UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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IMPERATIVE CARE, INC.,

Petitioner

vs.

INARI MEDICAL, INC.,

Patent Owner

****

Case No. IRP2025-00289

U.S. Patent No. 11,554,005

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VIDEOTAPED DEPOSITION of PAUL ZALESKY, Ph.D.

Friday, November 7, 2025
9:01 a.m.

Held at: Hilton Boston Airport
One Hotel Drive
Boston, Massachusetts

------- Megan M. Castro, RPR, Court Reporter -------

Imperative Care v. Inari Medical
IPR2026-00169
Imperative Care Ex. 1018

APPEARANCES:

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ALSO PRESENT:

Bob Giannini, videographer

I N D E X

Witness Page
PAUL ZALESKY, Ph.D.
Examination by Attorney Barnes 5, 137
Examination by Attorney Miller 129

E X H I B I T S

No exhibits were marked.

P R O C E E D I N G S

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THE VIDEOGRAPHER: Good morning. We are on the record.

This is the videographer speaking, Bob Giannini. I am with court reporter Megan Castro with Digital Evidence Group. Today's date is November 7, 2025, and the time is 9:01 a.m.

We are currently at the Hilton Boston Logan Airport which is located in Boston, Massachusetts, to take the video deposition of Paul Zalesky in the matter of Imperative Care, Inc., versus Inari Medical, Inc.

Will counsel please introduce themselves for the record.

ATTORNEY BARNES: This is Brian Barnes of Knobbe Martens on behalf of the petitioner, Imperative Care.

ATTORNEY MILLER: James Miller of Perkins Coie on behalf of Inari Medical.

THE VIDEOGRAPHER: Thank you.

Will the court reporter please swear in the witness.

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PAUL ZALESKY, PH.D., first having been satisfactorily identified by the production of his driver's license and duly sworn by the Notary Public, testified under oath as follows in answer to examination by ATTORNEY BARNES.

- - -

Q. Good morning, Dr. Zalesky.

A. Good morning.

Q. Welcome back.

A. Thanks.

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

A. Paul John Zalesky, 124 Gilbert Stuart Drive, East Greenwich, Rhode Island.

Q. You are been retained to serve as an expert witness on behalf of the patent owner, Inari Medical, in this inter partes review proceeding. Is that correct?

A. Yes.

Q. And you understand today's deposition concerns an IPR filed by Imperative Care relating to U.S. Patent Number 11,554,005?

A. Yes.

Q. Can we agree to refer to the patent at issue today as the '005 patent for shorthand?
A. Sure.
Q. And similarly, for inter partes review, if I refer to them as an "IPR," will you understand what I am talking about?
A. Yes.
Q. And I understand you have been previously deposed in two prior IPRs that were filed by Imperative Care that relate to today's IPR. Is that correct?
A. Yes.
Q. I believe your most recent deposition in a related IPR was in August of this year. Does that sound right?
A. In L.A., yes.
Q. After that August deposition, did you have a chance to review the transcript from that deposition?
A. I did very briefly.
Q. I understand that you prepared an errata sheet that identified certain errors transcript of that deposition. Is that correct?

ATTORNEY MILLER: Objection. Scope.
A. Yes.
BY ATTORNEY BARNES:
Q. Other than the errors that you identified in that errata sheet, are you aware of any other errors in your testimony from your prior deposition?
ATTORNEY MILLER: Objection. Scope.
A. None that I recall, no.
BY ATTORNEY BARNES:
Q. Do you stand by your testimony in your prior depositions related to the IPRs filed by Imperative Care?
ATTORNEY MILLER: Objection. Scope.
A. I believe so, yes.
BY ATTORNEY BARNES:
Q. Since that August deposition, have you been deposed in any other cases?
A. Yes. One other case.
Q. Was that a patent case?
A. Yes.
Q. Was that an IPR or a district court case. Do you know?
A. It is a complex case that included an

IPR and a district case.
Q. Do you know whether your deposition related to the IPR specifically?
A. It encompassed the IPR.
Q. Do you recall when that deposition was?
A. I do. It is kind of a date to forget. September 11.
Q. What type of technology is at issue in that case?
A. It was a cardiovascular device.
Q. What type of cardiovascular device?
A. Something called a guide extension catheter, which is effectively a small version of a guide catheter used in interventional procedures.
Q. Are the guide extension catheters at issue in that case used in any blood clot aspiration procedures?
ATTORNEY MILLER: Objection. Scope.
A. Not that I am aware.
BY ATTORNEY BARNES:
Q. Does that case involves hemostasis valves at all?
A. Sorry. Involve what?

Q. Hemostasis valves?
ATTORNEY MILLER: Objection.
A. Yes, a Tuohy-Borst valve is traditionally used in almost all of these procedures.
Q. Since your August deposition, have you given testimony at any trial or court hearing?
A. No.
Q. And I know that we personally have gone through lot of these instructions before. But I think it is always helpful to have a refresher and to have it on the record. So we will just go over the ground rules for today to make sure everything goes smoothly.
So do you understand that you are under oath just as if you were in court, and you are obligated to testify truthfully?
A. Yes.
Q. Do you understand that all of your answers need to be verbal so that the court reporter can take down an accurate record of today's deposition?
A. Yes.
Q. Just like last time, I ask that you do

your best to wait until I finish a question before you start your answer. And I, of course, will do my best to wait until you finish your answer to ask my next question. Is that fair?

A. Yes.

Q. And, again, like last time, please let me know if you don't understand one of my questions. If you do not tell me that you don't understand, I will assume that you have understood the question. Is that fair?

A. Yes.

Q. Your counsel may make short objections from time to time during today's deposition. But if -- however, you will need to answer my question unless your counsel specifically instructs you not to. Do you understand?

A. I understand.

Q. And like our last deposition, I will try to go roughly an hour and we will take several breaks throughout the day. If at any point you need a break, please let me know and I can go off the record. The only thing I ask is that, if we are in the middle of an answer

to a question, we finish that question and answer before we take a break. Is that fair?

A. Yes.

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

A. No.

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

A. No.

Q. Since your August deposition, have you performed any work for Inari, other than work that is related to the IPRs that are been filed by Imperative Care?

ATTORNEY MILLER: Objection. Scope.

A. No.

BY ATTORNEY BARNES:

Q. Have you acquired any stock in Inari since your last deposition?

A. No.

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

A. No.

Q. Have you spoken to anyone at Inari

about any of the IPRs that have been filed by Imperative Care?

A. No.

Q. Has your billing rate changed for your work on these IPRs, changed since your last --

ATTORNEY BARNES: Let me rephrase the question.

BY ATTORNEY BARNES:

Q. Has your billing rate for your work on these IPRs changed since your August deposition?

A. No.

Q. Do you know how many total hours that you have billed Inari for this specific IPR involving the '005 patent?

ATTORNEY MILLER: Objection. Scope.

A. I would estimate less than 20.

BY ATTORNEY BARNES:

Q. Do you know how many total hours you have billed Inari for all of the IPRs that have been filed by Imperative Care?

ATTORNEY MILLER: Objection. Scope.

A. Likely 40 and change total hours.

BY ATTORNEY BARNES:

Q. Since your August deposition, have you perform any work for Inari related to the district court litigation involving Inari and Imperative Care?

ATTORNEY MILLER: Objection. Scope.

A. No.

BY ATTORNEY BARNES:

Q. Other than your work on these IPRs, have you performed any work for Stryker since your August deposition?

ATTORNEY MILLER: Objection. Scope. And to the extent it requires confidential information.

You are not required to disclose the client's information, but if you can talk about it generally, that is fine.

A. No.

BY ATTORNEY BARNES:

Q. Have you acquired any stock in Stryker since your last deposition?

A. No.

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 IPRs that have been filed by Imperative Care?

A. No.

Q. In your August deposition, you testified that you had not had the opportunity to physically inspect Inari's ClotTriever or FlowTriever device. Do you recall that?

ATTORNEY MILLER: Objection. Scope.

A. I do recall that.

BY ATTORNEY BARNES:

Q. Have you had the opportunity to physically inspect either the ClotTriever or the FlowTriever devices since your August deposition?

ATTORNEY MILLER: Objection. Scope.

A. No.

BY ATTORNEY BARNES:

Q. Have you virtually inspected either the ClotTriever or the FlowTriever devices since your August deposition?

ATTORNEY MILLER: Objection. Scope.

A. Very briefly via websites for either.

BY ATTORNEY BARNES:

Q. Do you recall when that was?
A. Probably six months ago.
Q. So that was before your August deposition. Is that right?
A. Yes.
Q. Have you virtually inspected either the ClotTriever or FlowTriever device again since that initial visit to the website?
ATTORNEY MILLER: Objection. Scope.
A. No.
BY ATTORNEY BARNES:
Q. Have you physically inspected any of Imperative Care's products since your August deposition?
ATTORNEY MILLER: Objection. Scope.
A. No.
BY ATTORNEY BARNES:
Q. Have you virtually inspected any of Imperative Care's products since your last deposition?
ATTORNEY MILLER: Objection. Scope.
A. No.
BY ATTORNEY BARNES:
Q. Did you do anything to prepare for

today's deposition?
A. I did a brief review of my supplemental response.
Q. Did you meet with anyone to prepare for today's deposition?
A. I meet with counsel for approximately -- very brief time, an hour and a half.
Q. And when you refer to counsel, are you referring to Mr. Miller?
A. Yes.
Q. Was that meeting in person?
A. Yes.
Q. Where did that meeting take place?
A. An interesting restaurant known as Sonsie here in Boston.
Q. Did you just have the one meeting with Mr. Miller to prepare for today's deposition?
A. Yes, we had breakfast, but that was just eating.
Q. In total, how long did you spend preparing for today's deposition?
A. Probably four or five hours.
Q. Did you review any documents as part of

your preparation for today's deposition, other than your supplemental declaration?

ATTORNEY MILLER: Objection to the extent it calls for privileged information.

To the extent you answer with a yes or no, that is fine.

A. I briefly reviewed a few figures from some of the relevant prior art patents.

BY ATTORNEY BARNES:

Q. Do you recall which prior art patents you reviewed?

ATTORNEY MILLER: Objection to the extent it called for privileged information.

To the extent you can answer without revealing conversations with counsel, you can.

A. Schaffer and Hartley.

BY ATTORNEY BARNES:

Q. Did you review the Garrison prior art reference in preparation for today's deposition?

ATTORNEY MILLER: Same objection.

A. No.

BY ATTORNEY BARNES:

Q. Did you review the Eller prior art

reference in preparation for today's deposition?

ATTORNEY MILLER: Same objection.

A. No.

BY ATTORNEY BARNES:

Q. Other than your supplemental declaration and the two prior art references you reviewed, did you review any other documents to prepare for today's deposition?

ATTORNEY MILLER: Objection to the extent it calls for privileged information.

A. No.

BY ATTORNEY BARNES:

Q. You have prepared two declarations for the '005 patent IPR. Is that correct?

A. I believe so. I have lost track over documents and supplements, but I believe so.

Q. Understood. That is fair.

I am going to hand you a document that has been marked as Exhibit 2001 in this IPR.

(Handing document to the witness.)

BY ATTORNEY BARNES:

Q. Dr. Zalesky, do you recognize Exhibit 2001?

A. Yes.
Q. What is Exhibit 2001?
A. It is my declaration regarding the Imperative versus Inari case.
Q. And this is your declaration regarding the '005 patent. Correct?
A. Yes.
Q. If you could turn to page 132 at the end of or towards the end of Exhibit 2001.
Is that your signature on page 132?
A. Yes.
Q. Did you sign Exhibit 2001 on March 31, 2025?
A. I did.
Q. Do you recall where you signed this document at?
A. My home office in Rhode Island.
Q. And when you signed this declaration, you declared that you believed all of the statements in the declaration were true. Was that an accurate statement when you signed the declaration?
A. Yes.
Q. Do you still believe all of the

statements in the declaration are true?
A. Yes.
Q. Are you aware of any errors or misstatements in Exhibit 2001?
A. I don't think so.
Q. Did you personally draft Exhibit 2001?
A. It was a collaborative effort with patent counsel.
Q. Do you recall who that counsel was?
A. Joe Hamilton and Matt, whose last name is escaping me, from the Seattle office.
Q. Is it Matt Williams?
A. Yes, Matt Williams.
Q. What role did you play in the drafting process of Exhibit 2001?
ATTORNEY MILLER: Objection to the extent it calls for communications, drafts, or anything between counsel and yourself. To extent you can answer without revealing any of that, you can.
A. Outline, composition of certain specific segments, and then back-and-forth with red-lines.
BY ATTORNEY BARNES:

Q. Do you recall which specific sections of Exhibit 2001 that you composed?

ATTORNEY MILLER: Objection to the extent the question calls for privileged information.

I instruct you not to answer.

A. So no.

BY ATTORNEY BARNES:

Q. To clarify, are you refusing to answer my question based on your counsel's instruction or do you not recall which portions of the declaration you personally drafted?

