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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Also Present:
Bob Giannini, Videographer

I N D E X

P R O C E E D I N G S

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

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

Will counsel introduce themselves for the record.

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

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

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

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

EXAMINATION BY COUNSEL FOR PETITIONER IMPERATIVE CARE, INC.

BY MR. BARNES:

Q. Good morning, Dr. Zalesky.

A. Good morning.

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

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

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

A. Yes.

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

A. Yes.

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Q. Can we also agree to refer to U.S. Patent Number 11,697,011 as "the '011 patent" in today's deposition?
A. Yes.
Q. Are you aware that Imperative Care has filed IPRs for several of Inari's other patents as well?
A. I know only that that has occurred. I don't have any real information, though.
Q. You've submitted expert declarations in some of the IPRs challenging some of Inari's other patents as well. Is that correct?
A. Yes.
Q. I understand that you've been deposed before. Is that right?
A. I have.
Q. Do you recall how many times you've been deposed before?
A. In the last seven or eight years, I would say probably 15. Mostly on Zoom because of conditions, as you know.
Q. So you're probably familiar with all of

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this, but just at the outset I'm just going to go over some ground rules to make sure we're on the same page and to make sure everything goes smoothly today.
Do you understand that you're under oath and you must testify truthfully, accurately, and completely, the same as if you were in court?
A. Yes.
Q. And do you understand that all of your answers need to be verbal so that the court reporter can take down a complete record of today's deposition?
A. Yes.
Q. I'd just ask that you please do your best to wait until I finish asking my question before you begin your answer and I will also do my best to wait until you complete your answer before I ask my next question. Is that fair?
A. Yes, it is.
Q. And can you please let me know if at any point today you don't understand one of my questions? And I will do my best to clarify. If

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you don't let me know that you don't understand a question, I will assume that you've understood. Is that fair?
A. Okay.
Q. And your counsel may make short objections from time to time. However, you will still need to answer my question even if he objects unless Counsel instructs you not to answer. Is that okay?
A. Right.
Q. And I'll do my best to go roughly about an hour and we'll take several breaks throughout the day. And if at any point you need a break, please just let me know and we can go off the record. The only thing I ask is that if we're in the middle of a question and answer we just finish that question before taking a break. Is that fair?
A. Okay.
Q. Is there any reason you can't provide truthful and accurate testimony today?
A. No.

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Q. You were hired as an expert witness by patent owner Inari Medical in relation to this IPR. Is that correct?
A. Yes.
Q. Who were you contacted by to work on this matter initially?
A. I can't recall her last name. She went by "Benje." And it was via a phone call she made to me to introduce herself and the potential case.
Q. Do you recall when that phone call took place?
A. I want to say approximately a year and a half ago, a little less than that, I think.
Q. Prior to that phone call, were you familiar with Inari Medical?
A. I was not.
Q. And I assume that you had never done any work for Inari in the past before this case?
A. That's correct.
Q. Outside of this IPR and the other IPRs, have you done any work with Inari since that phone call?

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

Q. Do you own any stock in Inari?

A. I do not.

Q. Are you familiar with Stryker Corporation?

A. Yes.

Q. How so?

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

Q. Have you ever done any work for Stryker?

A. I have not.

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

A. No.

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

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declarations?

A. No.

Q. Do you own any stock in Stryker?

A. No.

Q. Do you know Mr. Troy Thornton?

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

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

A. I was not. No.

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

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

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

A. I have not.

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

A. I am.

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

A. I recall seeing something, some reference

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

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

A. Yes. I think so.

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

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

A. No.

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

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

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

THE WITNESS: Understood, understood.

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MR. HAMILTON: Thank you.

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

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

Q. Were your meetings with Joe in person?

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

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

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

Q. Do you recall how long those calls were?

A. Approximately two hours each.

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

A. Not very long, quite honestly. Probably

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something like an hour and a half.
Q. Other than your declaration, did you review any other documents to prepare for your deposition?
A. I probably glanced at the '011 patent but just briefly reminding myself again of figures and legends.
Q. Did you review any of the prior art that was asserted in Imperative Care's IPR petition?
A. I had done that prior to producing my declaration.
Q. And you prepared and submitted two declarations --
A. Yes.
Q. -- in connection with this IPR. Correct?
A. Yes.
Q. And when you were referring to reviewing your declaration in your prior answer, were you referring to the first declaration you submitted or the second declaration?
A. The first.
Q. I'm going to hand you a document that has

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been marked in this IPR as Exhibit 2001.
(Previously marked Exhibit 2001)
Q. Do you recognize Exhibit 2001?
A. Yes.
Q. Exhibit 2001 is a copy of the first declaration that you submitted in this IPR. Is that correct?
A. Yes.
Q. And if we go to page 104 of Exhibit 2001, is that your signature on page 104?
A. Yes.
Q. And you signed this declaration on October 29th, 2024. Is that correct?
A. Yes.
Q. And when you signed the declaration, you declared that you believed all the statements in the declaration were true. Is that correct?
A. Yes.
Q. And was that an accurate statement when you signed the declaration?
A. Yes.
Q. Do you still believe that all the

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statements in the declaration are true?
A. I do.
Q. Are you aware of any errors in the statements in the declaration?
A. I'm not aware of any.
Q. How much time did you spend preparing Exhibit 2001?
A. It's frankly a hard thing to estimate because I would do it piecemeal, not in one sitting, of course.
Cumulatively, maybe 12, 15 hours total.
Q. Did you draft the declaration yourself?
A. I collaborated with another counsel.
Q. Do you recall who that was?
A. Matt Williams.
Q. What role did you play in drafting the declaration?
A. What role did I play or did he play?
Q. Did you play.
A. I identified what I thought were the major issues after reviewing the petition. And then we went back and forth on those various issues.

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Q. Do you recall how many drafts of the declaration you reviewed before you signed it?
A. I'm guessing two or three.
Q. And other than counsel, did you speak with anyone regarding your declaration?
A. Only my wife.
Q. And what did you and your wife discuss regarding your declaration?
A. Very, very minimal, very high level, Here is a case I'm working on as an expert.
Q. I'm now going to hand you a document that's been marked as Exhibit 2008 in this IPR.
(Previously marked Exhibit 2008)
Q. Do you recognize Exhibit 2008?
A. Yes.
Q. Is Exhibit 2008 a copy of your supplemental declaration that you submitted in this IPR?
A. I believe --
MR. HAMILTON: If you could just wait for a minute, give me a minute to review it.
Okay. You can go ahead and answer.

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A. Yes.
Q. And if you'd turn to page 122 at the end of the declaration, is that your signature on page 122?
A. Yes.
Q. And you signed your supplemental declaration on April 18th, 2025. Is that correct?
A. Seems to be so. Yes.
Q. And when you signed your supplemental declaration, you declared that you believed all of the statements in the declaration were true. Is that correct?
A. Yes.
Q. Was that an accurate statement when you signed the declaration?
A. Yes.
Q. Do you still believe all the statements in the declaration are true?
A. I do.
Q. Are you aware of any errors or misstatements in your supplemental declaration?
A. No.

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Q. Did you draft your supplemental declaration?
A. There was a significant amount of material common with the initial declaration. So drafting or composition was fairly minimal compared to the first.
Q. Do you recall roughly how long you spent in preparing your supplemental declaration?
A. Significantly less time than the first.
Q. Did you work with the same counsel to prepare your supplemental declaration as your initial declaration?
A. I did.
Q. Do you recall how many drafts of your supplemental declaration you reviewed before you signed it?
A. Probably the same, two or three.
Q. Did you speak with anyone besides counsel regarding your supplemental declaration?
A. No.
Q. Other than counsel for Inari, did you speak with anyone regarding this IPR?

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A. No.
Q. Other than counsel, have you spoken with anyone at Inari regarding this IPR?
A. No.
Q. I understand you are charging your normal hourly consulting rate for your work in this IPR. Is that right?
A. That's correct.
Q. What is your normal hourly consulting rate?
THE WITNESS: Is that pertinent?
MR. HAMILTON: You can answer.
A. $300 an hour.
Q. And you're also being reimbursed for your out-of-pocket expenses. Is that correct?
A. Yes.
Q. How many total hours have you billed to Inari for this IPR?
A. I'd have to check my records, but I would estimate somewhere in the neighborhood of 20, perhaps 25.
Q. And do you know roughly how many total

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hours you've billed to Inari for all of the IPRs in which you've submitted declarations?
A. When I give you that number, that's for all work related to the Inari case.
Q. I understand that in the last five years you have testified in both depositions and court settings. Is that correct?
A. Yes.
Q. I believe previously -- actually, let me just reask the question.
Prior to today, do you recall how many times you've testified in depositions?
A. I think I mentioned the number 15 or so.
Q. And were any of those depositions involving patent cases?
A. Actually, most. Yes.
Q. Do you recall how many of those depositions involved patent cases?
A. Probably 12 out of 15.
Q. For those patent case, what was your role in the case?
A. Expert witness.

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Q. Do you recall what technology was involved in your prior patent cases?
A. Generally related to interventional cardiovascular devices and methods of using those devices.
Q. Did any of your prior cases involve devices used to aspirate blood clots?
A. They did not.
Q. Did any of your prior cases involve hemostasis valves?
A. I'm sorry. Involve?
Q. Hemostasis valves.
A. Not specifically.
Q. Did any of your prior cases involve catheters used for interventional cardiology procedures?
A. Yes. Many.
Q. And do you recall what specifically those catheters were used for in those cases?
A. They were involved with balloon angioplasty, other interventions such as arthrectomy, stent delivery, followup stent

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procedures, and something called guide extension catheters.
Q. What is a guide extension catheter?
A. In a typical interventional cardiology procedure to treat coronary artery disease, a standard guiding catheter, which is basically just a single lumen tube, is advanced from the groin to the ostium of the coronary artery in the heart.
And then a guide extension catheter goes inside that guide catheter and is advanced into the coronary vasculature to gain access to the difficult geometry or complex lesions.
Q. And for those procedure, what size of standard guiding catheters are typically used?
A. Almost always between 6 French and 8 French.
Q. And what is the size of the guide extension catheters in those procedures?
A. Necessarily smaller, so typically 4 to 5 French.
Q. And are any hemostasis valves typically used for those procedures?

