clip? What if you bent
10 a paper clip around a pencil? Would that
11 constitute a filament?

12 MR. HAMILTON: Objection, vague.

13 A. In my opinion, that's in the outermost
14 extreme of what a filament's properties would
15 possess.

16 Q. But it would qualify as a filament under
17 your construction?

18 MR. HAMILTON: Objection, vague,
19 incomplete hypothetical.

20 A. In the sense that a paper clip comes
21 close, but I'm not sure close enough to a flexible
22 wire, a very low-gauge wire. I think it can

1 approximate that but certainly not preferred as a
2 filament.

3 Q. But it would count?

4 MR. HAMILTON: Objection, asked and
5 answered, vague, incomplete hypothetical.

6 A. The same comment I made earlier.

7 Q. How thin does a material need to be to
8 constitute a filament, under your construction?

9 A. I don't think there's an absolute
10 dimensional requirement. I think it's thin enough
11 to effect a carefully coapted circumferential
12 constriction or compression.

13 And so to create the described garrote
14 effect, quite small, but I don't know that there's
15 an absolute maximum to that.

16 Q. So could a material that has a diameter of
17 5 millimeters be a filament?

18 MR. HAMILTON: Objection, incomplete
19 hypothetical.

20 A. It would depend upon the material, of
21 course. But I think that would be on the extreme
22 large size for a filament.

1 Q. What about 10 millimeters? Would that be
2 too thick?

3 MR. HAMILTON: Objection, incomplete
4 hypothetical.

5 A. Same answer but worse. Larger is not
6 better.

7 Q. What about 20 millimeters? Would that be
8 too thick?

9 MR. HAMILTON: Objection, incomplete
10 hypothetical.

11 A. Again, the same comment.

12 Q. And so to clarify, a 20-millimeter-
13 diameter material could qualify as a filament
14 under your construction. Is that correct?

15 MR. HAMILTON: Objection, incomplete
16 hypothetical.

17 A. I think the answer would be the trial and
18 error methodology I described earlier, consistent
19 with the properties in the specification.

20 Q. So you would agree with me that a thin and
21 flexible piece of aluminum could qualify as a
22 filament under your construction. Correct?

1 MR. HAMILTON: Objection, incomplete
2 hypothetical.

3 A. In theory, yes. I haven't had personal
4 experience with metal filaments that you're
5 describing, so it's a theoretical proposition.

6 Q. And let's say someone hands you a piece of
7 aluminum and asks, "Can you tell me whether this
8 is a filament or not under the '011 patent?" How
9 would you go about determining that answer?

10 MR. HAMILTON: Objection, incomplete
11 hypothetical.

12 A. I'd wrap it around a pencil or a finger
13 and see what force is required and how well it
14 coapted. So hence my comments earlier about trial
15 and error.

16 Q. So if you were able to wrap the piece of
17 aluminum around a pencil using your own hand,
18 let's say, would that be flexible enough to be a
19 filament?

20 MR. HAMILTON: Objection, mischaracterizes
21 the testimony.

22 A. It's very qualitative, so very hard to

1 answer that without looking at a very specific
2 configuration of this aluminum whether or not it
3 satisfies filament properties as taught by the
4 '011.

5 Q. Is it correct that there's not a certain
6 force that would be a cutoff for determining if
7 the material is flexible enough? Is that fair to
8 say?

9 A. I don't believe that '011 teaches a very
10 specific measurement of the tensile properties, if
11 you will. But it does describe what I would call
12 significant flexibility and small size and
13 consistency with the definition of "filament" that
14 we just read a minute ago.

15 Q. In Paragraph 79 of your supplemental
16 declaration, do you see in the third sentence of
17 Paragraph 79 you stated, "If the filament of
18 Figure 6 were completely inflexible and could not
19 work as intended." Do you see that?

20 A. Yes.

21 Q. And what did you mean by the phrase
22 "completely inflexible"?

1 A. Stiff, rigid.

2 Q. Can you give an example of a completely
3 inflexible material?

4 MR. HAMILTON: Objection, vague,
5 incomplete hypothetical.

6 A. I think a steel I beam comes pretty close
7 to that.

8 Q. How thick are steel I beams typically?

9 A. I honestly don't know the exact dimensions
10 of steel I beams. I'd be guessing if I gave you a
11 dimension.

12 Q. Are they less than 10 millimeters thick
13 typically?

14 A. As you are aware, the I beam has different
15 pieces or different parts of the structure. But
16 that seems excessively thin, to me, for a steel
17 I beam.

18 Q. Are there any components of intravascular
19 medical devices that you're aware of that you
20 would consider to be completely inflexible?

21 MR. HAMILTON: Objection, vague.

22 A. I think the metal arthrectomy

1 components -- "completely inflexible" is an
2 interesting term, but certainly nonflexible by
3 definition.

4 The arthrectomy cutting apparatus is going
5 to encounter calcium, which is basically a rock,
6 and not bend nor flex. So in that context,
7 inflexible.

8 Q. Are you aware of any components of a
9 hemostasis valve that you would consider to be
10 completely inflexible?

11 MR. HAMILTON: Objection, vague.

12 A. I'm most familiar with the variations of
13 the Tuohy Borst. And no, I would not term any of
14 its components completely inflexible.

15 Q. If you'd turn to page -- the prior page of
16 your supplemental declaration, page 41,
17 specifically, Paragraph 77.

18 You cite to a dictionary definition for
19 the word "loose" that is provided in Exhibit 2009
20 in that paragraph. Correct?

21 A. Yes.

22 Q. I'm handing you what has been marked as

1 Exhibit 2009 in this IPR.

2 (Previously marked Exhibit 2009)

3 Q. Exhibit 2009 is an excerpt of
4 Merriam-Webster's Collegiate Dictionary,
5 11th Edition. Correct?

6 A. Appears to be. Yes.

7 Q. And this is the dictionary that you cited
8 to in Paragraph 77 of your supplemental
9 declaration. Correct?

10 A. I'm just checking the actual verbiage of
11 page 41. Yes.

12 Q. How did you choose this dictionary that is
13 Exhibit 2009 to cite in Paragraph 77 of your
14 declaration?

15 A. Convenience.

16 Q. Did you consider any other dictionaries
17 that define the word "loose"?

18 A. I may have. I honestly don't recall. I
19 may have used Google.

20 Q. Other than convenience, was there any
21 other reason why you selected Exhibit 2009 as the
22 dictionary to use?

1 A. Certainly a well-accepted reference.

2 Q. Did you consider any -- let me rephrase.

3 Did you consider any technical

4 dictionaries?

5 A. I don't believe so.

6 Q. Why not?

7 A. It's such a common word. I was looking
8 for the common understanding or definition of that
9 word.

10 Q. And do you agree with the definition of
11 the word "loose" that is provided in Exhibit 2009?

12 A. Yes.

13 Q. It's your opinion that the definition of
14 the word "loose" is relevant to the meaning of the
15 term "filament" that's claimed in the '011 patent.
16 Correct?

17 A. Yes. The relaxation of the filament is
18 loosened.

19 Q. And in that answer, are you referring to
20 the statement in the '011 patent that says that
21 "the filament 150 is loosened, thereby allowing
22 the expansion of the elongate member 132 and the

1 unsealing of the central lumen 138"?

2 A. That's what I cite in Paragraph 77.

3 Q. If we look at Exhibit 2009, this
4 dictionary provides a definition for the word
5 "loosened." Correct?

6 A. Yes.

7 Q. You don't discuss the definition for
8 "loosened" that is provided in Exhibit 9 or -- let
9 me rephrase.

10 You don't discuss the definition for
11 "loosened" that is provided in Exhibit 2009 in
12 your supplemental declaration. Correct?

13 A. Right. I'm just citing "loose," not
14 "loosened."

15 Q. Why did you choose to cite to the
16 definition for "loose" and not "loosened" in your
17 supplemental declaration?

18 A. I mean this in a semi-comedic perspective.
19 "Loosened" unfortunately often connotes valve
20 function.

21 Q. The word that is used in the '011 patent
22 to describe the filament is "loosened." Correct?

1 A. You want to point me to that in the
2 written description?

3 Q. Sure. And I believe you quoted in
4 Paragraph 77 of your supplemental declaration,
5 bolded there, that the '011 patent says that "the
6 filament 150 is loosened." Correct?