A. I am following a counsel objection.

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

ATTORNEY MILLER: Objection to the extent it calls for communications or drafts between counsel and yourself.

A. Several. Probably four or five.

BY ATTORNEY BARNES:

Q. Do you recall how much time you spent drafting Exhibit 2001 before you signed it?

ATTORNEY MILLER: Objection. Vague.

A. This goes back several months to the

early part of this year. So I am guesstimating 15 to 20 hours.

BY ATTORNEY BARNES:

Q. Other than Mr. Hamilton and Mr. Williams, did you work with anyone else in the preparation of Exhibit 2001?

ATTORNEY MILLER: Objection to the extent it calls for communications with counsel.

To the extent you can answer without revealing those.

A. No.

BY ATTORNEY BARNES:

Q. Other than Mr. Hamilton and Mr. Williams, did you speak to anyone about Exhibit 2001?

ATTORNEY MILLER: Same objection.

A. No.

BY ATTORNEY BARNES:

Q. I am now going to hand you what has been marked as Exhibit 2026 in this IPR.

(Handing document to the witness.)

Q. Do you recognize Exhibit 2026?

A. Yes.

Q. What is Exhibit 2026?
A. It is my supplemental declaration regarding the IPR case on the '005 patent.
Q. If we turn to page 144 at the end of Exhibit 2006. Is that your signature on page 144?
A. Yes.
Q. Did you sign your supplemental declaration on September 9, 2025?
A. Yes.
Q. Do you recall where you were when you signed Exhibit 2026?
A. The same home office in East Greenwich, Rhode Island.
Q. When you signed Exhibit 2026, you declared that you believed all of the statements in the declaration were true. Was that an accurate statement when you signed the declaration?
A. Yes.
Q. Do you still believe all of the statements in 2026 are true?
A. Yes.
Q. Are you aware of any errors or

1 misstatements in Exhibit 2026?
2 A. No.
3 Q. Had your opinions regarding any of the
4 issues in this IPR changed between your first
5 declaration, Exhibit 2001, and your
6 supplemental declaration, Exhibit 2026?
7 ATTORNEY MILLER: Objection. Vague.
8 A. No.
9 BY ATTORNEY BARNES:
10 Q. Why did you prepare a supplemental
11 declaration for this IPR?
12 ATTORNEY MILLER: Objection to the
13 extent it calls for privileged communications.
14 To the extent you can answer without
15 revealing conversations with counsel, you may.
16 A. Requested by counsel.
17 BY ATTORNEY BARNES:
18 Q. Did you not fully set forth your
19 opinions regarding this IPR in your first
20 declaration?
21 ATTORNEY MILLER: Objection. Vague.
22 A. I think there is only minor additions.
23 BY ATTORNEY BARNES:
24 Q. Did you develop any new opinions about

this IPR after signing your first declaration?
ATTORNEY MILLER: Objection. Asked and answered. Vague.
A. No.
BY ATTORNEY BARNES:
Q. Did you personally draft Exhibit 2026?
A. Again, a collaboration with patent counsel.
Q. Was that counsel Mr. Hamilton and Mr. Williams?
A. Yes.
Q. Anyone else?
A. No.
Q. Did you draft any specific portions of Exhibit 2026?
ATTORNEY MILLER: Objection.
To the extent it calls for a communications or drafts between counsel and yourself, I instruct you not to answer.
A. I will follow counsel advice.
BY ATTORNEY BARNES:
Q. Do you recall how many drafts of Exhibit 2026 you reviewed before you signed it?
ATTORNEY MILLER: Objection to the

extent it calls for communications or drafts between counsel.

To the extent you can answer without revealing that.

A. Only two or three.

BY ATTORNEY BARNES:

Q. Do you recall roughly how much time you spent preparing Exhibit 2026 before you signed it?

A. I guesstimate 15 hours or so.

Q. Other than Mr. Williams --

ATTORNEY BARNES: Or let me rephrase.

BY ATTORNEY BARNES:

Q. Other than legal counsel, did you discuss Exhibit 2026 with anyone?

A. No.

Q. Are all of the opinions that you have regarding this IPR set forth in your supplemental declaration?

ATTORNEY MILLER: Objection. Vague.

A. I think all of my relevant opinions are, yes.

BY ATTORNEY BARNES:

Q. Does your supplemental declaration

supersede your first declaration?
ATTORNEY MILLER: Objection. Vague.
A. In my opinion, it largely confirm.
BY ATTORNEY BARNES:
Q. Can you turn to paragraph 5 of your supplemental declaration, which is on page 2. Bottom of page 2.
A. I am there.
Q. In paragraph 5, you state, "My analysis of the materials produced in this matter are ongoing and I will continue any new material as it is provided. This declaration represents only those opinions I have formed to date. I reserve the right to revise, supplement, and/or amend my opinions stated herein based on new information and on my continuing analysis of the materials already provided."
Did I read that correctly?
A. Yes.
Q. Have you reviewed any materials since signing your supplemental declaration that have impacted any of your opinions?
ATTORNEY MILLER: Objection. Vague.
A. No.

BY ATTORNEY BARNES:

Q. Have any of your opinions that you set forth in your supplemental declaration changed since you signed it?

A. No.

Q. If you look higher up on page 2, and this will be at the end of paragraph 2 of your supplemental declaration, you stated, "I have been asked by counsel for Inari Medical, Inc., ('Inari' or 'patent owner') to opine on the patentability of the claims of the '005 patent and, in particular, the patentability of independent claims 1 and 10 with respect to grounds 1 through 4."

Did I read that correctly?

A. Yes.

Q. Why did you focus your opinions on independent claims 1 and 10?

ATTORNEY MILLER: Objection to the extent it called for privileges information.

To the extent you can answer without revealing that information, you may proceed.

A. Primarily because of the importance of independent claims.

BY ATTORNEY BARNES:

Q. You do you present any opinions specific to any of the dependent claims of the '005 patent in your supplemental declaration. Correct?

ATTORNEY MILLER: Objection. Vague.

A. I would have to look through it. I don't think so, but I would have to look through it.

BY ATTORNEY BARNES:

Q. Can you turn to paragraph 65 of your supplemental declaration, which is on page 35.

A. I am there.

Q. In paragraph 65 of your supplemental declaration, you state, "Petitioner has cited three different references, Schaffer, Hartley, and Eller, in its petition challenging the patentability of the claims of the '005 patent."

Did I read that correctly?

A. Yes.

Q. Why did you reference a petition challenging the '012 patent in paragraph 65 of your supplemental declaration?

A. Would you repeat the question?
Q. Sure.
Why did you reference a petition challenging '012 patent in paragraph 65?
ATTORNEY MILLER: Objection to the extent it calls for privileged information.
To the extent you can answer without revealing that information, you may answer.
ATTORNEY BARNES: Counsel, are you suggesting that Dr. Zalesky cannot testify about the material in his declaration because it is privileged?
ATTORNEY MILLER: No. You asked him a "why" question. And to the extent it involves conversations with counsel and he needs to reveal those or wants to reveal those, I am telling him not to.
ATTORNEY BARNES: So is patent owner attempting to prevent Dr. Zalesky from testifying about why he put statements in his own declaration because patent owner believes those reasons are privileged?
ATTORNEY MILLER: Well, if those reasons involve him describing conversations

with counsel, yes, those are privileged. But to the extent that he can answer technically why it is in there, yes, he can say that.

ATTORNEY BARNES: For the record, petitioner disagrees with patent owner's characterizations and reserves the right to potentially seek an additional deposition of Dr. Zalesky if patent owner is preventing him from testifying as to the contents or reasoning of the opinions set forth in this declaration.

ATTORNEY MILLER: Patent owner disagrees with that characterization.

BY ATTORNEY BARNES:

Q. Would you like me to repeat it question, Dr. Zalesky?

A. No, I recall the question.

I was asked to review prior art and opine on '005 independent claims with respect to prior art.

Q. And this paragraph refers to the claims of the '012 patent. Correct?

A. Sorry. Yes, '012.

Q. So why were you referencing the claims of the '012 patent in paragraph 65?

A. It is my understanding that going back to the 2018 application that culminated in '012 issue was inherited, if that is the right word, by the '005 patent.

Q. So is it your understanding that the claims of the '005 patent incorporate the claims of the '012 patent?

ATTORNEY MILLER: Objection. Misstates testimony.

A. I wouldn't put it precisely like that. It is certainly -- the written description and the claims do, in fact, integrate the material from the '012.

BY ATTORNEY BARNES:

Q. Is your reference to the '012 patent in paragraph 65 a typo?

A. It is possible.

Q. Did you use your declaration that you submitted for the '012 patent IPR as a template for your supplemental declaration for the '005 patent?

ATTORNEY MILLER: Objection to the extent it calls for confidential information regarding drafts or communications with

1 counsel.
2 If you can answer without revealing
3 that information, you may.
4 A. More as background than template.
5 BY ATTORNEY BARNES:
6 Q. And you would agree that petitioner is
7 not only relying on Schaffer, Hartley, and
8 Eller in its petition challenging the
9 patentability of the '005 patent. Correct?
10 A. That is my understanding, yes.
11 Q. Further down on page 35, in
12 paragraph 67, you state, "The sealing mechanism
13 present in the hemostasis valve of the '012
14 patent is different from the sealing mechanism
15 employed in Schaffer."
16 Did I read that correctly?
17 A. Yes.
18 Q. Again, why were you referencing the
19 hemostasis valve of the '012 patent in
20 paragraph 67?
21 ATTORNEY MILLER: Same objection with
22 regards to privilege.
23 You may answer.
24 A. The written description and the claims

of '005 incorporate the material disclosed in the '012.

BY ATTORNEY BARNES:

Q. If you turn to page 143, at the end of your supplemental declaration, and specifically looking at paragraph 210.

In paragraph 210, you state, "I have not rendered any opinions on secondary considerations of nonobviousness at this time but reserve the right to analyze evidence of secondary considerations at a later stage if asked to do so."

Did I read that correctly?

A. Yes.

Q. Have you analyzed any evidence of secondary considerations since signing your supplemental declaration?

A. No.

Q. Other than legal counsel for Inari, did you discuss the '005 patent IPR with anyone?

A. No.

Q. If you could turn to paragraph 3 at the beginning of your supplemental declaration. The second sentence of paragraph 3 states, "The

materials that I evaluated in support of this declaration include all exhibits cited in this declaration and in the petition." Correct?

A. Yes.

Q. And is that an accurate statement?

A. I believe so.

Q. Did you consider the board's decision granting institution of the '005 patent IPR in forming any of the opinions in your supplemental declaration?

A. Very briefly.

Q. And when you say you considered them very briefly, can you explain what you mean by that?

A. I am aware of conclusions without analyzing any content.

Q. If you could turn to paragraph 143 of your supplemental declaration, which is on page 86.

A. Okay.

Q. And at the beginning of paragraph 143, you state, "I understand that in the Institution decision the board stated that Schaffer's disclosure of the, quote, use of

1 certain materials for portions of a seal module
2 that provide a nearly fluid/gas tight seal and
3 exhibit a self-closing nature concern only some
4 embodiments using optional features and that
5 the valve of Schaffer's figures 30 through 34
6 does not require a seal module that includes
7 the above described optional third seal member
8 with an extremely compliant, soft, gelatinous,
9 self-closing material."
10 Did I read that correctly?
11 A. Yes.
12 Q. Do you disagree with the board's
13 conclusion that the valve in Schaffer's
14 figures 30 through 34 does not require a seal
15 module with an extremely compliant, soft,
16 gelatinous, self-closing material?
17 ATTORNEY MILLER: Objection. Vague.
18 A. I would have to remind myself of the
19 specific figures.
20 BY ATTORNEY BARNES:
21 Q. So sitting here right now, you don't
22 recall whether you agree or disagree with the
23 board's conclusion?
24 A. I don't, yes. Without looking at the

figures.

Q. If you could turn to paragraph 168 of your supplemental declaration. And that is on page 107. Okay. Are you there?

A. Yes.

Q. And the first sentence of paragraph 168 states, "I understand that the board contends that Schaffer's two actuating members apply constricting force to the valve seal module when pulled by opposing spring-actuated buttons and that replacing those members with a single string or wire would provide substantially the same function."

Did I read that correctly?

A. Yes.

Q. Do you disagree with the board's conclusion that replacing Schaffer's actuating members with a single string or wire would provide substantially the same function as the actuating members?

ATTORNEY MILLER: Objection. Vague.

A. Yes, I disagree.

BY ATTORNEY BARNES:

Q. So you think the board got it wrong

when it found that replacing Schaffer's actuating members with a single string or wire would provide substantially the same function as the actuating members?

A. I believe they are incorrect.

Q. How would the function differ if the actuating members were replaced by a string or wire?

A. The valve operation or mechanism is dramatically different for a filament such as a string compared to two opposing blades or actuator elements in the Schaffer configuration.

Q. Is the valve operation dramatically different for a string --

ATTORNEY BARNES: Let me rephrase.