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A. Hemostasis valves are used in virtually all of those procedures. Yes.
Q. What kinds of hemostasis valves are typically used?
A. Again, almost always Tuohy Borst has been the standard for many years.
Q. Are there any other types of hemostasis valves that you recall being used for those procedures?
A. I've seen clamps. I've seen the use of suture material. Different physicians have their own different approaches to providing hemostasis depending on the equipment they're using.
Q. And when you referred to the use of suture material, what do you mean by that?
A. Simply wrapping a suture material around an object or objects.
Q. Would the suture material be wrapped around the standard guide catheter?
A. It could be. More often it would be wrapped around some juncture of a guide catheter with another device or with a needle or with an

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introducer.
Q. And then would the physician place tension on the suture material to close the juncture around the catheter tool being inserted?
A. In some of those case, yes, that was the purpose.
Q. And are you aware of any -- let me rephrase.
For those procedures that used suture material for the hemostasis valve, were any of those included in a device that was used for the hemostasis valve or were they just simply being operated by the physician pulling on the suture material?
A. The latter. Just operated by the physician.
MR. HAMILTON: Just a reminder, if you'd wait until he finishes the question. You're kind of -- it's hard for the court reporter to get that when you speak.
Q. Do you recall when you first became aware of physicians using suture material to apply

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hemostasis to the catheter?
A. It would be quite a while ago. Angioplasty took off really in the '80s, stents took off in the '90s, so probably in that time frame.
Q. Was that a common practice to use suture materials to form hemostasis?
A. No, I wouldn't call it common. The Tuohy Borst was the standard.
Q. Do you recall roughly how many times you've seen physicians use suture materials to form hemostasis valves?
MR. HAMILTON: Objection, vague.
A. Not many. So probably single digits.
Q. Do you know why the physicians would use sutures to form hemostasis valves?
MR. HAMILTON: Same objection, vague.
A. I don't think I could represent the interventional cardiologist in that. My observation was there was some seepage that wasn't being controlled well enough by the Tuohy Borst.
Q. So in your experience, did the suture

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material work better than the Tuohy Borst valves?
A. It appeared to.
Q. Do you know why that was?
A. I think it's simple mechanics of exerting an additional source of constriction.
Q. And when you say "additional source of constriction," what do you mean by that?
A. At the percutaneous entry site, you typically have a device inside of a device, a tube within a tube, sometimes a tube within a tube within another tube. And each of those annuli are capable of having back bleeds.
There are some cases where you get more than others, depending on what procedure you're doing and what size devices you're using.
Q. So how would a suture material apply an additional source of constriction compared to a Tuohy Borst valve?
A. It's essentially ligation. You're strangling what was otherwise an open space and closing it.
Q. And does a Tuohy Borst valve not apply the

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same type of closing mechanism as the suture material did?
A. It's a different mechanism. The Tuohy Borst uses a flexible silicone material but it squashes, if you will, inside of a lumen. And in the preponderance of cases, the Tuohy Borst works fine.
Q. But there were some cases in which the suture material was used because the Tuohy Borst valves were not working well enough. Is that accurate?
MR. HAMILTON: Objection, vague.
A. You know, I'm just an observer in these cases, so I can't really definitively say that's what was going on. That was my observation, but I don't know for sure. It's not something I would inquire or analyze.
Q. And so shifting gears again a little bit back to your prior testifying experience, do you recall how many times you've testified in court settings?
A. In terms of the court with a jury

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involved, really only one time. And that was a patent litigation case, patent infringement case.
I testified in front of arbitration judges several times. So those are probably the two main court testimony experiences.
Q. And for the patent infringement case that was in front of a jury, do you recall what type of technology was at issue there?
A. It was a balloon angioplasty catheter.
Q. And do you recall whether hemostasis valves were at issue in that case at all?
A. They were not.
Q. Do you recall what size of balloon angioplasty catheters were at issue in that case?
A. These were typically 7 or 8 French devices.
Q. I assume that case did not involve aspirating blood clots. Is that correct?
A. That's correct.
Q. And for the arbitrations that you've testified in, were any of those patent matters?
A. Patents were involved only tangentially.

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The case was really about contract violation.
Q. And were you acting as an expert witness in any of those cases?
A. I was.
Q. Were you testifying regarding patents in any of those cases?
A. In the arbitration cases, no.
Q. Do you recall -- let me rephrase.
Do you recall what type of technology was at issue in those arbitrations?
A. It was an area called tissue augmentation conducted by plastic surgeons.
Q. I assume that didn't involve aspirating blood clots. Is that right?
A. That's right.
Q. For any of your prior depositions that you've testified in, were any of those related to IPRs?
A. Yes. I can recall one in particular -- actually, two in particular that were IPR cases.
Q. Do you recall what the technology at issue was in those prior IPRs?

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A. One was a very sophisticated mathematical algorithm associated with cardiac arrhythmias, and the other involved the guide extension catheters that I just described.
Q. I understand that you have a Ph.D. in biomedical engineering from the University of Michigan. Is that right?
A. Yes.
Q. When did you obtain your Ph.D.?
A. In the late '70s.
Q. And I understand your Ph.D. research focused on the prediction of optimal surgical timing for the repair of congenital heart defects. Is that right?
A. Yes.
Q. Did your Ph.D. work involve designing any intravascular catheters?
A. It did not.
Q. Did you use any intravascular catheters during your Ph.D. project?
A. No.
Q. I assume your Ph.D. research did not involve aspirating blood clots. Is that right?

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A. That's correct.
Q. Your industrial career has focused on the development and commercialization of medical devices for diagnosing and treating heart disease. Is that right?
A. Yes. I've been involved in other categories, but that's been the primary experience.
Q. What types of heart disease have you focused on during your career?
A. Pretty much all, including congenital heart disease, valvular disease, coronary artery disease, and heart failure.
Q. Do you consider pulmonary embolism to be a heart disease?
A. No. Different category.
Q. Have you ever worked on developing any medical devices for treating pulmonary embolism during your career?
A. Yes, indirectly. One example is what's called intravascular ultrasound for imaging within

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a vessel, which can be used to identify and characterize things like pulmonary emboli.
Q. Did your work on the intravascular ultrasound devices involve aspirating any pulmonary emboli?
A. So some of the cases, some of the patients in fact were treated for aspirating thrombus.
Q. Were you involved in designing any of the devices used to aspirate the patient's pulmonary embolism?
MR. HAMILTON: Objection, vague.
A. I wasn't directly involved in the actual product development, but I was involved in recommendations, observations, and testing.
Q. And for those devices that were used to aspirate pulmonary embolisms, do you recall the size of catheters that were used?
A. Depending upon the anatomy involved, they could be larger for things like deep veins or the pulmonary artery, so 10 French, 9 French. For the coronaries, about half that size, typically 4 or 5 French.

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

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

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

MR. HAMILTON: Objection, vague.

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

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

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

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

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

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

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

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

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

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

A. Not that I observed. No.

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

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

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

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

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

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

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

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

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

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

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

A. You'd compress --

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

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

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

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

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

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

Q. Why was that convenient?

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

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

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

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

MR. HAMILTON: Objection, mischaracterizes the testimony.

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

Q. And do you recall when that was?

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

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

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

A. Yes.

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

A. Yes, as opposed to a vein.

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

A. Yes.

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

A. Yes.

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

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

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

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

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

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

A. None that I observed.

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

A. Yes.

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

MR. HAMILTON: Objection, vague.

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

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

MR. HAMILTON: Objection, vague.

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

Q. Why is that?

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

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

MR. HAMILTON: Objection, vague, incomplete hypothetical.

A. So not that I was aware of.

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

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

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

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

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

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

Q. Let me rephrase.

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

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

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

A. Yes.

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

MR. HAMILTON: Objection, vague.

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

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

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

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

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

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

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

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

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

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

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

Q. What types of material alternatives would you investigate with the manufacturers?

A. Almost exclusively high-density polymers.

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

A. Yes.

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

MR. HAMILTON: Objection, vague.

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

Q. Would you ever modify the hemostasis valves yourself?

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

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

A. Use more than one in series with each

Page 46

other.
Q. What would the purpose of that be?
A. It's effectively a two-stage hemostasis.
Q. Would that provide more effective sealing than using just a single hemostasis valve?
A. That was clearly the objective in that configuration on the bench to achieve that, yes.
Q. Did you ever use any devices in clinical practice that used multiple hemostasis valves placed in a series?
A. We did some limited clinical studies with modified Tuohy Borsts that we had customized because of the application.
Q. And how had you customized those Tuohy Borst valves?
A. We simply modified the geometry.
Q. And when you refer to "the geometry," are you referring to the size of the lumen for the Tuohy Borst valves?
A. Primarily the length and the outside diameter of the device.
Q. Do you recall what that diameter was,

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roughly?
A. I don't.
Q. And do you recall what type of procedure those modified Tuohy Borst valves were being used for?
A. This was doing the infusion of very high-pressure oxygenated solutions.
Q. Have you ever designed a hemostasis valve that was used with an aspiration catheter?
A. Again, I've not specifically overseen that design. We simply utilized the devices available or observed what the physician chose in the cath lab.
Q. In 1986, you were working as the director of R&D for Boston Scientific. Is that right?
A. Yes.
Q. And during your time at Boston Scientific, you supervised the development of guide catheters used to diagnose and treat cardiovascular disorders. Is that right?
A. Among others. Yes.
Q. Do you recall what cardiovascular

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disorders the catheters you worked on at Boston Scientific were used for?
A. The primary market target and the primary clinical setting was coronary artery disease.
Q. Were any of those devices you worked on at Boston Scientific used to aspirate blood clots?
A. Yes. You could use a simple standard guide catheter, having its tip placed proximal to a thrombus, and with simple syringe evacuation accomplish thrombectomy.
Q. And when you referred to a simple standard guide catheter, what size of catheter would that be?
A. These were almost always between 6 and 8 French OD.
Q. And do you recall what types of blood clots those were used to aspirate?
A. Consistent with the primary market target, thrombi in the coronary arteries that led to or would lead to acute ischemia or heart attack. But also peripherally as in peripheral arteries and also in pulmonary arteries.

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Q. And based on your prior testimony, I assume that those devices you worked on -- let me rephrase.
Based on your prior testimony, I assume that those catheter devices you worked on at Boston Scientific also involved the use of hemostasis valves. Is that right?
A. Again, the standard being Tuohy Borst.
Q. Were there any other types of hemostasis valves besides Tuohy Borst that you used while at Boston Scientific?
A. None that I recall.
Q. For those Tuohy Borst valves that you used while at Boston Scientific, would you purchase them from a supplier or would you design them and manufacture them yourself?
A. We purchased from a supplier.
Q. In 1986, you founded a company called Inter Therapy. Is that right?
A. Yes.
Q. Inter Therapy was focused on developing intravascular ultrasound for assessment of

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coronary and peripheral vascular disease. Is that right?
A. Yes.
Q. And based on your prior testimony, is it correct that that intravascular ultrasound device could be used to assess the presence of pulmonary embolism or deep vein thrombosis?
A. Yes.
Q. Was the Inter Therapy device used to aspirate any blood clots?
A. The Inter Therapy device itself, no. It was specifically an intravascular imaging device. It was used in some cases in conjunction with aspiration devices.
Q. The Inter Therapy device included a 5 French catheter that was passed through a guide catheter into the patient's vasculature. Is that correct?
A. Yes.
Q. Do you recall what the size of the guide catheter was that was used with the Inter Therapy device?

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A. Most of the procedures involved either a 7 or 8 French guide.
Q. And did the Inter Therapy device include a hemostasis valve?
A. The entire assembly of the IVIS device, as it's called, inside of a guide catheter required a Tuohy Borst.
Q. And was that Tuohy Borst valve that was used purchased from a supplier or was that something that you designed yourselves?
A. Purchased from a supplier.
Q. After Inter Therapy, you worked as a VP of R&D at Baxter International. Is that right?
A. Yes.
Q. Did you work on the development of any interventional catheters while at Baxter?
A. I worked primarily on cardiopulmonary bypass equipment and accessories but was also involved with a separate division developing angioplasty devices.
Q. What were the angioplasty devices that you worked on used for?

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A. Again, these were balloon angioplasty devices and/or related therapy devices for coronary disease and peripheral artery disease.
Q. Were any of those devices used to aspirate blood clots?
A. Baxter was not developing a thrombectomy system or device.
Q. Did the angioplasty devices you worked on include a hemostasis valve?
A. Again, necessarily. These are devices within a guide catheter and that assembly requires a hemostasis valve.
Q. Did you use Tuohy Borst valves for those devices?
A. Yes.
Q. Did you use any other types of hemostasis valves besides Tuohy Borst valves?
A. None that I recall. No.
Q. Do you recall whether those Tuohy Borst valves were purchased from a supplier or whether they were designed yourselves?
A. I wasn't directly involved in the

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acquisition, but I believe they were purchased from a supplier.
Q. After your work at Baxter, you founded a company called TherOx in 1995. Is that right?
A. Yes.
Q. TherOx was focused on developing a device for delivering oxygen supersaturated solutions to a patient's coronary artery after a heart attack. Is that right?
A. Yes.
Q. And the TherOx device included a subselective catheter that was delivered through a larger catheter. Is that right?
A. That's right.
Q. Do you recall what the size of the subselective catheter was?
A. We had a bit of variation, but it was typically 4 or 5 French.
Q. Do you recall what the size of the larger catheter that was used with the TherOx device was?
A. Again, that would have been a standard guide between the 7 and 8 French variety.