7 A. Yes.

8 Q. And so wouldn't the definition for the
9 word "loosened" be more appropriate here than the
10 definition for "loose"?

11 A. I'm not sure how to answer that. My
12 comment earlier applies. But in this context of
13 the patent teaching it's not nearly as confusing,
14 if that's the right term. So in my opinion, I
15 chose a definition that better reflected the
16 actual properties.

17 Q. And how did you determine which definition
18 better reflected the actual properties of the
19 filament?

20 A. I like the words "slackened" and inclusion
21 of the word "flexible."

22 Q. And why do you like that?

1 A. Because of their consistency with my
2 understanding of the '011 teaching. I guess I
3 should say the operating basis for the '011
4 teaching.

5 Q. So is it correct that you chose the
6 definition of the word "loose" because it referred
7 to flexibility?

8 MR. HAMILTON: Objection, mischaracterizes
9 the testimony.

10 A. I'm trying to keep this very brief. When
11 I look at a patent, I look at it two different
12 ways on two different days. One is from a high
13 level of overall what is this, what is this
14 invention. And then on another day, detailed
15 written and figure description in the
16 specification to look at the actual details of the
17 invention.

18 My understanding from the first
19 perspective of the top view is how this would
20 actually operate because of the filament's
21 properties. And so I tried to be consistent with
22 that in my description of operating principle and

1 operating characteristics and more specifically
2 properties of the filament.

3 Q. And so I'm asking specifically about how
4 you chose this definition for the word "loose"
5 that you cited to in Paragraph 77.

6 And was part of the reason that you chose
7 that definition because it states flexibility as
8 part of the definition for the word "loose"?

9 MR. HAMILTON: Objection, vague.

10 A. That was part of my rationale. Not
11 completely, but part.

12 Q. Is it impossible to loosen something that
13 isn't flexible?

14 MR. HAMILTON: Objection, vague,
15 incomplete hypothetical.

16 A. I guess you could loosen a nut from a
17 bolt. Very different mechanisms.

18 Q. So just because something can be loosened
19 doesn't mean it's necessarily flexible. Is that
20 fair to say?

21 A. I think the context is critical.

22 Q. But referring to something as being

1 loosened on its own doesn't connote flexibility
2 necessarily. Is that fair?

3 A. I'll just repeat. I think the context is
4 critical here. And as I said, you could apply
5 "loosened" to a rigid nut and bolt, and that's a
6 dramatically different context than a hemostasis
7 context.

8 Q. In Paragraph 80 of your supplemental
9 declaration, which is on page 43, you cite to the
10 definition of the word "bight" that is provided in
11 Exhibit 2009. Is that correct?

12 A. I'm looking for your reference to "bight."

13 Q. So in Paragraph 80, the second --

14 A. Oh, 80? I'm sorry. I thought you said
15 81.

16 Q. No worries. Yes, in Paragraph 80, in the
17 second sentence you cite to the definition of
18 "bight" that is provided in Exhibit 2009.
19 Correct?

20 A. Yes.

21 Q. Did you consider any other dictionaries
22 other than Exhibit 2009 that define the word

1 "bight?

2 A. I recall going online. And I'm not sure
3 what different references I looked at, but
4 certainly more than one from different
5 dictionaries.

6 Q. And why did you choose Exhibit 2009 as the
7 dictionary that you cited to in your supplemental
8 declaration?

9 A. Brevity.

10 Q. And what about Exhibit 2009 lent itself to
11 brevity?

12 A. It wasn't the exhibit that drove that. It
13 was my own perspective, how best to describe a
14 bight in three or four words.

15 Q. And so do you agree with the definition of
16 "bight" that is provided in Exhibit 2009?

17 A. Yes.

18 Q. In Paragraph 83 of your supplemental
19 declaration, you cite to definitions of the word
20 "filament" that are provided in two different
21 dictionaries that are identified as Exhibits 2002
22 and 2003. Correct?

1 A. Yes.

2 Q. I'm handing you what has been marked as
3 Exhibit 2002 in this IPR.

4 (Previously marked Exhibit 2002)

5 Q. Exhibit 2002 is one of the dictionaries
6 that you cite to in Paragraph 83 of your
7 supplemental declaration. Correct?

8 A. It appears to be. Yes.

9 Q. Why did you choose this dictionary to cite
10 in Paragraph 83 of your supplemental declaration?

11 A. I recall looking at multiple sources for
12 both definitions and synonyms, frankly, for
13 "filament" since it seems to be an important
14 feature of this case. I thought these two
15 definitions were as accurate as any I could find.

16 Q. And how did you determine that these two
17 definitions you cited to in Exhibit 83 were
18 accurate?

19 A. My understanding of the properties and
20 physical appearance of the word as used in the
21 context of a hemostasis valve.

22 Q. Did you consider any -- let me rephrase.

1 Did you consider any technical
2 dictionaries that defined the word "filament"?

3 A. No.

4 (Previously marked Exhibit 2003)

5 Q. I'll hand you what's been marked as
6 Exhibit 2003 in this IPR. Is Exhibit 2003 that I
7 just handed you a copy of the second dictionary
8 that you cited to in Paragraph 83?

9 A. It appears to be. Yes.

10 Q. And did you also select Exhibit 2003 as
11 one of the dictionaries to cite to because you
12 believed it accurately defined the word
13 "filament"?

14 A. Yes.

15 Q. The claims of the '011 patent require that
16 the filament circumferentially constricts the
17 lumen of the valve. Correct?

18 A. Yes.

19 Q. What does the term "circumferentially
20 constrict" mean?

21 A. So two words. "Circumferential" is quite
22 specific and defines the outer boundary of a

1 structure, typically circular but not necessarily.
2 But it defines the 360-degree perimeter of the
3 structure circumference, circumferential being the
4 adjective based on circumference.

5 "Constrict" means diminishing in lumen
6 size or diameter.

7 Q. Would reducing the size of a loop around
8 the valve's lumen circumferentially constrict the
9 lumen?

10 A. Yes.

11 Q. Would reducing the size of an encircled
12 area around the valve lumen circumferentially
13 constrict the lumen?

14 MR. HAMILTON: Objection, vague,
15 incomplete hypothetical.

16 A. I don't really understand that question.
17 Say that again.

18 Q. Would reducing the size of an encircled
19 area around the valve's lumen circumferentially
20 constrict the lumen?

21 MR. HAMILTON: Same objections.

22 A. The questions aren't making a lot of

1 sense. The constriction does that. It reduces
2 the external diameter. So if you're saying
3 reducing the external diameter, that's what the
4 constriction is doing.

5 Q. Is it your opinion that a filament must
6 cross the same portion of the lumen in order to
7 circumferentially constrict the lumen?

8 MR. HAMILTON: Objection, vague.

9 A. I'm not quite sure what you mean by "same
10 portion."

11 Q. If you'd turn to Paragraph 88 of your
12 supplemental declaration, which is on page 47, do
13 you see the second-to-last sentence there in
14 Paragraph 88 states, "This parallel configuration
15 means that the actuating members are positioned
16 next to each other and do not cross any part of
17 the same portion of the lumen. Consequently, they
18 do not circumferentially constrict any point of
19 the lumen." Do you see that?

20 A. Yes.

21 Q. And so what did you mean by "cross any
22 part of the same portion of the lumen" in

1 Paragraph 88?

2 A. A flexible filament in the context of the
3 '011 meets itself, if you will, at the end of the
4 turn around the circumference of the tubular
5 member. And so it's constrained over a very, very
6 short, extremely short portion or segment of the
7 tubular member.

8 Q. When you say it's constrained over a very,
9 very short portion, are you referring to the
10 filament being constrained?

11 A. Yes.

12 Q. And so if we look at Figure 6 of the '011
13 patent, would the filament that's illustrated in
14 Figure 6 cross any part of the same portion of the
15 lumen of the hemostasis valve?