BY ATTORNEY BARNES:

Q. Is the valve operation dramatically different for a single string as compared to two bites?

A. I wouldn't say dramatically different, no.

Q. Is it substantially the same?

A. I believe both of those configurations

1 operate with circumferential constriction.
2 Q. If you could turn to paragraph 26 of
3 your supplemental declaration.
4 A. Okay.
5 Q. And the first sentence of paragraph 26,
6 you state, "I understand that my opinions
7 regarding patentability are from the viewpoint
8 of a person having ordinary skill in the field
9 of the technology of the patent as of the time
10 of the invention."
11 Did I read that correctly?
12 A. Yes.
13 Q. What is the field of the technology of
14 the '005 patent?
15 A. Broadly, medical devices that
16 incorporate mechanical components.
17 Q. I am going to hand you what has been
18 marked as Exhibit 1001 in this IPR.
19 (Handing document to the witness.)
20 Q. Do you recognize Exhibit 1001,
21 Dr. Zalesky?
22 A. Yes.
23 Q. What is Exhibit 1001?
24 A. It the referenced '005 patent.

Q. If you could turn to -- sorry to switch gears on you a little bit. But if you could turn back to your supplemental declaration and paragraph 35, which is on page 13.

A. Okay.

Q. The first sentence of paragraph 35 states, "The '005 patent is directed to vacuum aspiration systems for rapidly aspirating clot material from a patient's blood vessel that offers significant benefits over such conventional treatments."

Did I read that correctly?

A. Yes.

Q. What are the conventional treatments that you are referring to in paragraph 35?

A. In general, a simple single lumen catheter or tube, and a connected syringe.

Q. How would --

ATTORNEY BARNES: Let me rephrase.

BY ATTORNEY BARNES:

Q. How were the simple single lumen catheters and a connected syringe used to treat blood clots prior to the '005 patent?

A. Simply manual withdrawal for

aspiration.

Q. What are the significant benefits over those conventional treatments that you were referring to in paragraph 35?

A. I think there is two perspectives.

One is an integrated system which involves multiple components for aspiration and control of the aspiration. And integrated into that system are particular elements are components such as hemostasis valve that provide incremental benefits.

Q. So focusing on the first perspective you identified, what are the significant benefits that are provided by the integrated system?

A. It is a combination of elements that provide controlled aspiration with various assemblies of syringes, manifolds, stopcocks, and fluid pathways, as well as filter and collection devices.

Q. How do those --

ATTORNEY BARNES: Let me rephrase.

BY ATTORNEY BARNES:

Q. How does that combination of elements

provide the controlled aspiration that you are referring to?

A. Compared to previous procedures and assemblies that were jerry-rigged, this is an integrated approach that includes stopcock control of fluid flows and application of aspiration pressures.

Q. Prior to 2018, were there no integrated blood clot aspiration systems that were used or available?

ATTORNEY MILLER: Objection. Vague.

A. I am not sure.

BY ATTORNEY BARNES:

Q. Are you familiar with the AngioVac blood clot aspiration system?

A. Not especially, no.

Q. Are you familiar with the blood clot aspiration system developed by Penumbra?

A. I am aware of it. I am not familiar with it.

Q. You would agree with me that aspirating blood clots with a catheter and a syringe was not new in 2018. Right?

ATTORNEY MILLER: Objection. Vague.

A. Generally, yes, that is true.
BY ATTORNEY BARNES:
Q. You would also agree with me that using a stopcock in a blood clot aspiration system that included a catheter and a syringe was not new in 2018. Right?
ATTORNEY MILLER: Objection. Vague.
A. I am not sure how commonly a stopcock was used in those previous procedures.
BY ATTORNEY BARNES:
Q. Do you know whether it was used?
A. I believe so, but, again, I don't have particular examples.
Q. So if we turn back to the '005 patent and if you could go to claim 1 at the end of the patent.
Are there any components that are recited in claim 1 of the '005 patent that provide the significance benefits that you were referring to in paragraph 35?
ATTORNEY MILLER: Objection. Vague.
A. I think the housing, which includes several components, integrated. And the constricting mechanism used for hemostasis are

1 part of those benefits.
2 BY ATTORNEY BARNES:
3 Q. How does the housing provide
4 significant benefits over the conventional
5 treatments that were available in 2018?
6 ATTORNEY MILLER: Objection. Scope.
7 A. It integrates discreet components.
8 BY ATTORNEY BARNES:
9 Q. How does that provide a benefit?
10 A. Primarily convenience to the operator.
11 Q. If you look back at paragraph 35 of
12 your supplemental declaration. In
13 paragraph 35, you discuss or --
14 ATTORNEY BARNES: Let me rephrase.
15 BY ATTORNEY BARNES:
16 Q. In paragraph 35, you refer to the
17 aspiration of PE or DVT. Correct?
18 A. Yes.
19 Q. And if you look at paragraphs 32
20 through 34, in those paragraphs, you also
21 discuss the treatment of PE and DVT. Correct?
22 A. Yes.
23 Q. Why did you focus on PE and DVT in your
24 discussion in paragraphs 32 through 35?

ATTORNEY MILLER: Objection to the extent it calls for privileged information and communications with counsel.

To the extent you can answer without revealing those communications, you may.

A. It is my understanding that the pulmonary and deep vein thrombosis scenarios are the most common and most challenging.

BY ATTORNEY BARNES:

Q. I probably should have done this before this whole line of questioning.

But when you refer to "PE" in your supplemental declaration, does that refer to pulmonary embolism?

A. Yes.

Q. When you refer to "DVT" in your supplemental declaration, does that refer to deep vein thrombosis?

A. Yes.

Q. Is it your opinion that the claims of the '005 patent are limited to aspiration systems that are used to treat PE or DVT?

A. No.

Q. So the claims of the '005 patent

1 encompass aspiration systems used to treat
2 other types of blood clots. Correct?
3 A. I believe so, yes.
4 Q. What other types of blood clots would
5 the claims of the '005 patent encompass?
6 A. Potentially, heart-related, as in
7 coronaries. Certainly, gastrointestinal
8 vessels in proximity to key organs. And also
9 peripheral arteries.
10 Q. What about neurovascular blood clots?
11 Would the claims of the '005 patent encompass
12 systems used to treat neurovascular blood
13 clots?
14 A. I should have included that, yes.
15 Q. Can you turn to paragraph 36, which is
16 on page 13 of your supplemental declaration.
17 And in paragraph 36, you state, "Figure 1 of
18 the '005 patent shows a vacuum aspiration
19 system with a flow path extending through a
20 housing, a valve 126 in the flow path, (e.g.,
21 an on-off control), and a first catheter 102 in
22 fluid communication with a pressure source 140
23 via a connector 108."
24 Did I read that correctly?

A. Yes.
Q. And after that statement, you provide an annotated version of figure 1 from the '005 patent. Correct?
A. Yes.
Q. In the annotated version of figure 1 on page 14 of your supplemental declaration, you added a blue line to illustrate the flow path extending through a housing. Correct?
A. Yes.
Q. In your annotated version of figure 1, you identified the component labeled with number 126 as an on-off control. Correct?
A. Yes.
Q. You stated that the component 126 is an on-off control that is in the flow path, in paragraph 36. Correct?
A. Yes.
Q. Can you explain why you believe that the valve 126 is in the flow path that extends through a housing in figure 1?
A. It is the path between the negative pressure source and the target.
Q. And how is the valve 126 in that flow

path?
A. I don't understand the question.
Q. What don't you understand about it?
A. You are saying "how." I am not sure what you mean by "how."
Q. Why do you believe that the valve 126 is in the flow path?
A. The patent describes that configuration.
Q. In your annotated figure on page 14, you did not identify the housing that you referred to earlier in that paragraph. Correct?
A. I don't cite it specifically.
Q. Can you identify where in figure 1 the housing that you are referring to is?
A. It is in the vicinity of 106.
Q. Does that housing in 106 include a hemostasis valve?
A. As shown, the hemostasis valve is to the right of the housing, but could be incorporated as well.
Q. You would agree with me that in figure 1 of the '005 patent, the valve 126 is

not in the housing 106. Correct?
A. That appears to be the case.
Q. The valve 126 is connected to the housing 106 by tubing. Correct?
ATTORNEY MILLER: Objection. Vague.
A. Yes.
BY ATTORNEY BARNES:
Q. Despite that configures, it is your opinion that in figure 1, the valve 126 is in the flow path that extends through the housing 106. Correct?
ATTORNEY MILLER: Objection. Misstates testimony.
A. Would you repeat that?
BY ATTORNEY BARNES:
Q. Sure.
It is your opinion that in figure 1, the valve 126 is in the flow path that extends through the housing 106. Correct?
ATTORNEY MILLER: Objection. Misstates testimony.
A. The control 126, yes.
BY ATTORNEY BARNES:
Q. In your annotated version of figure 1

on page 14, you identify the reference number 108 as a connector. Correct?

A. Yes.

Q. And if you pull up the '005 patent and specifically turn to column 5. If you look to lines 43 through 47, you would agree with me that the '005 patent describes the reference number 108 as a branch or side port on the valve 106. Correct?

A. Yes.

Q. Why do you believe that the branch or side port 108 is a connector in figure 1?

A. The diagram suggests that.

Q. How does the diagram suggest that the side port 108 is a connector?

ATTORNEY MILLER: Objection. Vague.

A. It is a discrete component attached to the catheter body.

BY ATTORNEY BARNES:

Q. What is the purpose of the side port 108 in figure 1?

A. The application of negative pressure for aspiration.

Q. Does the side port 108 place the

pressure source in communication with the flow path that you identified in your annotated version of figure 1?

A. Yes.

Q. How does it do that?

ATTORNEY MILLER: Objection. Vague.

A. It is part of the specification.

BY ATTORNEY BARNES:

Q. When you refer to the specification in your last answer, are you referring to the specification of the '005 patent?

A. Yes.

Q. How does being part of the specification of the '005 patent enable the side port to place the pressure source in communication with the flow path?

ATTORNEY MILLER: Objection. Vague.

A. A written description walks through the process.

BY ATTORNEY BARNES:

Q. What is the process that is described in the written description?

A. The application using a pressure source with various components between the pressure

source and the target thrombus. The wash through the components and the process of aspiration.

Q. Does the side port 108 in figure 1 need to have any specific type of structure?

ATTORNEY MILLER: Objection. Vague.

A. Not sure how to answer that. It certainly has to have certain geometry, certain dimensions, and certain materials.

Q. Could the side port be a barbed connector?

A. I don't believe so.

Q. Why not?

A. That wouldn't satisfy the aspiration requirement.

Q. Why would having a barbed connector as the side port not satisfy the aspiration?

A. It would interfere, is my understanding, with the pressure transfer.

Q. How would a barbed connector interfere with the transfer of the pressure?

A. An additional pressure gradient creation.

Q. What type of connector would the side

port 108 need to be in order to not interfere with the pressure transfer?

A. A relatively simple luer comes to mind as an example.

Q. Any other type of connector?

A. I am sure there are, but nothing on my plate right now.

Q. But it can't be a barbed connector. Is that right?

A. That is my understanding.

ATTORNEY BARNES: We have been going for a little over an hour. Would you like to take a break?

THE WITNESS: Sure.

ATTORNEY BARNES: We can go off the record.

THE VIDEOGRAPHER: The time is 10:04. We are off the record.

(Recess taken at 10:04 a.m.)

(Recess ended at 10:19 a.m.)

THE VIDEOGRAPHER: Time is 10:19. We are back on the record.

BY ATTORNEY BARNES:

Q. Welcome back, Dr. Zalesky. Did you

speak to anyone about the substance of your testimony during the break?

A. No.

Q. Did you review any documents during the break?

A. No.

Q. If you could turn back to page 14 of your supplemental declaration. In the annotated version of figure 1 on page 14, there is a box labeled pressure source 140. Correct?

A. Yes.

Q. What is the pressure source 140 in the system that is shown in figure 1?

A. The is a means of creating and exerting negative pressure.

Q. Is it a syringe?

A. That is one option, yes.

Q. What are the other options for the pressure source 140?

A. The options include ganged syringes and motors of various configurations that create negative pressure.

Q. When you refer to ganged syringes, can you explain what you mean by that?

A. Two or more syringes arranged typically in parallel.

Q. Could the pressure source 140 be an aspiration pump?

A. Yes.

Q. What kind of aspiration pump could the pressure source 140 be?

ATTORNEY MILLER: Objection. Scope. Objection. Vague.

A. Really what I refer to as the motors or engines that create negative pressures so a pretty wide description.

BY ATTORNEY BARNES:

Q. Could it be a centrifugal pump?

A. Yes.

Q. Could it be a peristaltic pump?

A. Yes.

Q. Are there any other types of aspiration pumps that were known in 2018 that it could be?

ATTORNEY MILLER: Objection. Scope. Objection. Vague.