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

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

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

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

Q. Were they Tuohy Borst valves?

A. Yes.

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

A. Yes, as far as I can recall.

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

So in Paragraph 16 of your supplemental

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

A. Yes.

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

A. Yes.

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

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

Q. What was the purpose of the multihardness?

A. To enhance manipulation or steerability.

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

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on?

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

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

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

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

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

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

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

A. Yes, which is a close relative of

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multihardness.

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

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

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

A. Yes.

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

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

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

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cross-sectional geometries of lumens.

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

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

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

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

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

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

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

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

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

A. No, not that I recall.

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

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

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

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

A. Yes.

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

A. In my experience, yes.

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

A. Yes. That's my recollection.

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

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

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

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

A. No. The distal end in the patient.

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

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

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

A. Yes.

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

MR. HAMILTON: Objection vague.

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

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Q. What were the types of methodologies that you were aware of for applying suction pressure?
A. Pretty simple variations in how forcefully to withdraw -- in other words, the plunger of the syringe or other variations of handling a syringe.
Q. And you referred to a stopcock that was used in those aspiration devices. What was the purpose of the stopcock?
A. You typically had at least two different lumens distal to the stopcock so that you could segregate aspiration from infusion, infusion being used to either do a contrast imaging or perhaps pharmacologic infusion, whereas the suction lumen would collect the thrombus and keep it segregated from an infusion lumen.
Q. Were the stopcocks used to build up vacuum pressure in the syringes?
MR. HAMILTON: Objection, vague and ambiguous.
A. I recall seeing some cases where the plunger and the syringe would be pulled back with a stopcock in the closed position and then

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released, presumably -- I didn't really get involved directly in the physician's methodology, but presumably to apply an abrupt pressure change.
Q. Do you recall when you first observed that being done?
MR. HAMILTON: Objection, vague and ambiguous, calls for speculation.
A. I don't recall specifically when, but it was certainly in that time period mentioned in Paragraph 16.
Q. So in 1995 to 2005, is that the rough time period?
A. Yes.
Q. Do you recall roughly how many cases you observed that methodology being done?
A. I don't recall specifically, but I would guesstimate 10 or 15.
MR. HAMILTON: Objection, calls for speculation.
Q. Were you done with your answer?
A. Yeah. I'm guessing.
Q. Was it more than five cases?

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A. Sure. Yes.
Q. More than 10?
A. I'm guesstimating between 10 and 15.
Q. And I believe you also, in your prior answer you referred to the catheter geometry as one of the variations in thrombectomy procedures. Is that right?
A. Yes.
Q. And what did you -- let me rephrase. What types of variations in catheter geometry were developed during that time for thrombectomy procedures?
A. As we discussed a couple of minutes ago, variations in the port geometry at the distal end of the device as well as the diameter of the device.
Q. What types of variations in the diameter of the devices do you recall being developed?
A. So really simply consistent with the indication. A coronary artery thrombectomy requires a pretty small catheter. A distal venous or even a main pulmonary artery thrombectomy can

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accommodate a much larger catheter.
Q. And when you refer to much larger, what range of size would that be?
A. In general, I would say larger than 8 French going up to the teens in French sizes.
Q. Do you recall any catheters that were 20 French being used for thrombectomy procedures?
A. I have seen that size catheter used in distal veins.
Q. What's the largest catheter that you've seen being used for aspirating blood clots?
A. Probably the one I just mentioned.
Q. And that would be 20 French?
A. Yes.
Q. Do you recall when you first saw a 20 French catheter being used for aspirating a blood clot?
A. It was quite a while ago. I would say late '80s, early '90s, with a vascular surgeon colleague of mine.
Q. Would the physicians typically be the ones to select the size of the catheters that were

Page 66

being used for the procedures?
A. Always, yes.
Q. Was the size of the catheter being used for the device something that you would take into consideration during the design of the device?
A. The cases I observed were using commercially available, simple catheters, quite honestly.
Q. How would the size of the catheter being used for the device impact the choice of a hemostasis valve that you used with the device?
MR. HAMILTON: Objection, vague.
A. Yeah. That's simply diameter matching on the proximal end of the catheter.
Q. Were there any other considerations for the design of the hemostasis valve other than matching the diameter?
MR. HAMILTON: Same objection, vague.
A. Not that I was aware of.
Q. We've been going for almost an hour and a half. Would you like to take a break?
A. Sure.

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MR. BARNES: Can we go off the record, please.
THE VIDEOGRAPHER: The time is 10:28. We're off the record.
(Recess, 10:28 a.m. to 10:36 a.m.)
THE VIDEOGRAPHER: The time is 10:36. We're back on the record.
BY MR. BARNES:
Q. Welcome back, Dr. Zalesky.
From 2007 to 2009, you worked as a vice president of R&D at Volcano Corporation. Is that right?
A. Yes.
Q. While at Volcano, you supervised the development of coronary and peripheral artery catheters. Is that right?
A. Yes.
Q. What were those catheters used for?
A. These were primarily continuation of intravascular ultrasound, so internal imaging of vessels.
Q. Were any of those catheters that you were

Page 68

developing used to aspirate blood clots?
A. None that we were actually developing internally, but many of our procedures were associated with aspiration procedures.
Q. In those cases that also involved aspiration procedures, would the imaging catheter be introduced through the same guide catheter as the aspiration catheter?
A. Almost always. Yes.
Q. Would they be introduced into the patient's vasculature at the same time?
A. Quite a few variations on a theme there, depending upon which vessel, size of that vessel, and other procedures being done at the same time.
Q. Would there be situations in which both the imaging catheter and the aspiration catheter were introduced through the guide catheter at the same time?
MR. HAMILTON: Objection, vague.
A. There were some cases where you could accommodate within a guide catheter both devices simultaneously.

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Q. What types of hemostasis valves did you use with those catheters?
A. I only recall Tuohy Borst's.
Q. Do you recall if you purchased those Tuohy Borst valves from a supplier or did you design them yourself?
A. We did not design them ourselves.
Q. I understand that in 2011 you served as the interim CEO for a company called Keystone Heart Ltd. Is that right?
A. Yes. I'm smiling because it was quite an adventure.
Q. I understand that Keystone was focused on developing cerebral protection devices for use with transcatheter heart valve replacement procedures. Is that right?
A. Yes.
Q. At a general level, can you explain how the Keystone cerebral protection device worked?
A. It was basically a nitinol screen that served as a filter. It was positioned at the arch of the aorta where all three vessels that feed the

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

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

A. That's right.

Q. Do you have any experience with Inari's ClotTriever thrombectomy system?

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

Q. Do you know whether the ClotTriever system includes a hemostasis valve?

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

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

A. That's correct.

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

Page 71

the valve?

A. Not that I recall.

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

A. Not that I recall.

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

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

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

Q. What is the other part of the qualification?

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

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Q. What are those other requirements?

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

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

MR. HAMILTON: Objection, vague.

A. Yes.

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

MR. HAMILTON: Just one second.

Also, for the last question, mischaracterizes the testimony.

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

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

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hemostasis valve. Is that right?

A. I think that's fair. Yes.

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

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

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

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

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

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

MR. HAMILTON: Objection, mischaracterizes

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the testimony.
A. I wouldn't specify designing.
Q. So what type of work would a person of ordinary skill -- let me rephrase.
What type of work would someone have had to have done to qualify as a person of ordinary skill in the art with respect to those vascular devices and procedures?
MR. HAMILTON: Objection, vague and ambiguous.
A. Be involved in the development. And specifically, that could be as simple as bench testing and looking at clinical data. It could be an engineer involved in just one aspect of said catheter or device. But obviously being cognizant and learning to be aware of the requirements for human anatomy and blood interaction.
Q. But they wouldn't specifically need experience in designing the devices. Is that correct?
MR. HAMILTON: Objection, asked and answered.

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A. Yeah. I think that's correct.
Q. You would agree that providing a strong seal around a variety of instruments is an important feature for a hemostasis valve to possess. Is that right?
MR. HAMILTON: Objection, incomplete hypothetical.
A. Hemostasis is preventing blood loss. So in general, that's what a hemostasis valve is.
Q. And you would agree that providing easy one-handed operation of the hemostasis valve is an important feature for a hemostasis valve to possess. Is that right?
MR. HAMILTON: Objection, incomplete hypothetical.
A. I believe one-handed operation can be very important depending upon the particular procedure.
Q. What types of procedures would one-handed operation be important for?
A. In the case of advancing a catheter or a guidewire into complex anatomy such as the coronary vasculature or even the distal pulmonary

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vasculature, he or she needs to be able to manipulate as in steering, pushing, pulling, rotating that device with a hand. If at the same time that hand is required to hold a hemostasis valve, he or she doesn't have that ability.
Q. Would aspirating deep vein thrombosis be one of the procedures that's important to have a hemostasis valve that can be operated by a single hand?
MR. HAMILTON: Objection, incomplete hypothetical.
A. I think in general a one-handed operation of the hemostasis valve is advantageous, for the same reason I just observed.
In the case of DVT, he or she is likely to be manipulating the aspiration catheter to different locations proximal and distal to the thrombus material, as an example.
So if one hand is free to do that manipulation while the other hand is handling the hemostasis valve, that's an advantage to the time and the safety of that procedure.

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Q. Would those advantages have been something that a person of ordinary skill would have recognized prior to 2017?
A. I believe so. Yes.
Q. You believe that the design of the hemostasis valve disclosed in the '011 patent enables ease of use while maintaining an effective and strong seal under the high pressure differential caused by vacuum aspiration during aspiration thrombectomy procedures. Is that right?
MR. BARNES: Counsel --
MR. HAMILTON: You can answer.
MR. BARNES: -- while I'm fine with you making objections on the record, I'm going to ask that you refrain from the hand gestures.
MR. HAMILTON: I just want to stop the witness until he gives me a chance to answer.
MR. BARNES: I would just ask that you make your objections and, again, stop with the hand gestures.
MR. HAMILTON: Would you prefer I just

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

MR. BARNES: That would be fine.

MR. HAMILTON: I can do that.

Q. Do you need me to repeat the question?

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

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

(Previously marked Exhibit 1001)

Q. Do you recognize Exhibit 1001?

A. Yes.

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

A. Yes.

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

Okay.

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

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A. Okay.

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

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

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

A. Yes.

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

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

Q. And how does the mechanism of garrote effect very complete occlusion or closure of the valve?

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

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

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

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

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

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

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

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

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

Sorry. I put my hand up out of habit.

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

Objection, incomplete hypothetical.

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

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

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MR. HAMILTON: Objection, vague, incomplete hypothetical.
A. I don't believe a POSITA has to have specific experience with different methodologies of hemostasis. So he or she may well not know the efficacy.
Q. Could the filament that is disclosed in the '011 patent slide along the tubular member when the actuators are depressed and the slack on the filament is relaxed?
A. Would you repeat that?
Q. Sure. Could the filament that is disclosed in the '011 patent slide along the tubular member when the actuators are depressed and the slack on the filament is relaxed?
MR. HAMILTON: Objection, vague, incomplete hypothetical.
A. From my reading of the written description and the figures, I don't think that's likely.
Q. Why wouldn't that be likely?
A. The properties of the filament essentially keep it constrained.

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Q. What properties of the filament would keep it constrained?
A. Its small diameter and inherent flexibility.
Q. So when you say that "the properties of the filament essentially keep it constrained," what do you mean by "keep it constrained"?
A. Your question was could it slide, and I interpreted that to mean axially. And I'm saying I think that's unlikely based on the specification and properties of the filament.
Q. How would the filament disclosed in the '011 patent remain constrained when the actuator buttons are depressed?
A. It's going to loosen, but necessarily loosen in sort of a coaxial orientation because of the actuator's attachment.
Q. When the filament loosens in that coaxial orientation, if the valve were rotated by the operator, tipped on its side, wouldn't the filament potentially move along the tubular member?