16 A. At the point where you see the -- you see
17 the filament touching itself with just the
18 different part of itself, you've got almost a
19 point definition. Microscopically, it's a very
20 short length. It's almost a point definition of
21 where they cross each other, the two ends.

22 Q. You'd agree that in Figure 6 the two

1 portions of the lumen -- let me rephrase.

2 You'd agree that in Figure 6 the two
3 portions of the filament that are forming the loop
4 run parallel to each other at the top of that
5 loop. Correct?

6 A. Yes.

7 Q. So there wouldn't be any point at which
8 this filament in Figure 6 crosses the same portion
9 of the lumen. Correct?

10 MR. HAMILTON: Objection, vague,
11 mischaracterizes the testimony.

12 A. No. My earlier statement said just the
13 opposite of that, that there is, in fact, a point
14 where they cross.

15 Q. Where do they cross?

16 A. When they are in closest apposition to
17 each other.

18 Q. And would that be at the top of the loop
19 where the two portions of the filament are running
20 parallel to one another?

21 A. In this depiction, yes.

22 Q. So if we go back to Paragraph 88 of your

1 declaration, you say that a parallel configuration
2 of the actuator members in Schaffer means that
3 they would not cross any part of the same portion
4 of the lumen. Correct?

5 A. Uh-hmm. Yes.

6 Q. So why does a parallel configuration in
7 Schaffer mean that there's no circumferential
8 constriction when parallel configuration in the
9 '011 patent doesn't?

10 MR. HAMILTON: Objection, vague.

11 A. Context is really important here, as are
12 the separate teachings of Schaffer versus the
13 '011.

14 The operating principle of Schaffer is
15 distinctly different from the operating principle
16 of the '011. He is imposing significant force in
17 a system from a semicircular blade or element,
18 from either side of the tubular structure.

19 So you have side-by-side blades creating a
20 constriction, almost a pinching, if you will, so
21 you get a zigzag effect on the target tubular
22 structure versus the garrote effect of a very

1 small filament. It's a very different closure
2 mechanism or physic.

3 Q. If we look at Figure 7 of the '011 patent,
4 would that filament be circumferentially
5 constricting a lumen?

6 A. Yes. Again, this is just taking a shot of
7 it in free space. As either end is pulled, it
8 assumes the circumference of the tubular structure
9 and constricts it to a smaller diameter.

10 Q. And I believe we covered this already, but
11 Figures 8 and 9 would also be circumferentially
12 constricting the lumen. Is that correct?

13 A. Yes, we did cover that earlier.

14 Q. We've been going for a while and I think
15 lunch may be here. Would you like to take a
16 break?

17 A. Sure.

18 THE VIDEOGRAPHER: The time is 12:06. We
19 are going off the record.

20 (Lunch recess, 12:06 p.m. to 12:30 p.m.)

21

22

1 A F T E R N O O N S E S S I O N

2 THE VIDEOGRAPHER: The time is 12:30.

3 We're back on the record.

4 BY MR. BARNES:

5 Q. Welcome back, Dr. Zalesky.

6 The claims of the '011 patent require that
7 the hemostatic valve includes an actuator with a
8 first member and a second member. Correct?

9 A. Yes.

10 Q. The specification of the '011 patent
11 doesn't use the term "first member." Is that
12 correct?

13 A. I'd have to review the written
14 description.

15 Q. You did not propose a definition for the
16 term "first member" or "second member" in either
17 of the declarations that you submitted in this
18 IPR. Is that correct?

19 A. I think that's correct.

20 Q. Is it your opinion that a single actuator
21 cannot have both a first member and a second
22 member under the claims of the '011 patent?

1 MR. HAMILTON: Objection, vague, calls for
2 a legal conclusion.

3 A. In this context, yes, that's my
4 interpretation.

5 Q. So it's your opinion that the first member
6 and the second member as cited in the claims of
7 the '011 patent must be part of separate
8 actuators. Is that correct?

9 MR. HAMILTON: Objection, vague, calls for
10 a legal conclusion. The claims speak for
11 themselves.

12 A. That is my interpretation.

13 Q. I'm going to hand you what has been marked
14 as Exhibit 1005 in this IPR.

15 (Previously marked Exhibit 1005)

16 Q. Do you recognize Exhibit 1005,
17 Dr. Zalesky?

18 A. It looks a lot like the Schaffer patent.

19 Q. And the Schaffer patent is one of the
20 prior art references that you discussed in your
21 declarations. Correct?

22 A. Yes.

1 Q. And you agree that the patent examiner did
2 not consider Schaffer during the prosecution of
3 the '011 patent. Correct?

4 MR. HAMILTON: Objection. The '011 patent
5 speaks for itself.

6 A. I didn't see the entire record of the
7 patent examiner. The portions that I did review
8 did not include reference to Schaffer.

9 Q. You agree that Schaffer discloses a
10 hemostasis valve for use with catheters. Correct?

11 A. Yes.

12 Q. You don't disagree that Schaffer's
13 hemostasis valve has a lumen configured to
14 slidably receive a catheter. Correct?

15 MR. HAMILTON: Objection, calls for a
16 legal conclusion.

17 A. I don't disagree.

18 Q. And you don't disagree that Schaffer's
19 tubular member is pliable. Is that correct?

20 A. That is my understanding.

21 Q. You don't disagree that Schaffer's
22 hemostasis valve has an actuator, as that term is

1 claimed in the '011 patent. Correct?

2 MR. HAMILTON: Objection, calls for a
3 legal conclusion.

4 A. I don't know that they're identical. I
5 know they bear some resemblances. Yes.

6 Q. You're not opining that Schaffer's
7 hemostasis valve doesn't have an actuator, in your
8 supplemental declaration. Correct?

9 A. No, I am not opining that.

10 Q. You don't disagree that Schaffer's
11 actuator has a first member and a second member.
12 Correct?

13 MR. HAMILTON: Objection, calls for a
14 legal conclusion, beyond the scope of the direct
15 testimony.

16 A. I guess, to use my own terminology, it
17 appears to have opposing actuators.

18 Q. And you don't disagree that Schaffer's
19 hemostasis valve that's depicted in Figures 30
20 through 34 of Schaffer includes a biasing system
21 that's configured to bias the actuator towards the
22 closed position. Correct?

1 MR. HAMILTON: Objection, calls for legal
2 conclusion, beyond the scope of his direct
3 testimony.

4 A. It appears to do that.

5 Q. And Schaffer's biasing system includes two
6 compression springs. Correct?

7 A. Yes.

8 Q. And for the embodiment that's depicted in
9 Figures 30 through 34 of Schaffer, that embodiment
10 includes two U-shaped actuating members. Correct?

11 A. Yes.

12 Q. Would you agree that the purpose of
13 Schaffer's U-shaped actuating members is to open
14 and close the lumen of Schaffer's hemostasis
15 valve?

16 MR. HAMILTON: Objection, vague.

17 A. Yes. They impose an external force --
18 staggered external force that forces one side at a
19 time to close down on itself.

20 Q. When you say that the actuating members in
21 Schaffer force one side at a time to close down on
22 itself, what do you mean by that?

1 A. Because the elements connected to the
2 actuators are semicircular in geometry, and so
3 they impose that force over one-half,
4 approximately, or one portion of the external
5 circumference of the enclosed tube.

6 Q. And there are semicircular actuating
7 members positioned on either side of the lumen.
8 Correct?

9 A. One on each side. Yes.

10 Q. And so collectively those actuating
11 members would constrict the entirety of the
12 circumference of the lumen. Correct?

13 A. They don't circumferentially constrict the
14 lumen. They impose staggered force that crushes
15 or pinches the lumen, so a very different closure
16 than circumferential compression.

17 Q. And do you believe that the actuating
18 members in Schaffer impose a crushing force
19 because you think that they are rigid?

20 A. For them to work according to the
21 specification, they have to be rigid.

22 Q. Schaffer doesn't ever say that the

1 actuating members are rigid. Correct?

2 MR. HAMILTON: Objection, the document
3 speaks for itself.

4 A. Yeah. My recollection is he describes
5 candidate materials all of which are quite rigid.

6 Q. So it's your opinion that Schaffer's
7 U-shaped actuating members are rigid because of
8 the materials that they're made from?