A. Roller pump would be one option.

BY ATTORNEY BARNES:

Q. Any others?

A. Not that come to mind.
Q. Before -- or let me rephrase.
Earlier, you testified that the pressure source is a means of creating and exerting negative pressure.
How does the pressure source create and exert negative pressure in the system?
ATTORNEY MILLER: Objection. Vague. Scope.
A. The simplest description is to consider a syringe where the pullback of the -- the one component creates a negative pressure in the connected chamber.
BY ATTORNEY BARNES:
Q. How about the example wheres the pressure source is an aspiration pump? How would the aspiration pump create negative pressure in the system?
ATTORNEY MILLER: Objection. Vague. Objection. Scope.
A. The physics is pretty much the same as with a syringe, just created with an energy-driven device versus manual.
BY ATTORNEY BARNES:

Q. In the aspiration pumps, is there a chamber like there is for the syringe where the negative pressure is generated in?

ATTORNEY MILLER: Objection. Vague and scope.

A. There can be but not necessarily.

BY ATTORNEY BARNES:

Q. If you turn to the next page of your supplemental declaration, page 15. On page 15, and I believe this is part of paragraph 37, you state, "Figure 19 of the '005 patent shows another example of the pressure source comprising a clot canister 1940 that is fluidly coupled to the fluid path and the source of aspiration 460 shown in figures 4A through 4C."

Did I read that correct?

A. Yes.

Q. Do you have an understanding of how the pressure source with a clot canister that is shown in figure 19 works?

A. Yes, in general.

Q. How does the pressure source with the clot canister shown in figure 19 work?

A. This seems to indicate a syringe that

would be used via withdrawal of the piston to create a negative pressure, which would be the source of the aspiration.

Q. How does the arrangement in figure 19 apply the negative pressure to the system?

ATTORNEY MILLER: Objection. Vague. Scope.

A. It is controllably connected to the flow path.

BY ATTORNEY BARNES:

Q. Is it correct that in figure 19, aspirated blood and clot material would enter the clot canister along the flow path that you have illustrated on page 16?

A. Yes.

Q. Does the blood get aspirated into the source of aspiration 460?

A. It is possible but minimally.

Q. What happens to the aspirated blood and the clot material once it is drawn into the clot canister?

ATTORNEY MILLER: Objection. Vague. Scope.

A. It is collected and either filtered for

clot material versus plasma or otherwise discarded.

BY ATTORNEY BARNES:

Q. How would it be filtered for clot material versus plasma?

A. I believe other figures demonstrate the integration of a filter that would trap the clot material.

Q. In figure 19, it shows a filter 1942 in the clot canister. Is that correct?

A. Yes.

Q. How does the filter 1942 work to filter the clot versus plasma?

A. It is simply a passive filter, the equivalent of a screen that traps solid material and lets liquid flow through it.

Q. Does the clot canister need to include a filter in order to work?

A. I wouldn't say needs to, no.

Q. How would the clot canister function without a filter?

A. It would simply collect the conglomerate thrombus and blood materials.

Q. Are there any advantages to the

arrangement of components in the clot canister and source of aspiration shown in figure 19 on page 16 of your supplemental declaration?

A. One could argue it is convenient integration of components and simplifies the procedure.

Q. How does it simplify the procedure?

A. It is a ready-to-use apparatus.

Q. Are there any advantages to the arrangement of the filter and the clot canister that is shown on figure 19?

ATTORNEY MILLER: Objection. Vague. Scope.

A. The filter segregation of thrombus material enables the capture of thrombus -- essentially thrombus-free blood that can then be returned to the patient.

BY ATTORNEY BARNES:

Q. Is there any advantage to placing the filter closer to the outflow port versus the in-flow port in figure 19?

ATTORNEY MILLER: Objection. Vague. Scope.

A. Potentially in that it thereby

encompasses the entire volume of blood and material in the canister.

BY ATTORNEY BARNES:

Q. Looking at the bottom of page 16 of your supplemental declaration, in paragraph 38, you state, "Figure 1 of the '005 patent shows a hemostasis valve 106 (i.e., a valve that inhibits or prevents blood from flowing through the valve) attached to a proximal end of the first catheter 102."

Did I read that right?

A. Yes.

Q. On the next page, on page 17, you provide another annotated version of figure 1. Correct?

A. Yes.

Q. In the annotated version on page 17, you identified the reference number 106 as a hemostasis valve. Correct?

A. That is what is cited here, yes.

Q. On the next page of your supplemental declaration, you provide an annotated version of figure 11 from the '005 patent. Correct?

A. Yes.

Q. In the annotated version of figure 11, you identified three components, the first catheter 1002, a hemostasis valve 1006, and a second catheter 1102. Correct?

A. Yes.

Q. Does figure 11 of the '005 patent disclose a housing with a hemostasis valve in the housing?

A. It doesn't specify it but it appears to show it in the configuration.

Q. Can you identify the housing that is shown in figure 11?

A. I believe 1007A.

Q. Does figure 11 disclose a connector?

A. I see what could be construed as a connector just below 1007A.

Q. So the side port attached to the housing 1007A would be a connector?

A. It could well be, yes.

Q. Does figure 11 disclose a flow path extending through the housing?

A. Yes.

Q. Can you identify where the flow path extending through housing would be in

figure 11?

A. From left to right in the figure.

Q. Would there be a flow path that extends through the side port of the housing in the direction of component 1026?

ATTORNEY MILLER: Objection. Vague.

A. Yes. This is a dual pressure source configuration. So both of the side arms, if you will, are connected to separate pressure sources or the same pressure source, conceivably.

BY ATTORNEY BARNES:

Q. One of the pressure sources that is identified in figure 11 is the pressure source 1040. Correct?

A. Yes.

Q. Is that pressure source 1040 in fluid communication with the first catheter 1002?

A. Yes.

Q. Does figure 11 disclose an on-off control that is in the flow path?

A. Yes.

Q. Can you identify where in figure 11 the on-off control is?

A. Labeled as 1026 and 1126.
Q. You would agree that in figure 11, the on-off control 1026 is not located in the housing of the hemostasis valve. Correct?
A. In this particular figure, no, it is not in the housing.
Q. If you could turn to the '005 patent, which is Exhibit 1001, and specifically if you could turn to figure 3D.
A. Sorry. Which figure?
Q. 3D.
A. Okay.
Q. Can you explain what is shown in figure 3D?
A. From bottom right, you have a syringe, which is a pressure source, connected to a tubing that goes through an on-off switch, if you will, which, in turn, is connected via side arm to the housing, and the housing is distal to the hemostasis valve with an aspiration catheter exiting the housing and going to the target clot.
Q. Does the system shown in figure 3D include a flow path that extends through the

housing?

ATTORNEY MILLER: Objection. Vague.

A. I am not sure "through the housing" is correct. It involves the housing.

BY ATTORNEY BARNES:

Q. Why would there not be a flow path that extends through the housing in figure 3D?

A. "Through" suggests an axial path from left to right as opposed to a side arm path.

Q. Well, if you turn back to page 14 of your supplemental declaration, on page 14 of your declaration, you illustrated a flow path that extends through the side port of the housing. Correct?

A. It extends through the side port of the housing, yes.

Q. And in paragraph 36, you described that flow path as "a flow path extending through a housing." Correct?

A. I did. But in retrospect, I would probably choose a slightly different term than "through."

Q. So is your description in paragraph 36 inaccurate?

ATTORNEY MILLER: Objection. Vague. Misstates testimony.

A. It is not inaccurate but it is not precise.

BY ATTORNEY BARNES:

Q. So as you described it in paragraph 36 of your supplemental declaration, wouldn't figure 3D of the '005 patent include the same flow path extending through the housing?

ATTORNEY MILLER: Objection. Vague.

A. Yes.

BY ATTORNEY BARNES:

Q. Figure 3D also includes an on-off control in that flow path. Correct?

A. Yes.

Q. You would agree that in figure 3D of the '005 patent, the on-off control is not located in the housing of the hemostasis valve. Correct?

A. In this particular configuration, correct.

Q. Can you turn to figures 9A through 9C of the '005 patent.

A. Okay.

Q. Can you explain what is shown in figures 9A through 9C?

A. My interpretation is equivalent aspiration flow paths using a syringe for pressure creation and control with the piston in different positions from A to B and C. And showing different on-off control configurations labeled as 126.

Q. Would you agree that the figures 9A, 9B, and 9C illustrate the same system, just at different points during the aspiration procedure?

ATTORNEY MILLER: Objection. Vague.

A. That is part of what they depict, yes. That is not the whole -- that wouldn't be my entire description, but they do depict that.

BY ATTORNEY BARNES:

Q. Would you agree that figures 9A and 9B and 9C show generally the same configuration of components?

A. Generally the same, yes.

Q. If we look first to figure 9A, does figure 9A include a housing with a hemostasis valve within it?

A. It appears to, yes.
Q. And it looks like that is generally the same housing that is shown in figure 1 of the '005 patent. Would you agree with that?
A. I think they are consistent. Without going to the written description, it is hard to evaluate whether it is integrated in the housing or connected to the housing via tubing.
Q. I believe you stated that figure 9A includes an on-off control which is identified as reference number 126. Is that right?
A. Yes.
Q. Would you agree with me that in figure 9A, the on-off control is not located in the housing of the hemostasis valve?
A. The drawn 126 element in this figure is not part of the housing.
Q. Would you agree that that is also the case for figure 9B?
A. Yes.
Q. Would you agree that that is also the case for figure 9C?
A. Yes.
Q. Can you turn to figures 20C through E.

A. 20, which letters?
Q. C through E.
A. Okay.
Q. Can you explain what is shown in figures 20C through E?
ATTORNEY MILLER: Objection. Vague.
A. My understanding is they are depicting different steps in the aspiration process.
BY ATTORNEY BARNES:
Q. If we start with figure 20C, does figure 20C include a housing within that --
ATTORNEY BARNES: Let me rephrase.
BY ATTORNEY BARNES:
Q. Does figure 20C include a housing with a hemostasis valve in the housing?
A. I guess to answer this question I need to clarify my previous answer, that the figures are not terribly well done in terms of defining the integration of the hemostasis valve with the housing. So hence, my commenting that it could be either, based on just the figures by themselves.
Q. When you say "could be either," what are the options you are referring to by

"either"?

A. One option is indeed the hemostasis valve integral with the housing. But the other option would be discreet from the housing.

Q. Would you agree that figure 20C includes an on-off control identified with reference number 126?

A. Yes.

Q. Would you agree that the on-off control in figure 20C is not located in a housing with the hemostasis valve?

A. As I answered previously, in this particular embodiment, it is separate from the housing.

Q. If you turn to figure 20D. Would you agree that in figure 20D, it also shows that the on-off control 126 is not located in a housing that also includes the hemostasis valve?

A. Yes. The same answer to the previous question. It doesn't rule out an embodiment where it is part or there is an additional on-off valve.

Q. But that is not shown in figure 20D.

Correct?

A. That's correct.

Q. In figure 20E, would you also agree that in that figure, the on-off control 126 is not located in the housing that includes the hemostasis valve?

A. This is either a poorly drawn figure or for some reason 126 appears different than in figures C and D of that same number.

It's presumably been rotated to enable flow to the right, from left to right, but that is not clearly depicted in the figure.

Q. Would you agree that the on-off control 126 is not located in the housing that includes the hemostasis valve?

ATTORNEY MILLER: Objection. Vague.

A. The same answer to the previous two in that regard.

BY ATTORNEY BARNES:

Q. Can you turn to figure 24 of the '005 patent.

A. Okay.

Q. Does figure 24 include an on-off control?

A. It doesn't spell it out, but it appears to be between elements 128 and 120.

Q. Does figure 24 include a housing that includes a hemostasis valve?

A. As I mentioned earlier, that is one of the two interpretations of these depictions, yes.

Q. You would agree that in figure 24, the on-off control is not located in the housing that includes the hemostasis valve. Correct?

A. This figure depicts only one on-off control that is not integrated into the housing, but it doesn't rule out there being a parallel on-off control in the housing.

Q. You would agree with me that none of the figures in the '005 patent disclose an on-off control located in the same housing as a hemostasis valve. Correct?

A. All of the figures that we have just reviewed clearly show an on-off valve by itself that is not integrated, and they don't indicate that there is not another or is another on-off valve within the housing.

Q. I am going to repeat my question.

You would agree that none of the figures in the '005 patent disclose an on-off control located in the same housing as a hemostasis valve. Correct?

A. I would have to look at all of the other figures we didn't address this morning.

Q. Please do so.

(Pause.)

A. I am not seeing any figures that clearly depict an on-off control switch within the housing.

Q. Why did you qualify your answer with, "clearly depict"?

A. There is no detail regarding the housing in the figures. Or I should say there is minimal dealing.

Q. You would agree that the '005 patent, including the written description, does not disclose any examples of an aspiration system with a single housing that includes both a hemostasis valve and an on-off control within it. Correct?

ATTORNEY MILLER: Objection. Vague. Misstates the document and his testimony.