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MR. HAMILTON: Objection, incomplete hypothetical, vague.
A. Again, I think that's unlikely. Among the main reasons for that would be the flexibility of the filament is going to relax but stay coaptive with the internal tube.
Q. So is it your opinion that the filament disclosed in the '011 patent remains coapted to the tubular member even when the actuator buttons are depressed?
A. It is my understanding it would remain in close proximity to the tubular member. Yes.
Q. Is that specified anywhere in the '011 patent?
A. I don't recall. I'd have to go read through the entire description.
Q. Would the filament disclosed in the '011 patent remain in contact with the tubular member when the actuator buttons are depressed and the tension on the filament is relaxed?
MR. HAMILTON: Objection, vague, incomplete hypothetical.

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A. I think that's most likely. It's going to be dependent on the size of the tubular member.
Q. Is it possible that portions of the filament would disengage from the tubular member when the actuator buttons are depressed?
MR. HAMILTON: Same objections.
A. I think the keyword "possible" is -- yes, it's possible. But I'm purely speculating.
MR. HAMILTON: I just want to add one more objection to that last question: calls for speculation.
Q. The '011 patent doesn't require that the filament remains in contact with the tubular member even when the actuator buttons are depressed. Correct?
A. I don't believe so.
Q. If you'd turn to Paragraph 50 of your supplemental declaration. It's on page 26. Do you see towards the middle of that Paragraph 50 the sentence that begins with, "A garrote valve"?
A. Uh-hmm.
Q. Do you see where you stated, "A garrote

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

A. Yes.

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

A. Yes.

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

MR. HAMILTON: Objection, vague, incomplete hypothetical.

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

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

MR. HAMILTON: Same objections.

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

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

A. Spread out or not concentrated.

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

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

Q. And why is that?

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

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

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

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

MR. HAMILTON: Objection, vague, incomplete hypothetical.

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

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

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

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

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

MR. HAMILTON: Objection, incomplete hypothetical.

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

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

A. That's my understanding. Yes.

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

MR. HAMILTON: Objection, incomplete hypothetical.

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

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

MR. HAMILTON: Objection, incomplete hypothetical.

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

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

MR. HAMILTON: Objection, mischaracterizes the testimony.

A. Not necessarily, but certainly optional. Yes.

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

MR. HAMILTON: Again, objection, incomplete hypothetical.

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A. No. I don't believe so.

Q. And why not?

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

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

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

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

A. Or some state in between the two extremes.

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

MR. HAMILTON: Objection, incomplete hypothetical.

A. Among other things, it would depend what

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

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

MR. HAMILTON: Objection, incomplete hypothetical.

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

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

MR. HAMILTON: Objection, vague.

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

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

MR. HAMILTON: Objection, incomplete hypothetical.

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

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

A. The amount of constrictive force.

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

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

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

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

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MR. HAMILTON: Objection, incomplete hypothetical.
A. I don't believe that's required. It could be an option.
Q. How else would the physician adjust the bias setting other than replacing the compression spring?
MR. HAMILTON: Objection, incomplete hypothetical.
A. By controlling the actuator buttons.
Q. And that would require the physician to be applying force to the actuator buttons while the tool is being inserted or manipulated through the hemostasis valve. Correct?
A. From my experience, there's a lot of feel and eye-to-hand coordination involved in these procedures. And he or she would modify the actuator force somewhat dependent on the friction or resistance he's encountering while advancing a device inside the tubular element.
Q. If you'd turn to Paragraph 72 of your supplemental declaration, which is on page 39.

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It's your opinion that the term "filament" as used in the '011 patent means a thin flexible length of material formed by one or more strands of material. Is that right?
A. Yes.
Q. You agree that the filament that's claimed by the '011 patent can be made from metal. Correct?
A. Yes.
Q. You agree that the filament can be made from stainless steel. Correct?
A. It's a qualified yes. And strands of metal can be produced that are incredibly small in diameter and therefore have significant inherent flexibility, but far from ideal.
Q. You would agree at least that the '011 patent states that the filament could be made from stainless steel. Correct?
A. That's my recollection. Yes.
Q. You'd agree that the filament can be made from nitinol. Correct?
A. Same comment about stainless steel.

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Q. You would agree that the filament could be made from aluminum. Correct?
A. Same comment. Yes.
Q. It's your opinion that a filament that's formed from a metal or polymeric material would be manufactured by rolling or drawing. Is that correct?
A. Those are the primary methodologies. There may well be others.
Q. Are you aware of any other methodologies for manufacturing a filament from metal or polymeric material?
A. I believe injection molding is one.
Q. Any others?
A. Possibly modified extrusion.
Q. Any others?
A. That's all that comes to mind.
Q. Did the process of rolling a metallic material to form a filament exist prior to 2017?
A. I believe so. Yes.
Q. That would have been something that a person of ordinary skill in the art would have

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been familiar with?
A. Not necessarily.
Q. Why not?
A. It's a relatively specialized fabrication methodology specific to metals, not used commonly with polymers. And polymers are the backbone of medical devices, especially catheters and therapeutic devices.
Q. So a person of ordinary skill in the art would not have needed to be familiar with the manufacturing processes used to make the hemostasis valve that's disclosed in the '011 patent. Is that right?
MR. HAMILTON: Objection, mischaracterizes the testimony.
A. The process you just described previously was not the manufacture of the valve. It was the production of a component, and that's what I was responding to.
Q. The '011 patent doesn't describe how the filament is manufactured. Correct?
MR. HAMILTON: Objection, the document

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speaks for itself.
A. I don't believe so.
Q. So the claims of the '011 patent aren't limited to filaments that are manufactured using any specific technique. Would that be correct?
MR. HAMILTON: Objection, calls for a legal conclusion.
A. That's my understanding.
Q. Did the process of using drawing to form a metallic filament exist prior to 2017?
A. I believe so.
Q. Would that have been something that a person of ordinary skill in the art would have been familiar with?
A. My comment is the same as to the earlier. The methodology of working with, you know, very limited, very specific production methodologies such as metal, not necessarily.
Q. What about the process of using drawing to form a polymeric filament? Did that exist prior to 2017?
A. I don't believe he or she would need to

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have experience or knowledge specific to the methodology of producing that material. But they would, because of their engineering or other technical expertise or perspective, understand the properties associated with the resulting component.
Q. Can a metallic filament be manufactured by machine?
MR. HAMILTON: Objection, vague.
A. I haven't personally observed it, but I think it's quite likely.
Q. What about a polymeric filament? Could that be manufactured by machining?
MR. HAMILTON: Again, same objection, vague.
A. Polymeric materials are typically extruded or injection molded and sometimes machined.
Q. If we turn to the '011 patent, which is Exhibit 1001, and if you turn to Figures 8 and 9, those figures illustrate the filament being formed into bights. Correct?
A. Yes.

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Q. Is the filament that's depicted in Figures 8 and 9 of the '011 patent flexible?
A. Yes.
Q. How do you know that?
A. From the written description.
Q. The written description of the '011 patent doesn't use the word "flexible." Correct?
A. You know, I honestly am not sure if that word is used in there. But the properties of the filament necessarily require flexibility.
Q. What properties of the filament illustrated in Figures 8 and 9 require flexibility?
A. In particular, the ability to circumferentially circumscribe or circumferentially impose a force.
Q. Does the filament that's illustrated in Figures 8 and 9 circumferentially circumscribe the tubular member?
A. It would in the final configuration. This is showing a -- one particular static positioning of the filament.

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Q. Could the filament depicted in Figures 8 and 9 be rigid?
A. No.
Q. Why not?
A. A rigid filament would not be able to accommodate the circular circumference of the internal tubular element.
Q. And as depicted here in Figures 8 and 9, the shape of the bights doesn't change as the filament is closed between Figures 8 and 9. Correct?
A. It doesn't show that. No.
Q. And that doesn't suggest that those filaments are rigid?
A. No. Again, as in the written description specification and the needed properties for circumferential constriction, flexibility is absolutely essential.
Q. And that includes the embodiments where the filament forms bights. Correct?
A. Yes.
Q. How flexible does a material need to be in

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order to constitute a filament, under your construction?
A. I'm laughing because the word "very" comes to mind. I don't have a quantitative answer to that.
Q. How would a person of ordinary skill in the art measure the flexibility of a material to determine whether it's a filament or not?
A. There are common methodologies. There are instruments like the Instron device, which can be used to measure the tension or the strength or the flexibility of some configuration.
Q. Would there be a minimum amount of force needed to bend a material in order for it to constitute a filament under your construction?
A. I think that's one way of assessing flexibility. I think more commonly would be its conformativeness or its adaptability to accommodate a structure that it's surrounding or encountering.
Q. How would you test whether a material has enough of an ability to conform to a structure

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that it's surrounding to constitute a filament?
A. One way to do it would be simply wrap the filament around a chosen structure, such as a tubular element or a catheter, and observe its compliance and its coaption to the external wall of the device.
Q. How compliant would the material need to be in order to constitute a filament?
A. Again, very. But I think it would be more of a visual observation of its property.
MR. HAMILTON: I just want to put in for that last question, incomplete hypothetical, objection.
Q. How would a person of ordinary skill in the art go about determining whether a given material is compliant enough to be a filament or to not be a filament?
MR. HAMILTON: Objection, incomplete hypothetical.
A. Primarily trial and error.
Q. What specific properties would the person of ordinary skill in the art be looking for in

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order to determine whether something is a filament or not?
MR. HAMILTON: Objection, asked and answered.
A. As I responded a minute ago, both its coaptability or its adaptability to a structure it's circumscribing and its coaption to the external surface of that structure.
Q. What about a paper clip? What if you bent a paper clip around a pencil? Would that constitute a filament?
MR. HAMILTON: Objection, vague.
A. In my opinion, that's in the outermost extreme of what a filament's properties would possess.
Q. But it would qualify as a filament under your construction?
MR. HAMILTON: Objection, vague, incomplete hypothetical.
A. In the sense that a paper clip comes close, but I'm not sure close enough to a flexible wire, a very low-gauge wire. I think it can

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approximate that but certainly not preferred as a filament.
Q. But it would count?
MR. HAMILTON: Objection, asked and answered, vague, incomplete hypothetical.
A. The same comment I made earlier.
Q. How thin does a material need to be to constitute a filament, under your construction?
A. I don't think there's an absolute dimensional requirement. I think it's thin enough to effect a carefully coapted circumferential constriction or compression.
And so to create the described garrote effect, quite small, but I don't know that there's an absolute maximum to that.
Q. So could a material that has a diameter of 5 millimeters be a filament?
MR. HAMILTON: Objection, incomplete hypothetical.
A. It would depend upon the material, of course. But I think that would be on the extreme large size for a filament.

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Q. What about 10 millimeters? Would that be too thick?
MR. HAMILTON: Objection, incomplete hypothetical.
A. Same answer but worse. Larger is not better.
Q. What about 20 millimeters? Would that be too thick?
MR. HAMILTON: Objection, incomplete hypothetical.
A. Again, the same comment.
Q. And so to clarify, a 20-millimeter-diameter material could qualify as a filament under your construction. Is that correct?
MR. HAMILTON: Objection, incomplete hypothetical.
A. I think the answer would be the trial and error methodology I described earlier, consistent with the properties in the specification.
Q. So you would agree with me that a thin and flexible piece of aluminum could qualify as a filament under your construction. Correct?