9 MR. HAMILTON: Objection, mischaracterizes
10 the testimony.

11 A. In order to achieve the closure mechanism
12 that he's describing, they need inherent
13 stiffness.

14 Q. So you can't achieve Schaffer's closure
15 mechanism with flexible bights. Is that a correct
16 interpretation of your testimony?

17 A. I really have to think about that. I
18 think it's unlikely.

19 MR. HAMILTON: I'll just add to that last
20 question objection, incomplete hypothetical.

21 Q. Do you agree that Schaffer's U-shaped
22 actuating members form bights around the lumen of

1 its valve?

2 MR. HAMILTON: Objection, calls for a
3 legal conclusion.

4 A. As defined earlier, bights are loose
5 flexible structures or configurations of a
6 structure. Schaffer's elements do not have any
7 inherent flexibility nor compliance to form a
8 bight.

9 Q. So it's your opinion that Schaffer's
10 U-shaped actuating members would be completely
11 inflexible. Is that correct?

12 MR. HAMILTON: Objection.
13 Mischaracterizes the testimony.

14 A. I think I used that term in a topic we
15 covered earlier. But certainly not flexible.

16 Q. And what about the U-shaped actuating
17 members described in Schaffer makes you believe
18 that they're certainly not flexible?

19 MR. HAMILTON: Objection, asked and
20 answered.

21 A. I thought I already addressed that.

22 Q. So in your prior answer I believe you

1 said, "My recollection is he describes candidate
2 materials all of which are quite rigid."

3 So is it your opinion that Schaffer's
4 actuating members must be rigid based on the
5 description of the materials that the actuating
6 members are formed from?

7 MR. HAMILTON: Objection, mischaracterizes
8 the testimony, asked and answered.

9 A. The materials cited and the function
10 required in the specification.

11 Q. And what is the function required in the
12 specification that requires the actuating members
13 to be rigid?

14 A. Without going into, you know, the actual
15 precise sentences, he's imposing substantial
16 external force from two sides of an enclosed
17 tubular element and creating a constriction by the
18 staggered C-shaped or semicircular actuators.

19 Q. And how is that mechanism any different
20 from applying constriction with two flexible
21 bights of a string?

22 A. It's not circumferential. These actuators

1 are staggered. They're side by side. They can't
2 be directly opposed because if they would, they
3 would simply butt into each other and not impose
4 any constricting force on the tubular element, so
5 they're staggered.

6 And they operate by creating this zig
7 constriction in between or amidst the semicircular
8 actuators. Quite different from a strangulation
9 or garrote, which is indeed circumferential and
10 uniform compression around that circumference.

11 Q. Is it your opinion that a flexible string
12 could not be used to constrict a hemostasis valve
13 using two side-by-side bights placed around the
14 lumen of the valve?

15 MR. HAMILTON: Objection, vague,
16 incomplete hypothetical.

17 A. I think you're suggesting taking the
18 Schaffer configuration of both ends of an element
19 or an actuator element attached to that same
20 actuator mechanism, and now instead of pushing as
21 you would do with a rigid element, I think you're
22 asking could you do that by pulling.

1 Is that what you're asking?

2 Q. Is it your opinion that Schaffer's
3 hemostasis valve disclosed in Figures 30 through
4 34 pushes the actuator members against the lumen?

5 MR. HAMILTON: Objection, the document
6 speaks for itself.

7 A. Yes.

8 Q. So for example, if we look at Figure 32 of
9 Schaffer, it's your interpretation of this figure
10 that the actuator members are being pushed by the
11 springs against the lumen and that's what's
12 constricting the valve?

13 MR. HAMILTON: Objection. Figure 32 is
14 illegible.

15 Figure -- did you say 32?

16 A. That's my interpretation. Yes.

17 Q. How under your understanding of Schaffer,
18 how does the -- let me rephrase.

19 Under your understanding of Schaffer, how
20 is the lumen unsealed when the actuator buttons
21 are depressed?

22 MR. HAMILTON: Objection. The document

1 speaks for itself, vague.

2 A. So his written description and probably
3 claims specifically mentions forcible detachment
4 that incorporates -- that description incorporates
5 a seal member that responds to the release of the
6 actuator force.

7 Q. And I'll just hand you what has been
8 marked as Exhibit 1008 in this IPR --

9 (Previously marked Exhibit 1008)

10 Q. -- which are the figures from the
11 prosecution of Schaffer that were submitted to the
12 Patent Office.

13 Do you recognize Exhibit 1008?

14 A. I do.

15 Q. And so if we turn to Figure 32 of
16 Exhibit 1008, can you explain how Figure 32
17 illustrates the actuating members being pushed
18 against the lumen of Schaffer's valve?

19 MR. HAMILTON: Objection, mischaracterizes
20 the testimony. The document speaks for itself.

21 A. Well, you've got one actuator pushing from
22 above and one pushing from below to force the zig

1 compression that I described of the tubular
2 structure.

3 Q. Would you agree that each of those
4 U-shaped actuating members are being folded
5 against the lumen by the compressive force applied
6 by the springs attached to the actuator button?

7 MR. HAMILTON: Objection, vague.

8 A. They don't fold. They push.

9 Q. And why is that?

10 A. That's just -- that's his mechanism.
11 That's his configuration.

12 Q. Can you explain what the differences
13 between the configuration shown in Figure 32 of
14 Exhibit 1008 and the bight embodiments of the '011
15 patent are?

16 MR. HAMILTON: Objection, vague.

17 A. To me, they're dramatically different.
18 You've got a rigid -- you've got a pair of rigid
19 actuators being imposed from opposing sides of a
20 tubular structure to create that zig compression
21 of the tubular structure versus a nonrigid, very
22 flexible coacting bight or filament that

1 circumferentially first encircles and then
2 constricts in a uniform circumferential fashion
3 via a garrote or strangulation effect. So
4 dramatically different.

5 Q. And it's your opinion that Schaffer's
6 Figure 32 is pushing the actuating members against
7 the lumen whereas the valve described in the '011
8 patent is pulling the bights against the lumen.
9 Is that correct?

10 MR. HAMILTON: Hold on. Objection, vague,
11 mischaracterizes the testimony.

12 A. Not pulling. Circumferentially
13 compressing. There's a difference.

14 Q. If Schaffer's actuating members were
15 flexible, would they be circumferentially
16 constricting?

17 MR. HAMILTON: Objection, incomplete
18 hypothetical.

19 A. No. But in addition, I don't think they
20 could exert the necessary force for closure if
21 they were flexible.

22 Q. Why not?

1 A. Schaffer -- I'm waiting to see if . . .

2 MR. HAMILTON: Objection, vague.

3 A. I'm sorry. Say that question again,
4 please.

5 Q. Sure. So I asked if Schaffer's actuating
6 members were flexible, would they be
7 circumferentially constricting.

8 And you responded, "No. But in addition,
9 I don't think they could exert the necessary force
10 for closure if they were flexible."

11 And I asked, "Why not?"

12 A. When you say "flexible," depending on how
13 flexible these actuator elements were, they would
14 likely disform or deform during the application of
15 force. Since they're only semicircular elements,
16 flexible material or construction would make them
17 susceptible to being deformed with any significant
18 force.

19 Q. Wouldn't a filament that's formed in a
20 loop also be susceptible to being deformed with
21 any significant force?

22 A. No. As I said, it's a very different

1 mechanism. Now you've got a uniform concentric
2 displacement of the outside circumference of the
3 contained structure tubular element.

4 Q. What about the bight embodiments that are
5 disclosed in the '011 patent? Are those
6 semicircular elements that are flexible?

7 A. Let me just remind myself of the figure
8 you're referencing.

9 Q. It's Figures 8 and 9 of the '011 patent.

10 A. I'm getting 7 and 8.

11 Q. It's Figures 8 and 9.

12 A. And your question was, would they be
13 deformed similar to my description of the Schaffer
14 elements or be deformable?