A. I would, frankly, have to go back through the text of the written description.
BY ATTORNEY BARNES:
Q. Did you consider whether the '005 patent discloses any examples of a single housing that includes both a hemostasis valve and an on-off control when forming your opinions presented in your supplemental declaration?
A. It has been a while since I reviewed the details of the written description. But certainly only selected embodiments are described, not all-inclusive.
Q. So for the embodiments that are actually described in the '005 patent, you would agree with me that none of those embodiments are described as having a single housing that includes both a hemostasis valve and an on-off control. Correct?
ATTORNEY MILLER: Objection. Misstates testimony. Misstates document.
A. I don't recall. As I said, I would have to go back through this specific embodiment citation.

But as I said earlier, these are just example embodiments, not all-inclusive.

BY ATTORNEY BARNES:

Q. Did you identify any embodiment disclosed in the '005 patent that includes a single housing with both a hemostasis valve and an on-off control in your supplemental declaration?

A. I honestly don't recall.

Q. Was that something you considered when forming the opinions you presented in your supplemental declaration?

ATTORNEY MILLER: Objection. Asked and answered.

A. I looked at claim 1 in particular and certainly reviewed the written description and, frankly, looked at it from a high altitude perspective without going into minute detail of the housing.

BY ATTORNEY BARNES:

Q. If you turn to paragraph 93 of your supplemental declaration.

A. Okay.

Q. In the last sentence of paragraph 93,

you state, "The '005 patent description reflects this difference as well, drawing a distinction between embodiments in which a fluid control device is fluidly coupled to a valve housing (e.g., via tubing) and embodiments in which the fluid control device is part of the valve housing."

Did I read that correctly?

A. Yes.

Q. Then in the citation after that sentence, you compared column 6, 3 through 11, in figure 1 of the '005 patent with column 6, lines 45 through 49. Correct?

A. That is what it says there, yes.

Q. Would you agree with me that none of the sections of the '005 patent that you cite here in figure 93 disclose an embodiment that includes a single housing with both a hemostasis valve and an on-off control in it?

ATTORNEY MILLER: Objection. Vague. Misstates the document.

A. I am rereading column 3, lines 3 to 11 -- or column 6. Sorry.

(Pause.)

A. My interpretation of the citation column 6 does not exclude an integrated control within the housing.

Q. Would you agree that it does not describe an on-off control within the same housing as a hemostasis valve?

ATTORNEY MILLER: Objection. Vague. Can you specify which section of column 6 you are talking about?

A. It is not that specific, no.

BY ATTORNEY BARNES:

Q. And specifically you would agree that column 6, lines 3 through 11, of the '005 patent does not describe an on-off control within the same housing as a hemostasis valve. Correct?

A. It describes a stopcock that is fluidly coupled which doesn't specify where exactly it is located in the fluid path.

Q. While in column 6, lines 3 through 11, it describes that, "The fluid control device 126 is a stopcock that is fluidly coupled to (I) the side port 108 of the valve 106 via the first tubing section 124A."

Correct?

A. Yes, that is one specific embodiment.

Q. That is the only embodiment that is described in that cited portion of the '005 patent. Correct?

A. Yes.

Q. If we go down further in column 6, in the other portion of the '005 patent you cited, at lines 45 through 49, you would agree that lines 45 through 49 also don't disclose a single housing that includes both the hemostasis valve and an on-off control. Correct?

ATTORNEY MILLER: Objection. Misstates the document. Vague.

A. I interpret this to be broader than you just suggested. In particular, the phrase "integrally formed" in line 49, which suggests an integration of components such as would be a control device within the housing.

BY ATTORNEY BARNES:

Q. So beginning at line 45 of column 6 --

ATTORNEY BARNES: Let me rephrase.

BY ATTORNEY BARNES:

Q. You would agree with me that lines 45 through 49 of column 6 are describing configurations of the tubing subsystem 120. Correct?

ATTORNEY MILLER: Objection. Vague. Misstates the document.

A. Yes.

BY ATTORNEY BARNES:

Q. And the on-off control is part of the tubing subsystem 120. Correct?

ATTORNEY MILLER: Objection. Vague. Misstates document.

A. The key word is, "can have."

BY ATTORNEY BARNES:

Q. If you look to column 5, lines 27 through 29, you would agree with me that the '005 patent states that the valve 106 is part of the catheter subsystem 100, not the tubing subsystem 120. Correct?

A. That is how this reads, yes.

Q. So looking back to column 6 at lines 45 through 49, is it your interpretation of the statement, "In some embodiments, one or more of the components can be permanently connected

and/or integrally formed" that "integrally formed" is referring to every single component of the aspiration system?

ATTORNEY MILLER: Objection. Vague.

A. I think there is at least two interpretations of that line, "integrally formed." One is the point you just made about describing the conglomerate, if you will, of individual components. The other is the integration of select components into a subassembly, in particular, potentially a housing.

And I just want to point out, again, these are selected embodiments, not all-inclusive.

BY ATTORNEY BARNES:

Q. Earlier I believe you agreed that this portion of the specification in lines 45 through 49 is referring to configurations of the tubing subsystem 120. Correct?

ATTORNEY MILLER: Objection. Misstates testimony.

A. Yes.

BY ATTORNEY BARNES:

Q. So doesn't that statement regarding integrally formed components refer to components of the tubing subsystem 120?

ATTORNEY MILLER: Objection. Misstates testimony. Vague.

A. I don't interpret it to be that restrictive, no.

BY ATTORNEY BARNES:

Q. How are you interpreting it?

A. I just pointed out, it could go -- it could be interpreted at least two different ways, one of which is selected components integrated into a subassembly.

Q. Which components?

A. It could be a filter, it could be an on-off control device. It could be a connector.

Q. This statement doesn't reference any of those components. Right?

ATTORNEY MILLER: Objection. Vague. Misstates testimony. Misstates document.

A. No. But there is another key line in here, "can have other suitable configurations."

BY ATTORNEY BARNES:

Q. Is it your interpretation that that statement means any possible configuration is encompassed by that statement?

A. I am not sure I would say "any."

ATTORNEY MILLER: Objection. Vague.

A. But it has to be functionally consistent with the intended use of the device.

BY ATTORNEY BARNES:

Q. How would a person of skill in the art go about determining if a configuration is within this statement, under your interpretation?

A. It is a combination of the intended use, which is aspiration of clot material, with a reasonable combination of negative pressure application to a fluid path.

Q. In this portion of your supplemental declaration, which I believe is section VI.A, you are opining that the combination of Garrison and Schaffer does not disclose the housing of claims 1 and 10. Correct?

A. Sorry. Where are you?

Q. If you look at page 54 of your supplemental declaration. In this section,

which is section 6A, you are providing an opinion that the combination of Garrison and Schaffer does not disclose the housing of claims 1 and 10. Correct?

A. Correct.

Q. And it is your opinion that Garrison does not disclose an on-off control in the flow path as recited in claim 1 because Garrison's valve 3325 is not located in the same housing as the hemostasis valve. Correct?

ATTORNEY MILLER: Objection. Misstates the document.

A. You are going to have to repeat that. Sorry.

BY ATTORNEY BARNES:

Q. Sure.

It is your opinion that Garrison does not disclose an on-off control in the flow path as recited in claim 1 because Garrison's valve 3325 is not located in the same housing as the hemostasis valve. Correct?

A. Yes, that is what I am stating.

Q. So you are construing claim 1 to require that the housing --

ATTORNEY BARNES: Let me rephrase.
BY ATTORNEY BARNES:
Q. You are construing claim 1 to require that the on-off control is in the housing. Correct?
A. No. That is one option. It is not constrained to that.
Q. What are the other options?
A. In the flow path but not in the housing.
Q. So it is your opinion that the on-off control recited in claim 1 does not need to be in the housing. Is that right?
A. I am allowing for the two options, in or not in the housing.
Q. So then why do you believe that Garrison's valve 3325 is not in the flow path as recited in claim 1?
A. It is, frankly, a confusing figure because of the dashed reds.
Q. So it is your opinion that Garrison does not disclose that valve 3325 is in the flow path because it is a confusing figure because of the dashed red line -- dots?

A. That is part of my observation, yes.
Q. Did you do any personal analysis of whether Garrison's figure 34 without the dashed red dots includes an on-off control that is in the flow path extending through housing?
ATTORNEY MILLER: Objection. Vague.
A. No. I simply looked at his depicted figures.
BY ATTORNEY BARNES:
Q. In paragraph 92, in the second sentence, you say, "First, the red dashed line that petitioner uses to denote the purported flow path extends well beyond either end of the alleged housing and thus tracks more than just 'the flow path' 'extending through the housing.' A POSITA would understand that the proper illustration of the flow path extending through the housing would be from one end of the proximal adapter to the other."
Did I read that correctly?
A. Yes.
Q. If we turn back to page 13 of your supplemental declaration -- or page 14, rather.
You would agree with me that, in the

annotated version of figure 1 that you prepared, you illustrated a flow path that extends through the housing that extends well beyond the proximal and distal ends of the housing. Correct?

A. No, that is not exactly what I said.

Q. Why is that wrong?

A. Your descriptor suggests axial flow throughout the entire assembly.

Q. What descriptor?

A. The phrase that you just used for my interpretation.

Q. So in your own phrasing in paragraph 36 than is on page 13, you said, "Figure 1 of the '005 patent shows a vacuum aspiration system with a flow path extending through a housing."

Did I read that right?

A. Yes, we addressed this earlier. The key word here is "through." And "through" connotes completely through as opposed to partially through.

Q. That is words that you used in your declaration. Right?

A. Those are the words. And as I said

earlier, in retrospect, I should have been more precise.

Q. So your figure -- your annotated version of figure 1, it is your testimony that that figure is wrong. Is that right?

A. No.

Q. So does figure one accurately show a flow path --

ATTORNEY BARNES: Let me rephrase.

BY ATTORNEY BARNES:

Q. Does the annotated version of figure 1 that you prepared on page 14 accurately show a flow path extending through the housing as you have shown it with the blue lines?

A. Again, in retrospect, I would have been more precise. It shows a flow path through part of the housing.

Q. Is it your interpretation of claim 1 of the '005 patent that the flow path must extend through the entirety of the housing?

ATTORNEY MILLER: Objection. Vague.

A. No, that is not my interpretation.

BY ATTORNEY BARNES:

Q. So as it is recited in claim 1, the

1 blue flow path you illustrated on page 14 of
2 your supplemental declaration is a flow path
3 extending through the housing. Correct?
4 A. Yes, I will try this one more time.
5 "Through" can be interpreted different
6 ways by different POSITAs. One interpretation
7 is an axial flow through the entire length of
8 the housing. Another interpretation is it goes
9 through a part of the housing and certainly is
10 still through, but a different flow path
11 configuration.
12 Q. Which is the interpretation that
13 applies to claim 1 of the '005 patent?
14 A. My interpretation is it covers both.
15 Q. So if we turn back to page 55 of your
16 supplemental declaration, you would agree with
17 me that the fact that Garrison's valve 3325 is
18 not located within the same housing as the
19 hemostasis valve is not relevant for purposes
20 of claim 1 of the '005 patent?
21 A. That is not exactly correct. It is not
22 that it is not relevant; it is not precise.
23 Q. What is not precise?
24 A. The control device is clearly not

integrated with the hemostasis valve in this configuration.

Q. Right.

A. That is one of the option that I interpreted in the '005 patent.

Q. But the integration of a hemostasis valve and the on-off control is not required by claim 1 of the '005 patent. Correct?

ATTORNEY MILLER: Objection. Misstates the document. Calls for a legal conclusion.

A. It is not required but it is included.

BY ATTORNEY BARNES:

Q. So because the claim 1 does not require the hemostasis valve and the on-off control to be integrated, the fact that Garrison's on-off control valve is not integrated with the hemostasis valve does not matter for purposes of invalidity. Correct?

ATTORNEY MILLER: Objection. Calls for a legal conclusion. Misstates the testimony.

A. He is not specifying optional configurations, he is specifying a very specific configuration where the on-off control is segregated from the hemostasis valve.

BY ATTORNEY BARNES:
Q. And that configuration is one of the configurations that is encompassed by claim 1 of the '005 patent. Correct?
A. The segregation aspect is, yes.
ATTORNEY BARNES: We have been going for another hour. Would you like to take a break?
ATTORNEY MILLER: Let's do that.
ATTORNEY BARNES: Sure.
THE VIDEOGRAPHER: The time is 11:16. We are off the record.
(Recess taken at 11:16 a.m.)
(Recess ended at 11:29 a.m.)
THE VIDEOGRAPHER: The time is 11:29. We are back on the record.
BY ATTORNEY BARNES:
Q. Welcome back, Dr. Zalesky. Did you discuss the substance of your testimony with anyone during the break?
A. No.
Q. Did you review any documents during the break?
A. No.

Q. Does claim 1 of the '005 patent cover the system that is shown in figure 1 of the '005 patent?

ATTORNEY MILLER: Objection. Calls for a legal conclusion.

A. I believe so.

BY ATTORNEY BARNES:

Q. If you could turn to paragraph 39 of your supplemental declaration, which is on page 17.

Or, actually, it is on page 18.