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MR. HAMILTON: Objection, incomplete hypothetical.
A. In theory, yes. I haven't had personal experience with metal filaments that you're describing, so it's a theoretical proposition.
Q. And let's say someone hands you a piece of aluminum and asks, "Can you tell me whether this is a filament or not under the '011 patent?" How would you go about determining that answer?
MR. HAMILTON: Objection, incomplete hypothetical.
A. I'd wrap it around a pencil or a finger and see what force is required and how well it coapted. So hence my comments earlier about trial and error.
Q. So if you were able to wrap the piece of aluminum around a pencil using your own hand, let's say, would that be flexible enough to be a filament?
MR. HAMILTON: Objection, mischaracterizes the testimony.
A. It's very qualitative, so very hard to

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answer that without looking at a very specific configuration of this aluminum whether or not it satisfies filament properties as taught by the '011.
Q. Is it correct that there's not a certain force that would be a cutoff for determining if the material is flexible enough? Is that fair to say?
A. I don't believe that '011 teaches a very specific measurement of the tensile properties, if you will. But it does describe what I would call significant flexibility and small size and consistency with the definition of "filament" that we just read a minute ago.
Q. In Paragraph 79 of your supplemental declaration, do you see in the third sentence of Paragraph 79 you stated, "If the filament of Figure 6 were completely inflexible and could not work as intended." Do you see that?
A. Yes.
Q. And what did you mean by the phrase "completely inflexible"?

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A. Stiff, rigid.
Q. Can you give an example of a completely inflexible material?
MR. HAMILTON: Objection, vague, incomplete hypothetical.
A. I think a steel I beam comes pretty close to that.
Q. How thick are steel I beams typically?
A. I honestly don't know the exact dimensions of steel I beams. I'd be guessing if I gave you a dimension.
Q. Are they less than 10 millimeters thick typically?
A. As you are aware, the I beam has different pieces or different parts of the structure. But that seems excessively thin, to me, for a steel I beam.
Q. Are there any components of intravascular medical devices that you're aware of that you would consider to be completely inflexible?
MR. HAMILTON: Objection, vague.
A. I think the metal arthrectomy

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

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

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

MR. HAMILTON: Objection, vague.

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

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

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

A. Yes.

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

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Exhibit 2009 in this IPR.

(Previously marked Exhibit 2009)

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

A. Appears to be. Yes.

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

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

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

A. Convenience.

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

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

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

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A. Certainly a well-accepted reference.

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

Did you consider any technical dictionaries?

A. I don't believe so.

Q. Why not?

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

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

A. Yes.

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

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

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

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unsealing of the central lumen 138"?

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

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

A. Yes.

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

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

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

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

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

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

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A. You want to point me to that in the written description?
Q. Sure. And I believe you quoted in Paragraph 77 of your supplemental declaration, bolded there, that the '011 patent says that "the filament 150 is loosened." Correct?
A. Yes.
Q. And so wouldn't the definition for the word "loosened" be more appropriate here than the definition for "loose"?
A. I'm not sure how to answer that. My comment earlier applies. But in this context of the patent teaching it's not nearly as confusing, if that's the right term. So in my opinion, I chose a definition that better reflected the actual properties.
Q. And how did you determine which definition better reflected the actual properties of the filament?
A. I like the words "slackened" and inclusion of the word "flexible."
Q. And why do you like that?

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A. Because of their consistency with my understanding of the '011 teaching. I guess I should say the operating basis for the '011 teaching.
Q. So is it correct that you chose the definition of the word "loose" because it referred to flexibility?
MR. HAMILTON: Objection, mischaracterizes the testimony.
A. I'm trying to keep this very brief. When I look at a patent, I look at it two different ways on two different days. One is from a high level of overall what is this, what is this invention. And then on another day, detailed written and figure description in the specification to look at the actual details of the invention.
My understanding from the first perspective of the top view is how this would actually operate because of the filament's properties. And so I tried to be consistent with that in my description of operating principle and

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operating characteristics and more specifically properties of the filament.
Q. And so I'm asking specifically about how you chose this definition for the word "loose" that you cited to in Paragraph 77.
And was part of the reason that you chose that definition because it states flexibility as part of the definition for the word "loose"?
MR. HAMILTON: Objection, vague.
A. That was part of my rationale. Not completely, but part.
Q. Is it impossible to loosen something that isn't flexible?
MR. HAMILTON: Objection, vague, incomplete hypothetical.
A. I guess you could loosen a nut from a bolt. Very different mechanisms.
Q. So just because something can be loosened doesn't mean it's necessarily flexible. Is that fair to say?
A. I think the context is critical.
Q. But referring to something as being

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loosened on its own doesn't connote flexibility necessarily. Is that fair?
A. I'll just repeat. I think the context is critical here. And as I said, you could apply "loosened" to a rigid nut and bolt, and that's a dramatically different context than a hemostasis context.
Q. In Paragraph 80 of your supplemental declaration, which is on page 43, you cite to the definition of the word "bight" that is provided in Exhibit 2009. Is that correct?
A. I'm looking for your reference to "bight."
Q. So in Paragraph 80, the second --
A. Oh, 80? I'm sorry. I thought you said 81.
Q. No worries. Yes, in Paragraph 80, in the second sentence you cite to the definition of "bight" that is provided in Exhibit 2009. Correct?
A. Yes.
Q. Did you consider any other dictionaries other than Exhibit 2009 that define the word

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"bight?
A. I recall going online. And I'm not sure what different references I looked at, but certainly more than one from different dictionaries.
Q. And why did you choose Exhibit 2009 as the dictionary that you cited to in your supplemental declaration?
A. Brevity.
Q. And what about Exhibit 2009 lent itself to brevity?
A. It wasn't the exhibit that drove that. It was my own perspective, how best to describe a bight in three or four words.
Q. And so do you agree with the definition of "bight" that is provided in Exhibit 2009?
A. Yes.
Q. In Paragraph 83 of your supplemental declaration, you cite to definitions of the word "filament" that are provided in two different dictionaries that are identified as Exhibits 2002 and 2003. Correct?

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A. Yes.
Q. I'm handing you what has been marked as Exhibit 2002 in this IPR.
(Previously marked Exhibit 2002)
Q. Exhibit 2002 is one of the dictionaries that you cite to in Paragraph 83 of your supplemental declaration. Correct?
A. It appears to be. Yes.
Q. Why did you choose this dictionary to cite in Paragraph 83 of your supplemental declaration?
A. I recall looking at multiple sources for both definitions and synonyms, frankly, for "filament" since it seems to be an important feature of this case. I thought these two definitions were as accurate as any I could find.
Q. And how did you determine that these two definitions you cited to in Exhibit 83 were accurate?
A. My understanding of the properties and physical appearance of the word as used in the context of a hemostasis valve.
Q. Did you consider any -- let me rephrase.

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Did you consider any technical dictionaries that defined the word "filament"?
A. No.
(Previously marked Exhibit 2003)
Q. I'll hand you what's been marked as Exhibit 2003 in this IPR. Is Exhibit 2003 that I just handed you a copy of the second dictionary that you cited to in Paragraph 83?
A. It appears to be. Yes.
Q. And did you also select Exhibit 2003 as one of the dictionaries to cite to because you believed it accurately defined the word "filament"?
A. Yes.
Q. The claims of the '011 patent require that the filament circumferentially constricts the lumen of the valve. Correct?
A. Yes.
Q. What does the term "circumferentially constrict" mean?
A. So two words. "Circumferential" is quite specific and defines the outer boundary of a

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structure, typically circular but not necessarily. But it defines the 360-degree perimeter of the structure circumference, circumferential being the adjective based on circumference.
"Constrict" means diminishing in lumen size or diameter.
Q. Would reducing the size of a loop around the valve's lumen circumferentially constrict the lumen?
A. Yes.
Q. Would reducing the size of an encircled area around the valve lumen circumferentially constrict the lumen?
MR. HAMILTON: Objection, vague, incomplete hypothetical.
A. I don't really understand that question. Say that again.
Q. Would reducing the size of an encircled area around the valve's lumen circumferentially constrict the lumen?
MR. HAMILTON: Same objections.
A. The questions aren't making a lot of

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

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

MR. HAMILTON: Objection, vague.

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

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

A. Yes.

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

Page 123

Paragraph 88?

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

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

A. Yes.

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

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

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

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portions of the lumen -- let me rephrase.

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

A. Yes.

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

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

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

Q. Where do they cross?

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

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

A. In this depiction, yes.

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

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

A. Uh-hmm. Yes.

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

MR. HAMILTON: Objection, vague.

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

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

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

Page 126

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

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

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

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

A. Yes, we did cover that earlier.

Q. We've been going for a while and I think lunch may be here. Would you like to take a break?

A. Sure.

THE VIDEOGRAPHER: The time is 12:06. We are going off the record.

(Lunch recess, 12:06 p.m. to 12:30 p.m.)

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AFTERNOON SESSION

THE VIDEOGRAPHER: The time is 12:30. We're back on the record.

BY MR. BARNES:

Q. Welcome back, Dr. Zalesky.

The claims of the '011 patent require that the hemostatic valve includes an actuator with a first member and a second member. Correct?

A. Yes.

Q. The specification of the '011 patent doesn't use the term "first member." Is that correct?

A. I'd have to review the written description.

Q. You did not propose a definition for the term "first member" or "second member" in either of the declarations that you submitted in this IPR. Is that correct?

A. I think that's correct.

Q. Is it your opinion that a single actuator cannot have both a first member and a second member under the claims of the '011 patent?

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MR. HAMILTON: Objection, vague, calls for a legal conclusion.

A. In this context, yes, that's my interpretation.

Q. So it's your opinion that the first member and the second member as cited in the claims of the '011 patent must be part of separate actuators. Is that correct?

MR. HAMILTON: Objection, vague, calls for a legal conclusion. The claims speak for themselves.

A. That is my interpretation.

Q. I'm going to hand you what has been marked as Exhibit 1005 in this IPR.

(Previously marked Exhibit 1005)

Q. Do you recognize Exhibit 1005, Dr. Zalesky?

A. It looks a lot like the Schaffer patent.

Q. And the Schaffer patent is one of the prior art references that you discussed in your declarations. Correct?

A. Yes.

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Q. And you agree that the patent examiner did not consider Schaffer during the prosecution of the '011 patent. Correct?

MR. HAMILTON: Objection. The '011 patent speaks for itself.

A. I didn't see the entire record of the patent examiner. The portions that I did review did not include reference to Schaffer.

Q. You agree that Schaffer discloses a hemostasis valve for use with catheters. Correct?

A. Yes.

Q. You don't disagree that Schaffer's hemostasis valve has a lumen configured to slidably receive a catheter. Correct?

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

A. I don't disagree.

Q. And you don't disagree that Schaffer's tubular member is pliable. Is that correct?

A. That is my understanding.

Q. You don't disagree that Schaffer's hemostasis valve has an actuator, as that term is

Page 130

claimed in the '011 patent. Correct?
MR. HAMILTON: Objection, calls for a legal conclusion.
A. I don't know that they're identical. I know they bear some resemblances. Yes.
Q. You're not opining that Schaffer's hemostasis valve doesn't have an actuator, in your supplemental declaration. Correct?
A. No, I am not opining that.
Q. You don't disagree that Schaffer's actuator has a first member and a second member. Correct?
MR. HAMILTON: Objection, calls for a legal conclusion, beyond the scope of the direct testimony.
A. I guess, to use my own terminology, it appears to have opposing actuators.
Q. And you don't disagree that Schaffer's hemostasis valve that's depicted in Figures 30 through 34 of Schaffer includes a biasing system that's configured to bias the actuator towards the closed position. Correct?

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MR. HAMILTON: Objection, calls for legal conclusion, beyond the scope of his direct testimony.
A. It appears to do that.
Q. And Schaffer's biasing system includes two compression springs. Correct?
A. Yes.
Q. And for the embodiment that's depicted in Figures 30 through 34 of Schaffer, that embodiment includes two U-shaped actuating members. Correct?
A. Yes.
Q. Would you agree that the purpose of Schaffer's U-shaped actuating members is to open and close the lumen of Schaffer's hemostasis valve?
MR. HAMILTON: Objection, vague.
A. Yes. They impose an external force -- staggered external force that forces one side at a time to close down on itself.
Q. When you say that the actuating members in Schaffer force one side at a time to close down on itself, what do you mean by that?