15 Q. Well, just to take a step back, the shape
16 of the filaments in Figures 8 and 9 are
17 semicircular. Correct?

18 MR. HAMILTON: Objection, vague.

19 A. As shown, they are. Yes. They're shown
20 in space here. They're not shown containing a
21 structure and being pulled to circumferentially
22 constrict. They're shown as not having changed

1 their orientation, which is frankly misleading.

2 Q. And so the semicircular bights depicted in
3 Figures 8 and 9 of the '011 patent are flexible.

4 Correct?

5 A. Yes.

6 Q. And so forming a semicircular shape does
7 not mean that the filaments are not flexible.

8 Correct?

9 MR. HAMILTON: Objection, vague.

10 A. Not in itself. No. But again, the
11 mechanism of action here is a uniform radially
12 directed force from the outside via tensioning of
13 the bights or the filaments, quite different from
14 the imposition of an external force bearing down
15 on the external surface in the Schaffer actuators.

16 Q. And so in the '011 patent, that tensioning
17 force is being supplied by the springs of the
18 biasing system, correct, that's pulling the
19 filament in either direction?

20 MR. HAMILTON: Objection, vague.

21 A. Yes.

22 Q. And that's the exact same configuration in

1 Schaffer for the U-shaped actuating members.

2 Correct?

3 MR. HAMILTON: Objection, vague.

4 A. No, it's not.

5 Q. How is it different?

6 A. In Figure 8 you would have an actuator
7 pushing on the 702 filament from the left side
8 towards the right side. So you'd be displacing
9 with that outside force -- with a rigid outside
10 force a portion of the contained tubular element.

11 With '011, you've got opposing flexible
12 filaments that form a concentric geometry when
13 actuated.

14 Q. So if we turn back to Schaffer, if you
15 look -- if we just look at Figure 32 of
16 Exhibit 1008.

17 So you would agree with me that the
18 actuating member 55 is attached to the actuator
19 button in Schaffer's valve. Correct?

20 MR. HAMILTON: Objection, vague.

21 A. It appears to be. Yes.

22 Q. And the actuator button is connected to

1 the spring 210. Correct?

2 MR. HAMILTON: Objection, vague.

3 A. Again, it appears to be. Yes.

4 Q. And when Schaffer's actuator buttons are
5 undepressed, you'd agree that the compressive
6 forces from that spring to 10 are pulling the
7 actuator button in an outward direction. Correct?

8 MR. HAMILTON: Objection, vague.

9 A. Yeah. Releasing the button releases the
10 tension in the spring and the actuating members
11 retract.

12 Q. And when the buttons are not depressed,
13 the force from the spring moves the actuator
14 button and the actuator member towards the outward
15 direction of the hemostasis valve. Correct?

16 MR. HAMILTON: Objection, vague.

17 A. Away from the targeted tubular element.
18 Yes.

19 Q. And that force is what causes the actuator
20 members to constrict the valve. Correct?

21 A. No. That's the forcible disengagement.

22 Q. So it's your opinion that Schaffer's

1 actuating members are forcibly disengaged when the
2 actuator buttons are undepressed?

3 MR. HAMILTON: Objection, vague. The
4 document speaks for itself.

5 A. That's my understanding.

6 Q. If you'd turn to Exhibit 1005. And in
7 Paragraph 77 of Schaffer, do you see in the
8 left-hand column at the bottom of Paragraph 77
9 Schaffer states, "As each actuator button 261 is
10 depressed, each actuator 50 slides along the
11 cylindrical interior wall 11 of the housing 20.
12 The proximal end 273 of each actuator button
13 compresses the distal end 271 of each resilient
14 member 267 which in turn the proximal end 269 of
15 each resilient member 267 compresses against the
16 inner flange wall 265 of the housing 20.

17 "Such movement allows the engaged
18 actuating member 55 to forcibly disengage opposing
19 outer walls 27 of the seal module 100, allowing
20 the portion 108 of the containment structure 160
21 to retract to an uncollapsed configuration."

22 Do you see that?

1 A. Yeah. I'm just reading it again to make
2 sure I understand his precise description here.
3 This is pretty cumbersome language. I'm reading
4 what you just recited.

5 Q. And would you agree that, based on that
6 disclosure, Schaffer is teaching that the
7 actuating members are disengaged from the lumen
8 when the actuator buttons are depressed? Correct?

9 A. In this embodiment, that appears to be
10 what he's citing.

11 Q. So when the actuator buttons are
12 undepressed, the lumen is constricted by the
13 actuating members which are being pulled in
14 opposite directions by the actuator buttons.
15 Correct?

16 A. In this embodiment.

17 Q. And you would agree with me that that's
18 the same configuration that is disclosed for the
19 bight embodiments of the '011 patent. Correct?

20 MR. HAMILTON: Objection, vague,
21 incomplete.

22 A. No. I mean, as I think I said several

1 times now, the sealing or the constricting
2 mechanism or physics are significantly different.

3 Actuator buttons are utilized in each
4 case. But because of the different properties,
5 configuration and nature of the '011 filaments or
6 bights, it results in very different closure
7 mechanisms resulting. So it's apples and
8 grapefruit.

9 Q. And you believe that the configuration of
10 the '011 patent is different because the filament
11 of the '011 patent is flexible whereas you believe
12 Schaffer's actuator members are rigid. Is that
13 correct?

14 MR. HAMILTON: Objection, vague.

15 A. It's a combination of physical properties
16 and geometry. But certainly the inherent
17 flexibility of the '011 filaments is critical to
18 the circumferential noose or tightening as opposed
19 to a semicircular externally imposed force.

20 Q. And when you refer to the geometry in your
21 prior answer, what do you mean by that?

22 A. Schaffer has two semicircular actuator

1 elements that are forcibly imposed on the external
2 surface of the tubular member.

3 The '011, in either the filament or the
4 bight configuration, creates a circumferential or
5 a circumscribing of the tubular element, which the
6 Schaffer configuration because of its geometry is
7 simply incapable of doing.

8 Q. In the bight embodiments of the '011
9 patent, aren't the bights applying opposing forces
10 via semicircular filaments wrapped around the
11 lumen?

12 MR. HAMILTON: Objection, vague.

13 A. Because of the properties and the
14 compliance of the filaments or the bights, the
15 semicircular is a uniform semicircular over
16 approximately the same point and space of the
17 tubular element, as opposed to the Schaffer
18 staggered imposition of semicircular forces
19 because of the rigidity and geometry of his
20 actuator elements.

21 Q. And other than the fact that Schaffer
22 describes the U-shaped actuating members as being

1 formed from aluminum or plastic material, are
2 there any other reasons why you believe that
3 Schaffer's actuating members must be rigid?

4 MR. HAMILTON: Objection, vague.

5 A. Yeah. My understanding -- my
6 interpretation of his mechanism of action requires
7 a substantial rigidity to create the necessary
8 force to create closure of that tubular element.

9 A soft or pliable or very flexible
10 material, as I said, would likely be deformed
11 because, again, there's no force opposing.

12 So as opposed to the '011 where you have
13 basically uniform almost literally directly across
14 from each other creating a circumferential
15 compression, with Schaffer you've got one element
16 pushing a wall on one side and the wall on the
17 opposing side having no resistance whatsoever to
18 compression. So just going along for the ride, if
19 you will.

20 And then upstream or downstream a little
21 bit, the opposing Schaffer actuator is doing the
22 same thing, again with its opposing wall just

1 going along for the ride.

2 So you're creating a pinch between two
3 actuator elements. You're not creating a
4 circumferential constriction.

5 Q. Is it your opinion that in the bight
6 embodiments disclosed in the '011 patent, the
7 bights cannot be placed side by side along the
8 tubular member like they are in Schaffer?

9 MR. HAMILTON: Objection, vague.

10 A. Well, again, this depiction is a bit
11 misleading because these are in space as opposed
12 to being utilized around a tubular structure. And
13 they literally are in direct contact uniformly
14 around the circumference of the tubular structure
15 because of not only the flexibility but also the
16 very thin geometry.

17 Q. But you would agree that the bight
18 embodiments disclosed in the '011 patent can be
19 placed in a parallel configuration where the two
20 bights do not overlap one another. Correct?