A. Okay.

Q. In paragraph 39, you state, "The '005 patent incorporates by reference all the subject matter of U.S. Patent Application Number 16-117519." Correct?

A. Yes.

Q. And you refer to that application by the shorthand "the '519 application." Correct?

A. Yes.

Q. What is your understanding of what it means for the '005 patent to incorporate by reference the subject matter of the '519 application?

A. My interpretation is that the '005 invention includes the inventive description in the 519.

Q. Did that understanding impact any of the opinions that you presented in your supplemental declaration?

A. No.

Q. I am going to hand you what has been marked as Exhibit 1017 in this IPR.

(Handing document to the witness.)

Q. Do you recognize Exhibit 1017?

A. I don't believe I have ever seen this, at least the front page.

Sorry, it looks like it is excerpted, I guess.

Q. Does Exhibit 1017 appear to be a copy of the '519 application that you referred to in your declaration?

A. That is what I was trying to verify by paging through. I believe so.

Q. At the bottom of page 18 of your supplemental declaration, or -- you can finish your review.

A. That is okay. Page 18?

Q. Correct. And in paragraph 40, the first sentence of paragraph 40, you state, "The '005 patent, via its incorporation of the '519 application, explains that, while traditional hemostasis valves are greatly beneficial for intravascular access, they have some drawbacks." Is that correct?

A. Yes.

Q. Do you have an understanding of what types of hemostasis valves the '519 patent --

ATTORNEY BARNES: Let me restate.

BY ATTORNEY BARNES:

Q. Did I have an understanding of what types of hemostasis valves the '519 application was referring to when it references traditional hemostasis valves?

ATTORNEY MILLER: Objection. Vague.

A. In general, the Tuohy-Borst family, and there are variations to Tuohy-Borst, but essentially the same closing principle in the Tuohy-Borst family.

BY ATTORNEY BARNES:

Q. Can you explain what you mean when you refer to the Tuohy-Borst family of hemostasis

valves?

A. So it is an axial-configured valve with silicone valves or flutters or whatever you want to call them that, upon a screwing rotation aspect of the device, creates a sealing around the enclosed catheter or tube or other device.

Q. Were passive hemostasis valves included within the traditional hemostasis valves that the '519 application is referring to?

A. I would think so, yes.

Q. Do you agree with the '519 application statement that traditional hemostasis valves had some drawbacks?

A. Yes.

Q. What are the drawbacks that traditional hemostasis valves had?

A. Those traditional valves don't seal well on large devices or complex configuration devices thought are not circular. They sometimes struggle with high pressure scenarios and require two hands to operate.

Q. Any other drawbacks that you can think of?

A. Just pressure gradient as well as pressure itself.

Q. Can you identify any examples of the complex configuration devices that you were referring to in your previous answer?

A. There are different therapeutic tools used for procedures -- interventional procedures, such as atherectomy devices, different stent configurations around balloons, and others that I could come up with if I had enough time that present either a complex geometry or a complex enclosure.

Q. If you turn to paragraph 57 of your supplemental declaration. That is going to start at the bottom of page 31.

A. Okay.

Q. And the first sentence of paragraph 57, you state, "The easy one-handed operation and strong seal of the garrote valve is particularly useful in vacuum aspiration systems such as those disclosed and claimed in the '005 patent." Is that correct?

A. Yes.

Q. How does the valve that is claimed in

the '005 patent provide for easy one-handed operation?

A. The opposing actuators can be easily compressed with the digits of one hand.

Q. Are there any other components of the valve that is claimed in the '005 patent that enable it to provide the easy one-handed operation?

A. That is the most important, the one I just described.

Q. Does the biassing system contribute to the easy one-handed operation?

A. The biassing system enables tactile control by the operator. I am not sure that is the same as easy one-handed operation.

Q. How does the hemostasis valve that is claimed in the '005 patent provide a strong seal?

A. I think the word "garrote" best describes the mechanism of sealing where there is a circumferential choking of the enclosed structure.

Q. So if we look at claim 1 of the '005 patent, can you identify the component or

components that are recited in claim 1 that help create the strong seal that you refer to in your declaration?

ATTORNEY MILLER: Objection. Vague.

A. I think the middle of the top paragraph on column 36 where the filament circumferentially constricts the lumen to create a seal, as supported by the written description, talks about a garrote seal which is quite robust.

BY ATTORNEY BARNES:

Q. How does the filament that is recited in claim 1 of the '005 patent create a strong seal?

A. The actuators are spring-loaded, if you will, to pull the filament in opposing directions, creating a circumferential constriction.

Q. What are the features of the filament that makes it particularly useful for creating a strong seal?

A. Its inherent flexibility and geometry.

Q. Can you explain what you mean when you refer to geometry?

A. Size matters. And you can't rule out hexagons, pentagons, and so forth, but circular would probably be the most preferred.

Q. With respect to size, what about the size of the filament helps it create a strong seal?

A. A smaller diameter filament is going to have a concentrated force at a reduced area. So pressure, being force divided by area, gives you a higher pressure at a focal point.

Q. Besides the filament, do any of the other components that are recited in claim 1 help to create the strong seal?

A. The force of the actuators of course are critical to that.

Q. And that force is provided by the biassing system. Correct?

A. Partially. As I said earlier, spring-loaded force.

Q. Any other components listed in claim 1 that contribute to the strong seal?

A. I mean, those are clearly the drivers, the filament and the actuators.

Q. In paragraph 58 of your supplemental

1 declaration, in that last sentence of
2 paragraph 58, you state, "Thus, a POSITA would
3 understand, for example, the garrote valve to
4 be particularly useful in thrombectomy
5 procedures using large-bore catheters to apply
6 significant vacuum pressure such as
7 thrombectomy procedures used to treat pulmonary
8 embolism or deep vein thrombosis."
9 Did I read that right?
10 A. Yes.
11 Q. Would that understanding that the
12 POSITA would have had --
13 ATTORNEY BARNES: Let me rephrase.
14 BY ATTORNEY BARNES:
15 Q. Would the POSITA have had this
16 understanding that you are referring to prior
17 to 2018?
18 ATTORNEY MILLER: Objection.
19 A. Would you repeat that?
20 BY ATTORNEY BARNES:
21 Q. Sure.
22 Would a POSITA have had this
23 understanding that you are referring to in
24 paragraph 58 prior to 2018?

A. I think the reason I am hesitating is I am not sure how many large thrombectomy procedures were common prior to 2018. It became more common late in that decade, into the following decade.

Q. Is it your opinion that the garrote valve would only be useful for thrombectomy procedures to treat pulmonary embolism or deep vein thrombosis?

ATTORNEY MILLER: Objection. Vague.

A. No, it could be used in procedures we described earlier in this process, including peripheral, coronary, cerebral.

BY ATTORNEY BARNES:

Q. Would it be useful in procedures that involved smaller bore catheters?

ATTORNEY MILLER: Objection. Vague.

A. I don't think it would be any worse. I don't know how much incrementally better it would be in a smaller, whereas it is significantly more effective in larger.

BY ATTORNEY BARNES:

Q. Would it provide any benefit over traditional hemostasis valves in systems that

1 used catheters with sizes that were less than
2 20 French?
3 ATTORNEY MILLER: Objection. Vague.
4 Scope.
5 A. Conceivably, sure, in particular where
6 there is a large pressure gradient supplied or
7 sudden bursts of pressure to dislodge a tough
8 thrombus, and that could occur in small vessels
9 as well as large vessels.
10 BY ATTORNEY BARNES:
11 Q. In that sentence in paragraph 58, you
12 refer to significant vacuum pressure.
13 Do you see that?
14 A. Yes.
15 Q. Can you explain what you meant by
16 significant vacuum pressure?
17 A. It applies to the question we just
18 addressed in terms of small versus large.
19 Because of the volume involved in a larger
20 catheter body, a larger total vacuum pressure
21 would need to be generated.
22 Q. Are significant vacuum pressures used
23 during thrombectomy procedures for clots other
24 than pulmonary embolisms or deep vein

thrombosis?

ATTORNEY MILLER: Objection. Vague.

A. They could well be, as I said with a difficult thrombus or a mature or older thrombus which tends to be harder and tougher to dislodge.

BY ATTORNEY BARNES:

Q. If you turn to next page, page 33 of your supplemental declaration.

Towards the center of paragraph 59, you state, "A robust seal and quick self-closing valve are critical to reduce patient blood loss during procedures, which can be significant through a large catheter. Traditional rotating hemostasis valves take many turns to seal the large-bore catheters used in such procedures. The incorporation of bias features and springs ensures that the actuator can quickly and easily function effectively."

Did I read that right?

A. Yes.

Q. Would the fact that traditional rotating hemostasis valves take many turns to seal larger bore catheters have been one of the

1 drawbacks that those valves were known to have
2 prior to 2018?
3 A. Yes.
4 Q. How do the bias features and springs of
5 the '005 patent's hemostasis valve ensure that
6 the actuator can quickly and easily function
7 effectively?
8 ATTORNEY MILLER: Objection. Vague.
9 A. The spring-loaded mechanism means that,
10 almost instantly upon release, there is
11 closure.
12 BY ATTORNEY BARNES:
13 Q. Why is that a useful benefit?
14 A. Among other things, the time factor.
15 Taking an extra 10, 15 seconds with a
16 Tuohy-Borst traditional means that during that
17 10 or 15 seconds you could -- results with some
18 significant blood loss, whereas with almost
19 instant closure, you are preventing or
20 minimizing blood loss.
21 Q. If you turn to paragraph 48 of your
22 supplemental declaration.
23 You would agree that the filament 150
24 that is described in the '519 application can

comprise multiple filaments. Correct?
A. Yes.
Q. And you would agree that the '519 application describes the filament 150 in the singular being comprised of multiple filaments. Correct?
A. Not sure I understood the question.
Q. Maybe it will be more helpful to just turn to the '519 application.
A. Okay.
Q. If you look at paragraph 65, which is on page 17. And the first sentence of paragraph 65 says, "In some embodiments the filament 150 can comprise multiple filaments." Correct?
A. Yes.
Q. In that statement, it is referring to the filament 150 in the singular. Correct?
A. Yes.
Q. And that singular component 150 can comprise multiple filaments. Correct?
A. Yes.
Q. You would agree with me that paragraph 65 of the '519 application defines

the reference number 700 as the first end?
A. Yes.
Q. You would also agree that the '519 application defined reference number 702 as the second end of the filament. Correct?
A. Yes.
Q. It is your opinion that figures 8 and 9 of the '519 application contain typographical errors. Is that right?
ATTORNEY MILLER: Objection. Vague.
A. Yes.
BY ATTORNEY BARNES:
Q. Do you believe that there are any other errors in the '519 application, besides those alleged errors that you identified in figures 8 and 9?
A. Not that I recall.
Q. How did you determine that figures 8 and 9 contained typographical errors?
ATTORNEY MILLER: Objection. Vague. And to the extent it calls for privileged information or communications with counsel.
A. Based on the written description.
BY ATTORNEY BARNES:

Q. What about the written description?
A. It includes the mechanism of garroting. In other words, the circumferential constricting mechanism and how that occurs with one end and the other end of a filament.
Q. Can you identify what portion of the written description you relied on in determining that figures 8 and 9 contain typographical errors?
A. I would have to go back through it, but I believe it is in multiple portions of the written description.
And, again, I make reference to the garrote closing dynamic.
Q. Are you aware that a patentee can seek to correct errors in its patents with the patent office?
ATTORNEY MILLER: Objection. Scope.
A. I think generally, yes.
BY ATTORNEY BARNES:
Q. Do you know whether Inari has attempted to correct the alleged error in the '519 application or any of the related patents?
ATTORNEY MILLER: Objection. Scope.

A. I honestly have no idea.
BY ATTORNEY BARNES:
Q. Is that something you considered in forming your opinions?
A. No.
Q. If you turn to paragraph 54 of your supplemental declaration.
A. Okay.
Q. Towards the middle of paragraph 54, you state, "As expressly set forth in the specification, each of those individual filaments 150A and 150B has a first end and a second end."
Did I read that right?
A. Yes.
Q. And you are not quoting any disclosure from the '519 application in that sentence. Correct?
A. I am citing the specification, I don't see what particular reference I made here. It talks about the '005. But by reference, the '519 was incorporated. So I think it probably encompasses both.
Q. Are you aware at the '519 application

never uses the term "individual filaments"?
ATTORNEY MILLER: Objection. Vague.
A. I would have to review it again.
BY ATTORNEY BARNES:
Q. If we look up to paragraph 53 of your supplemental declaration, the actual quote from the '519 application that you provide states, "In embodiments in which the filament 150 comprises multiple filaments, each of the multiple filaments can have a first end 700 and a second end 702."
Did I read that right?
A. Yes.
Q. That statement doesn't refer to the phrase "individual filaments." Correct?
A. That refers to embodiments that include multiple filaments.
Q. And this quoted statement in paragraph 53 does not state that each individual filament has a first end 700 and a second end 702. Correct?
A. Maybe I misheard that.
It says each individual filament has a first end and a second end as follows.