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A. Because the elements connected to the actuators are semicircular in geometry, and so they impose that force over one-half, approximately, or one portion of the external circumference of the enclosed tube.
Q. And there are semicircular actuating members positioned on either side of the lumen. Correct?
A. One on each side. Yes.
Q. And so collectively those actuating members would constrict the entirety of the circumference of the lumen. Correct?
A. They don't circumferentially constrict the lumen. They impose staggered force that crushes or pinches the lumen, so a very different closure than circumferential compression.
Q. And do you believe that the actuating members in Schaffer impose a crushing force because you think that they are rigid?
A. For them to work according to the specification, they have to be rigid.
Q. Schaffer doesn't ever say that the

Page 133

actuating members are rigid. Correct?
MR. HAMILTON: Objection, the document speaks for itself.
A. Yeah. My recollection is he describes candidate materials all of which are quite rigid.
Q. So it's your opinion that Schaffer's U-shaped actuating members are rigid because of the materials that they're made from?
MR. HAMILTON: Objection, mischaracterizes the testimony.
A. In order to achieve the closure mechanism that he's describing, they need inherent stiffness.
Q. So you can't achieve Schaffer's closure mechanism with flexible bights. Is that a correct interpretation of your testimony?
A. I really have to think about that. I think it's unlikely.
MR. HAMILTON: I'll just add to that last question objection, incomplete hypothetical.
Q. Do you agree that Schaffer's U-shaped actuating members form bights around the lumen of

Page 134

its valve?
MR. HAMILTON: Objection, calls for a legal conclusion.
A. As defined earlier, bights are loose flexible structures or configurations of a structure. Schaffer's elements do not have any inherent flexibility nor compliance to form a bight.
Q. So it's your opinion that Schaffer's U-shaped actuating members would be completely inflexible. Is that correct?
MR. HAMILTON: Objection. Mischaracterizes the testimony.
A. I think I used that term in a topic we covered earlier. But certainly not flexible.
Q. And what about the U-shaped actuating members described in Schaffer makes you believe that they're certainly not flexible?
MR. HAMILTON: Objection, asked and answered.
A. I thought I already addressed that.
Q. So in your prior answer I believe you

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said, "My recollection is he describes candidate materials all of which are quite rigid."
So is it your opinion that Schaffer's actuating members must be rigid based on the description of the materials that the actuating members are formed from?
MR. HAMILTON: Objection, mischaracterizes the testimony, asked and answered.
A. The materials cited and the function required in the specification.
Q. And what is the function required in the specification that requires the actuating members to be rigid?
A. Without going into, you know, the actual precise sentences, he's imposing substantial external force from two sides of an enclosed tubular element and creating a constriction by the staggered C-shaped or semicircular actuators.
Q. And how is that mechanism any different from applying constriction with two flexible bights of a string?
A. It's not circumferential. These actuators

Page 136

are staggered. They're side by side. They can't be directly opposed because if they would, they would simply butt into each other and not impose any constricting force on the tubular element, so they're staggered.
And they operate by creating this zig constriction in between or amidst the semicircular actuators. Quite different from a strangulation or garrote, which is indeed circumferential and uniform compression around that circumference.
Q. Is it your opinion that a flexible string could not be used to constrict a hemostasis valve using two side-by-side bights placed around the lumen of the valve?
MR. HAMILTON: Objection, vague, incomplete hypothetical.
A. I think you're suggesting taking the Schaffer configuration of both ends of an element or an actuator element attached to that same actuator mechanism, and now instead of pushing as you would do with a rigid element, I think you're asking could you do that by pulling.

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Is that what you're asking?
Q. Is it your opinion that Schaffer's hemostasis valve disclosed in Figures 30 through 34 pushes the actuator members against the lumen?
MR. HAMILTON: Objection, the document speaks for itself.
A. Yes.
Q. So for example, if we look at Figure 32 of Schaffer, it's your interpretation of this figure that the actuator members are being pushed by the springs against the lumen and that's what's constricting the valve?
MR. HAMILTON: Objection. Figure 32 is illegible.
Figure -- did you say 32?
A. That's my interpretation. Yes.
Q. How under your understanding of Schaffer, how does the -- let me rephrase.
Under your understanding of Schaffer, how is the lumen unsealed when the actuator buttons are depressed?
MR. HAMILTON: Objection. The document

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speaks for itself, vague.
A. So his written description and probably claims specifically mentions forcible detachment that incorporates -- that description incorporates a seal member that responds to the release of the actuator force.
Q. And I'll just hand you what has been marked as Exhibit 1008 in this IPR --
(Previously marked Exhibit 1008)
Q. -- which are the figures from the prosecution of Schaffer that were submitted to the Patent Office.
Do you recognize Exhibit 1008?
A. I do.
Q. And so if we turn to Figure 32 of Exhibit 1008, can you explain how Figure 32 illustrates the actuating members being pushed against the lumen of Schaffer's valve?
MR. HAMILTON: Objection, mischaracterizes the testimony. The document speaks for itself.
A. Well, you've got one actuator pushing from above and one pushing from below to force the zig

Page 139

compression that I described of the tubular structure.
Q. Would you agree that each of those U-shaped actuating members are being folded against the lumen by the compressive force applied by the springs attached to the actuator button?
MR. HAMILTON: Objection, vague.
A. They don't fold. They push.
Q. And why is that?
A. That's just -- that's his mechanism. That's his configuration.
Q. Can you explain what the differences between the configuration shown in Figure 32 of Exhibit 1008 and the bight embodiments of the '011 patent are?
MR. HAMILTON: Objection, vague.
A. To me, they're dramatically different. You've got a rigid -- you've got a pair of rigid actuators being imposed from opposing sides of a tubular structure to create that zig compression of the tubular structure versus a nonrigid, very flexible coapting bight or filament that

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circumferentially first encircles and then constricts in a uniform circumferential fashion via a garrote or strangulation effect. So dramatically different.
Q. And it's your opinion that Schaffer's Figure 32 is pushing the actuating members against the lumen whereas the valve described in the '011 patent is pulling the bights against the lumen. Is that correct?
MR. HAMILTON: Hold on. Objection, vague, mischaracterizes the testimony.
A. Not pulling. Circumferentially compressing. There's a difference.
Q. If Schaffer's actuating members were flexible, would they be circumferentially constricting?
MR. HAMILTON: Objection, incomplete hypothetical.
A. No. But in addition, I don't think they could exert the necessary force for closure if they were flexible.
Q. Why not?

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A. Schaffer -- I'm waiting to see if . . .
MR. HAMILTON: Objection, vague.
A. I'm sorry. Say that question again, please.
Q. Sure. So I asked if Schaffer's actuating members were flexible, would they be circumferentially constricting.
And you responded, "No. But in addition, I don't think they could exert the necessary force for closure if they were flexible."
And I asked, "Why not?"
A. When you say "flexible," depending on how flexible these actuator elements were, they would likely disform or deform during the application of force. Since they're only semicircular elements, flexible material or construction would make them susceptible to being deformed with any significant force.
Q. Wouldn't a filament that's formed in a loop also be susceptible to being deformed with any significant force?
A. No. As I said, it's a very different

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mechanism. Now you've got a uniform concentric displacement of the outside circumference of the contained structure tubular element.

Q. What about the bight embodiments that are disclosed in the '011 patent? Are those semicircular elements that are flexible?

A. Let me just remind myself of the figure you're referencing.

Q. It's Figures 8 and 9 of the '011 patent.

A. I'm getting 7 and 8.

Q. It's Figures 8 and 9.

A. And your question was, would they be deformed similar to my description of the Schaffer elements or be deformable?

Q. Well, just to take a step back, the shape of the filaments in Figures 8 and 9 are semicircular. Correct?

MR. HAMILTON: Objection, vague.

A. As shown, they are. Yes. They're shown in space here. They're not shown containing a structure and being pulled to circumferentially constrict. They're shown as not having changed

Page 143

their orientation, which is frankly misleading.

Q. And so the semicircular bights depicted in Figures 8 and 9 of the '011 patent are flexible. Correct?

A. Yes.

Q. And so forming a semicircular shape does not mean that the filaments are not flexible. Correct?

MR. HAMILTON: Objection, vague.

A. Not in itself. No. But again, the mechanism of action here is a uniform radially directed force from the outside via tensioning of the bights or the filaments, quite different from the imposition of an external force bearing down on the external surface in the Schaffer actuators.

Q. And so in the '011 patent, that tensioning force is being supplied by the springs of the biasing system, correct, that's pulling the filament in either direction?

MR. HAMILTON: Objection, vague.

A. Yes.

Q. And that's the exact same configuration in

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Schaffer for the U-shaped actuating members. Correct?

MR. HAMILTON: Objection, vague.

A. No, it's not.

Q. How is it different?

A. In Figure 8 you would have an actuator pushing on the 702 filament from the left side towards the right side. So you'd be displacing with that outside force -- with a rigid outside force a portion of the contained tubular element.

With '011, you've got opposing flexible filaments that form a concentric geometry when actuated.

Q. So if we turn back to Schaffer, if you look -- if we just look at Figure 32 of Exhibit 1008.

So you would agree with me that the actuating member 55 is attached to the actuator button in Schaffer's valve. Correct?

MR. HAMILTON: Objection, vague.

A. It appears to be. Yes.

Q. And the actuator button is connected to

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the spring 210. Correct?

MR. HAMILTON: Objection, vague.

A. Again, it appears to be. Yes.

Q. And when Schaffer's actuator buttons are undepressed, you'd agree that the compressive forces from that spring to 10 are pulling the actuator button in an outward direction. Correct?

MR. HAMILTON: Objection, vague.

A. Yeah. Releasing the button releases the tension in the spring and the actuating members retract.

Q. And when the buttons are not depressed, the force from the spring moves the actuator button and the actuator member towards the outward direction of the hemostasis valve. Correct?

MR. HAMILTON: Objection, vague.

A. Away from the targeted tubular element. Yes.

Q. And that force is what causes the actuator members to constrict the valve. Correct?

A. No. That's the forcible disengagement.

Q. So it's your opinion that Schaffer's

Page 146

actuating members are forcibly disengaged when the actuator buttons are undepressed?

MR. HAMILTON: Objection, vague. The document speaks for itself.

A. That's my understanding.

Q. If you'd turn to Exhibit 1005. And in Paragraph 77 of Schaffer, do you see in the left-hand column at the bottom of Paragraph 77 Schaffer states, "As each actuator button 261 is depressed, each actuator 50 slides along the cylindrical interior wall 11 of the housing 20. The proximal end 273 of each actuator button compresses the distal end 271 of each resilient member 267 which in turn the proximal end 269 of each resilient member 267 compresses against the inner flange wall 265 of the housing 20.

"Such movement allows the engaged actuating member 55 to forcibly disengage opposing outer walls 27 of the seal module 100, allowing the portion 108 of the containment structure 160 to retract to an uncollapsed configuration."

Do you see that?

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A. Yeah. I'm just reading it again to make sure I understand his precise description here. This is pretty cumbersome language. I'm reading what you just recited.

Q. And would you agree that, based on that disclosure, Schaffer is teaching that the actuating members are disengaged from the lumen when the actuator buttons are depressed? Correct?

A. In this embodiment, that appears to be what he's citing.

Q. So when the actuator buttons are undepressed, the lumen is constricted by the actuating members which are being pulled in opposite directions by the actuator buttons. Correct?

A. In this embodiment.

Q. And you would agree with me that that's the same configuration that is disclosed for the bight embodiments of the '011 patent. Correct?

MR. HAMILTON: Objection, vague, incomplete.

A. No. I mean, as I think I said several

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times now, the sealing or the constricting mechanism or physics are significantly different.