21 MR. HAMILTON: Objection. Sorry.

22 Were you finished?

1 MR. BARNES: Yes.

2 MR. HAMILTON: Objection, mischaracterizes
3 the document and figures.

4 A. As I look at Figure 8 and Figure 9, they,
5 in fact, are overlapping.

6 Q. And is it your opinion that those are the
7 only embodiments that would be encompassed by the
8 '011 patent?

9 MR. HAMILTON: Objection, vague.

10 A. No. I mean, Figure 6, for instance, shows
11 a single -- not a bight but a single loop with a
12 filament, which creates the same circumferential
13 compression force for closure but in a different
14 embodiment.

15 Q. And specifically for the bight embodiment,
16 is it your opinion that the bights must overlap
17 one another according to the '011 patent?

18 A. I'd have to review his written description
19 to see if he requires that limitation.

20 Q. Well, wouldn't the bights be inoperable if
21 they didn't overlap because they're flexible?

22 MR. HAMILTON: Objection, vague.

1 A. I'd have to, like, play with that, quite
2 honestly. I think it's less optimal if they don't
3 overlap. But I wouldn't rule out that they're
4 still functional by not overlapping.

5 Q. Well, isn't it your testimony that
6 Schaffer's actuator members would not be
7 functional if they're flexible because they don't
8 overlap?

9 A. Again, totally different physics and
10 geometry.

11 Q. And that's because you believe Schaffer's
12 actuator members push against the lumen of the
13 valve rather than being pulled against the lumen
14 like the bights in the '011 patent?

15 MR. HAMILTON: I'm sorry. Was that a
16 question?

17 MR. BARNES: Yes.

18 MR. HAMILTON: Objection, vague,
19 mischaracterizes the testimony.

20 A. There's a critical difference in force
21 application here. With the bight configuration as
22 shown in Figures 8 and 9, you have uniform

1 circumferential force because of the flexibility
2 and dimensions of the filaments that compose the
3 bights.

4 With Schaffer, you have a semicircular
5 force on one side of a tubular structure and no
6 constraining opposing force on the other side
7 until you're staggered a certain length down along
8 the tubular structure, hence my comment earlier
9 about creating a zig closure as opposed to a
10 uniform circumferential closure.

11 Q. I'm trying to understand what difference
12 you believe there to be in the geometry other than
13 the flexibility of the material, because you keep
14 referring to the flexibility of the filament in
15 the '011 patent as being what causes this
16 different geometry.

17 Is there anything besides the difference
18 in flexibility of the material that makes the
19 operation of Schaffer's valve disclosed in
20 Figures 30 through 34 different than the bight
21 embodiments of the '011 patent?

22 MR. HAMILTON: Objection, vague,

1 mischaracterizes the testimony, compound.

2 A. So certainly flexibility is a critical
3 parameter to enable circumferential compression.
4 With a bight configuration -- actually, in both
5 the bight configuration and the single loop
6 configuration, you end up with a
7 circumferential -- completely circumferential
8 encirclement of that particular spot or location
9 of the tubular element.

10 And you get that because there's directly
11 across from each other a uniform circumferential
12 force resisting the other, if you will. So you
13 end up with a uniform compression force.

14 Schaffer can't do that because of the
15 nature of his actuators and their geometry, which
16 are pushing one wall, not really affecting the
17 directly opposite wall, as is done with '011.

18 Q. Is your opinion that the '011 bight
19 embodiments impose force on directly opposite
20 sides of the lumen based on the fact that the
21 bights overlap one another?

22 A. In these configurations, you know, as

1 Figures 8 and 9, they do, in fact, overlap each
2 other per your earlier reference.

3 But as I answered earlier, I wouldn't rule
4 out that them not overlapping would still not
5 effect a circumferential compression closing.

6 Q. And that's because the filament would be
7 flexible even if it's not overlapping in the
8 bight. Correct?

9 MR. HAMILTON: Objection, vague, asked and
10 answered.

11 A. Flexible and thin.

12 Q. And so if Schaffer's actuating members
13 were flexible and thin, they would apply
14 circumferential constriction to the lumen.
15 Correct?

16 A. No, I don't believe they would, because of
17 the way the force is imposed.

18 Q. What about the way that the force is
19 imposed would prevent flexible and thin actuating
20 members in Schaffer from circumferentially
21 constricting the lumen?

22 MR. HAMILTON: Objection, incomplete

1 hypothetical.

2 A. Geometrically, the only way that
3 Schaffer's actuator elements could be
4 circumferential would be if they were in direct
5 opposition to each other.

6 But if they were in direct opposition,
7 that would prevent them from effecting the
8 closure, per his mechanism. Hence, they have to
9 be staggered. By being staggered, they cannot be
10 circumferential.

11 Q. And I'm trying to square that answer with
12 your prior testimony regarding the '011 patent
13 where you testified that if the bights were
14 parallel to one another such that they didn't
15 overlap, that could still be circumferentially
16 constricting.

17 How can that be true for the '011 patent
18 but not true for Schaffer?

19 MR. HAMILTON: Objection, mischaracterizes
20 the testimony, asked and answered.

21 A. Because of the filament's physical
22 properties and dimensions.

1 Q. So the flexibility and thinness of the
2 filament?

3 A. Correct.

4 Q. And so if Schaffer's actuating members
5 were thin and flexible, they would
6 circumferentially constrict the lumen. Correct?

7 MR. HAMILTON: Objection, incomplete
8 hypothetical, asked and answered.

9 A. I think that would be inconsistent with
10 the mechanism that I understand Schaffer is
11 teaching.

12 Q. How thick do you think Schaffer's
13 actuating members need to be?

14 MR. HAMILTON: Objection, vague,
15 incomplete hypothetical.

16 A. I don't know in terms of dimension, but
17 certainly thicker than filaments.

18 Q. Does Schaffer specify anywhere the
19 thickness of the actuating members?

20 A. I don't recall.

21 Q. So why do you believe that Schaffer's
22 actuating members must be thicker than a filament?

1 A. His -- the figures in his specification
2 depict that.

3 Q. Anything other than the figures that makes
4 you believe that Schaffer's actuating members
5 cannot be as thin as a filament?

6 MR. HAMILTON: Objection, mischaracterizes
7 the testimony.

8 A. Well, certainly the figures are -- in my
9 opinion, are a very key aspect of the
10 specification. I'd have to review in detail his
11 written description.

12 But my reading of his invention is
13 teaching some significant potential mechanical
14 force from the external surface that would require
15 nonflexible properties.

16 Q. And I'm specifically focused on the
17 thickness of Schaffer's actuating members. Is
18 there anything about Schaffer's disclosure other
19 than the figures that makes you believe that
20 Schaffer's actuating members must be thicker than
21 a filament?

22 MR. HAMILTON: Objection, asked and

1 answered.

2 A. Yeah. I mean, again, the figures for
3 sure. His mechanism of action in his written
4 description, in my opinion, and his suggested
5 materials that are machineable and durable and
6 have other properties like that would require a
7 significant thickness relative to the thickness of
8 a filament.

9 Q. What is that? Can you give a ballpark on
10 what you think that thickness would be in terms of
11 millimeters?

12 MR. HAMILTON: Objection, incomplete
13 hypothetical.

14 A. Just that, you know, 10 millimeters versus
15 1 millimeter.

16 Q. Could a 10-millimeter-thick piece of
17 aluminum be flexible enough to be a filament?

18 MR. HAMILTON: Objection, incomplete
19 hypothetical.

20 A. In my experience, no.

21 Q. What about a 10-millimeter-thick piece of
22 polymer?

1 MR. HAMILTON: Objection, incomplete
2 hypothetical.

3 A. That would depend on the durometer, which
4 is a measure of hardness, of the polymer. But
5 anything softer than 70 or 80 durometer would --
6 it would deform when exposed to significant
7 external pressure. So in the action of trying to
8 compress a tubular structure, if it's soft polymer
9 it would likely deform.

10 Q. Would that be an issue for a hemostasis
11 valve?

12 MR. HAMILTON: Objection, incomplete
13 hypothetical.

14 A. As an example, in that semicircular
15 configuration of his actuator, deforming would
16 give you a different force along the arc of that
17 actuator contact with the tubular element as
18 opposed to a uniform force from the outside.