Q. So I am specifically looking at the quoted language that is the quote from the '519 application.

A. Okay.

Q. So the quoted language from the '519 application does not state that each individual filament has a first end 700 and a second end 702. Right?

A. It says each of the multiple filaments has a first end and a second end.

Q. And it does not refer to each individual filament. Correct?

A. It doesn't use that word, but it says "each," which indicates an individual filament.

Q. So the '519 application does not expressly say that each individual filament has a first end and a second end. Correct? That is just your interpretation of the patent. Correct?

ATTORNEY MILLER: Objection. Vague. Asked and answered.

A. I would have to review the precise language to answer that.

I wanted to add a sentence to that last

answer, which is: In the '519 application, if you look at selected figures, they depict an individual filament, which is part of the specification.

BY ATTORNEY BARNES:

Q. Would you agree that there are figures that also depict multiple filaments?

A. Yes.

Q. Would you agree that figures 8 and 9, which are the figures you believe include a typographical error, depict multiple filaments?

ATTORNEY MILLER: Objection. Vague.

A. Yes.

BY ATTORNEY BARNES:

Q. I am going to hand you what has been marked as Exhibit 1011 in this IPR.

(Handing document to the witness.)

Q. Do you recognize Exhibit 1011?

A. It appears to be the Garrison patent.

Q. Is Exhibit 1011 one of the prior art references that are relied on in the petition?

A. That is my understanding, yes.

Q. Did you review the Garrison patent in preparing the opinions that you set forth in

your supplemental declaration?

A. I had reviewed the Garrison patent in my original declaration earlier in the year and didn't rereview in detail the Garrison patent as I found it largely irrelevant.

Q. Why did you find the Garrison patent largely irrelevant?

A. The Garrison patent is very specific to a cerebrovascular, what is called a transcarotid procedure -- transcarotid procedure -- which is in the neck area of the body, that utilizes very small devices and catheters because of the small vasculature in the brain.

Q. Why does that make Garrison largely irrelevant?

A. Because of its specificity as opposed to generality for hemostasis.

It is very specific to intracerebral neurovascular interventional devices, which are typically less than 6 French in size and very specific to navigating a very short length of vessel between the carotid insertion point and the location of the thrombus in the

mid-cerebral artery.

Q. So is it your opinion that prior art references that relate to treating intravascular blood clots are irrelevant to the '005 patent?

ATTORNEY MILLER: Objection. Misstates testimony. Vague.

A. I wouldn't say "completely irrelevant." But they are very limiting. And using Garrison in particular, he provides no description of any inventive aspect related to a hemostasis valve.

BY ATTORNEY BARNES:

Q. When was the last time that you reviewed Garrison?

A. I reviewed it very briefly, probably last week, not in detail, as I mentioned earlier. The detailed review I did prior to June of this year.

Q. The first page of the Garrison reference lists two individuals as inventors. Correct?

A. Yes.

Q. Are you personally familiar with either

of those individuals?

A. I don't know Mr. Garrison. I know a person with the name Tony Chow, but I am not sure of the spelling and I can't imagine it is the same person because he was a finance person.

Q. Understood.

The Garrison reference identifies Silk Road Medical, Inc., as the applicant. Correct?

A. Yes.

Q. Are you familiar with that company?

A. Only third-hand references. No specifics, no details.

Q. Can you turn to figure 34 of the Garrison reference.

A. Okay.

Q. Do you have an understanding of what is shown in figure 34 of Garrison?

A. Yes.

Q. What is that understanding?

A. He has his version of an aspiration system on the bottom connected via tubing or small catheter inserted into the CCA, which is the common carotid artery, then advanced into

the internal carotid artery with a small catheter inside the catheter then advanced to the MCA, the mid-cerebral artery.

Q. Do you agree that the system shown in figure 34 of Garrison is a vacuum aspiration system?

A. That is my understanding, yes.

Q. Do you agree that the system in figure 34 of Garrison includes an aspiration source?

A. Yes.

Q. The aspiration source in figure 34 is identified by reference number 3430. Correct?

A. Yes.

Q. Do you agree that the aspiration source in figure 34 could be an aspiration pump?

A. I think it wouldn't commonly be but it could be.

Q. Do you agree that the aspiration source in figure 34 could be a syringe?

A. Yes.

Q. Do you agree that the aspiration source in figure 34 could be a locking syringe?

A. Yes.

Q. Do you agree that the aspiration source in figure 34 could be a centrifugal aspiration pump?

A. Yes.

Q. Do you agree that the aspiration source in figure 34 could be a peristaltic aspiration pump?

A. Yes.

But I want to modify my answer. I am saying could be. In terms of physically possible, yes. Practically useable, unlikely, because of the very restrictive anatomy in the neck area of a patient.

This is something that I think I show in one of my declarations that a POSITA needs to have some exposure to the use of medical devices in procedures like this to understand both the requirements and the limitations associated with anatomy and pathology.

Q. So the restrictive anatomy in the neck area of a patient would make it difficult to use a peristaltic pump as the aspiration source? Am I understand your testimony correctly?

A. Yes. I think it would make it difficult to use almost any energized pump because of the restrictive space.

Q. What about the restrictive space makes it difficult to use an aspiration pump?

A. The doc has to get his arms -- or his hands, sorry, his gloved hands into the neck procedure to navigate, advance, withdraw, advance, withdraw, aspirate, close, and so forth.

If you have got a significantly sized apparatus in that same space, it would require -- it would be positioned further away, which would mean a longer length of tubing, which complicates the geometry of treating the patient.

There is just not enough physical space in that area of the body.

Q. Are you aware of any prior art aspiration systems that used aspiration pumps to treat neurovascular blood clots?

A. I am not familiar with them, no.

Q. Are you familiar with the Penumbra aspiration bump?

A. As commented earlier, I know of it. I haven't looked at it in great detail.

Q. And I believe earlier you testified that you are not familiar with the AngioVac aspiration pump. Is that correct?

A. Correct.

Q. So you don't know whether either of those pumps had been used in procedures to treat neurovascular clots. Is that right?

A. I don't know that they have or have not been used. But just to augment what I said earlier, many of these patients have a mask on, an oxygen mask or oxygen tubing. In addition to everything else going on, they may have an IV tube. So there is a lot going on in this area, this anatomical area.

Q. How close does the aspiration source in Garrison's system need to be to, for example, the check valve 3419?

A. I don't have an exact number but relatively close so that it could be controlled.

Q. Can you give a ballpark distance?

A. Inches.

Q. Would a foot be too far away?
A. That is right on the edge of practicality, I would say.
Q. So looking again at figure 34, do you agree that figure 34 discloses an aspiration catheter that is identified by reference number 2030?
A. Yes.
Q. Do you agree that in figure 34, the aspiration catheter 2030 is fluidly coupled to the aspiration source by a connector?
A. It appears to be.
Q. Did you agree that in figure 34, is a flow path that runs from the aspiration source to the aspiration catheter 2030?
A. Yes.
Q. Do you agree that that flow path would run through the tubing that is identified as reference number 2045?
A. In this figure, yes.
Q. Would you agree that that flow path would extend through the proximal adaptor housing that is shown in figure 34?
A. Which citation is that?

Q. Let me actually have you turn to paragraph 91 of your declaration -- supplemental declaration. This is on page 55.

A. Okay.

Q. On page 55 of your supplemental declaration, you reproduced an annotated version of figure 34 of Garrison that was included in the petition. Correct?

A. Yes.

Q. And in this annotated version of figure 34, there is a portion of the system circled in yellow.

Do you see that?

A. Yes.

Q. Do you agree that the portion of Garrison's system circled in yellow includes a hemostasis valve within a proximal adapter?

A. Yes. To use his written description, that would be either a Tuohy-Borst or a passive seal valve.

Q. So going back to my prior question, with reference to that flow path that extends from the aspiration source to the aspiration catheter 2030, would you agree with me that

that flow path extends through the housing identified in the yellow circle in this annotated version of the figure?

A. I don't believe that is a housing, at least not in the same terminology that is used in '005.

Q. Why don't you believe that is a housing?

A. It doesn't appear to be any integration of any components, other than, as you pointed out, a flow path and a connector.

Q. Did you present any opinions on whether that portion of Garrison's figure 34 is a housing in your supplemental declaration?

A. I have to read through paragraph 92 because I think I make reference to housing. It is, frankly, confusing because it is labeled as housing and, yet, it is not depicted as what I would describe as a housing.

Q. So do you not understand figure 34 of Garrison?

A. As I said much earlier, it is a confusing figure.

Q. Were there any other portions of

Garrison that you could not understand when you reviewed it?

ATTORNEY MILLER: Objection. Vague. Misstates testimony.

A. Not that I recall.

BY ATTORNEY BARNES:

Q. So just figure 34?

A. In particular, yes.

Q. Would you agree that Garrison's figure 34 includes an on-off control valve that is identified as reference number 3325?

A. Yes, that is what is depicted.

Q. And you would agree that Garrison describes that the valve 3325 can control whether aspiration is applied to the catheter 2030. Correct?

A. Yes.

Q. Do you agree that the system in figure 34 includes a filter that is identified by reference number 3418?

A. That appears to be the case, yes.

Q. Do you have an understanding of how Garrison's filter shown in figure 34 would work?

ATTORNEY MILLER: Objection. Vague. Scope.

A. Part of the confusion with the figure is not showing the collection and retention of aspirated material.

BY ATTORNEY BARNES:

Q. Isn't the purpose of the filter to collect the aspirated clot material and prevent it from passing through to the check valve 3419?

A. The primary purpose is to selectively trap the particulate matter which came from the thrombus, yes.

Q. How would it do that?

A. As I mentioned earlier, it is a simple passive screening device with opening or pore sizes that freely allow fluid to go through but prevent solid material from going through.

Q. Would that screening device be placed within some sort of housing to make up the filter?

A. It could be, yes.

Q. Would you agree that this filter needs to have openings on either end of its housing

so that blood can flow through it?
A. Yes.
Q. Do you agree that this filter 3418 in figure 34 is a clot canister?
ATTORNEY MILLER: Objection.
A. I would have to go to the written description to confirm that.
BY ATTORNEY BARNES:
Q. What is a clot canister?
ATTORNEY MILLER: Objection. Scope.
A. As the name connotes, it is a collection chamber or canister for thrombus material.
BY ATTORNEY BARNES:
Q. So if aspirated thrombus material is collected by the filter 3418 in figure 34, wouldn't that filter be a clot canister under the definition you just gave?
A. Well, hence my earlier comment about the confusion because it is not clear where the unfiltered material, in other words, the fluid material goes.
Q. Why is that unclear in your view?
A. There is no depiction of a collection

chamber of any sort. It looks like -- it appears to simply be a standalone filter in the fluid path.

Q. Could the aspiration source 3430 include a collection chamber?

ATTORNEY MILLER: Objection. Scope. Calls for speculation.

A. I think terminology is important.

The fact that is an aspiration source means it is a pressure source. It is not a collection chamber. Collection chamber would be an incremental or separate component of a package. But by definition, the aspiration source is a syringe or a pump that creates the negative pressure aspiration. In and of itself, it doesn't collect material.

BY ATTORNEY BARNES:

Q. So starting with a syringe, if the aspiration source is a syringe, doesn't a syringe have a vacuum chamber that would potentially collect the aspirated blood within it?

ATTORNEY MILLER: Objection. Vague. Calls for speculation and legal conclusion.

A. I guess, again, terminology. I am trying to imagine the steps in a procedure of using the syringe both as the pressure source and the collection canister and then changing it out regularly to enable regeneration of aspiration pressure.

BY ATTORNEY BARNES:

Q. Well, let's look at figure 9C of the '005 patent.

A. Sorry, figure what?

Q. Figures 9A through 9C.

A. Okay.

Q. So in these figures, 9A through 9C, isn't the aspirated blood and clot material being collected within the syringe that is also the pressure source?

A. I will go back to my statement about terminology.

It is not a discreet collection chamber. It is a pressure source that is also used in this particular embodiment to collect the material. But it is not a separate component used for the collection of that material.

Q. Right. So if your aspiration source is a syringe, you don't necessarily need a separate blood collection chamber to collect the aspirated blood. Correct?

A. It encumbers the procedure about returning blood to the patient by not have a discrete collection chamber. For small volumes, your statement is correct. For larger volumes, it would be cumbersome.

And I think that is the rationale in the '005 for having the various embodiments.

Q. Are you aware of any electrical aspiration pumps that included a blood collection canister as part of the pump assembly?

ATTORNEY MILLER: Objection. Vague. Calls for speculation.

ATTORNEY BARNES: Let me rephase the question, actually.

BY ATTORNEY BARNES:

Q. Are you aware of any electric aspiration pumps that were known or available prior to 2018 that included a blood collection canister as part of the pump assembly?