Actuator buttons are utilized in each case. But because of the different properties, configuration and nature of the '011 filaments or bights, it results in very different closure mechanisms resulting. So it's apples and grapefruit.

Q. And you believe that the configuration of the '011 patent is different because the filament of the '011 patent is flexible whereas you believe Schaffer's actuator members are rigid. Is that correct?

MR. HAMILTON: Objection, vague.

A. It's a combination of physical properties and geometry. But certainly the inherent flexibility of the '011 filaments is critical to the circumferential noose or tightening as opposed to a semicircular externally imposed force.

Q. And when you refer to the geometry in your prior answer, what do you mean by that?

A. Schaffer has two semicircular actuator

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elements that are forcibly imposed on the external surface of the tubular member.

The '011, in either the filament or the bight configuration, creates a circumferential or a circumscribing of the tubular element, which the Schaffer configuration because of its geometry is simply incapable of doing.

Q. In the bight embodiments of the '011 patent, aren't the bights applying opposing forces via semicircular filaments wrapped around the lumen?

MR. HAMILTON: Objection, vague.

A. Because of the properties and the compliance of the filaments or the bights, the semicircular is a uniform semicircular over approximately the same point and space of the tubular element, as opposed to the Schaffer staggered imposition of semicircular forces because of the rigidity and geometry of his actuator elements.

Q. And other than the fact that Schaffer describes the U-shaped actuating members as being

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formed from aluminum or plastic material, are there any other reasons why you believe that Schaffer's actuating members must be rigid?

MR. HAMILTON: Objection, vague.

A. Yeah. My understanding -- my interpretation of his mechanism of action requires a substantial rigidity to create the necessary force to create closure of that tubular element.

A soft or pliable or very flexible material, as I said, would likely be deformed because, again, there's no force opposing.

So as opposed to the '011 where you have basically uniform almost literally directly across from each other creating a circumferential compression, with Schaffer you've got one element pushing a wall on one side and the wall on the opposing side having no resistance whatsoever to compression. So just going along for the ride, if you will.

And then upstream or downstream a little bit, the opposing Schaffer actuator is doing the same thing, again with its opposing wall just

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going along for the ride.

So you're creating a pinch between two actuator elements. You're not creating a circumferential constriction.

Q. Is it your opinion that in the bight embodiments disclosed in the '011 patent, the bights cannot be placed side by side along the tubular member like they are in Schaffer?

MR. HAMILTON: Objection, vague.

A. Well, again, this depiction is a bit misleading because these are in space as opposed to being utilized around a tubular structure. And they literally are in direct contact uniformly around the circumference of the tubular structure because of not only the flexibility but also the very thin geometry.

Q. But you would agree that the bight embodiments disclosed in the '011 patent can be placed in a parallel configuration where the two bights do not overlap one another. Correct?

MR. HAMILTON: Objection. Sorry.

Were you finished?

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MR. BARNES: Yes.

MR. HAMILTON: Objection, mischaracterizes the document and figures.

A. As I look at Figure 8 and Figure 9, they, in fact, are overlapping.

Q. And is it your opinion that those are the only embodiments that would be encompassed by the '011 patent?

MR. HAMILTON: Objection, vague.

A. No. I mean, Figure 6, for instance, shows a single -- not a bight but a single loop with a filament, which creates the same circumferential compression force for closure but in a different embodiment.

Q. And specifically for the bight embodiment, is it your opinion that the bights must overlap one another according to the '011 patent?

A. I'd have to review his written description to see if he requires that limitation.

Q. Well, wouldn't the bights be inoperable if they didn't overlap because they're flexible?

MR. HAMILTON: Objection, vague.

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A. I'd have to, like, play with that, quite honestly. I think it's less optimal if they don't overlap. But I wouldn't rule out that they're still functional by not overlapping.

Q. Well, isn't it your testimony that Schaffer's actuator members would not be functional if they're flexible because they don't overlap?

A. Again, totally different physics and geometry.

Q. And that's because you believe Schaffer's actuator members push against the lumen of the valve rather than being pulled against the lumen like the bights in the '011 patent?

MR. HAMILTON: I'm sorry. Was that a question?

MR. BARNES: Yes.

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

A. There's a critical difference in force application here. With the bight configuration as shown in Figures 8 and 9, you have uniform

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circumferential force because of the flexibility and dimensions of the filaments that compose the bights.

With Schaffer, you have a semicircular force on one side of a tubular structure and no constraining opposing force on the other side until you're staggered a certain length down along the tubular structure, hence my comment earlier about creating a zig closure as opposed to a uniform circumferential closure.

Q. I'm trying to understand what difference you believe there to be in the geometry other than the flexibility of the material, because you keep referring to the flexibility of the filament in the '011 patent as being what causes this different geometry.

Is there anything besides the difference in flexibility of the material that makes the operation of Schaffer's valve disclosed in Figures 30 through 34 different than the bight embodiments of the '011 patent?

MR. HAMILTON: Objection, vague,

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mischaracterizes the testimony, compound.

A. So certainly flexibility is a critical parameter to enable circumferential compression. With a bight configuration -- actually, in both the bight configuration and the single loop configuration, you end up with a circumferential -- completely circumferential encirclement of that particular spot or location of the tubular element.

And you get that because there's directly across from each other a uniform circumferential force resisting the other, if you will. So you end up with a uniform compression force.

Schaffer can't do that because of the nature of his actuators and their geometry, which are pushing one wall, not really affecting the directly opposite wall, as is done with '011.

Q. Is your opinion that the '011 bight embodiments impose force on directly opposite sides of the lumen based on the fact that the bights overlap one another?

A. In these configurations, you know, as

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Figures 8 and 9, they do, in fact, overlap each other per your earlier reference.

But as I answered earlier, I wouldn't rule out that them not overlapping would still not effect a circumferential compression closing.

Q. And that's because the filament would be flexible even if it's not overlapping in the bight. Correct?

MR. HAMILTON: Objection, vague, asked and answered.

A. Flexible and thin.

Q. And so if Schaffer's actuating members were flexible and thin, they would apply circumferential constriction to the lumen. Correct?

A. No, I don't believe they would, because of the way the force is imposed.

Q. What about the way that the force is imposed would prevent flexible and thin actuating members in Schaffer from circumferentially constricting the lumen?

MR. HAMILTON: Objection, incomplete

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hypothetical.

A. Geometrically, the only way that Schaffer's actuator elements could be circumferential would be if they were in direct opposition to each other.

But if they were in direct opposition, that would prevent them from effecting the closure, per his mechanism. Hence, they have to be staggered. By being staggered, they cannot be circumferential.

Q. And I'm trying to square that answer with your prior testimony regarding the '011 patent where you testified that if the bights were parallel to one another such that they didn't overlap, that could still be circumferentially constricting.

How can that be true for the '011 patent but not true for Schaffer?

MR. HAMILTON: Objection, mischaracterizes the testimony, asked and answered.

A. Because of the filament's physical properties and dimensions.

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Q. So the flexibility and thinness of the filament?
A. Correct.
Q. And so if Schaffer's actuating members were thin and flexible, they would circumferentially constrict the lumen. Correct?
MR. HAMILTON: Objection, incomplete hypothetical, asked and answered.
A. I think that would be inconsistent with the mechanism that I understand Schaffer is teaching.
Q. How thick do you think Schaffer's actuating members need to be?
MR. HAMILTON: Objection, vague, incomplete hypothetical.
A. I don't know in terms of dimension, but certainly thicker than filaments.
Q. Does Schaffer specify anywhere the thickness of the actuating members?
A. I don't recall.
Q. So why do you believe that Schaffer's actuating members must be thicker than a filament?

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A. His -- the figures in his specification depict that.
Q. Anything other than the figures that makes you believe that Schaffer's actuating members cannot be as thin as a filament?
MR. HAMILTON: Objection, mischaracterizes the testimony.
A. Well, certainly the figures are -- in my opinion, are a very key aspect of the specification. I'd have to review in detail his written description.
But my reading of his invention is teaching some significant potential mechanical force from the external surface that would require nonflexible properties.
Q. And I'm specifically focused on the thickness of Schaffer's actuating members. Is there anything about Schaffer's disclosure other than the figures that makes you believe that Schaffer's actuating members must be thicker than a filament?
MR. HAMILTON: Objection, asked and answered.
A. Yeah. I mean, again, the figures for sure. His mechanism of action in his written description, in my opinion, and his suggested materials that are machineable and durable and have other properties like that would require a significant thickness relative to the thickness of a filament.
Q. What is that? Can you give a ballpark on what you think that thickness would be in terms of millimeters?
MR. HAMILTON: Objection, incomplete hypothetical.
A. Just that, you know, 10 millimeters versus 1 millimeter.
Q. Could a 10-millimeter-thick piece of aluminum be flexible enough to be a filament?
MR. HAMILTON: Objection, incomplete hypothetical.
A. In my experience, no.
Q. What about a 10-millimeter-thick piece of polymer?

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MR. HAMILTON: Objection, incomplete hypothetical.
A. That would depend on the durometer, which is a measure of hardness, of the polymer. But anything softer than 70 or 80 durometer would -- it would deform when exposed to significant external pressure. So in the action of trying to compress a tubular structure, if it's soft polymer it would likely deform.
Q. Would that be an issue for a hemostasis valve?
MR. HAMILTON: Objection, incomplete hypothetical.
A. As an example, in that semicircular configuration of his actuator, deforming would give you a different force along the arc of that actuator contact with the tubular element as opposed to a uniform force from the outside.
Q. Do the bight embodiments in the '011 patent deform against the tubular member when tension is applied to them?
A. They deform only in the sense of a

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constricting circle. So a diminishing radius, diminishing circumference in uniform fashion.

Q. Does that apply the different force along the arc of the bight that you referenced in relation to Schaffer?

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

A. No. Because of the physical properties and dimensions of the filament components of the bights.

Q. What physical properties and components of the filaments of the bights makes them not apply that different force along the arc of the bight?

MR. HAMILTON: Objection, asked and answered.

A. Yeah. The flexibility and the dimension.

Q. Is it your understanding that Schaffer's figures are drawn to scale?

MR. HAMILTON: Objection, vague.

A. I honestly didn't consider that in my review.

Q. But your opinion regarding the thickness

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of Schaffer's actuating members is based on how they are depicted in the figures. Correct?

A. I look at relative -- the relativity, if you will. So relative to the rest of his structure is my interpretation of thickness of his actuator elements.

Q. Is it your opinion that Schaffer's seal member must be made from a sticky or gelatinous substance?

MR. HAMILTON: Objection, mischaracterizes his direct testimony.

A. My understanding is a gelatinous material is one embodiment but not necessary.

Q. Would you agree that having a sticky sealing member could increase the push forces required to insert a tool through the hemostasis valve?

MR. HAMILTON: Objection, vague, incomplete hypothetical.

A. I think it's possible. I'm not sure it would be significant.

Q. You agree that for the embodiment of

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Schaffer's hemostasis valve disclosed in Figures 30 through 34, the seal module is able to retract in an unsealed configuration when the actuator buttons are depressed. Correct?

A. Using Schaffer's language, a forcible disengagement.

Q. So you'd agree that the seal module in the embodiment in Figures 30 through 34 could not be so sticky as to prevent the seal module from returning to the unsealed state in the absence of compressive force. Correct?

MR. HAMILTON: Objection, vague, incomplete hypothetical.

A. What you just described is my understanding upon the release of the actuated force, the seal member would restore to its original diameter.

Q. Is it your opinion that Schaffer's seal module would be unable to retract to its unsealed state if a slack string was looped around the seal module?

MR. HAMILTON: Objection, incomplete

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hypothetical, vague.

A. I honestly think that's impossible to answer without experimenting. And it would depend upon the material selected for that seal member.

I think a garrote effect of a flexible filament is going to be substantially different than the pinching closure effect of semicircular actuating members. So very different force imposition and force-release dynamics.