19 Q. Do the bight embodiments in the '011
20 patent deform against the tubular member when
21 tension is applied to them?

22 A. They deform only in the sense of a

1 constricting circle. So a diminishing radius,
2 diminishing circumference in uniform fashion.

3 Q. Does that apply the different force along
4 the arc of the bight that you referenced in
5 relation to Schaffer?

6 MR. HAMILTON: Objection, vague,
7 mischaracterizes the testimony.

8 A. No. Because of the physical properties
9 and dimensions of the filament components of the
10 bights.

11 Q. What physical properties and components of
12 the filaments of the bights makes them not apply
13 that different force along the arc of the bight?

14 MR. HAMILTON: Objection, asked and
15 answered.

16 A. Yeah. The flexibility and the dimension.

17 Q. Is it your understanding that Schaffer's
18 figures are drawn to scale?

19 MR. HAMILTON: Objection, vague.

20 A. I honestly didn't consider that in my
21 review.

22 Q. But your opinion regarding the thickness

1 of Schaffer's actuating members is based on how
2 they are depicted in the figures. Correct?

3 A. I look at relative -- the relativity, if
4 you will. So relative to the rest of his
5 structure is my interpretation of thickness of his
6 actuator elements.

7 Q. Is it your opinion that Schaffer's seal
8 member must be made from a sticky or gelatinous
9 substance?

10 MR. HAMILTON: Objection, mischaracterizes
11 his direct testimony.

12 A. My understanding is a gelatinous material
13 is one embodiment but not necessary.

14 Q. Would you agree that having a sticky
15 sealing member could increase the push forces
16 required to insert a tool through the hemostasis
17 valve?

18 MR. HAMILTON: Objection, vague,
19 incomplete hypothetical.

20 A. I think it's possible. I'm not sure it
21 would be significant.

22 Q. You agree that for the embodiment of

1 Schaffer's hemostasis valve disclosed in
2 Figures 30 through 34, the seal module is able to
3 retract in an unsealed configuration when the
4 actuator buttons are depressed. Correct?

5 A. Using Schaffer's language, a forcible
6 disengagement.

7 Q. So you'd agree that the seal module in the
8 embodiment in Figures 30 through 34 could not be
9 so sticky as to prevent the seal module from
10 returning to the unsealed state in the absence of
11 compressive force. Correct?

12 MR. HAMILTON: Objection, vague,
13 incomplete hypothetical.

14 A. What you just described is my
15 understanding upon the release of the actuated
16 force, the seal member would restore to its
17 original diameter.

18 Q. Is it your opinion that Schaffer's seal
19 module would be unable to retract to its unsealed
20 state if a slack string was looped around the seal
21 module?

22 MR. HAMILTON: Objection, incomplete

1 hypothetical, vague.

2 A. I honestly think that's impossible to
3 answer without experimenting. And it would depend
4 upon the material selected for that seal member.

5 I think a garrote effect of a flexible
6 filament is going to be substantially different
7 than the pinching closure effect of semicircular
8 actuating members. So very different force
9 imposition and force-release dynamics.

10 Q. Is it your opinion that the outer surface
11 of Schaffer's seal module is formed from a
12 stickier gelatinous substance?

13 MR. HAMILTON: Objection, vague.

14 A. Not necessarily.

15 Q. If the outer surface of Schaffer's seal
16 module was formed from a sticky substance, that
17 could prevent the actuating members from
18 disengaging the seal module. Correct?

19 MR. HAMILTON: Objection, vague,
20 incomplete hypothetical.

21 A. I certainly think that's a possibility.

22 Q. So you'd agree that there would be reason

1 to not form the outer surface of the seal module
2 from a sticky substance. Correct?

3 MR. HAMILTON: Objection, vague,
4 incomplete hypothetical.

5 A. I could see where in certain cases it
6 might even be preferable to enable a faster
7 restoration of the seal member's lumen.

8 Q. If we look at Schaffer Exhibit 1005, and
9 specifically, if we look at Paragraph 83,
10 Paragraph 83 discloses an example of an assembly
11 method for the hemostasis valve. Correct?

12 A. Yes.

13 Q. Is it your opinion that Schaffer's
14 hemostasis valve must be assembled using the
15 process that's described in Paragraph 83?

16 A. I'd have to think through, you know,
17 potentially different geometries. But this is the
18 configuration he's describing. And his mechanism
19 of action requires them to be opposed from each
20 other, and he requires a solid housing for their
21 placement and operation.

22 So I think the variations would be

1 minimal.

2 Q. Would it be impossible to assemble
3 Schaffer's hemostasis valve using any other
4 methods other than what's described in
5 Paragraph 83?

6 A. I'd be speculating.

7 Q. Is it your opinion that it would be
8 impossible to manufacture Schaffer's hemostasis
9 valve according to that procedure described in
10 Paragraph 83 if the U-shaped actuating members
11 were flexible?

12 MR. HAMILTON: Objection, vague, asked and
13 answered.

14 A. Again, it depends on the definition or the
15 description of the flexibility of the actuating
16 structures. If they're very malleable, very
17 flexible, I think that would interfere with the
18 way he's describing the insertion process here.

19 Q. If the actuating members were flexible
20 enough to be filaments, is it your opinion that it
21 would be impossible to assemble the valve
22 according to the procedure in Paragraph 83 of

1 Schaffer?

2 MR. HAMILTON: Objection, incomplete
3 hypothetical, vague.

4 A. I don't know. Again, I'd be speculating.
5 It's such a different configuration.

6 Q. Is it your opinion that the flexible
7 string that is disclosed in the Hartley prior art
8 reference is not durable?

9 MR. HAMILTON: Objection, vague, beyond
10 the scope of the direct testimony.

11 A. I think the keyword is what I used
12 earlier, relatively. Certainly it's less durable
13 than aluminum or stainless steel or nitinol cited
14 by Schaffer, especially with repeated use.

15 Q. What about the wire member that's
16 disclosed in the Aller prior art reference? Is it
17 your opinion that that would be less durable than
18 Schaffer's actuating members?

19 MR. HAMILTON: Objection, vague, beyond
20 the scope, incomplete hypothetical..

21 A. I think, again, relatively speaking, yes,
22 less durable than the Schaffer actuating elements.

1 And small dimension wires clearly have fatigue
2 properties. Over time, there is a decrease in
3 mechanical integrity or strength of a
4 small-dimension wire.

5 Q. Is it your opinion that a person of
6 ordinary skill in the art would never want to use
7 a small-dimension wire as part of a hemostasis
8 valve because it could be susceptible to damage
9 over time?

10 MR. HAMILTON: Objection, incomplete
11 hypothetical, mischaracterizes the testimony.

12 A. I don't think it would be necessarily
13 ruled out, but I think it would have to be tested
14 for durability via repeated cycling compared to
15 more durable alternatives.

16 Q. Are you aware of any durable string
17 materials that can be used to manufacture medical
18 devices?

19 A. So, yeah, polypropylene, polyurethane,
20 suture catgut are amazingly durable.

21 Q. Are you aware of any durable wires that
22 can be used to manufacture medical devices?

1 A. There are certain small-braid
2 constructions that are probably more durable than
3 a rolled or drawn small wire. But again, testing
4 would have to confirm that.

5 Q. And were polypropylene, polyurethane
6 sutures and catgut available prior to 2017?

7 A. Yes.

8 Q. And what about the small-braid
9 constructions for the wires that you referred to?
10 Were those available prior to 2017?

11 A. Yes.

12 Q. Is it your opinion that Schaffer's
13 U-shaped actuating members cannot be contacting
14 the outer wall of the seal member for the lumen of
15 the valve to open?

16 MR. HAMILTON: Objection, mischaracterizes
17 the testimony, vague and incomplete hypothetical.

18 A. As I visualized the release of the
19 U-shaped elements, I didn't really opine on
20 whether they were in contact or completely out of
21 contact. The underlying mechanism is the seal
22 member restoring itself.

1 Q. So if Schaffer's actuator buttons were
2 depressed three-quarters of the way, would that
3 allow the seal module to partially open?