ATTORNEY MILLER: Objection. Scope.
A. It wasn't part of my assessment, frankly.
BY ATTORNEY BARNES:
Q. So do you not know whether any such pumps were known at the time?
ATTORNEY MILLER: Objection. Asked and answered. Scope.
A. If proposed, I would do some homework to discover.
ATTORNEY MILLER: Do you want to take lunch soon to avoid food getting cold?
ATTORNEY BARNES: Yes, we can take a break for lunch. Off the record.
THE VIDEOGRAPHER: The time is 12:26. We are off the record.
(Recess taken at 12:26 p.m.)
(Recess ended at 1:02 p.m.)
THE VIDEOGRAPHER: The time is 1:02. We are back on the record.
BY ATTORNEY BARNES:
Q. Welcome back, Dr. Zalesky. Did you speak to anybody about the substance of your testimony during the break?

A. No.
Q. Did you review any documents during the break?
A. No.
Q. If you could just look again back at figure 34 of Garrison. And I believe earlier you testified that in figure 34, there would be a flow path that extends from the aspiration source to the proximal end of the aspiration catheter. Is that correct?
ATTORNEY MILLER: Objection.
A. Yes.
BY ATTORNEY BARNES:
Q. In operation, would you agree that Garrison's aspiration source would generate vacuum pressure along that flow path?
ATTORNEY MILLER: Objection. Vague. Calls for speculation.
A. In general, yes.
BY ATTORNEY BARNES:
Q. And you would agree that Garrison discloses a method in which the aspiration is built up while the valve 3325 is in the closed position. Correct?

ATTORNEY MILLER: Same objection.
A. I didn't address that specific aspect of Garrison, but it appears to be the case.
BY ATTORNEY BARNES:
Q. When the aspiration is built up while the valve 3325 is in the closed position, would you agree that vacuum pressure would be generated in each of the components that are distal to the valve, including the filter 3418 and the check valve 3419?
ATTORNEY MILLER: Objection. Vague. Calls for speculation.
A. That appears to be the case.
ATTORNEY BARNES: I have no further questions. Pass the witness.

EXAMINATION

BY ATTORNEY MILLER:
Q. Dr. Zalesky, if you turn to page 35 of your supplemental declaration. That is paragraph 65.
A. Okay.
Q. You were asked earlier about whether the testimony here is referring to the '012 patent or the '005 patent.

Do you recall those questions?
A. I do.
Q. It is correct that you submitted this supplemental declaration in the matter involving the '005 patent. Correct?
A. Correct.
Q. And this testimony contained in paragraph 65 and 67 pertains to the '005 patent. Correct?
A. Yes.
Q. And is the testimony in paragraph 65 accurate?
A. It should speak to the '005 patent.
Q. And same with paragraph 67?
A. Yes.
Q. Can you turn to page 54 of your supplemental declaration, starting on paragraph 91.
A. Okay.
Q. You were asked questions by counsel about paragraphs 91 through 93 related to the housing. Can you take a moment and read those paragraphs for me.
(Pause.)

A. Okay.
Q. And can you read the first sentence of paragraph 92 out loud?
A. "A POSITA would not have considered Garrison's valve 3325 to be in the flow path extending through the housing as recited in claims 1 and 10."
Do you want me to go on?
Q. No. That is okay.
Is that your testimony that you are submitting in connection with this IPR?
A. Yes.
Q. Is that testimony accurate?
A. Yes.
Q. If we turn to the patent, the '005 patent, in column 6, you were asked about lines, I believe, 48 to 49 in part.
A. I have lost my copy of the '005.
Q. I might have stolen it.
A. I think you took it. Do you have your own over there?
Q. No.
Oh, it is right here.
A. Sorry. I was looking at the wrong

number. Okay. There you go.
So redirect me.
Q. Column 6, and part of the way down, the second-to-last paragraph, it says, on lines 48 to 49, "In some embodiments, one or more of the components can be permanently connected and/or integrally formed." Correct?
A. Correct.
Q. This sentence doesn't specify or limit the components here to the tubing subsystem 120. Correct?
A. That's correct.
Q. And when forming your opinions with respect to whether the on-off switch could be included in the housing, did you rely on, in part, lines 48 to 49?
A. I did, as I tried to explain earlier, yes.
Q. In considering figure 34 of Garrison, in paragraphs 91 through 93, did you -- you interpreted Garrison based on your understanding of figure 34 and the specification of Garrison. Correct?
ATTORNEY BARNES: Objection. Leading.

A. Yes.
BY ATTORNEY MILLER:
Q. And based on that understanding, you believe that paragraphs 91 through 93 are accurate?
A. I do.
Q. Is it your view that claims 1 and 10 of the '005 patent require that the on-off control be integrated into the housing?
ATTORNEY BARNES: Objection. Leading.
A. Let me just look at claim 1 one more time here.
(Pause.)
A. Sorry. Repeat that, please.
Regarding claim 1 and 10?
BY ATTORNEY MILLER:
Q. Yes. That claim 1 requires the on-off control to be in the flow path extending through the housing. Correct?
A. Yes. That is exactly how it reads, yes.
Q. Which, in your opinion, requires that the on-off control be in the housing, correct, or integrated into it?

ATTORNEY BARNES: Objection. Leading.
A. Via the interpretation of housing, yes, that is what it says.
BY ATTORNEY MILLER:
Q. Earlier, you were asked about Schaffer and the filament. Did you provide opinions regarding why a person of ordinary skill in the art would not have substituted the valve in Garrison with Schaffer?
ATTORNEY BARNES: Objection. Beyond the scope of cross.
A. Yes. I presented more than one argument, one of which is lack of motivation because of the specification feature claims in the Schaffer patent and invention. Secondly, the principal of operation, the mechanism of closure are dramatically different between Schaffer and the '012. And then, thirdly, the unlikely ability to actually design and manufacture using the Schaffer configuration with a flexible filament.
BY ATTORNEY MILLER:
Q. You were asked about the independent actuators. Would a person of ordinary skill in

the art have expected a hemostasis valve with independent actuators and a string from Hartley to have worked efficiently for sealing in a hemostasis valve?

ATTORNEY BARNES: Objection. Beyond the scope of cross.

A. As a POSITA, I really struggled with how to enable that configuration because the inherent character of a filament or string, its flexibility makes it uncontrollable in open space, which the Schaffer configuration requires, hence the rigidity of the structures in the Schaffer device.

BY ATTORNEY MILLER:

Q. You mentioned open space. I believe you talked earlier about the necessary size or placement of the valve and the pressure source.

What about the space is important here?

A. The fact that, with a filament in the Schaffer configuration, you have no geometric or location control over that filament. And so it is not at all clear how you do a couple things, including inserting the seal element and how to control in both the constrained and

1 the flexed position of a flexible string or
2 filament.
3 Q. Why is it important to have an
4 effective seal on these devices?
5 A. Well, hemostasis is what this is all
6 about. So you are trying to prevent the escape
7 of a fluid, and that requires a very effective
8 seal.
9 Q. What could happen in a procedure if
10 that escape happened?
11 A. Significant blood loss, complications
12 to the patient.
13 Q. Could the patient die?
14 A. That is particularly applicable to
15 places like cerebral and neurovascular
16 applications and cardiac/coronary applications
17 where indeed some acute event like that could
18 be life-threatening, yes.
19 Q. How about with respect to Garrison's
20 disclosures? Is that applicable there?
21 A. Yes. That is why I mentioned the
22 neurovascular, because he is very specific to
23 that particular intended use.
24 Q. So if the wrong valve was put in -- or

an ineffective valve was put into Garrison's disclosure or its catheter, could that result in death?

A. It could certainly result in brain damage, which, if significant enough, could be life or death.

ATTORNEY MILLER: No furthers question.

ATTORNEY BARNES: I have a few questions for you, Dr. Zalesky.

CONTINUED EXAMINATION

BY ATTORNEY BARNES:

Q. First, did you discuss any of the questions Mr. Miller just asked you before he asked you them?

A. No.

ATTORNEY MILLER: Objection to the extent that calls for privilege.

A. Same answer, though.

BY ATTORNEY BARNES:

Q. The '005 patent and the '519 application don't say anything about how to assemble the hemostasis valve that has the filament. Correct?

A. I would have to review again, but I

1 don't recall any assembly process detail.
2 Q. Would a person of skill in the art have
3 had no idea how to assemble the valve that is
4 described in the '519 application?
5 A. I think a POSITA could look carefully
6 at the drawings and come up with an assembly
7 that would provide the features described in
8 the spec.
9 Q. How difficult would it have been for a
10 POSITA to do that?
11 A. Not trivial, but not impossible.
12 Q. Again, the '519 application itself
13 doesn't provide any guidance to the POSITA on
14 how to go about doing that. Right?
15 ATTORNEY MILLER: Objection. Vague.
16 A. As I said, I don't recall any
17 delineated fabrication or assembly methodology.
18 BY ATTORNEY BARNES:
19 Q. How does the '519 --
20 ATTORNEY MILLER: Let me rephrase.
21 BY ATTORNEY BARNES:
22 Q. How does the hemostasis valve that is
23 described in the '519 application control the
24 filament in its flexed and unflexed state?

A. It has a constrained internal geometry that provides that garrote effect that we talked about.

Q. When you say "constrained internal geometry," what are you referring to?

A. The arrangement of the actuators orthogonal to the seal element internally assures a very controlled alignment.

Q. Mr. Miller asked you about Schaffer's valve. Schaffer's valve also has two actuators arranged orthogonally to the seal element. Right?

A. It does, yes.

Q. So that would allow you to control the constraint of a filament that was attached to those orthogonal actuators. Right?

A. Only if there is significant modifications to the Schaffer configuration. He is very clear that rigid materials are necessary for his mechanism of action, which is not a garrote mechanism; it is an opposing pinching action.

So the geometry and the materials and the arrangement of those would have to be

significantly different.

Q. If you had an arrangement where you had a filament going from one actuator that is orthogonal to the tubular member to the other, just like you have in the '519 application, wouldn't that allow you to control how the filament acts?

ATTORNEY MILLER: Objection. Vague.

A. Not it and of itself. You would need an extra component or components to enable that.

BY ATTORNEY MILLER:

Q. What extra components would be necessary?

A. The configuration of the internal surface, the bore used for the filament, and related aspects.

Q. In the '519 application, what are the aspects of the filament that are necessary to provide control?

A. So it is the geometry of the entrance and exit of the filament in the actuating elements. The geometry and the material and the assembly.

Q. Can you -- you have the '519 application in front of you.

Can you identify specifically where -- let's start with the geometry -- where the geometry that is required to provide control is disclosed in the '519 application?

ATTORNEY MILLER: Objection. Outside the scope of redirect.

A. If you look at figure 5 or figure 4, the filament has really minimal degrees of freedom of lateral movement. I am trying to see -- yes, figure 3, I guess, is better.

So compare figure 3 and figure 4 where there is no -- in each case, because of the orientation, there is no vertical displacement of the filament. It remains orthogonal because of its configuration with the actuators. And there is sort of a fitted tubule on the proximal -- on the inner aspect of the actuator spring, if you see, through which the filament is threaded.

So it is constrained around the seal element.

BY ATTORNEY BARNES:

Q. And that would be the case --
ATTORNEY BARNES: Let me rephrase.
BY ATTORNEY BARNES:
Q. And that is the case because the two actuator buttons are located on opposing sides of the tubular member orthogonally. Correct?
A. They are directly opposing, correct.
Q. And in your prior answer, I believe you also referred to the material and assembly of the filament.
Can you identify the disclosure of the material and assembly in the '519 application that provides control of the filament?
A. Well, by assembly, again, referencing those figures, the respective placement of the components and their operation enables that garrote closure effect.
Q. What about the materials that you referenced in your prior answer?
A. The materials in the actuators, I think, speak for themselves, that they are supposed to be non-compliant structures that can accommodate spring loading and the ability for a biassing option.

But most importantly is the filament itself. Its flexibility and its other properties are what provide the garrote closing effect.

Q. So as long as the filament material is flexible, it could provide this control and seal that is provided by the '519 hemostasis valve?

ATTORNEY MILLER: Objection. Vague. Misstates testimony.

A. In the appropriate geometric constraint, which it shows.

ATTORNEY BARNES: I have no further questions.

ATTORNEY MILLER: All good.

THE VIDEOGRAPHER: The time is 1:25. We are off the record.

(Whereupon, at 1:25 p.m., the deposition was adjourned.)

CERTIFICATE

Commonwealth of Massachusetts

Suffolk, ss.

I, Megan M. Castro, Registered Professional Reporter and Notary Public in and for the Commonwealth of Massachusetts, do hereby certify:

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

IN WITNESS WHEREOF, I have hereunto set my hand on November 11, 2025.

Megan M. Castro
Registered Professional Reporter
Certified Shorthand Reporter No. 152614

My Commission expires:
July 22, 2027

Case: Imperative Care, Inc. vs Inari Medical Inc.
Witness Name: Paul Zalesky, Ph.D.
Deposition Date: 11/07/2025

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