Q. Is it your opinion that the outer surface of Schaffer's seal module is formed from a stickier gelatinous substance?

MR. HAMILTON: Objection, vague.

A. Not necessarily.

Q. If the outer surface of Schaffer's seal module was formed from a sticky substance, that could prevent the actuating members from disengaging the seal module. Correct?

MR. HAMILTON: Objection, vague, incomplete hypothetical.

A. I certainly think that's a possibility.

Q. So you'd agree that there would be reason

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to not form the outer surface of the seal module from a sticky substance. Correct?

MR. HAMILTON: Objection, vague, incomplete hypothetical.

A. I could see where in certain cases it might even be preferable to enable a faster restoration of the seal member's lumen.

Q. If we look at Schaffer Exhibit 1005, and specifically, if we look at Paragraph 83, Paragraph 83 discloses an example of an assembly method for the hemostasis valve. Correct?

A. Yes.

Q. Is it your opinion that Schaffer's hemostasis valve must be assembled using the process that's described in Paragraph 83?

A. I'd have to think through, you know, potentially different geometries. But this is the configuration he's describing. And his mechanism of action requires them to be opposed from each other, and he requires a solid housing for their placement and operation.

So I think the variations would be

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minimal.

Q. Would it be impossible to assemble Schaffer's hemostasis valve using any other methods other than what's described in Paragraph 83?

A. I'd be speculating.

Q. Is it your opinion that it would be impossible to manufacture Schaffer's hemostasis valve according to that procedure described in Paragraph 83 if the U-shaped actuating members were flexible?

MR. HAMILTON: Objection, vague, asked and answered.

A. Again, it depends on the definition or the description of the flexibility of the actuating structures. If they're very malleable, very flexible, I think that would interfere with the way he's describing the insertion process here.

Q. If the actuating members were flexible enough to be filaments, is it your opinion that it would be impossible to assemble the valve according to the procedure in Paragraph 83 of Schaffer?

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MR. HAMILTON: Objection, incomplete hypothetical, vague.

A. I don't know. Again, I'd be speculating. It's such a different configuration.

Q. Is it your opinion that the flexible string that is disclosed in the Hartley prior art reference is not durable?

MR. HAMILTON: Objection, vague, beyond the scope of the direct testimony.

A. I think the keyword is what I used earlier, relatively. Certainly it's less durable than aluminum or stainless steel or nitinol cited by Schaffer, especially with repeated use.

Q. What about the wire member that's disclosed in the Aller prior art reference? Is it your opinion that that would be less durable than Schaffer's actuating members?

MR. HAMILTON: Objection, vague, beyond the scope, incomplete hypothetical..

A. I think, again, relatively speaking, yes, less durable than the Schaffer actuating elements.

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And small dimension wires clearly have fatigue properties. Over time, there is a decrease in mechanical integrity or strength of a small-dimension wire.

Q. Is it your opinion that a person of ordinary skill in the art would never want to use a small-dimension wire as part of a hemostasis valve because it could be susceptible to damage over time?

MR. HAMILTON: Objection, incomplete hypothetical, mischaracterizes the testimony.

A. I don't think it would be necessarily ruled out, but I think it would have to be tested for durability via repeated cycling compared to more durable alternatives.

Q. Are you aware of any durable string materials that can be used to manufacture medical devices?

A. So, yeah, polypropylene, polyurethane, suture catgut are amazingly durable.

Q. Are you aware of any durable wires that can be used to manufacture medical devices?

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A. There are certain small-braid constructions that are probably more durable than a rolled or drawn small wire. But again, testing would have to confirm that.

Q. And were polypropylene, polyurethane sutures and catgut available prior to 2017?

A. Yes.

Q. And what about the small-braid constructions for the wires that you referred to? Were those available prior to 2017?

A. Yes.

Q. Is it your opinion that Schaffer's U-shaped actuating members cannot be contacting the outer wall of the seal member for the lumen of the valve to open?

MR. HAMILTON: Objection, mischaracterizes the testimony, vague and incomplete hypothetical.

A. As I visualized the release of the U-shaped elements, I didn't really opine on whether they were in contact or completely out of contact. The underlying mechanism is the seal member restoring itself.

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Q. So if Schaffer's actuator buttons were depressed three-quarters of the way, would that allow the seal module to partially open?

MR. HAMILTON: Objection, incomplete hypothetical.

A. I believe so.

Q. I'm going to hand you what has been marked as Exhibit 1006 in this IPR.

(Previously marked Exhibit 1006)

MR. HAMILTON: We've been going for another hour and a half. Can we take a five-minute break?

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

THE VIDEOGRAPHER: The time is 1:38. We're going off the record.

(Recess, 1:38 p.m. to 1:42 p.m.)

THE VIDEOGRAPHER: The time is 1:42. We're back on the record.

BY MR. BARNES:

Q. Welcome back, Dr. Zalesky. During the breaks today during your deposition, did you discuss the substance with anyone?

A. Not at all.

Q. Did you review any documents during any of the breaks?

A. No.

Q. I'm handing you what's been marked as Exhibit 1006.

(Previously marked Exhibit 1006)

Q. Do you recognize Exhibit 1006 to be a copy of the Hartley prior art reference that you discussed in your declaration?

A. It appears to be. Yes.

Q. You agree that Hartley discloses a hemostasis valve. Correct?

A. Yes.

Q. You agree that the string disclosed in Hartley is a filament even under your proposed construction of that term. Correct?

A. I believe it can be quite similar. Yes.

Q. You're not opining in your supplemental declaration that Hartley's string is not a filament. Correct?

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A. I don't believe I said that, did I?

So at this point I'm thinking no.

Q. Would you agree that the purpose of Hartley's string is to open and close the lumen of its hemostasis valve?

A. No, not that wording. I mean, it's a hemostasis valve that opens and closes the lumen of an internal tubular element.

Q. What is the purpose of Hartley's string?

A. To close via constriction an enclosed circular element or structure.

Q. You agree that Hartley's string circumferentially constricts the lumen of its hemostasis valve. Correct?

A. So that's a really interesting question that I've -- I've stared at Figure 4 over and over and over, and it's hard to answer that question without looking at a dynamic representation as the rotary actuator is wound.

Because of the geometry of where the string comes into the lumen, they're not opposed. They end up opposed, but they're not imposed as

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they're being withdrawn or pulled. So I don't think there's a uniform circumferential compression during the whole cycle of actuation.

Q. You didn't provide any opinions in your supplemental declaration that Hartley's string does not circumferentially constrict the lumen of the valve. Correct?

A. I'd have to review my declaration. I remember thinking about it. I'm not sure what I recited with regard to that. I'd have to review it, if you want me to.

Q. Sure.

A. It might take a while.

Q. I guess sitting here today, are you aware of any opinions presented in your supplemental declaration regarding whether Hartley's string circumferentially constricts the lumen of its valve?

A. I honestly don't recall making that point.

Q. You'd agree that Hartley's string forms a loop around the cylindrical diaphragm of its valve. Correct?

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A. Yes.

Q. And would you agree that Hartley's valve is sealed by constricting the string around the cylindrical diaphragm when the actuator is rotated around the housing?

A. Yes, that is his described mechanism.

Q. I'm going to hand you what has been marked as Exhibit 1007.

(Previously marked Exhibit 1007)

Q. Do you recognize Exhibit 1007 as a copy of the Eller prior art reference?

A. It appears to be. Yes.

Q. You would agree that Eller discloses a hemostasis valve. Correct?

A. Yes.

Q. You would agree that Eller's wire member would constitute a filament under your proposed construction of that term. Correct?

A. That's my understanding.

Q. And would you agree that the purpose of Eller's wire member is to constrict the lumen of its hemostasis valve to form a seal?

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A. Yes.

Q. You agree that the tension spring disclosed in Eller is a biasing member that biases its hemostasis valve to the closed position. Correct?

MR. HAMILTON: Objection, beyond the scope.

A. I'm well aware of his so-called detents. I'm not aware of a biasing system.

Q. Are you aware of a tension spring that's disclosed in Eller to bias the valve towards the closed position?

A. I'm aware of a tension spring. Yes.

Q. And you don't disagree that that tension spring constitutes a biasing system. Correct?

A. I think it's a definition issue when you say "biasing system," especially in light of his other features.

Q. You don't present any opinions in your supplemental declaration asserting that Eller's tension spring is not a biasing system. Correct?

A. I don't believe I spoke to that.

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Q. You'd agree that Eller's wire member can form a loop around the lumen of its hemostasis valve. Correct?

A. So I'm hesitating on your choice of the word "loop" as I look at Figure 19. It's a -- it's an unusual geometry circumlocution but not what I would call "loop."

Q. And you'd agree that you don't present any opinions in your supplemental declaration asserting that Eller's wire member cannot form a loop around the lumen of its hemostasis valve. Correct?

A. Again, I don't think I specifically address that feature.

Q. You'd agree that you don't present any opinions in your supplemental declaration asserting that Eller's wire member does not circumferentially constrict the lumen of its hemostasis valve. Correct?

MR. HAMILTON: Objection. His declaration speaks for itself.

A. Yeah. I mean, I'm not trying to negate my

declaration.

MR. BARNES: I have no further questions for you, Dr. Zalesky.

MR. HAMILTON: Let's do five minutes. Let me think if I have anything else.

THE VIDEOGRAPHER: The time is 1:52. We're off the record.

(Recess, 1:52 p.m. to 1:58 p.m.)

THE VIDEOGRAPHER: The time is 1:58. We're back on the record.

MR. HAMILTON: And the patent owner has no questions on redirect for this witness.

THE VIDEOGRAPHER: The time is 1:59. We are off the record.

(Off the record at 1:58 p.m.)

CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC

I, Michelle Keegan, Registered Merit Reporter and Notary Public within and for the Commonwealth of Massachusetts, do hereby certify:

That PAUL J. ZALESKY, PH.D., the witness whose deposition is hereinbefore set forth, was duly sworn by me before the commencement of such deposition and that such deposition was taken before me and is a true record of the testimony given by such witness.

I further certify that the adverse party was represented by counsel at the deposition.

I further certify that the deposition of PAUL J. ZALESKY, PH.D. occurred at Hilton Boston Logan Airport, One Hotel Drive, Boston, Massachusetts 02128, on Monday, June 23, 2025, commencing at 9:07 a.m. to 1:58 p.m.

I further certify the inspection, reading, and signing of said deposition was waived on the record by agreement of all parties.

I further certify that I am not related to any of the parties to this action by blood or marriage, I am not employed by or an attorney to any of the parties in this action, and that I am in no way interested, financially or otherwise, in the outcome of this matter.

I declare under penalty of perjury that the foregoing is true and correct. Executed on 23rd day of June, 2025.

My commission expires May 15, 2026.

NOTARY PUBLIC IN AND FOR THE COMMONWEALTH OF MASSACHUSETTS

Paul J. Zalesky, Ph.D., c/o
PERKINS COIE LLP
1888 Century Park East, Suite 1700
Los Angeles, California 90067-1721

Case: Imperative Care, Inc. v. Inari Medical Inc.
Date of deposition: June 23, 2025
Deponent: Paul J. Zalesky, Ph.D.

Please be advised that the transcript in the above referenced matter is now complete and ready for signature. The deponent may come to this office to sign the transcript, a copy may be purchased for the witness to review and sign, or the deponent and/or counsel may waive the option of signing. Please advise us of the option selected. Please forward the errata sheet and the original signed signature page to counsel noticing the deposition, noting the applicable time period allowed for such by the governing Rules of Procedure. If you have any questions, please do not hesitate to call our office at (202)-232-0646.

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Deposition Date: June 23, 2025

I do hereby acknowledge that I have read and examined the foregoing pages of the transcript of my deposition and that:

(Check appropriate box):
( ) The same is a true, correct and complete transcription of the answers given by me to the questions therein recorded.
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