4 MR. HAMILTON: Objection, incomplete
5 hypothetical.

6 A. I believe so.

7 Q. I'm going to hand you what has been marked
8 as Exhibit 1006 in this IPR.

9 (Previously marked Exhibit 1006)

10 MR. HAMILTON: We've been going for
11 another hour and a half. Can we take a
12 five-minute break?

13 MR. BARNES: Yeah. Can we go off the
14 record, please.

15 THE VIDEOGRAPHER: The time is 1:38.
16 We're going off the record.

17 (Recess, 1:38 p.m. to 1:42 p.m.)

18 THE VIDEOGRAPHER: The time is 1:42.
19 We're back on the record.

20 BY MR. BARNES:

21 Q. Welcome back, Dr. Zalesky. During the
22 breaks today during your deposition, did you

1 discuss the substance with anyone?

2 A. Not at all.

3 Q. Did you review any documents during any of
4 the breaks?

5 A. No.

6 Q. I'm handing you what's been marked as
7 Exhibit 1006.

8 (Previously marked Exhibit 1006)

9 Q. Do you recognize Exhibit 1006 to be a copy
10 of the Hartley prior art reference that you
11 discussed in your declaration?

12 A. It appears to be. Yes.

13 Q. You agree that Hartley discloses a
14 hemostasis valve. Correct?

15 A. Yes.

16 Q. You agree that the string disclosed in
17 Hartley is a filament even under your proposed
18 construction of that term. Correct?

19 A. I believe it can be quite similar. Yes.

20 Q. You're not opining in your supplemental
21 declaration that Hartley's string is not a
22 filament. Correct?

1 A. I don't believe I said that, did I?

2 So at this point I'm thinking no.

3 Q. Would you agree that the purpose of
4 Hartley's string is to open and close the lumen of
5 its hemostasis valve?

6 A. No, not that wording. I mean, it's a
7 hemostasis valve that opens and closes the lumen
8 of an internal tubular element.

9 Q. What is the purpose of Hartley's string?

10 A. To close via constriction an enclosed
11 circular element or structure.

12 Q. You agree that Hartley's string
13 circumferentially constricts the lumen of its
14 hemostasis valve. Correct?

15 A. So that's a really interesting question
16 that I've -- I've stared at Figure 4 over and over
17 and over, and it's hard to answer that question
18 without looking at a dynamic representation as the
19 rotary actuator is wound.

20 Because of the geometry of where the
21 string comes into the lumen, they're not opposed.
22 They end up opposed, but they're not imposed as

1 they're being withdrawn or pulled. So I don't
2 think there's a uniform circumferential
3 compression during the whole cycle of actuation.

4 Q. You didn't provide any opinions in your
5 supplemental declaration that Hartley's string
6 does not circumferentially constrict the lumen of
7 the valve. Correct?

8 A. I'd have to review my declaration. I
9 remember thinking about it. I'm not sure what I
10 recited with regard to that. I'd have to review
11 it, if you want me to.

12 Q. Sure.

13 A. It might take a while.

14 Q. I guess sitting here today, are you aware
15 of any opinions presented in your supplemental
16 declaration regarding whether Hartley's string
17 circumferentially constricts the lumen of its
18 valve?

19 A. I honestly don't recall making that point.

20 Q. You'd agree that Hartley's string forms a
21 loop around the cylindrical diaphragm of its
22 valve. Correct?

1 A. Yes.

2 Q. And would you agree that Hartley's valve
3 is sealed by constricting the string around the
4 cylindrical diaphragm when the actuator is rotated
5 around the housing?

6 A. Yes, that is his described mechanism.

7 Q. I'm going to hand you what has been marked
8 as Exhibit 1007.

9 (Previously marked Exhibit 1007)

10 Q. Do you recognize Exhibit 1007 as a copy of
11 the Eller prior art reference?

12 A. It appears to be. Yes.

13 Q. You would agree that Eller discloses a
14 hemostasis valve. Correct?

15 A. Yes.

16 Q. You would agree that Eller's wire member
17 would constitute a filament under your proposed
18 construction of that term. Correct?

19 A. That's my understanding.

20 Q. And would you agree that the purpose of
21 Eller's wire member is to constrict the lumen of
22 its hemostasis valve to form a seal?

1 A. Yes.

2 Q. You agree that the tension spring
3 disclosed in Eller is a biasing member that biases
4 its hemostasis valve to the closed position.
5 Correct?

6 MR. HAMILTON: Objection, beyond the
7 scope.

8 A. I'm well aware of his so-called detents.
9 I'm not aware of a biasing system.

10 Q. Are you aware of a tension spring that's
11 disclosed in Eller to bias the valve towards the
12 closed position?

13 A. I'm aware of a tension spring. Yes.

14 Q. And you don't disagree that that tension
15 spring constitutes a biasing system. Correct?

16 A. I think it's a definition issue when you
17 say "biasing system," especially in light of his
18 other features.

19 Q. You don't present any opinions in your
20 supplemental declaration asserting that Eller's
21 tension spring is not a biasing system. Correct?

22 A. I don't believe I spoke to that.

1 Q. You'd agree that Eller's wire member can
2 form a loop around the lumen of its hemostasis
3 valve. Correct?

4 A. So I'm hesitating on your choice of the
5 word "loop" as I look at Figure 19. It's a --
6 it's an unusual geometry circumlocution but not
7 what I would call "loop."

8 Q. And you'd agree that you don't present any
9 opinions in your supplemental declaration
10 asserting that Eller's wire member cannot form a
11 loop around the lumen of its hemostasis valve.
12 Correct?

13 A. Again, I don't think I specifically
14 address that feature.

15 Q. You'd agree that you don't present any
16 opinions in your supplemental declaration
17 asserting that Eller's wire member does not
18 circumferentially constrict the lumen of its
19 hemostasis valve. Correct?

20 MR. HAMILTON: Objection. His declaration
21 speaks for itself.

22 A. Yeah. I mean, I'm not trying to negate my

1 declaration.

2 MR. BARNES: I have no further questions
3 for you, Dr. Zalesky.

4 MR. HAMILTON: Let's do five minutes. Let
5 me think if I have anything else.

6 THE VIDEOGRAPHER: The time is 1:52.
7 We're off the record.

8 (Recess, 1:52 p.m. to 1:58 p.m.)

9 THE VIDEOGRAPHER: The time is 1:58.
10 We're back on the record.

11 MR. HAMILTON: And the patent owner has no
12 questions on redirect for this witness.

13 THE VIDEOGRAPHER: The time is 1:59. We
14 are off the record.

15 (Off the record at 1:58 p.m.)

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1 CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC

2 I, Michelle Keegan, Registered Merit
Reporter and Notary Public within and for the
3 Commonwealth of Massachusetts, do hereby certify:

That PAUL J. ZALESKY, PH.D., the witness
4 whose deposition is hereinbefore set forth, was
duly sworn by me before the commencement of such
5 deposition and that such deposition was taken
before me and is a true record of the testimony
6 given by such witness.

I further certify that the adverse party
7 was represented by counsel at the deposition.

I further certify that the deposition of
8 PAUL J. ZALESKY, PH.D. occurred at Hilton Boston
Logan Airport, One Hotel Drive, Boston,
9 Massachusetts 02128, on Monday, June 23, 2025,
commencing at 9:07 a.m. to 1:58 p.m.

10 I further certify the inspection, reading,
and signing of said deposition was waived on the
11 record by agreement of all parties.

I further certify that I am not related to
12 any of the parties to this action by blood or
marriage, I am not employed by or an attorney to
13 any of the parties in this action, and that I am
in no way interested, financially or otherwise, in
14 the outcome of this matter.

15 I declare under penalty of perjury that
the foregoing is true and correct. Executed on
16 23rd day of June, 2025.

17 My commission expires May 15, 2026.

18

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2 1888 Century Park East, Suite 1700
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3
Case: Imperative Care, Inc. v. Inari Medical Inc.

4 Date of deposition: June 23, 2025

Deponent: Paul J. Zalesky, Ph.D.

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7 and examined the foregoing pages
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10 Deposition Date: June 23, 2025

11 Page No. Line No. Change

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